TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for *Quassia amara* L. wood extract for use in plant protection as insecticide and repellent

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, EFSAs scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Quassia amara* L. wood extract 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 *Quassia amara* L. wood extract as a basic substance for use in plant protection as insecticide and repellent. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSAs scientific views on the individual comments received.

Keywords: *Quassia amara* L. wood extract, basic substance, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00680

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Summary

Quassia amara L. wood extract 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 IFOAM EU Group 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 2017, EFSA was asked to organise a consultation on the basic substance application for *Quassia amara* L. wood extract, 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 *Quassia amara* L. wood extract, organised by EFSA, was conducted with Member States via a written procedure in June-August 2017. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for *Quassia amara* L. wood extract and presents EFSAs scientific views on the individual comments received in the format of a reporting table.

Quassia amara L. wood extract is obtained by extraction with water or ethanol-water mixture of the bitter principles, mainly quassinoids, from the wood of *Quassia amara* L. Quassin, which is present in concentrations of about 0.1 % in the wood, is used as analytical lead substance to qualify the extracts. Other quassinoids are also present in the wood like neoquassin, paraine, quassimarin, quassinol. The extract contains also indole alkaloids of the family of beta-carbolines.

Extracts of the wood of *Quassia amara* L. are used in cosmetics as denaturant, tonic and for skin conditioning. Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, lists quassin as a substance which shall not be added as such to food and sets the maximum levels to 0.5 mg/kg in non-alcoholic beverages, 1 mg/kg in bakery wares and 1.5 mg/kg in alcoholic beverages. *Quassia amara* L. wood is available on the market as chips, shavings or powder from dry wood for the preparation of extracts or as off the shelf extract.

Extract of the wood of *Quassia amara* L. is intended to be used as an insecticide and repellent against aphids, sawflies and cecidomyiids in pome fruit and stone fruit and against aphids in hop.

The extract should contain sugar to assure the easy solubilisation of the *Quassia amara* L. extracts, as the extracts tend to glue together and form precipitates becoming insoluble in water.

In the area of mammalian toxicology data gaps already identified during the peer review of Quassia are currently not addressed by the applicant supporting extract of the wood of *Quassia amara* L. as basic substance. Data gaps were identified for a complete genotoxicity data package. In addition concerns regarding reproductive toxicity and endocrine disrupting potential were identified. The applicant conducted non-dietary risk assessment to extract of the wood of *Quassia amara* L. considering maximum limits of quassin in food. Annex III of Regulation (EC) No 1334/2008 states that quassin belongs to part A: '*substances which shall not be added as such to food*'. It is not clear to EFSA if the maximum limits set are health-based. EFSA would consider more appropriate to exclude first the genotoxic potential of the extract of the wood of *Quassia amara* L. and then to set specific health-based guideline values (e.g. Acceptable Operator Level) on the basis of available toxicity studies. During the commenting phase with Member Sates the Netherlands proposed an AOEL of 0.0003 mg quassin/kg bw per day based on a LOAEL of 0.1 mg/kg bw per day for toxic effects in fertility using a standard uncertainty factor of 10 and an additional uncertainty factor of 3 because of

the use of a LOAEL. Currently, non-dietary exposure estimates would be above this AOEL whereas there would not be exceedance of the maximum limits of quassin in food as set in Annex III of Regulation (EC) No 1334/2008. Non-dietary exposure would be below the proposed AOEL if dermal absorption values are lower than 25% and if operators use Personal Protective Equipment (PPE, i.e. gloves, broad-brimmed headwear, coverall and sturdy footwear) and Respiratory Protective Equipment (RPE; i.e. FFP2SL or P2).

The consumer exposure assessment to the residues of extracts of the wood of *Quassia amara* L. cannot be concluded on. Data gaps were identified for information to demonstrate that quassin/neoquassin compounds are actually the most valid residue markers of the residues and to identify other compounds that may be potentially toxicologically relevant to consumers exposure when the extract is applied according to the intended uses, for sufficient residue trials on pome fruit, stone fruit and hops to address the magnitude of the relevant compounds in these crops and for storage stability data supporting the submitted residue trials on the crops under consideration.

In relation to the fate and behaviour in the environment, data permitting to characterize the risk of the substance for the environment when used according to the proposed GAPs, are currently not available. Data gaps are identified for batch adsorption/desorption studies, and for data/information on the persistence in soil and surface water and sediment for quassin and other active components of *Quassia amara* L. wood extract that may be identified as biologically active and/or responsible for a potential impact on human health. A preliminary exposure assessment to quassin (one active component of *Quassia amara* L. wood extract) has been performed based on preliminary input values and FOCUS Step 2 calculations.

Overall, the information provided in the ecotoxicology section was sufficient to consider the risk to non-target organisms as low for the representative uses.

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1. Introduction

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

Regulation (EC) No 1107/2009[1] (hereinafter referred to as the Regulation) introduced the new category of basic substances, which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as basic and used for plant protection purposes.

Quassia amara L. wood extract is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from IFOAM (International Federation of Organic Agriculture Movements) for approval as a basic substance for use in plant protection as insecticide and repellent.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Quassia amara* L. wood extract, which was conducted via a written procedure in June-August 2017. The comments received, including EFSAs 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 *Quassia amara* L. wood extract and to present EFSAs 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 *Quassia amara* L. wood extract 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 (IFOAM; 2017a,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 27 September 2017, EFSA was asked to organise a consultation on the basic substance application for *Quassia amara* L. wood extract, 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 16 February 2018.

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 *Quassia amara* L. wood extract 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 EFSAs scientific views and conclusions are outlined in column 5 of the table.

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

Documentation provided to EFSA

1. IFOAM, 2017a. Basic substance application on *Quassia amara* L. wood extract submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2017. Documentation made available to EFSA by the European Commission.

2. IFOAM, 2017b. Basic substance application update on *Quassia amara* L. wood extract submitted in the context of Article 23 of Regulation (EC) No 1107/2009. December 2017. Documentation made available to EFSA by the applicant.

References

European Commission, 2008. Guidance Document, Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95. Rev. 10.3, 13 June 2017.

European Commission, 2012a. Guidance Document on botanical active substances used in plant protection products. 8. 20/03/2014. SANCO/11470/2012. rev. 8, 20 March 2014.

European Commission, 2012b. Guidance Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009. SANCO/10363/2012 rev.9. 21 March 2014.

OECD (2010), Test No. 487: *In Vitro* Mammalian Cell Micronucleus Test, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264091016-en

Abbreviations

AOEL	acceptable operator exposure level
a.s.	active substance
CLP	Classification labelling and packaging
DAR	draft assessment report
EPI	Estimation Programs Interface
EU	European Commission
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
Koc	organic carbon linear adsorption coefficient
LC50	lethal concentration, median
LD50	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MRL	maximum residue level
MS	Member State
NOAEL	no observed adverse effect level
PEC	predicted environmental concentration
PECgw	predicted environmental concentration in groundwater
PECsw	predicted environmental concentration in surface water
PflSchG	German Plant Protection Act
PPE	Personal Protective Equipment
PRIMo	Pesticide Residue Intake Model
QSAR	quantitative structure–activity relationship
RAC	Regulatory Acceptable Concentration
RMS	rapporteur Member State
RPE	Respiratory Protective Equipment

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Quassia amara* L. wood extract 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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)		DE: It is quite remarkable that an active substance which has been withdrawn by the notifier for the inclusion in Annex I of Directive 91/414/EEC[2] is now supported as a basic substance. There seem to have been clear indications for harmful effects of the active substance in the EU assessment and the intended uses of the present application are quite similar (see below a copy of GAP table from the Monograph on Quassia compared to summary of intended uses in chapter 3.3 of the basic substance application)[1]. Are concerns	EFSA: the applicant should clarify the current status of quassia, quassin or quassia extract as flavouring and food ingredient in Europe, in particular whether they are currently subject to a re-assessment.	There is no guidance nor evidence that this should be an obstacle to an application for basic substance. Quassia was voluntarily withdrawn by the notifier due to economic considerations since the cost and effort of the dossier preparation proved to be much higher than discussed previously with the RMS and were in no relation to a possible economic benefit. Quassia is a very selective substance useful in plant protection only for few uses. Thus, the market is very limited and there is no chance for a return of a considerable	The indications of harmful effects of the active substance, already identified by MSs in the previous EU assessment of Quassia as an active substance, have not been adequately addressed in the application as basic substance. See also comment 5(1)

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

General					
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		about the effects of *Quassia amara* L. wood extract cleared out?		investment. Since for these few uses Quassia is essential for organic farming this problem was discussed with EU and also German authorities and Art. 23 was mentioned as a possible solution. Quassia is listed on the DRAFT LIST OF POSSIBLE CANDIDATES FOR BASIC SUBSTANCES https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_basic-subst_list-candidates.pdf. The amount of Quassin needed for these essential uses has not changed. Thus, it is natural that the GAP table is quite similar. For other substances that were withdrawn or not renewed by the notifier the basic substance application was also discussed. (Example soy lecithin which is already approved as basic substance and previously was registered as active substance in the PPP	

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				'BioBlattMehltaumittel'). For the current status of Quassia extract as foodstuff see 5 (1).	
1(2)	Eligibility of *Quassia amara* L. wood extract as basic substance	DK: Agree with the comment from DE: '*To ensure a transparent and thorough assessment, it is proposed to provide an assessment of Quassia amara L. wood extract as botanical active substance in line with Guidance Document SANCO/11470/2012.'*	DK: Please consider re-submitting an active substance dossier; additionally please note the draft GD on Botanical active substances used in plant protection products (February 2017)	Applicants understand from this comment that there is a possibility for a professional farmers association that has no interest in trading PPP to submit an active substance dossier for a substance not already authorised. Applicants are interested to explore modalities of such a possibility for essential uses with low market potential as Quassia with EU and MS authorities. Due to simple economic reasons (see also 1(1)) it will not be possible to convince a company to invest time and money in an active substance dossier. Until now, Art. 23 of the Reg. (EC) 1107/2009 was understood by applicants to be the only chance for farmers	The issue whether *Quassia amara* L. wood extract fulfils the criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue and EFSA does not provide any further opinion in relation to the subject

General					
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				organisations to apply themselves for the possibility to use a substance for plant protection purposes.	
1(3)	1.Purpose of application	EFSA: the title of the submission supported is 'Extract of the wood of *Quassia amara* L.', while under point 1 it is mentioned that the application is for quassia originating from *Quassia amara* L. and *Picrasma excelsa*	This inconsistency should be solved by changing the title or removing the second reference.	The reference was changed. An updated proposal is attached.	Addressed. The second reference was removed from the purpose of the application.

