TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for *Castanea* and *Schinopsis* tannins for use in plant protection as bactericide, fungicide and nematicide

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Castanea* and *Schinopsis* tannins 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 *Castanea* and *Schinopsis* tannins as a basic substance for use in plant protection against bacteria, nematodes and fungi. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Keywords: *Castanea* and *Schinopsis* tannins, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00673

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Summary

Castanea and *Schinopsis* tannins 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 IAZ Développement 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 *Castanea* and *Schinopsis* tannins, 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 *Castanea* and *Schinopsis* tannins, 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 *Castanea* and *Schinopsis* tannins and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Castanea and *Schinopsis* sp. tannins is the name given to a 1:1 mixture of two types of tannins, extracted with water from the wood of chestnut tree (*Castanea sativa*) and red Quebracho (*Schinopsis lorentzii*). Chestnut tannins belong to the family of hydrolyzable tannins while Quebracho tannins belong to the family of condensed tannins. The most known representative of the category of hydrolysable tannins is tannic acid, the Quebracho tannins are mainly constituted by oligomers of flavan-3-ol units. Tannic acid is authorised as a feed additive for all animal species and is used as a flavouring substance in food, and tannins are used in the wine sector.

Castanea and *Schinopsis* sp. tannins are intended to be used as a soluble concentrate on tomatoes, aubergines, potatoes, lettuces and salads, carrots, celery, parsnip, horseradish, Jerusalem artichokes, parsley root, turnip, rutabaga, radishes, cucurbits, sugar beet, buckwheat, almond, walnuts, chestnuts, hazelnuts and stone fruits as bactericide, fungicide and nematicide. It is intended to be used also as an elicitor for buckwheat, rye, barley, wheat and oat.

The toxicological asssessment of *Castanea* and *Schinopsis* sp. tannins relied on a limited number of published toxicity studies. These studies related mainly to tannic acid. The toxicity studies included genotoxicity, oral short-term toxicity and oral long-term toxicity and showed low concern by the oral route. Low oral absorption is expected. Under this application the applicant proposed an ADI on the basis of background intake exposure in USA and then used the same value as the AOEL. The non-dietary risk assessment was only performed for operators[1] (other groups, i.e. workers, bystander and residents were not included). However the limited number of studies does not allow properly to set reference values and therefore to perform a- non-dietary risk assessment. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded in 2014 that the use of tannic acid as a feed additive up to 15 mg/kg feed is safe for all animal species. EFSA FEEDAP also considered that in the absence of data, it would be prudent to regard the additive as potentially hazardous to workers by exposure to the skin, eyes and mucous membranes or by inhalation exposure. According to ECHA, the substance is not classified; however they warn that the substance is

[1] EFSA also noted that the UK POEM model was used for greenhouse uses and this model is not applicable to greenhouse uses.

notified as causing serious eye irritations and skin irritation. According to the fist assessment of IARC in 1976 tannic acid is carcinogenic in rats and mice following its subcutaneous application. Condensed tannins produced both local sarcomas and liver tumours in mice. IARC in 1987 updated its assessment and considered the evidence of carcinogenicity for tannins, including tannic acid, is inadequate in humans and inadequate or limited in experimental animals.

Overall, there are indications that tannins are of low concern by the oral route and they are naturally occurring substances. However, considering other routes of exposure, relevant for non-dietary exposure groups further considerations are needed. In line with the EFSA FEEDAP Panel, EFSA considered that in the absence of adequate data, it would be prudent to regard tannins as potentially hazardous to non-dietary exposure groups by exposure to the skin, eyes and mucous membranes or by inhalation exposure. A proper non-dietary risk assessment cannot be conducted based on available data.

In the residues section, any data investigating degradation/metabolism of the components in the extracts on plants, or the degree of such potential breakdown, is not available. Degradation, if it was occurring, would likely lead to hydrolysis and the release of compounds with the flavan-3-ol unit (such as epigallocatechin and epicatechin) from Quebracho tannins and of mainly gallotannins (tannic acid, hydrolysable to gallic acid) from chestnut tannins. Considering the composition of the substance is 50% Quebracho tannins and 50% chestnut tannins, their sources of natural occurrence in food vs. their addition to food, their different chemical structures and possibly different properties, EFSA suggests considering chestnut tannins and Quebracho tannins separately in the consumer exposure and risk assessment. Comparison was made of the estimated chronic intakes from the use of the basic substance with habitual intake of flavan-3-ols via the regular diet (Quebracho tannins), and of the estimated concentrations of tannic acid on treated crops with permitted maximum concentrations when tannic acid is added to food (chestnut tannins; based on values from US FDA, since no evaluation at EU level and no exposure assessment is available), respectively. No specific concern was identified for adults, however, based on the scarce data an assessment could not be finalised for children.

A clear aquatic exposure assessment resulting from spray drift, indicating the exposure mitigation proposed (20 m for downward hydraulic spraying and 50 m for air assisted broadcast spraying) that would reduce exposure to demonstrate low risk, was not available.

On the basis of the available information, the risk to non-target organisms could not be excluded for the uses considered, except for the risk for soil organisms.