[1] From Quassia DAR (Monograph) Vol. 1 (July 2007), p 16:

Table 2. 1: Good agricultural practice (GAP) for Quassia Extract MD based on Quassin

Region, field, greenhouse or indoor, crop	Pests or group of pests controlled	Application			Application rate per treatment			PHI (days)
		method / kind	growth stage & season	nr (max)	kg as*/hL min/max	water 0L/ha min/max	kg as*/ha min/max	
Northern and Southern Europe Stone and Pome fruit	Saw flies	spraying	BBCH code 65-69	2	0.0008 - 0.0024	500-1500	0.012	F
Northern and Southern Europe Ornamentals	Aphids	spraying	During the vegetation period (independent from growth stage)	4	0.0024 - 0.0012	500-1000	0.012	1

F: pre-harvest interval covered by the vegetation period between application and harvest; N: pre-harvest interval not relevant
* as refers to the analytical leading compound Quassin

(In the application for *Quassia amara* L. wood extract, there has been an extension of the pest groups by sucking insects).

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1 Predominant use, p. 6	EFSA: clarification is needed if the term Quassia is used for both woods or only for *Quassia amara* L		Applicants used the term Quassia in the application only for *Quassia amara.* However, in literature and in common uses it is used for *Quassia amara* or for *Picrasma excelsa*. Results referring to *Picrasma excelsa* were given as references when they referred clearly to the content of Quassin which is the active ingredient and is present in both plants. In this case it was specified. However, in many of the publications dealing with the effects of Quassin the term Quassia is used for both plants. Often, *Picrasma excelsa* is also addressed as Jamaica Quassia, e.g. in WOO et al. (2007).	Addressed
2(2)	2.2.5 Description and specification of purity of the a.s. and product, p.11	EFSA: if the content of Quassin in the extract is standardised to 12 g quassin per packed product unity, this would mean to link it to a certain product (i.e. Quassia extract MD) which contradicts the	Linking the specification to products already commercialised as plant protection products is against the concept of basic substance. Instead a specification of the content of quassin	In the GAP table the amount to be used is defined referring to Quassin. Due to the comment 3 (2) the GAP table was updated introducing also the amount of wood chips per ha for the preparation. There is no reference to the	Addressed. The GAP table was updated accordingly.

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		concept of the basic substance.	should be proposed and the amount to be used will be defined by the GAP proposed.	Quassia extract MD. The information about the content of Quassin per packed product unity of Quassia extract MD was irrelevant and evidently confusing. Applicants removed it.	
2(3)	2.2.6 identity of inactive isomers, impurities, additives, p. 11	EFSA: again, this is linked to a product sold as a PPP, which is against the concept of a basic substance.	Clarification is also needed, what happens if a product is not containing stabilisers as the Trifolio-M one, it will not be effective?	Since Quassia extract MD is the only Quassia extract available that is good characterized and standardized with a known content of Quassin applicants often refer to this extract and research and studies are often done with it to get clear and repeatable results. For the equivalence of these results with the self prepared decoction – the classical basic substance – the equivalence of these results was discussed in Annex 4 to the updated proposal. To the question of stabilisers: The extract is dried and has a consistence like powder. It contains sugar to assure the easy solubilisation. Without this addition the extract tends to glue together, forms precipitates and becomes insoluble in water. Thus, the sugar is added only for the better handling and solution of	It is important to note that without the addition of sugar the extract tends to glue together, forms precipitates and becomes insoluble in water. As a consequence, the Decoction of quassia wood on farm should be modified to include this important step in the preparation procedure.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				the extract and has no effect on efficacy. The decoction of Quassia wood is also effective.	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
2(4)	2.2.3. Molecular and structural formula, molecular mass + 2.2.5. Description and specification of purity of the active substance and product, p. 9-10	NL: information of the 2 major compounds (Quassin and Neoquassin) are provided, additional other quassinoids are mentioned isoquassin, parain, quassimarin, quassinol and quassol). However, it is not clear in what % (content) or range these quassinoids (major and others) are present in the Quassia extract. If possible, this should be clarified. Although the standardised content of the compound Quassin is 12 g		Isoquassin proved to be identical to Quassin even if it is often mentioned as a separate ingredient (see Jacobson, 1982). The efficacy of pure Quassin on sawflies was similar to the efficacy of Quassia extract which shows that this substances are responsible for the effect on insects (Bathon et al. 2004). Bathon et al., (2004, pp. 34) also showed that Neoquassin is less effective than Quassin. Since the activity of Quassia extract on insects could be clearly correlated	Addressed. If quassin is considered the main component responsible for the effect, only raw materials with known quassin content can be used for the preparation of the extract, to be able to reach the effective concentration of the GAP

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		per packed produced unity, the specification (to some extent) should be proved, as multiple compounds next to quassin and neoquassin can be detected.		to the Quassin content and Quassin is also the component of concern that was identified as responsible for a potential impact on human health it was not considered necessary to identify fully all other components. Furthermore, it should be considered that all tests for potential health or environmental effects reported were conducted or with the full extract (so that the effect of all possible components is covered) or with Quassin as pure substance.	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
2(5)	2.4 Manufacturer of the substance, p.16	EFSA agrees with the statement that The content in Quassin should be specified to allow a correct dosage and to provide a reliable quality		Due to the problems with quality that arose in 2000, that did not only concern the use in plant protection but also of course other uses, some providers of	Addressed. Only raw material with specified quassin content should be used for the preparation of the extract.

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
				Quassia wood chips give information about the content of Quassin on request. Thus, this is feasible.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
2(6)	In the application 'Description of the recipe' is numbered under 2.6.	DE: The mode of preparation is described with definite amounts of wood and water, but put in question by the advice to consider the content of Quassin and adapt the amount of wood chips for cooking. That would require an additional testing especially if the content can also be higher than expected. The recipe recommends to macerate and cook 200g of Quassia chips in 10 l of water	Please specify how this can be done in a way that is practicable for the user. Please clarify.	*Content of Quassin*: Since 2000, the situation has improved so that it should be sufficient to give the amount of wood chips per ha as given in the updated GAP table. Experience from the last years is that higher contents of Quassin have not to be expected, lower contents may happen. Professional users buying Quassia chips will ask in their own interest to have some proof of product quality regarding the content of	Addressed. The recipe was updated in the updated submission. See also previous comments 2(4), 2(5)

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		and dilute it further by 10. This would result in almost 100 litres depending on how much of the water is boiled away during the first step. If not much of the water is boiled away 2kg Quassia wood chips would be needed for the preparation of the final product with 500-1000 litres/ha applied in the field or orchard. On the other hand the amount of Quassia wood needed per ha is given with 20 kg. This seems to be contradictory.		Quassin. Thus, it should not be necessary to specify further. Since in the updated GAP table both the amount of Quassin and the amount of wood chips is given this should be safe. (see updated GAP table in the updated proposal). *Recipe:* Since the wording was mistakeable the recipe was updated in the amount per ha following also the update of the GAP table: Macerate 20 kg of Quassia chips for 24 hours in 100 litres of natural or rain cold water and then allow boiling for 1 hour. Additional natural or rain cold water is added to achieve a final solution of 1000 L. This recipe was also used in the calculation of toxicity to operators (see Annex 8, 3.3.).	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
2(7)	Kienzle et al., 2003 or 2004: According to the text it was published 2003, according to the list of papers 2004.	DE: The relation of Quassin and Neoquassin in Quassia wood is strongly variable (between 1:0,3 and 1:4). Both can have effects on harmful and beneficial organisms. Only Quassin is considered in this chapter.	The role of Neoquassin in the extract and how it should be handled should be discussed.	The experience of the last years shows that there is some variation of the Neoquassin content but in size of magnitude it follows the content of Quassin. Since the effect of Neoquassin is much lower than the effect of Quassin some variation in the content will not have great effects (see also 2 (4)). Quassin is used as analytical lead substance to standardize the extracts and the amount that were used. However, the studies in question were always conducted with the full extract so that potential effects of Neoquassin were also considered.	Addressed. Since the effect of neoquassin is much lower than the effect of quassin, quassin is used as analytical lead substance to standardize the extracts.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
3(1)	Column 8	DE: There is no clear connection between the Table/summary of intended uses and the related legends. For example it is	It would be helpful to leave the original characters of the legend within the table. It should be written:	Applicants used the GAP table and the legend provided in the basic substance application form. Maximum number per use intends the maximum number of	Addressed. The GAP table was updated

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		not comprehensible what is meant by 'Max. number per use'	Maximum number of applications per crop/season.	applications for one single use e.g. sawfly. In the case of these applications, the max. number per crop/season is equal and both numbers are = 1.	
3(2)	Column 10	DE: The application rate kg product/ha is lacking. It is not sufficient to state that it depends on the content of Quassin. It would mean that a user who cannot analyse the content cannot use an own preparation.	Please specify.	In the GAP table in the updated proposal the information is now specified in Quassin and in kg wood chips per ha.	Addressed. The GAP table was updated.
3(3)	Column 11, row 4 and 5	DE: The differentiation between a) and b) is lacking.	Data should be given for a) and b)	GAP table was updated. Row 4 and 5 were removed.	Addressed. The GAP table was updated.
3(4)	PHI	DK: Please justify setting a PHI (e.g. of 60 days) when residue concerns are not mentioned in chapter 6. If however the very high PHIs are required, then this application does clearly not fulfil the basic substance criteria.	DK: Likely a mistake; please delete the inserted PHI days if acceptable.	PHI days were deleted.	Addressed. The GAP table was updated.

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)	Classification	DK: Please include the classification or if the case in none then please state that clearly in this chapter (not just refer the reader to an Annex)	DK: Update text to include relevant information from the Safety data sheet.	The following information was included in the text of the updated proposal attached: 'Quassia-Extract-MD is not a hazardous product according to Regulation (EC) No.1272/2008[3]. Quassia-Extract-MD is not a hazardous product according to Directive No. 67/548/EEC[4]'.	Addressed. The text was updated in the revised submission.

[3] 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.

[4] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ L 196, 16.8.1967, p. 1–98.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	Summary	NL: In Regulation 1334/2008 the limits for quassin of 0.5 mg/kg in non-alcoholic beverages, 1 mg/kg in bakery wares and 1.5 mg/kg in alcoholic beverages are for substances naturally present in flavouring and food ingredients with flavouring properties. Annex III of this Regulation states that Quassin belongs to part A: Substances which shall not be added as such to food. This puts into question if the maximum levels from Regulation EC 1334/2008 should be regarded as safe levels and we question the use of this levels in the exposure assessment (see also our comments on section 5.12).	EFSA: quassia, quassin the applicant should clarify the current status of or quassia extract as flavouring and food ingredient in Europe, in particular whether they are subject to a re-assessment. Please clarify the basis of maximum levels from Regulation (EC) No 1334/2008[5].	Applicants understand from the guidance to Regulation 1334/2008 at http://www.effa.eu/docs/default-source/guidance-documents/effa_guidance-document-on-the-ec-regulation-on-flavourings.pdf?sfvrsn=2 as follows: In Annex IV of the Regulation 1334/2008 Quassia ex *Quassia amara* or *Picrasma excelsa* would be the whole extract is listed and the conditions of use are specified: 'Flavourings and food ingredients with flavouring properties produced from the source material may only be used for the production of beverages and bakery wares'. This implicates that Quassia may be used as flavouring and/or food ingredient for these products. In Annex III, part A, of the	Quassin is not an approved flavouring substance. It is included in Annex III of Regulation (EC) 1334/2008 (part A) as a substance that shall not be added as such to food. In Annex III are listed substances that are naturally present in food, for which a maximum level was set. Specifically, in Regulation (EC) No 1334/2008 the limits for quassin of 0.5 mg/kg in non-alcoholic beverages, 1 mg/kg in bakery wares and 1.5 mg/kg in alcoholic beverages are for substances naturally present in flavouring and food ingredients with flavouring properties.

[5] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34–50

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				Regulation 1334/2008 pure Quassin is listed as pure substance that may not be added as such to food. Since the use of the Quassia extract as food additive is allowed, in Annex III, part B, the maximum contents of Quassin for beverages and bakery waves are specified. Thus, the levels specified in Annex III, part B are legally accepted in this Regulation and regarded as safe. Currently, Quassia is used and declared as flavouring in Europe in several products (see Annex 2). However, applicants are aware that the Regulation 1334/2008 is subject to re-assessment and that Quassia is not defended by any industry. This may compromise its legal use as foodstuff in the future.	As commented by the NL it is not clear if the maximum limits in Regulation (EC) No 1334/2008 are health-based.

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
5(2)		EFSA: during the previous assessment of the active substance Quassia EFSA commented that according to literature (Woo et al., 2007), it seems that several tests for mutagenicity have been performed : - Ames test (Asanoma and Tamura, 2006) - chromosome aberration test (M. Hayashi et al.,	EFSA: Available studies on Quassia and/or Quassia extract should be submitted by the applicant. Robust (OECD) summaries reports of all available studies should be available for an independent assessment since no previous assessment of these studies have been carried	The studies cited by Woo et al. (2007) were not available to applicants. However, they would be of very limited value since they refer to 'Jamaica Quassia' which is *Picrasma excelsa* and not *Quassia amara*. As already mentioned in 2 (4) and also in line with Guidance Document SANCO/11470/2012 it is crucial that tests are conducted with a well defined whole extract of the plant species in question.	Further data are needed to conclude on the genotoxic potential of extract of the wood of *Quassia amara* L.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		unpublished) - mouse bone marrow micronucleus (M. Hayashi et al., unpublished) - in vivo UDS (rat liver) (M. Hayashi et al., unpublished)	out during a regulatory process at EU level (as far as EFSA is aware). The genotoxic potential of *Quassia amara* L. wood extract should be excluded. An Ames test is not sufficient to conclude on its genotoxic potential.	However, until now it was difficult to explain to the supporters/sponsors of the application that genotoxicity studies should be needed for a foodstuff that is traditionally used for hundreds of years. Thus, only an Ames test was presented. Now there is a clear statement in column 3 that this is required. Based on this, applicants have applied in the Danish programme http://eng.mst.dk/chemicals/pesticides/grant-programmes/alternative-pesticides/ for a grant to execute an in vitro mammalian cell micronucleus test (OECD TG 487) with an extract from *Quassia amara*. This follows the scientific opinion for guidance for the submission of food additive evaluations (EFSA Journal 2012;10(7):2760) where it is stated that this test together with the Ames test already presented is required as the first step in genotoxicity testing. If the grant is permitted the test	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				will be started and the data will be transmitted as fast as possible. It was also applied for consultancy to design a roadmap to prepare a complete toxicological profile for *Quassia amara*.	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
5(3)		NL: a margin of safety of 160 between the dietary exposure in rats causing hepatocarcinogenesis promoting effect and the systemic exposure of operators is not very high considering that this comparison does not take into account any safety	EFSA: the risk assessment should take into account a standard uncertainty factor of 100 plus additional uncertainty factor because of lack of data and/or lack of a clear NOAEL.	See 5 (9)	EFSA would consider more appropriate to exclude first the genotoxic potential of the extract of the wood of *Quassia amara* L and then to set specific health-based guideline values (e.g. Acceptable Operator Level) on the basis of available toxicity studies. The NL

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		factors for intraspecies/interspecies extrapolation.			would propose an AOEL of 0.0003 mg quassin/kg bw per day based on a LOAEL of 0.1 mg/kg bw per day for toxic effects in fertility using an standard uncertainty factor of 10 and an additional uncertainty factor of 3 because of the use of a LOAEL
5(4)		NL: In the Arantes study an RfD was derived of 0.35 mg/kg bw. According the application this corresponds to an estimated RfD for Quassin of 0.000875 mg/kg bw. The operator exposure was 0.08 quassin/kg bw and therefore a factor of 91 higher than the estimated exposure.	EFSA: See point 5(3).	See 5 (9)	Currently, non-dietary exposure estimates would be above the AOEL of 0.0003 mg quassin/kg bw per day whereas there would not be exceedance of the maximum limits of quassin in food. Non-dietary exposure would be below the proposed AOEL if dermal absorption values are lower than 25% and if operators use Personal Protective Equipment (PPE, i.e. gloves, broad-brimmed headwear, coverall and sturdy footwear) and Respiratory Protective Equipment (RPE; i.e. FFP2SL or P2). The applicant is proposing to conduct dermal

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
					absorption studies.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		DE: According to the submitted information *Quassia amara* extract caused reproductive toxicity in different studies in rats and mice. Furthermore, clear indications of endocrine disrupting potential were observed. Serum levels of testosterone, luteinizing hormone, follicle stimulating hormone and estrogen were reduced and the secretion of testosterone by Leydig cells was inhibited. Therefore, *Quassia amara* does not comply with the approval	EFSA: see point 5(8).	Effects on the hormone system are also reported for *Salix s*sp. (Fiebich & Chrubasik, 2004) which is no foodstuff but a traditional medicine with an anti-inflammatory mode of action that seems similar to *Quassia amara*. The same Nigerian working group that reports the reproductive toxicity of Quassia has published similar findings for acetylsalicylic acid which is supposed to have similar mode of action as the active ingredients of Salix ssp. (Oyedeji et al., 2013). Soy lecithin is a foodstuff but	In the area of mammalian toxicology data gaps already identified during the peer review[6] of *Quassia* are currently not addressed by the applicant supporting extract of the wood of *Quassia amara* L as basic substance. Data gaps were identified for a complete genotoxicity datapackage. In addition concerns regarding reproductive toxicity and endocrine disrupting potential were identified.