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1. Introduction

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

Regulation (EC) No 1107/2009[2] (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.

Castanea and *Schinopsis* tannins is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from IAZ Développement for approval as a 'basic substance' for use in plant protection against bacteria, nematodes and fungi.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Castanea* and *Schinopsis* tannins, which was conducted via a written procedure in June-August 2017. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for *Castanea* and *Schinopsis* tannins and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of *Castanea* and *Schinopsis* tannins 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 (IAZ Développement; 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 21 September 2017, EFSA was asked to organise a consultation on the basic substance application for *Castanea* and *Schinopsis* tannins, 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 21 December 2017.

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

[2] 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 *Castanea* and *Schinopsis* tannins and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

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

Documentation provided to EFSA

1. IAZ Développement, 2017a. Basic substance application on *Castanea* and *Schinopsis* tannins 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. IAZ Développement, 2017b. Basic substance application update on *Castanea* and *Schinopsis* tannins submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2017. Documentation made available to EFSA by the applicant.

References

EFSA ANS Panel (EFSA Panel on Food additives and Nutrient Sources added to Food), 2014. Scientific Opinion on the re-evaluation of propyl gallate (E 310) as a food additive. EFSA Journal 2014;12(4):3642, 46 pp. doi:10.2903/j.efsa.2014.3642

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014. Scientific Opinion on the safety and efficacy of tannic acid when used as feed flavouring for all animal species. EFSA Journal 2014;12(10):3828, 18 pp. doi:10.2903/j.efsa.2014.38280.

European Commission, 2014a. Guidance on botanical active substances used in plant protection products. SANCO/11470/2012– rev. 8. 20 March 2014. 28 pp.European Commission, 2014b. Guidance 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. 27 pp.

FAO (Food and Agriculture Organization of the United Nations) JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2009. FAO JECFA Monographs 7. Tannic acid ins:181, superseding specifications prepared at the 39th JECFA (1992), published in the combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005).

IARC Monographs on the evaluation of the carcinogenic risk to Man, 1976. Some naturally occurring substances. Volume 10. 1976. Page 253.

IARC Monographs on the evaluation of the carcinogenic risk to Humans, 1987. Evaluation of Carcinogenicity. An update of IARC Monographs Volumes 1 to 42. Supplement 7. Page 72.

Vogiatzoglou, A., Mulligan, A., Luben, R., Lentjes, M., Heiss, C., Kelm, M.,Kuhnle, G., 2014. Assessment of the dietary intake of total flavan-3-ols, monomeric flavan-3-ols, proanthocyanidins and theaflavins in the European Union. British Journal of Nutrition, 111(8), 1463-1473. doi:10.1017/S0007114513003930

Vogiatzoglou A, Mulligan AA, Lentjes MAH, Luben RN, Spencer JPE, Schroeter H, et al, 2015. Flavonoid Intake in European Adults (18 to 64 Years). PLoS ONE 10(5): e0128132

Abbreviations

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
a.s.	active substance
CLP	Classification labelling and packaging
DAR	draft assessment report
ECHA	European Chemicals Agency
EU	European Commission
GAP	good agricultural practice
IARC	International agency for research on cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC50	lethal concentration, median
LD50	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
OASIS	Optimized Approach Based on Structural Indices Set
PCBs	polychlorinated biphenyls
PEC	predicted environmental concentration
PHI	pre-harvest interval
PNEC	Predicted non effect concentration
POEM	Predictive operator exposure model
PRIMo	Pesticide Residue Intake Model
QSAR	quantitative structure–activity relationship
RAC	regulatory acceptable concentration
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Castanea* and *Schinopsis* tannins and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	**Column 1** **Reference to application template**	**Column 2** **Comments from Member States/EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow-up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)	Tables in general	DK: Please hide the formatting symbols.	Delete/hide the formatting symbols from all the tables.	Tables corrected in BSA.	Addressed.
1(2)	Read across	DK: There are some read-acrosses included in the application e.g. Acacia and Mimosa). Please clearly justify in each case why this is acceptable for the purpose of the application (e.g. aquatic ecotox). Also consider if other substances may be relevant for a read-across e.g. acetic acid.	Include clear justification for inclusion and acceptability of read-across in each case it is done in the application.	Substance is natural extract, blend of two origins Tannins hydrolysed and condensed. Read across justification is added in different parts of basic substance application. Tannins are big polymers (300-3000 da) with various structures. Common point is their chemical reactivity (proteins) to be classified as Tannins. In BSA read-acrosses concern only Tannins origins substances witch is more relevant than other substances.	Addressed. Read across justification was added in different parts of the updated submission.
1(3)	Overall	DK: We do not agree based on this application that Article 23(2) has been fulfilled. According to Article 23(2) *a basic substance*	Include risk assessment for human health and the environment (especially soil micro- and macroorganisms). Please see the EFSA conclusion on acetic	Risk approach is completed in the basic substance application. Taking account proposed GAP, reference values are selected according bibliography, with justification or estimation for existing concentration for similar substances in the	Overall, there are indications that tannins are of low concern by the oral route. Therefore, considering other routes of exposure, relevant for non-dietary exposure groups