[6] Referring to previous EU pesticide peer review, list 4 review. The application was voluntarily withdrawn by applicant. http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1813

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		conditions of article 23(2), 23(1a) and 23 (1b) of Regulation (EC) No 1107/2009.		serious endocrine disrupting potential is reported (Behr et al., 2011, both references see Annex 36). It is well known that for women in menopause the consume of soy products is recommended. Both substances are reported to have an inherent capacity to cause endocrine disruption and are already approved as basic substances. In these cases the fact that a substance is a foodstuff or a traditional herbal medicine seem to have been considered.	
5(6)		NL: several studies report effects of Quassin on fertility, including effect on the testis, epididymis, seminal vesicle weight, epididymal sperm counts, serum levels of testosterone, luteinizing hormone and follicle stimulating hormone (FSH)	EFSA: see point 5(8).	See 5(6) and 5(9)	See comments 5(4) and 5(5)

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		in male rats. In female rats decreased ovary and uterus weight combined with a decrease in serum estrogen was observed. Mean litter number and litter weight was also observed. It therefore seems that Quassin is a reproductive toxicant acting through an endocrine mediated mode of action. In accordance with the Regulation a substance cannot be approved as a basic substance when it has the inherent capacity to cause endocrine disruption. The fact that these effects appeared to be reversible does not change this conclusion.			
5(7)	Overall	DK: Strongly agree with DE: `*According to the submitted information Quassia amara extract caused reproductive toxicity in different studies in rats and mice. Furthermore, clear indications of endocrine disrupting potential were*	DK: Please consider re-submitting an active substance dossier. EFSA: see point 5(8).	See 5(6), 5(9) and 1(2).	See comments 5(4) and 5(5).

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		observed. Serum levels of testosterone, luteinizing hormone, follicle stimulating hormone and estrogen were reduced and the secretion of testosterone by Leydig cells was inhibited. Therefore, Quassia amara ***does not comply with the approval conditions of article 23(2), 23(1a) and 23 (1b)*** *of Regulation (EC) No 1107/2009.'*			
5(8)	Overall	EFSA: during the previous assessment of the active substance Quassia there were concerns regarding the potential of Quassia to be and endocrine disruptor and potential adverse effects regarding reproductive toxicity. Similarly, available data on the updated proposal May 2017 does not allow to exclude a reproductive toxicity and endocrine disruption potential of extract of the	EFSA: The applicant should assess whether according to the proposed intended uses there could be concerns regarding endocrine disruption and reproductive toxicity; however current available data do not exclude the intrinsic properties *Quassia amara* L regarding reproductive toxicity and endocrine disruption.	Following the guidance given in the Working document SANCO/10363/2012 applicants demonstrated that the proposed intended uses are comparable to the existing exposure due to foodstuff use and add only a little to this existing exposure. In the course of the pilot project, the requirements for basic substance application have considerably changed. Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements	See comments 5(4) and, 5(5).

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		wood of *Quassia amara* L.		with an appropriate database. It is proposed that the risk assessment should follow the normal procedure for a botanical pesticide. Because of lack of data and/or the lack of a clear NOAEL it should take into account a standard uncertainty factor of 100 plus additional uncertainty factor (5 (4)). AOEL setting is based on the findings of Raj et al (1997) and the LOAEL is set to 0.1 mg/kg bw per day. An uncertainty factor of 100 plus 3 (i.e. 300) Would mean an AOEL=0.1/300=0.0003 mg/kg bw per day. The value of 0.08 mg/kg bw for the absolute worst case for the risk to operators was derived assuming that there were no gloves, no PPE or RPE and no body cover and using the 75 percentile values for calculation. Since there are no data for dermal adsorption, 100 % adsorption was assumed.	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				Assuming usual PPE (gloves, broad-brimmed headwear, coverall and sturdy footwear, and RPE(FFP2SL or P2) and an assumed adsorption rate of 25 % calculating with geometric mean values an operator exposure of 0.00043 mg/kg bw is calculated. The real adsorption could be considerably lower and might even reach levels that could reduce the risk operators exposure to the AOEL derived with the existing data base and the high uncertainty factor. Thus, dermal adsorption is the first data gap to close and applicants will consider this in the roadmap for a good and reliable toxicological profile for *Quassia amara* (see 5 (2)). In this roadmap it must be discussed further how the available data base with poor data quality and high uncertainty can be improved avoiding experiments with animals as much as possible.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

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

No comments

5.10. Additional Information related to therapeutic properties or health claims					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

5.11. Additional information related to use as food					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
5(9)		DE: The basic substance application on Extract of the wood of *Quassia amara* L. is based on the argument of the applicants that the substance is used as foodstuff. According to Article 23 an active substance which fulfils the criteria of a 'foodstuff' shall be considered as a basic substance. *Quassia amara* is used as flavouring agent in foods. However, it is not evidenced if the specification according to the basic substance application agrees with the specification of quassia in	EFSA: a comparison of the technical specification as basic substance to the technical specification as flavouring should be done.	In Annex IV of the Regulation 1334/2008 Quassia ex *Quassia amara* or *Picrasma excelsa* would be the extract is listed as source material. A method of extraction is not specified (e.g. alcoholic or water extract). Since pure Quassin is clearly excluded in the Regulation a purification of the extract would be even against this specification. Thus, it is understood by the applicants that Quassia extract without is used as flavouring. In Annex 2, examples for foodstuffs available on the market were given. All of them refer to Quassia extracts without any specification of a purification or a	See comment 5(1)

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		food.		specific extraction method. Thus, the only technical specification for the use as flavouring could be that the extract should respect the hygienic standards for food. For the self preparation of the decoction, this should be not really relevant but it could be important if ready extracts are used.	
5(10)		DE: According to the submitted information 'depending on the origin, the harvesting time and other unknown factors the content of Quassin varies … in the Quassia extract MD.' It can be expected that also the concentrations of other ingredients in the extract vary relevantly. Therefore, it is unclear if the criteria of a foodstuff are really fulfilled in this case.		In Annex IV of the Regulation 1334/2008 Quassia ex *Quassia amara* or *Picrasma excelsa* would be the extract is listed as source material. A method of extraction is not specified (e.g. alcoholic or water extract). There are even two botanical species identified as a source for the extract which have in common mainly the content of Quassin. Thus, a certain variation in the concentrations of other ingredients seem not to have been considered as relevant since the only substance that might cause concern is Quassin (see	See comment 5(1)

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				also 2 (4)).	
5(11)		DK: Agree with DE comment: '*The basic substance application on Extract of the wood of Quassia amara L. is based on the argument of the applicants that the substance is used as foodstuff. According to Article 23 an active substance which fulfils the criteria of a 'foodstuff' shall be considered as a basic substance.* *Quassia amara is used as flavouring agent in foods. However, it is not evidenced if the specification according to the basic substance application agrees with the specification of quassia in food.'* Also, even if the foodstuff criteria is fulfilled the application for approval as a basic substance is still questionable according to Article 23(1a,1b,1c,1d) and 23(2) of Regulation (EC) No 1107/2009.	DK: Please consider re-submitting an active substance dossier.	See also 5 (11), 5(6) and 1(2).The only technical specification for the use as flavouring could be eventually that the extract should respect the hygienic standards for food. This is not relevant for the self preparation from wood chips but it could be relevant for ready extracts.	The issue whether *Quassia amara* L. wood extract fulfils the criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue and EFSA does not provide any further opinion in relation to the subject

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
5(12)	Annex 8 risk assessment to operators	NL: The operator exposure is compared to the highest permitted content of Quassin in food. We do not agree with using these as reference value. Effects on male and female fertility in the Raji & Bolarinwa 1997 and Raji & Akinola 2010 already occurred at 0.1 mg/kg bw of quassin. Applying a standard safety factor of 10 and an additional safety factor of 3 to go from a LOAEL to a NOAEL would result in a reference value of 0.0003 mg Qaussin/kg bw/day. The operator, worker and resident exposure are all estimated to be far above this level. Therefore, in our opinion no safe use has been shown.	EFSA: the risk assessment should take into account a standard uncertainty factor of 100 plus additional uncertainty factor because of lack of data and/or lack of a clear NOAEL.	See 5(9)	See comments 5(4) and 5(5).
5(13)	Annex 8 risk assessment to operators	NL: In the exposure assessment a comparison is made to the acute oral toxicity study. This study is not suitable to		It should be very clearly specified which additional parameters should have been measured and which study should eventually be	See comments 5(4) and 5(5).

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		derive reference values for the operator, bystander, resident or worker as insufficient parameters are measured to determine the toxicity.		repeated and what is the exact reason why the studies are insufficient. For a repetition of these studies the absolute necessity must be proved.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
5(14)		NL: see comments in section 5.12			See comment 5(5).

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
6(1)	6.	NL: It would be helpful if the		In Annex 37 the tables were	Addressed

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		results for apples and plums were described in a little bit more detail in the application.		updated.	Detailed information on the residue trials on apples and plums was reported in the submitted Annex 37.
6(2)	6.	NL: Has it been investigated whether quassia metabolises? E.i., in the submitted trials, quassin has been analysed as a marker compound from the quassia extract, but can it be excluded that other (toxic?) metabolites could be formed?		There is no evidence nor literature available to applicants that refers to toxic metabolites of Quassin although the substance was studied rather intensively. Even in samples taken 1 - 2 month before harvest there were no detectable residues of Quassin/Neoquassin. This fact should contribute to balance eventual uncertainties.	The submitted data did not explore the fate and behaviour of *Quassia amara* L. extracts in plants when applied as a plant protection product according to the intended uses. It cannot therefore be excluded that other major metabolites besides quassin and neoquassin may be identified with a possible impact on the consumer exposure assessment, i.e. compounds determined above the LOQ of the method and/or toxicologically relevant.
6(3)	6.	NL: Although much appreciated that residue trials have been performed, the submitted trials are in a few cases difficult to interpret, either because of a high LOQ, or for example it is not always clear at what growth stage the second application took		In hop, one application was executed for each type of application: 2013: For the spray application at 18.7. and for the brush/wipe application at 12.6.2013. In 2014 the spray application was at 16.7. for the variety Hallertau and at 14.7. for the variety Perle. The	EFSA confirms that for most of the residue trials submitted on hops, the BBCH growth stage at application was not specified, respectively for the spray and brush applications. Since the PHI values were deleted for the uses on hops and pome and stone fruit uses,

Residues

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		place (hop trials from 2013 and 2014).		brush/wipe application took place at 14.7. in both varieties. Until now, it was not possible to obtain the informations about the growth stage during application from the institution that carried out the applications. Applicants will continue to try to obtain it.	the phenological growth stage at application is a key parameter. Without the information on the BBCH growth stage at application a reliable assessment of the residue trials cannot be finalised.
6(4)		DK: see DK comment in section 3 above.		PHI days were deleted.	See comment 3(4)
6(5)	6. Residues, Estimation of consumers exposition to residues due to hop cones treated with extract of Quassia amara in beer an tea.	EFSA: The consumer dietary intake assessment was conducted assuming that quassin was the valid marker of the residues in primary crop (hops, pome fruit and stone fruit) and in processed commodities whilst metabolism data addressing the fate of quassia extract in the relevant crops and standard hydrolysis studies addressing the nature of residues representative of the processing procedures were not conducted. Sufficient evidence that quassin compound is a valid		Quassia extract is a foodstuff. In line with the guidelines in SANCO/11470/2012 residue data should not even be required. Quassin is the active ingredient and also the component of concern that was identified as responsible for a potential impact on human health. Thus, for Quassin and a second ingredient, neoquassin, residue data are provided. Standard hydrolysis studies can be provided in the future. In the given time for the update of the proposal this is not possible.	See comment 6(2)

Residues

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		marker to be analysed in crops should be provided.			
6(6)	Annex 18; Determination of residues of Quassin in hop in Germany in 2008; Study No. TRI/QUA/08002	EFSA: Residue trials on hops were conducted with 2 x 24 g quassin/ha, PHI: 35 days (spray treatment) and 1 x 24 g quassin/ha, PHI: 35 days (brush treatment). Please clarify the BBCH growth stage at which the applications were made. Compliance with the representative uses on hops should be further discussed. Furthermore, EFSA is of the opinion that these trials cannot be considered as independent since only the variety of hops differs from one trial to another.		Until now, it was not possible to obtain the informations about the growth stage during application from the institution that carried out the applications. Applicants will continue to try to obtain it.	See comment 6(3)
6(7)	Annex 19; Determination of residues in apple, in Germany and Italy and in plum and hop in Germany in 2013	EFSA: Please report the LOQ value of the method that was used for the determination of quassin residues in apples, plums and hops in the 2013 residue trials.		Quassin, Isoquassin und Neoquassin were determined with LC-MS/MS (single method, LOQ: 0.005 mg/kg). This is documented in Annex 19 for each batch in the 'Untersuchungszeugnis' at 'Methode'.	Addressed
6(8)	Annex 19;	EFSA: Please clarify the following points:		The aim of this SEU trial was to investigate if such amounts	a) The residue trials on apples

Residues

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	Determination of residues in apple, in Germany and Italy and in plum and hop in Germany in 2013	a. SEU trials on apples referenced LB001A/B: the dose rate of application to be clarified, b. Residue trials on hops (T1:14.08.2013/T2:27.08.2013, spraying): the BBCH GS at application should be provided.		The aim of this study was to investigate if such amounts applied until BBCH 69 could lead to any residues in an early stage of the fruit. Unfortunately, the dose rate used could not be clarified definitively and applicants did not want to conceal this fact by an 'assumed rate'. Instead of this, the possible margin was given. The minimum should be 20.3 g Quassin/ha, the maximum 26.5 g/ha. Both concentrations are much higher than the uses proposed in the GAP table so that the aim of the study was met in each case. b)	and referenced LB001A/B cannot be considered as acceptable since the dose rate of application remains unclear. Furthermore the number of applications does not match with the number of applications in the critical GAP. It is also noted that quantifiable residues of quassin and neoquassin were determined in apple. b) See comments 6(3) and 6(6).
6(9)	Annexes 18, 19, 20, 21	EFSA: Considering the current recommendations, EFSA		Following the guidance given in the Working document	From the updated assessment of the residue trials and

Residues

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		concluded that for: Apples: the submitted residue trials are not compliant with the critical NEU and SEU GAPs. Plums: NEU residue trials were not compliant with the NEU GAP whilst no residue data were submitted to support the SEU GAP. Hops: 2 residue trials were submitted and considered as acceptable to support respectively the spray and brush treatments. As a minor crop, 2 additional trials respectively. for the spray and brush GAP should be provided.		SANCO/10363/2012 during the pilot project, applicants did not distinguish the residue studies in EU zones. If new requirements have to be fulfilled further studies will be necessary. (The number of studies required for apple and plum for each zone should be specified to avoid further delay). Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements with an appropriate database.	considering the current data requirements, sufficient residue trials on apples and plums compliant with the NEU GAP on pome fruit and stone fruit are available whilst sufficient residue trials on apples and stone fruit and compliant with the SEU GAP with a possible extrapolation to the whole group of pome fruit and stone fruit should be provided (cf. Extrapolation Guidance SANCO/7525/VI/95 rev.10.3. (European Commission, 2008)). Regarding hops, only 1 trial compliant with GAP on brushing is available since the BBCH GS at application is lacking in the other residue trials. Additional residue trials compliant with the GAPs on brushing and on spraying should be provided. This assessment can be considered as valid provided that quassin/neoquassin are the valid markers of the residues and that acceptable storage stability data on these

Residues

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					compounds and covering the maximum storage time interval of the residue samples from the trials on apples, plums and hops are submitted.
6(10)	Annexes 18, 19, 20, 21	EFSA: For all the submitted residue trials on apples, plums and hops, the maximum storage time interval of the residue samples should be provided. Consequently, storage stability data to cover this storage time interval should be provided. These data should cover the predominant compounds of the residues in the crops under consideration and in processed commodities.		In Annex 37 the respective overview tables for the residues were updated with this information with an additional column marked in yellow. Storage stability data can be provided in the future. In the given time for the update of the proposal this is not possible. For compounds see 6(13).	The maximum storage time interval of the residue samples has been provided for the residue trials on apples, plums and partially for hops (except for residue trials referenced 15L07136/01/RAPL). The validity of the submitted residue trials cannot be concluded in absence of acceptable storage stability data on the relevant compounds and covering the maximum storage time period of the residue samples from the trials.
6(11)	6. Residues, Estimation of consumers exposition to	EFSA: The consumer dietary intake calculations to quassin residues present in hops (dried) should be conducted using the food consumption		Applicants followed the guidance given in the Working Document SANCO 10363/2012 rev.9 and demonstrated that the proposed intended uses are	The consumer exposure assessment cannot be finalised considering the data gaps that were identified to identify the valid marker of the residues in

Residues

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	residues due to hop cones treated with extract of *Quassia amara* in beer an tea. See also Annex 22	data reported for this commodity in the EFSA PRIMo Model. Whether toxicological reference values for the compound/metabolite of relevance in hops can be derived from the available data should be assessed in the Mammalian toxicology Section.		comparable to the existing exposure due to foodstuff use and add only a little to this existing exposure. If This calculation was not possible for applicants in the available time for answering this comments. Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements with an appropriate database.	hops and fruit crops (pome fruit and stone fruit), sufficient residue trials analysing for the relevant residue markers in hops, apples and plums and supporting storage stability data.
6(12)	6. Residues, Estimation of consumers exposition to residues due to hop cones treated with extract of Quassia amara in beer an tea. See also Annex 22	EFSA: It is noted that the consumer exposure assessment was conducted by comparing the concentrations of quassin in beer to the exposition due to the existing uses of quassia extract as a food additive and to the maximum limits set for alcoholic and non alcoholic beverages. This approach cannot be considered as acceptable for the pesticide residues.		Following the guidance given in the Working document SANCO/10363/2012 applicants demonstrated that the proposed intended uses are comparable to the existing exposure due to foodstuff use and add only a little to this existing exposure. In the course of the pilot project, the requirements for basic substance application have considerably changed. If this new requirements have to be fulfilled further studies will be necessary (see also	See comment 6(11)

Residues

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				6(9). Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements with an appropriate database.	
6(13)	6. Residues, Estimation of consumers exposition to residues due to hop cones treated with extract of Quassia amara in beer an tea. See also Annex 22	EFSA: Quassin compound is only a minor component of the Quassa extract and cannot be considered representative of the whole extract. Since there is no metabolism data on any compound of the extract and based on the limited residues data for only one compound (quassin), it is impossible to conduct a robust consumer risk assessment.		For Quassia extract a use in human nutrition is largely documented. This should even give reason not to present residue data at all (SANCO/11470/2012– rev. 8). However, for the foodstuff use Quassin was defined as a substance of concern and limits were set for the content of this substance in food. Thus, for this compound of the Quassia extract – which is also the active ingredient – residue data are presented and are considered representative of the extract. As a second compound, Neoquassin was analysed.	See comment 6(11)
6(14)	Update summary of intended uses	EFSA: It is noted that the representative use on vegetable seed production and breeding was not		Applicants agree that this is a data gap. This use was proposed by some farmers just before the	EFSA confirms that there are insufficient residue trials analysing for all relevant compounds in the crops that

Residues

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		supported by any residue trial on the edible plants that are produced from these seeds. Since translocation/systemicity of Quassia extract cannot be excluded EFSA is of the opinion that sufficient trials on representative crops should be provided.		update of the applications was finished and data are not available. Thus, the use is removed from the updated GAP table due to lack of economic resources to produce the data necessary to support this use. If data should be available in the future, it will be added again.	are produced from these seeds. This use was removed from updated GAP

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Section 7 fate and behaviour In relation to 2.1. PREDOMINANT USES OF THE SUBSTANCE OUTSIDE PLANT PROTECTION	EFSA: Previous assessments of Quassia extract for food flavour uses do not cover fate and behaviour in the environment and the environmental exposure that may result from its agricultural uses. No data that allow concluding that the risk of the substance for the environment will be low in relation to the rate used seem to be available. Quassia extract was withdrawn from the market in relation to its use as feed additive in virtue of: COMMISSION IMPLEMENTING REGULATION (EU) No 230/2013 of 14 March 2013[7]		Applicants followed the guidance given in the Working Document SANCO 10363/2012 with data preparation and risk assessments for the environmental exposure. In the course of the pilot project, the requirements for basic substance application seem to have considerably changed. If this new requirements have to be fulfilled further studies will be necessary (see also 7(4), 7(3), 7(6)). Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements with an appropriate database.	Data permitting to characterize the risk of the substance for the environment when used according to the proposed GAPs, are currently not available.
7(2)	Section 7 fate and behaviour	EFSA: Quassia extract is a complex mixture of		Applicants fully agree. The study was attached only as a reference	Peer review agrees that available biodegradability

[7] Commission Implementing Regulation (EU) No 230/2013 of 14 March 2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances. OJ L 80, 21.3.2013, p. 1–65.