General

No.	Column 1 Reference to application template	Column 2 Comments from Member States/EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow-up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		shall be approved where any relevant evaluations, carried out in accordance with other Community legislation regulating the use of that substance (…) show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment. The application for tannins as a basic substance *may* not be feasible based on the general lack of data and risk assessments from other use areas. As the EFSA conclusion on acetic acid shows risk assessment of this type of substances may be challenging and should not per default	acid (*EFSA Journal 2013;11(1):3060*) as to what degree of risk assessment may be needed to show no unacceptable risk for tannic acid. Or clearly state why tannic acid may not be as challenging for risk assessors in this case. Please include background estimations (calculations?) and information, and clearly show whether or not use according to the applied for good agricultural practices (GAP) will be within this background exposure.	Environment (soil, plants and water). The following table summarize additional parts in the BSA: <table><tr><th>Risk</th><th>Models</th><th>Ref values</th><th>Results</th></tr><tr><td>Operator risk</td><td>UK POEM + greenhouse risk</td><td>AOEL 2 mg/kg/bw/day</td><td>Without adverse effect. (20.5 – 113%) AOEL</td></tr><tr><td>Consumer risk</td><td>Primo</td><td>ADI 2mg/kg</td><td>15-109% of the restrictive ADI</td></tr><tr><td>Environment soil risk</td><td>PEC calculs</td><td>PNEC soil 0,2 g/kg</td><td>PNEC/PEC 0,0067 – 0.04</td></tr><tr><td>Environment groundwater risk</td><td>PEC Calculs</td><td>Not relevant</td><td>No exposal</td></tr><tr><td>Aquatic ecotoxicology risk</td><td>Pnec calcul/pec<1</td><td>Castanea 0,2 mg/L Quebracho 0,11mg/L</td><td>Buffer zone management</td></tr><tr><td>Soil arthropods ecotoxicology risk</td><td>Pnec calcul/pec<1</td><td>Refer to Pnec soil</td><td>Argumentation</td></tr><tr><td>Microorganisms ecotoxicology risk</td><td>Pnec calcul/pec<1</td><td>Refer to Pnec soil</td><td>Argumentation</td></tr><tr><td>Soil earthworms ecotoxicology risk</td><td>Pnec calcul/pec<1</td><td>Refer to Pnec soil</td><td>Argumentation</td></tr></table>	further considerations are needed. In line with the EFSA FEEDAP Panel (2014) EFSA considered that in the absence of adequate data, it would be prudent to regard tannins as potentially hazardous to non-dietary exposure groups by exposure to the skin, eyes and mucous membranes or by inhalation exposure. A proper non-dietary risk assessment cannot be conducted based on the available data.

General					
No.	**Column 1** **Reference to application template**	**Column 2** **Comments from Member States/EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow-up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		be assumed as not problematic when used as a pesticide. The EFSA Scientific Opinion on the safety and efficacy of tannic acid when used as feed flavouring for all animal species (FEEDAP, 2014) gives a safe use up to 15 mg/kg feed. How does this dose relate to proposed uses for this application? What are the risk to human health and the environment? There is no risk assessments included *in accordance with other Community legislation regulating the use of that substance*. Our main concerns are regarding human health as well as the environment/ecotox (especially soil microorganisms and			

General					
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		earthworms). Applying tannins (tannic acid) in accordance with the proposed uses cannot be covered by risk assessment for the use as a feed additive. According to the draft GD on Botanical active substances used in PPP (February 2017) it is stated in point 47: '*For botanicals active substances lacking a substantially reported history of use or for botanical active substances whose intended use levels will significantly exceed historical use or background exposure levels the assessment has to rely on basically the same set of data as for synthesised chemical active*			

General					
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		substances in PPP (default approach) with options for scientifically justified deviations from data requirements.' Even though the guidance is currently a draft, please state the background exposure (in different environmental compartments e.g. soils, water bodies and ground water), and clearly show whether or not use according to the applied for good agricultural practices (GAP) will be within this background exposure.			

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		NL: No comments			Noted
2(2)	Identity	EFSA: the substance is defined as a 50:50 mixture of tannins from chestnut tree and from the Quebracho tree, but all the references to EU evaluations, authorisations relate to tannic acid from chestnut tree. Are these considered directly applicable to the tannins of the Quebracho tree, which are different chemical substances?	COMMISSION IMPLEMENTING REGULATION (EU) 2017/66[3] is making reference to tannic acid produced by extraction from different plants. Purity: min. 93 % on dry matter basis Chemical formula: C76H52O46 CAS number 72401-53-7 FLAVIS No: 16.080 Method of analysis(1) For the determination of tannic acid, in the feed additive: Qualitative colorimetric or precipitation tests (Ph. Eur. 6th edition, monograph 1477) and quantitative gravimetric method (FAO JECFA tannic acid monograph).	The chestnut tannins belong to the class of hydrolysable tannins, constituted by ellagic acid esters with glucose. The castalagin is representative substance, Tannic acid is a broad family which include it. The quebracho tannins belong to the class of condensed tannins, subclass profisetinidins being constituted by oligomers mainly of flavan-3-ol units. Molecules structure cannot be assimilated to Tannic acid, but in context of physical chemistry properties can be assimilated if no alternative pertinent data exists.	Addressed: The tannins of Quebracho, acacia and mimosa are part of the family of condensed tannins. Quebracho tannins are structurally related to the *Acacia mearnsii* tannins and Mimosa (*Acacia dealbata)* tannins.
2(3)	Identity, 2.1.5.1 Degree of purity	EFSA: it is stated that the purity is 100%, but this is the 'purity' of the 1:1 mixture of	Probably more correct would be to state that there is 50% chestnut tannin and 50%	Substance is 50% chestnut tannin and 50% Quebracho tannin	Addressed. The revised application was updated.