7.1 Fate and Behaviour in the environment

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	Biodegradability	substances. Ready biodegradation test on the mixture does not allow assessing the biodegradability of the active components on it. So this information is not useful to assess the persistence of these components into the environment.		for the content of Quassin of the batch used in the tests for acute toxicity (see Annex 7) and not for any information about the persistence of the component in the environment. In the estimations for the behavior in the environment worst case assumptions for the persistence were used.	test on quassia extract does not allow assessing the biodegradability of the active components on it. Applicants clarified that the study was not intended to inform on persistence of active components into the environment but just as a reference for the content of quassin of the batch used in the tests for acute toxicity (see Annex 7).
7(3)	Section 7 fate and behaviour Adsorption / desorption in soil of quassin.	EFSA: A QSAR calculation on quassin adsorption / desorption Koc in soil is provided. The appropriateness of this estimation is not assessed. No information is available on other active components.	EFSA: Batch desorption studies on quassin and other active components of *quassia amara* extract would need to be provided in order to address potential surface and groundwater pollution.	Quassin is the active ingredient and also the component of concern that was identified as responsible for a potential impact on human health. Thus, for Quassin and a second ingredient, neoquassin, data are provided (Quassin/Neoquassin mixture) If these requirements have to be fulfilled further studies must be provided by applicants. However, applicants should be given the time necessary to update their proposal to the modification of the requirements	A data gap is identified for batch adsorption/desorption studies on quassin and other active components of Q*uassia amara* L. wood extract that may be identified as biologically active and/or responsible for a potential impact on human health. These data is needed in order to address potential surface and groundwater exposure.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				with an appropriate database. .	
7(4)	Section 7 fate and behaviour Persistence in soil/ exposure to soil compartment	EFSA: No data/information is provided on the persistence of quassia extract active ingredients in soil. No estimation of exposure to the soil compartment as resulting from the agricultural use of quassia extract is provided.	EFSA: Data/information on the persistence of quassia extract active ingredients in soil needs to be provided. Estimation of exposure to the soil compartment as resulting from the agricultural use of quassia extract needs to be provided.	Applicants have discussed with a consultancy office a first possible roadmap for the generation of such data (see Annex 34) and would highly appreciate comments. Quassin is the active ingredient and also the component of concern that was identified as responsible for a potential impact on human health. Thus, for Quassin and a second ingredient, neoquassin, data generation is previsted.	A data gap for data / information on the persistence of *Quassia amara* L. wood extract active ingredients in soil is identified. Available regulation and agreed guidance and test guidelines will need to be used for the production of such data.
7(5)	Section 7 fate and behaviour Fate in the aquatic compartment of the environment	EFSA: No data/information is provided on the persistence of quassia extract active ingredients in surface water and sediment. No estimation of exposure to the aquatic compartment as resulting from the agricultural use of quassia	EFSA: Data/information on the persistence of quassia extract active ingredients in surface water and sediment. Estimation of exposure to the aquatic compartment as resulting from the agricultural use of	Estimation of exposure to the aquatic compartment as resulting from the agricultural use of Quassia extract was requested. Calculation with FOCUS Step 2 and comparison to ecotoxicological endpoints show an acceptable risk for aquatic organisms when default values for FOCUS calculation are chosen (critical use: application October to February in ornamentals with 4	No data/information is provided on the persistence of *Quassia amara* L. wood extract active ingredients in surface water and sediment. Worst case DT50 = 1000 d is to be assumed for surface water and sediment for the exposure assessment to

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		extract is provided.	quassia extract needs to be provided.	times 12 g/ha, interval 7 days). Worst case PECsw was 7.05 µg/l. Worst case PEC/RAC value was 0.81 for Danio rerio (LC50 Quassin (96h) > 870 µg/L). Detailed calculation see Annex 35.	aquatic environment.
7(6)	Section 7 fate and behaviour Potential groundwater pollution	EFSA: Assessment of potential groundwater contamination by quassia extract active components (quassin and other active quassinoids) is not available. The information provided is insufficient to perform such assessment.	EFSA: PECgw calculated following FOCUS guidance and using FOCUS models and scenarios need to be estimate for quassin and other active components of quassia extract.	Applicants followed the guidance given in the Working Document SANCO 10363/2012 with data preparation and risk assessments for the environmental exposure where calculations with FOCUS models were not mentioned. In the course of the pilot project, the requirements for basic substance application have changed considerably. If this new requirements have to be fulfilled further studies will be necessary before a calculation can be carried out with an appropriate database (see 7(4)). Applicants should therefore be given the time necessary to update their proposal to the modification of the requirements with an appropriate database.	Data gap for PECgw calculated following FOCUS guidance and using FOCUS models and scenarios has been identified for quassin and other active components of *Quassia amara* L. wood extract.
7(7)	Ready	DE: The studies have been		This is correct. The notifier has	Noted

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
	Biodegradability of as	submitted for the EU assessment of quassia. Quassia has not been included in Annex I of Directive 91/414/EEC.		withdrawn voluntarily due to economic reasons see 1(1). Since his notification was very much due to the fact that Quassia is an essential use for organic fruit growers and he was asked to notify by them, after the withdrawal for economic reasons he gave access to applicants to the existing data. Applicants presented a Letter of Access from the notifier for the studies subject to data protection.	
7(8)	Adsorption and Desorption of as	DE: EPI suite calculation has been submitted in the EU assessment of quassia, the calculation has been accepted. Quassia has not been included in Annex I of Directive 91/414/EEC.		This is correct. The notifier has withdrawn voluntarily due to economic reasons see 1(1). Since his notification was very much due to the fact that Quassia is an essential use for organic fruit growers and he was asked to notify by them, after the withdrawal for economic reasons he gave access to applicants to the existing data. Applicants presented a letter of access from the notifier for the studies subject to data protection.	Noted
7(9)	Photostability(DT50) (aqueous,	DE: The studies have been submitted for the EU		This is correct. The notifier has withdrawn voluntarily due to	Noted

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
	sunlight,state pH)	assessment of quassia. Quassia has not been included in Annex I of Directive 91/414/EEC.		economic reasons see 1(1). Since his notification was very much due to the fact that Quassia is an essential use for organic fruit growers and he was asked to notify by them, after the withdrawal for economic reasons he gave access to applicants to the existing data. Applicants presented a LoA from the notifier for the studies subject to data protection.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
7(10)		NL: No such paragraph was included in the concept dossier. Please include an overview of the relevant exposure routes into the environment related to the proposed use(s) including		Applicants presented estimations of the exposure into the environment in the Annexes 23 and 25. Since the calculation with FOCUS models is now required, a calculation for the exposure to the aquatic compartment with	A preliminary exposure assessment to quassin (one active component of *Quassia amara* L. wood extract) has been performed based on preliminary input values and FOCUS Step 2 calculations.

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		quantification of the fluxes if possible.		FOCUS s/w is presented. Calculation with FOCUS Step 2 and comparison to ecotoxicological endpoints show an acceptable risk for aquatic organisms when default values for FOCUS calculation are chosen (critical use: application October to February in ornamentals with 4 times 12 g/ha, interval 7 days). Worst case PECsw was 7.05 µg/l. Worst case PEC/RAC value was 0.81 for Danio rerio (LC50 Quassin (96h) > 870 µg/L). Detailed calculation see Annex 35. For a calculation of soil and groundwater exposure with FOCUS models further data have to be generated. before a calculation can be carried out with an appropriate database see also 7(6).	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8, page 43	NL: please adapt the sentence Supplementary to the first proposal of 2012 a review of scientific open literature with the main purpose to gain additional information about the impact on human and animal health and possible effects on non-target organisms or the environment with reference to the questions posed by EFSA and MS in the reporting table in the introduction of chapter 8 as it does not run well.		The sentence was changed in the updated proposal: 'In the first proposal of 2012 a review of available scientific open literature was provided. In this updated proposal, a new and very detailed research with the main purpose to gain additional information about the impact on human and animal health and possible effects on non-target organisms or the environment with reference to the questions posed by EFSA and MS in the reporting table was added. References already cited in the first proposal were not considered relevant in the search (Annex 31).'	Addressed

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
8(2)	8.2, oage 45	NL: please replace the word daphnies in the third bullet by daphnias		The typing error was corrected in the updated proposal.	Addressed
8(3)	8.2, page 46	NL: please refer to the CLP Regulation 1272/2008 instead of the DPD regulation 67/548/EEC (67/548/EWG does not exist) in the sentence above table 10.		The reference was replaced in the updated proposal.	Addressed
8(4)	8.2, oage 46	NL: please replace the word daphniae in first column of table 10 by daphnia		The word was replaced in the updated proposal	Addressed
8(5)	8.2, page 48	NL: please rewrite the first sentence of the conclusion as it is not clear to us what is meant with the initial situation is liable to worst case conditions		Rewritten in the updated proposal as follows: The highest tolerable levels for the active ingredient Quassin for *Danio rerio*, *Daphnia magna* and mosquitos are much higher than the calculated results beside the fact that the initial situation was calculated with worst case conditions.	Addressed It is noted that the highest tolerable levels calculated by dividing the toxicity endpoints by a factor of 10, is not an approach used for pesticides. The calculation of the RAC as reported in the Annex 35, and in general of the risk characterisation, is considered the appropriate approach and is not consistent with the assessment reported in the updated application

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	Calculation of the driftage for worst case conditions	DK: When a quantitative risk assessment is included please use FOCUSsw to estimate the worst case exposure.	DK: Please use FOCUSsw.	Estimation of exposure to the aquatic compartment as resulting from the agricultural use of quassia extract were requested. Calculation with FOCUS Step 2 and comparison to ecotoxicological endpoints show an acceptable risk for aquatic organisms when default values for FOCUS calculation are chosen (critical use: application October to February in ornamentals with 4 times 12 g/ha, interval 7 days). Worst case PECsw was 7.05 µg/l. Worst case PEC/RAC value was 0.81 for Danio rerio (LC50 Quassin (96h) > 870 µg/L). Details see Annex 35.	Addressed. The worst-case FOCUS PECsw is compared with the RAC in the annex 35 of the application. The risk to aquatic organisms is indicated as low for aquatic organisms.
8(7)	Long term risk estimate	DK: Please include the scenario for ornamentals and seed production (3.3 Intended uses) where there are 4 applications pr. year (7 d intervals) and a 4 times higher application rate than what has been included in the risk assessment for orchards.	DK: Please update the risk assessment to include worst case scenarios according to the intended uses (3.3 Intended uses)	These uses were withdrawn from the GAP table for several reasons. However, they were included in the calculations with FOCUS s/w see 8 (6).	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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
8(8)		DE: Data on the toxicity to bee larvae / bee brood are lacking.	Further data should be submitted to address this issue.	A new study is presented where the effect on bee brood was investigated in the field. It states that it can be concluded that an application of Quassia extract is very unlikely to pose acute threads to honey bees (Slave, J., 2017 Details see Annex 33).	The new study provided is insufficient to conclude on the effects on bee brood: the number of hives was low; the application rate was lower than the rates for the representative uses. However, the overall information provided (i.e. acute toxicity studies) allows to conclude that the risk to bees is expected to be low for the representative uses.
8(9)	Kienzle et al, 2004 and Vogt, 2001	DE: According to Kienzle et al. larvae of Aphelinus mali showed a mortality of 33 % compared to 3 % in the control when exposed to 18 g Quassin /ha. Also Chrysoperla carnea larvae showed a mortality of 30 % compared to 0 % in the control even at an application rate of no more than 8 g / ha (the requested application rate is between 6 and 18 g / ha).	It should be discussed why a mortality of this level is considered as harmless.	***Aphelinus:*** *Aphelinus mali* occurs only in apple orchards where the highest application rate is 12 g/ha so that 18 g/ha are not relevant. Regarding hop: For apple orchards, the amount of 18 g/ha used in the study referring to apple orchards, means higher concentration as for hops since the height of an apple orchard is usually between 2-3 m and hops are 4 m (Amount of water for apples about 500-1000 L/ha, for hop about 2.300 L/ha). Thus, the	Addressed The information provided for Non-target arthropods is considered sufficient for addressing the risk for the representative uses.

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
				concentration used in the study is also higher than the concentration applied for in hop. ***Chrysoperla***: Applicants understand that this comment refers to the study of VOGT (2001). The mortality was about 20 % compared to 0 % in the control. There was one significant effect which authors consider as coincidental themselves. The concentration of the 'Quassia solution' was not precise but estimated roughly by applicants. There are other data from studies from the same author with a defined extract of Quassia (Bathon et al., 2004, Kienzle et al., 2004) that clearly showed no effect of Quassia extract on *Chrysoperla carnea.*	
8(10)	8.3, page 49	NL: please check the last sentence in the section history of safe use as it contains typing errors.		The sentence was corrected in the updated proposal.	Addressed
8(11)	8.3.1 History of safe use	DK: Please justify the argumentation when compared with the intended	DK: Please justify why the argumentation is relevant for the intended use, also	The user history is mainly sawfly control and the recommendation for the effective concentration of	See 8(8) and 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** **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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		uses (3.3). The argumentation by the applicant mentions use at the end of blossom; however the intended uses against e.g. aphids in orchards are for the whole blossom period (BBCH 55-69). It is thus clear that the argument does not cover the intended uses. Also, please clarify how, where and why Quassia has been used by organic farmers for the last 15-20 years (as it is not approved in the EU as neither a.s. nor basic substance). Overall, the risk to honeybees (and other pollinator in 8.3.2) is not shown to be not unacceptable.	specify the user history of Quassia extracts in EU (MSs, dosages, timing etc.). Please consider re-submitting an active substance dossier.	6-12 g Quassin resp. 20 kg Quassia wood chips per ha has not changed during the years. Since new data on the effect on bees are presented, this is not discussed further. For the topic of the submission of an active substance dossier see 1(1). A new field study from the University of Hohenheim is presented that takes in consideration also effects on the brood. It states that it can be concluded that an application of Quassia extract is very unlikely to pose acute threads to honey bees (Slave, J., 2017 Details see Annex 33).	
8(12)	8.3.1 Literature survey	DK: Not acceptable to state that *It is always cited in prior literature that this product is safe for honeybees* based on references from 1972 and 1982.	DK: Please update the wording and/or argumentation, and include some more recent reference if available.	See 8 (12)	See 8(8) and 8(9)
8(13)	8.3.2	DK: The introduction for this		*Quassia amara* is a food additive	See comment 9(1)

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		section (and the introduction in 8.5) underlines the point in DE comment 9(1); that the substance is already predominately used for plant protection and therefore does not fulfil Article 32 (1c) of Reg. 1107/2009. This is attempted contradicted by the applicant in chapter 9 with the statement: '*The extract of the wood of Quassia amara is not predominantly used for plant protection purposes but nevertheless there is a traditional and essential use in organic farming for plant protecting product either.'* The sentence is confusing, and as a minimum the applicant should justify why the use in organic farming is not predominantly compared to e.g. the use as a food ingredient; especially when the information is added that the substance is		and there is a documented use in Europe see Annex 2. There was a use as feed additive and in cosmetics which seem no longer allowed in Europe for commercial products since Quassia was not defended by any industry during the renewal of the respective legislation. However, looking at the recommendations and comments on the appropriate homepages there may be still a considerable use in self preparation of cosmetics. Furthermore, the use in traditional herbal medicine has to be considered. In this context there is also a considerable self medication with teas from Quassia chips etc. to consider. Not all producers of drinks and bakery wave give the full recipe with quantification on their homepage and the self preparation is difficult to estimate so that it is impossible to quantify these uses of Quassia for Europe in kg of Quassia wood chips. Quassia can be found in the assortment of most major	

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
		already listed nationally as plant protection in Germany.		providers of herbage for different uses. This also underlines the widespread use for several purposes mentioned above and should be prove enough that the substance is not predominantly used for plant protection purposes. The use in plant protection is also limited to few uses and to organic farming. The traditional use of Quassia in plant protection is much more limited than the use of *Equisetum arvense* or *Urtica dioica* which are both already approved as basic substance. Regarding the situation in Germany this is a misunderstanding. Quassia was never listed as PPP in Germany. In the proposal (page 52, overall conclusion) it was already outlined: Quassia was listed according to § 6a of the Plant Protection Act (PflSchG) enacted until 14.2.2012 as a substance for self-preparation of products for plant protection on farm. This	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
				regulation was so similar to Article 23 of the Regulation (EC) of 1107/2009 that during the implementation of the Regulation 1107/2009 even a transitional rule (§ 74 Pfl.sch.ges.) was established to allow the use of these substances as long as the application for basic substance is under progress.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

8.5. Effects on soil microorganisms

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

No comments

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 EFSAs scientific views on the specific points raised in the commenting phase conducted on the application
8(14)	8.7, page 52	NL: Please remove the sentence For comparison: The EC50 for algae is (Pseudokirchneriella subcapitata) 1.57 mg/L. as the concentration of quassin in water should be compared to an endpoint for STP micro-organisms and not to an endpoint for algae.		The sentence was removed in the updated proposal.	Addressed

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** **EFSAs 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** **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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
9(1)	Eligibility of *Quassia amara* L. wood extract as basic substance	DE: To ensure a transparent and thorough assessment, it is proposed to provide an assessment of *Quassia amara* L. wood extract as botanical active substance in line with Guidance Document SANCO/11470/2012. Quassia was already used as pesticide in the past and a monograph was prepared in the context of inclusion in Annex I of the Council Directive 91/414/EEC in 2007. According to this monograph 'quassia is currently used in orchards against sawflies and in ornamentals against aphids.' Therefore, it is questionable if *Quassia amara* complies with the approval criteria of article 23 of Regulation (EC) No 1107/2009 that a basic		There will be no assessment of *Quassia amara* L. wood extract as botanical active substance in line with Guidance Document SANCO/11470/2012 since no company will apply for it. Due to simple economic reasons (see also 1(1)) it is not possible to convince a company to invest time and money in an active substance dossier. Applicants already tried this and the notifier drew back the monograph when it was clear that the cost of dossier preparation would overrun by far a possible return of investment. If there is a possibility for a professional farmers association that has no interest in trading PPP to submit an active substance dossier for a substance not already authorised in a procedure similar to Art. 51 of the Reg. 1107/2009, applicants are interested to explore the	As far as EFSA is aware quassia, quassin or quassia extract, are not approved as food or feed additive, flavouring or food ingredient in Europe. Quassin is included in Annex III of Regulation (EC) 1334/2008 as a substance that shall not be added as such to food (in Annex III are listed substances that are naturally present in food and for which a maximum level was set). The issue whether *Quassia amara* L. wood extract fulfils the criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue and EFSA does not provide any further opinion in relation to the subject