[3] Commission Implementing Regulation (EU) 2017/66 of 14 December 2016 concerning the authorisation of tannic acid as a feed additive for all animal species. C/2016/8213. OJ L 13, 17.1.2017, p. 259–262.

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		two different tannins composed by different substances.	Quebracho tannin.		
2(4)	2.1.5.1 Degree of purity	EFSA: under the purity clause reference is made to two REACH assessments of the extracts. Is there a possibility to propose a kind of min. specification of the extracts based on these documents? (Silva team, Quebracho extract: collection of the available information.Assesment report..Ledoga s.r.l-Silviachimica s.r.p; CRCF 2015; Castanea sativa mill:chestnut tannin.Centro ricerche per la chimica fine s.r.l.San Michele Mondovi 06-24-2016)	As the minimum purity and also the methods of analysis for the extracts are referenced to the two REACH assessments, it would be logical to propose a specification based on these documents or is the intention to propose a 'specification' for example based on the findings under 2.1.2 or this is the specification?	Intent is to refer analytical methods to the two REACH assessments. BSA is updated in 2.1.	Addressed. Composition of basic substance is 50% chestnut (*Castanea sativa*) tannins and 50% Quebracho (*Schinopsis lorentzii*) tannins extract according to ISO14088 method.
2(5)	2.1.7.2 Analytical methods for relevant impurities	EFSA: it is not clear from the paragraph whether analysis for heavy metals, dioxins, PCBs and micotoxyns have been carried out experimentally or just a theoretical consideration was done?		Heavy metals, dioxins, PCBs and mycotoxins have been carried out experimentally according manufacturer information. Specifications updated in BSA.	Addressed: The analytical results of the heavy metal content determination were included in the updated submission.

2.2. Current Former and in case proposed trade names					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(6)		NL: No comments			Noted

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(7)		NL: No comments			Noted
2(8)		EFSA: as a basic substance cannot be linked to a Company, probably Silvateam is mentioned as an example	A 1:1 mixture of chestnut tree extract and Quebracho tree extract from any origin meeting the specifications is the basic substance	SILVATEAM is potential supplier and provides various useful information to evaluate Basic substance profile.	Addressed

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(9)		NL: No comments			Addressed.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(10)		DE: The recipe is lacking. Some figures (application rate per treatment and total rate) given in the GAP table are not comprehensible without a clear description.	Please add a description of the recipe. For example it would be helpful to have a table with a list of the recommended dilutions.	Recipe Table is updated in the basic substance application, 2.5. GAP table were used to address all risk assessment calculation. New GAP table is presented in the basic substance application.	Addressed. The new GAP table was included in the revised submission.
2(11)		NL: No comments			Noted.

3. Uses of the substance and its product

3.1. Field of use

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

No comments

3.2. Effects on harmful organisms or on plants

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

No comments

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: Some figures (application rate per treatment and total rate) given in the GAP table are not comprehensible. There seem to be some mistakes in the calculations: - If the number of applications per season lies between 1 and 8 and kg	Please clarify or correct.	GAP table were used to address all risk assessment calculation. New GAP table is presented in the basic substance application. Several mistakes were noticed and corrected in the new version. An effort was done to homogenise	Addressed. An updated GAP table was included in the revised submission.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		as/ha is always 4 the total rate cannot be 4-24 kg but should be 4-32kg. - Another mistake seems to be in the calculation concerning nematodes (0,16-0,8 kg/hl and water 500-5000 l/ha cannot be the same (8 kg as/ha)) - For use as elicitor the total rate given is 4 kg as/ha for one treatment and 14,10 kg as/ha for 3 treatments. How can this be?		recommendations for various crops (uses, stage of application, spray volume…) for a better reading.	
3(2)	GAP table.	EFSA: if the heading is for kg a.s/ha the values in bracket indicating the amount of product probably should be deleted to avoid any confusion.		Amount of product in bracket is removed from GAP table. Only kg a.s/ha of the substance (50% chestnut tannin and 50% Quebracho tannin) is written.	Addressed. An updated GAP table was included in the revised submission.

4. Classification and labelling of the substance

Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)	Conclusion	DK: Please add 'U.S.' before 'Food and Drug Administration (FDA)'.	See Column 2.	Correction done in the basic substance application.	Addressed
4(2)	4	DK: Please elaborate why the substance should not be classified according to CLP. According to ECHA the substance is not classified, however they warn that the substance is notified as Eye Irrit. 2 (H319) and Aquatic Chronic 3 (H412) (https://echa.europa.eu/substance-information/-/substanceinfo/100.014.321). Also, it should be clearly stated in the chapter that there is almost no data available for classification.	Please add the warning from ECHA, as well as the lack of data for classification of tannins.	It can't be classified according to CLP as Eye Irrit. and Aquatic Chronic 3 thanks to QSAR modelling.(CRCF 2015; *Castanea sativa* mill: chestnut tannin. Centro ricerche per la chimica fine s.r.l. San Michele Mondovi 06-24-2017). Futhermore, the representative formulation 400 g/l SL (50:50 *Castanea*, *Shinopsis*) can't be classified as a H319 since the potential H319 component *Castanea* tannin - is 20% of the formulation, below the trigger value of H319. ECHA warning added in BSA.	According to ECHA website the substance is not classified, however they warn that the substance is notified as causing serious eye irritations and skin irritation. In line with the EFSA FEEDAP Panel (2014) EFSA considered that in the absence of adequate data, it would be prudent to regard tannins as potentially hazardous to non-dietary exposure groups by exposure to the skin, eyes and mucous membranes or by inhalation exposure.

5. Impact on Human and Animal Health

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

No comments

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

No comments

5.3. Short-term toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**		**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

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

No comments

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

No comments

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

No comments

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

No comments

5.8. Toxicity studies on metabolites

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

No comments

5.9. Medical Data: adverse effects reported in humans

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

No comments

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.10	DK: Interesting references, however the overview could be better (see column 3).	Suggestion: Shorten the summaries for references (e.g. methodology is not necessary in this context) in this section of the application as they are not of direct importance for this application as a basic substance. This will give a better overview.	Summaries removed from BSA.	Addressed

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	5.11. Additional information related to use as food	EFSA: The substance is an equivalent (50/50) mixture of two types of tannins: one from the chestnut tree and the other from the Quebracho, and is obtained by physical extraction. It is not agreed that read-across from an other specie (Mimosa) to Quebracho extract can be done without data or sound justification. From section 2 (identity of the substance/product as available on the market and predominant use), there is no other use given to the product than as plant protection product, and there is a lack of evidence that this product corresponds to a food additive or is commonly consumed by humans. If hydrolysable tannin (like chestnut tannin) is recognised as food flavouring agent in the EU, the same does not seem to		Tannic acid is recognised as a food flavouring agent and is included in the European Union list of food flavourings. Moreover, Quebracho Tannins are used in oenology in order to facilitate the clarification of wines and musts according to the Organisation Internationale de la vigne et du vin (OIV) (Oenological Tannins, INS 181, INS N°: 181 (Oeno 12/2002 modified by Oeno 5/2008, 6/2008 and OIV-Oeno 352-2009) OIV-OENO 554-2015.). Quebracho Tannins can be considered as food additive.	The toxicological asssesment of *Castanea* and *Schinopsis* sp. tannins relied on a limited number of published toxicity studies. These studies related mainly to hydrolised tannins as tannic acid. Since Mimosa contains condensed tannins it could be appropriate to extrapolate to Quebracho extract. However, very limited data are available with Mimosa (acute toxicity).

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

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(3)	Operator exposure level (page 45-46)	NL: we appreciate that the effort was made to include an operator exposure assessment. However, it is noted that this assessment does not cover all uses (e.g. the greenhouse uses). In addition, the justification for a 10% dermal absorption value is unclear. Moreover, it is unclear where the active substance concentration of 0.08 mg/ml comes from because in the intended use table it is indicated that the concentration of the formulation is 400 g/L. We consider the following input parameters should be used in the model. A.s. concentration: 400 g/L		Operator exposure is updated with more details regarding GAP and product field of use including Glass house uses using the recommended parameters. Details added in basic substance application.	The non-dietary risk assessment was only performed for operators (other groups, i.e. workers, bystander and residents were not included). However the limited number of studies does not allow properly to set reference values and therefore to perform a non-dietary risk assessment. EFSA also noted that the UK POEM model was used for greenhouse uses and this model is not applicable to greenhouse uses. Furthermore, in line with the EFSA FEEDAP Panel (2014),

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		Dose: 10 L Application Volume 100 L			in the absence of adequate data, it would be prudent to regard tannins as potentially hazardous to non-dietary exposure groups by exposure to the skin, eyes and mucous membranes or by inhalation exposure. Therefore, considering other routes of exposure, relevant for non-dietary exposure groups, further considerations are needed. See also comment 4(2)
5(4)	5.12. ADI, ARfD, AOEL	EFSA: there is no data to allow the setting of toxicological reference values. In addition, it is unclear whether the exposure data presented from the USA are applicable to BSA '*Castanea* and *Schinopsis* sp. Tannins'		AOEL reference dose is established by a comparison with an ADI due to the lack of operator exposure data. Taking into account an ADI for an AOEL is clearly a precautionary position that maximizes the theorical operator exposure.	See comment 5(3)