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
		substance is not predominantly used for plant protection purposes. Further doubts about the compliance with the approval criteria of article 23 are described in comments 5.16, 5.31 and 5.32.		modalities for essential uses with low market potential as Quassia with EU and MS authorities. There is no guidance and no evidence that a previous application in the context of inclusion in Annex I of the Council Directive 91/414/EEC should conflict with an application for basic substance. Quassia is listed on the DRAFT LIST OF POSSIBLE CANDIDATES FOR BASIC SUBSTANCES https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_basic-subst_list-candidates.pdf. Even substances with a history of approved plant protection product in commerce (e.g. soy lecithin) were applied and approved as basic substance. Quassia has traditional uses as foodstuff, in traditional medicine, in cosmetics and even in feed. Since it is very selective and effective only for few uses, the traditional use in plant protection is much more limited than e.g. for	See also comment 5(1)

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
				Equisetum arvense or *Urtica dioica*, botanical substances with traditional use in plant protection already approved as basic substance. Quassia extract is legally used as food additive. In Annex III, part A, of the Regulation 1334/2008 pure Quassin is listed as pure substance that may not be added as such to food. The use of Quassia extract as food additive is regulated in Annex III, part B of the Regulation 1334/2008 (see also 5(1). Currently, Quassia is used and declared as flavouring in Europe in several products (see Annex 2). In the course of the pilot project, the requirements for the basic substance application have considerably changed and now a dossier quality similar to a dossier for an assessment as botanical active substance in line with Guidance Document SANCO/11470/2012 is required.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
				Applicants should therefore be given the time to update their proposal and database to the modification of the requirements during the pilot stage.	
9(2)	Eligibility of *Quassia amara* L. wood extract as basic substance	DK: Agree with the comment from DE: '*To ensure a transparent and thorough assessment, it is proposed to provide an assessment of Quassia amara L. wood extract as botanical active substance in line with Guidance Document SANCO/11470/2012.'*	DK: Please consider re-submitting an active substance dossier; additionally please note the *draft GD on Botanical active substances used in plant protection products* (February 2017)	There will be no assessment of *Quassia amara* L. wood extract as botanical active substance in line with Guidance Document SANCO/11470/2012 in the frame of an application for an inclusion since no company will apply for it. Due to simple economic reasons (see also 1(1)) it is not possible to convince a company to invest time and money in an active substance dossier. Applicants already tried this and the notifier drew back the monograph when it was clear that the cost of dossier preparation would overrun by far a possible return of investment. If there is a possibility for a professional farmers association that has no interest in trading PPP to submit an active substance dossier for a substance not	See comment 9(1)

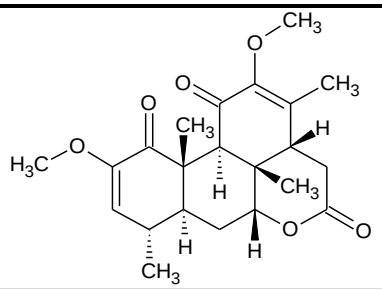
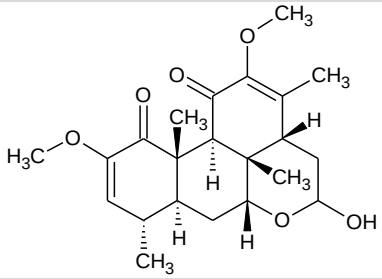
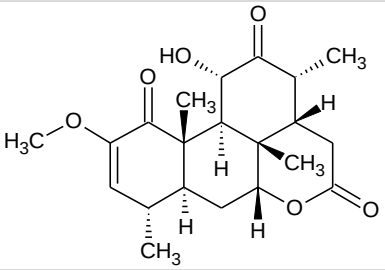
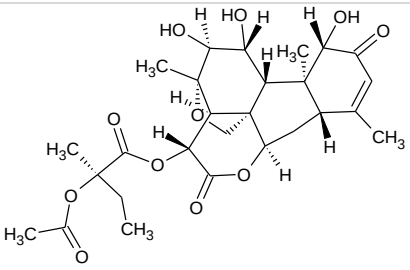
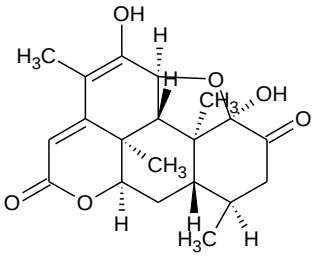
Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**
				already authorised in a procedure similar to Art. 51 of the Reg. 1107/2009, applicants are interested to explore the modalities for essential uses with low market potential as Quassia with EU and MS authorities.	

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** **EFSAs scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

Appendix B – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey*	Structural formula*
quassin	2,12-dimethoxypicrasa-2,12-diene-1,11,16-trione O=C2C(OC)=C(C)[C@@H]4CC(=O)O[C@@H]3C[C@H]1[C@H](C)C=C(OC)C(=O)[C@]1(C)[C@@H]2[C@@]34C IOSXSVZRTUWBHC-LBTVDEKVSA-N	
neoquassin	16-hydroxy-2,12-dimethoxypicrasa-2,12-diene-1,11-dione O=C1C(OC)=C[C@@H](C)[C@@H]2C[C@H]3OC(O)C[C@H]4C(C)=C(OC)C(=O)[C@H]([C@@]12C)[C@@]34C BDQNCUODBJZKIY-NUPPOKJBSA-N	
paraine	(11α)-11-hydroxy-2-methoxypicras-2-ene-1,12,16-trione C[C@@H]1C=C(OC)C(=O)[C@]2(C)[C@H]4[C@H](O)C(=O)[C@H](C)[C@@H]3CC(=O)O[C@H](C[C@@H]12)[C@@]34C WKQCYNCZDDJXEK-RKDOZKMISA-N	
quassimarin	(1β,11β,12α,15β)-1,11,12-trihydroxy-2,16-dioxo-13,20-epoxypicras-3-en-15-yl (2*R*)-2-(acetyloxy)-2-methylbutanoate CC(=O)O[C@](C)(CC)C(=O)O[C@H]2C(=O)O[C@@H]5C[C@H]1C(C)=CC(=O)[C@@H](O)[C@]1(C)[C@@H]4[C@]35CO[C@@](C)([C@H]23)[C@@H](O)[C@@H]4O FXMIXHYJCNZLFE-ACBKHETBSA-N	
quassinol	(1α,11α)-1,12-dihydroxy-1,11-epoxypicrasa-12,14-diene-2,16-dione C[C@@H]5CC(=O)[C@]4(O)O[C@@H]3C(O)=C(C)C1=CC(=O)O[C@@H]2C[C@@H]5[C@@]4(C)[C@@H]3[C@]12C WKNPIBKVHHVICI-DIPGMJKUSA-N	

* ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 Dec 2014) ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 Dec 2014)

Appendix C – Identity and biological properties

Common name	Extract of the wood of *Quassia amara* L.
Chemical name (IUPAC)	Not relevant, complex mixture
Chemical name (CA)	Not relevant, complex mixture
Common names	Amargo, Bitter-ash, Bitter-wood, Quassia wood, Ruda, Surinam Quassia, Surinam Wood
CAS No	84604-10-4
EINECS No	283-287-7
FAO specification	none
Minimum purity	Not applicable (quassin 0.1 %)
Relevant impurities	
Molecular mass and structural formula	Not applicable, complex mixture
Mode of Use	Spray, brush application
Preparation to be used	SC
Function of plant protection	Insecticide, repellent

Appendix D – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) per crop/ season	Interval between applications (min)	g a.s./hL	Water l/ha min max	g as/ha a) quassin/ha or b) quassia wood chips/ha		
Pome fruit and stone fruit	EU	Quassia extract	F	Sawflies, aphids and cecidomyiids	SC	200 g/l (Quassia chips)	spray	BBCH code 65-69 for sawfly, 55 -69 for aphids,and cecidomyiids; spring until the end of blossom	1	n.a.	Depends on the content of Quassin	500-1000	a) 6-12 g Quassin/ha or b) 10 – 20 kg Quassia wood chips/ha		
Hop	EU	Quassia extract	F	Hop aphids	SC	200 g/l (Quassia chips	spray	BBCH 39 End of June BBCH 69 mid of July	1	n.a.	Depends on the content of Quassin	2300	a) 18 g Quassin/ha or b) 30 kg Quassia wood chips/ha		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) per crop/ season	Interval between applications (min)	g a.s./hL	Water l/ha min max	g as/ha a) quassin/ha or b) quassia wood chips/ha		
Hop	EU	Quassia extract	F	Hop aphids	SC	200 g/l (Quassia chips	brush	BBCH37 First decade of June, efficient only if applied before BBCH 39	1	n.a.	Depends on the content of Quassin	Mixed in 4-5 L Trifolio S forte (plant oil) and 0,5 L water, brushed 25 cm on 3 stems at 1 m height	a) 18 g Quassin/ha or b) 30 kg Quassia wood chips/ha		

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
(d): e.g.wettablepowder (WP), emulsifiableconcentrate (EC), granule (GR) etc..
(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f): All abbreviations used must be explained
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k): Indicate the minimum and maximum number of application possible under practical conditions of use
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m): PHI - minimum pre-harvest interval