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

6. Residues

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	Chapter 6	NL: It is not clear whether any metabolism can be expected from the tannins or non-tannins in the extract after being sprayed on the crops, leading to toxicologically relevant metabolites?		There is no information that Tannins polymers degradation lead to toxicologically relevant metabolites, degradation by hydrolysis, phototransformation or mineralisation conducts to its basics components, ester of glucose or CH_4, CO_2. Tannins have hydrophilic properties ability to combines with proteins or Cations. Sprayed on plants, product works like a barrier on leaves. Sprayed on soil, product interacts with soil rhizosphere (literature added in the basic substance application).	It is not known whether any metabolism with molecule breakdown can be expected from the components of the extract after being sprayed on the crops. The applicant reported that tannins interact strongly with proteins or cations but also that 'tannins are natural substances instable with light and oxygen' (see comment 6(4)). Any data demonstrating that breakdown of the components in the extracts will occur on plants, or the degree of such potential breakdown, are not available. Quebracho proanthocyanidin polymers consist of a homologous series of flavan-3-ol based oligomers. Any degradation, if it was occurring, would likely lead to hydrolysis and release of flavan-3-ol units (e.g. chatechin, fisetinidol). Whether further breakdown into derivatives of phenol/phenolic acids or chromanols would happen in

Residues					
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					plants after spraying on crops is not known. *Castanea* tannins are mainly glucose esters of gallic acid. The primary component of *castanea* tannins, gallotannin (aka tannic acid) is reported to consist of poly-and oligo-galloylglucoses with the galloyl groups linked by depside bonds, while in ellagitannins, reportedly contained in lower proportions in *castanea* tannins, the galloyl groups are linked through C-C bonds. Hydrolysis of these components is reported to yield gallic acid and glucose, but also quinic acid, hexahydroxydiphenic acid/ellagic acid and/or sanguisorbic acid as hydrolysis products. Degradation, if occurring on plants, is assumed to release these or similarly structured phenolic acids and sugars.
6(2)	In general	NL: Although some tannins are being used as food additives, is it acceptable to conclude that tannins in general are safe when being consumed?		Tannins have clear chemical reactivity and are use as food additive respect dosage recommendations. For substance residue risk evaluation has be conducted	Refer to comment 6(4)

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				and added in the basic substance application.	
6(3)		PL: No comments – nonvolatile nature, and instability in the presence of light and oxygen, natural substances occurring in various plants, tannic acid is recognised as a food flavouring agent and is included in the European Union list of food flavourings)		Noted.	Noted.
6(4)		EFSA: It should be noted that if tannins (specifically tannic acid, vescalagin, castalagin, vescalin, castalin, procyanidins) are used as food additives or processing aids or flavouring agents for human consumption in the EU (evidence still to be submitted), the safety assessment in the respective area was considering the human dietary exposure potential to these substances from their use. Therefore, absence of dietary safety concerns established		Additional Residue risk assessment has been conducted in the basic substance application with the EFSA calculation model Pesticide Residue Intake Model 'PRIMo' revision 2. Furthermore the risk has been maximizing by three main basic premises: 1. According uses and GAP and timing of application, once edible part of the plant is present at treatment, consider all product reach it (entire plant for salad or fruit for tomatoes…) 2. For the LMR rate	EFSA acknowledges that residues estimates of tannins on crops resulting from the intended uses were provided and consumer dietary intake estimates were submitted. The estimated chronic intake of total tannins from treated crops would correspond to 1.34 mg/kg bw per day (=22 mg per day, DE child) and 1.15 mg/kg bw (= 77 mg per day IT adult). Considering the composition of the substance is 50% chestnut tannins (main component tannic acid) and 50% Quebracho tannins (flavan-3-ols such as epigallocatechin and epicatechin), their different chemical structures

Residues					
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		in a defined area of use (e.g. processing aid) does not necessarily mean that uses in other areas resulting into dietary consumer exposure are automatically safe. A use specific assessment has to be conducted. If tannins are authorised in areas other than pesticides, a comparison of dietary exposure resulting from these authorised uses in food vs. the requested use as a pesticide should be provided. It is noted in that context that the list of crops for pesticide uses is extensive and that the GAP table contains uses on food commodities with high application rates (24 kg/ha) and short PHIs (5 days), increasing the probability for significant residue levels and potentially consumer exposure resulting from the use of the product. Apart from the request for clarification of whether or		integrated in the Primo, we consider the basic premise that no degradation of the residue occurred and we consider a cumulative dose rate: the applicate dose is the dose applied cumulated for each application in the Primo without degradation. Even if we know that Tannins are natural substances instable with light and oxygen. 3. The tannins have been considered here as a non-systemic foliar pesticide due to their high molecular weight since they are polymers.	and thus possibly different properties, EFSA suggests considering chestnut tannins vs. Quebracho tannins separately in the consumer risk assessment. For Quebracho tannins, the estimated chronic intakes appear to be comparable or lower to figures reported in public literature as daily intake levels of flavan-3-ols from food for the adult EU population. Consumption figures for children are not available. (Vogiatzoglou A. et al, 2014, 2015). As for *Castanea* tannins, tannic acid (hydrolysable gallic acid glucose esters), is a defined flavouring substance positive-listed for which no restriction in use has been set. No evaluation at EU level and no exposure assessment are available. U.S. FDA defined maximum levels of use in a limited number of food products, corresponding to e.g. 100 mg/kg in baked goods/baking mixes; 50 mg/kg in beverages,

Residues					
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		not the compounds contained in *Castanea* and *Schinopsis* sp. Tannins will remain stable or decompose when applied to crops in the field, a more distinctive evaluation of their likely residue levels and the potential human dietary exposure is needed.			gelatins, puddings, fillings; 400 mg/kg in frozen dairy desserts and soft candy. The estimated concentrations of residues on treated crops (tomato, aubergine, lettuce, cucurbits) are ranging between 75 and 230 mg/kg, and can hence be considered in same order of magnitude as maximum levels of use defined by FDA. Comparison of actual consumer intakes could not be made. In view of the lack of evaluation of tannic acid on EU level and the hydrolysis potential of tannic acid to gallic acid, it may also appear a reasonable option to consider gallic acid in the consumer exposure/risk assessment. It is noted that the EFSA ANS Panel (2014) has assessed the gallic acid propyl ester as a food additive and derived an ADI of 0.5 mg/kg bw per day. Whether this approach could be appropriate may need further expert consideration if deemed necessary.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	The first listed reference (EFSA) Intro	DK: Please be more specific in reference summaries; do not repeat text that has already been included above in the application if not directly relevant.	Shorten the summary to be more specific for the purpose of the specific chapter (in this case chapter 7) e.g. '*In the absence of data, it would be prudent to regard the additive as potentially hazardous to workers by exposure to the skin, eyes and mucous membranes or by inhalation exposure*' is not relevant to include here.	Summary removed in basic substance application	Addressed
7(2)	IN general for chapter 7	DK: The application is for FR and all EU MS; please do not put surface water as equal to drinking water as it is done. Some MS use surface water and some use only ground water as drinking water, thus the term drinking water varies among MSs.	Please do not include the term 'drinking water' in the assessment. The terms surface water and groundwater will suffice here.	Drinking water term removed in basic substance application	The reference to drinking water remains in the application on page 69.
7(3)	general	NL: Whether a certain use is safe for the environment not only depends on the substances used, but also on the use rate. However, although the substance properties of	In the guidance for basic substances (SANCO/10363/2012 rev.9) it is stated that: 'the potential consequences of increased exposure with respect to	In the basic substance application several reference values are included, from literature or by calculation according available information about Tannins in	The applicant has calculated that typical soils will contain 200 mg tannins per kg soil. The applicant provided an equation that could be used to calculate the amount of

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		tannins are described in this section, the intended use rate is not included in the assessment of the environmental fate and behaviour.	natural exposure levels of water, soil or air or to exposure due to other uses should be considered'. To determine if the proposed use of these tannins will lead to increased exposure of the environment, information on the natural exposure is necessary. If the exposure (to soil and water) resulting from the proposed use is lower than for example the yearly leaf- or husk-fall from trees or the amount of tannins entering the environment upon death of a tree, no further assessment of the environmental fate and behaviour is necessary. The substance information now presented is appreciated as supporting information.	the environment. Soil and surface water risk assessment are proposed in the basic substance application. For ground water, we consider that soil is a strong filter and Tannins coming from vegetal or by product are strongly intercepted by the first cm of soil because their strong affinity to combine with substances and cations. Elements of literature are added in the basic substance application.	the two kinds of tannins that would result from the uses being requested, and calculated these values which represented 0.3 to 5.3% of the 200 mg tannins per kg soil. PEC surface water from spray drift stated to be with 50m non spray buffer zones have been calculated for uses where application will be by standard downward hydraulic spraying assuming 0.15% drift. Note that this is a mistake, this drift proportion (0.15%) is for a 20m no spray buffer for this kind of spray application. For air assisted broadcast spraying (used for taller fruit crops) with the 50m no spray buffer referred to, the standard value that would be used for % drift in any calculation would be 0.3% i.e. twice as high concentrations as currently presented.

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					It is unclear to EFSA that the PNEC quoted of 0.2 mg/l for *Castanea* (appears to be extrapolated from tannic acid) and 0.11mg/l for Quebracho are the appropriate values to use for the risk characterisation. Therefore it is unclear if the risk mitigation options being proposed to ensure low risk to aquatic organisms (20m for standard hydraulic spraying and 50m for air assisted broadcast spraying) would be effective or not. In any case valid PEC have not been presented for 50m no spray buffer zones stated to be needed for air assisted broadcast spraying
7(4)		PL: According to EFSA (FEEDAP) 2014, volume 12, Issue 10 the use of tannic acid as a food and feed additive is considered safe for the environment.	The content of the report does not raise any objections	Noted.	Opinion of Poland is noted. It should be noted that before reaching the environment, feed additives have passed through the digestive system of animals so the environmental risk assessment of EFSA for a feed additive does not

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					necessarily cover uses where the substance is added directly to the environment without first being digested by animals.
7(5)		PL: US EPA (2006),[4] described that while it is possible that tannin used for agricultural purposes could reach drinking water (from surface water), the environmental contribution from the use of tannin as basic substance is likely to be small in comparison to the tannin that is found naturally in the environment due to its natural occurrence in nearly all wood and vegetation		Calculation based on read acrosses and literature about natural concentration in environment are proposed in the basic substance application	The regulation in Europe defining basic substances used in plant protection only envisages using European regulatory assessments. I.e. where the underlying dossier has been made available to EU member state competent authorities and or the relevant European agency or institution. The US EPA assessment is not relevant considering this context.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(6)		PL: *Castanea* and *Schinopsis* sp.		Noted, this point is answered	Opinion of Poland is noted.

[4] US EPA (United States Environmental Protection Agency), 2006. , Inert reassessment-Tannin, Office of prevention pesticide and toxic substances, pp 1-13.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		Tannins can be put on the ground without it being toxic. These tannins can be degraded without negative impact for the environment. Tannin is expected to biodegrade in the environment with ultimate aerobic degradation estimated to be weeks and primary degradation estimated to be days. According to Pilot project: Proposal for approbation of basic substances, in the context of Regulation (EC) N°1107/2009		in point 7(3).	The statements of Poland do not appear to be supported with any evidence. Please refer to comment 7(3) where an assessment is made of the information that was included in the application.
7(7)		EFSA concurs with comment 7(3) from the NL.	See entry at comment 7(3) from the NL. The environmental exposure consequent to the uses requested has not been estimated. This needs to be done and compared to natural presence in the environment. Note comparisons with use as a feed additive are not relevant in this context as the tanins will not have passed through animal digestive tracts before environmental		See comment 7(3).

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
			exposure.		

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(1)	intro	DK: Please see the first comment by DK for chapter 7.		Summary removed in the basic substance application, if appropriate.	Addressed
8(2)	Birds	DK: Please shorten the reference summaries to include the relevant information only. For example, the reference Redondo et al (2014) is relevant here, but the whole introduction about antibiotics is not relevant for the potential risk to birds from agricultural use of tannins.		Abstract removed from the basic substance application to highlight relevant information.	Addressed
8(3)	general	NL: For chapter 8 it is concluded that 'at a requested dose in this application (see GAP) the mixture of these two	Make an effort to estimate expected environmental concentrations resulting from the intended uses, then	Environmental exposition is estimate in the basic substance application according GAP tables.	For aquatic organisms, the estimated PECs in surface water were compared with the PNEC. The PNEC can be

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		tannins is not considered toxic for non-target organisms'. However, an assessment in which the expected environmental concentrations resulting from the intended uses are related to the dose rates in the public ecotoxicity literature is missing.	compare with an estimation of natural background concentrations of the tannins and/or the ecotoxicity endpoints from the public literature.	Several literature and practical information are added to the basic substance application especially in case of using Tannins as a feeding agent for animals. This cover existing practice to add Tannins in fodder crop in field or in silage.	considered an analogous of the RAC (regulatory acceptable concentration) used in the pesticides aquatic risk assessment. It is noted that PNEC values were derived from acute studies (i.e. LD50 values) by an application of an assessment factor of 10. In analogy with the RAC an assessment factor of 100 should have been applied instead. It is noted that the acute toxicity endpoints reported on rainbow trout as bibliographic data in the updated application could not be retrieved and fully validated since the papers and/or full references were missing. Therefore, by considering also the answer to comment 7(3), the risk assessment presented for aquatic organisms cannot be considered as appropriate. Furthermore, it does not indicate the likely absence of

8.1. Effects on terrestrial vertebrates

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					risk for aquatic organisms. The available exposure estimations in soil were in the range of 0.3-5.3% of the natural background level. Consequently adverse effects on earthworms are not expected following the use of *Castanea* and *Schinopsis* tannins.
8(4)		PL: Quebracho tannin extract is not toxic for ruminants, except in concentrations too high to be encountered under practical conditions	no objections	Noted.	Addressed
8(5)		PL: EFSA, Scientific opinion on the safety and efficacy of tannic acid when used as feed flavouring for al animal species, EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) 2014, volume 12, Issue 10. Tannic acid is a synonym for hydrolysable tannins, which are widely distributed in nature. The use of tannic		Noted.	Noted

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		acid as a feed additive up to 15 mg/kg feed is safe for all animal species.			
8(6)	8. Effects on non-target organisms	EFSA: in accordance with the guidance 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) an assessment of the effects of *Castanea* and *Schinopsis* sp. tannins on non-target organisms should be provided.		Basic substance application completed.	No specific data were provided investigating the effects on non-target organisms. Furthermore, based on the available information, it was unclear whether the risk to non-target organisms could be excluded following the uses considered. The risk could only be excluded for soil organisms, where it was clear that the exposure will be below the background natural level. See also comment 8(3)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(7)	Overall	DK: The chapter is poorly written.	Please re-write the chapter on risk to aquatic organisms and	We upgrade this part of the basic substance application	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 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			include risk assessment. As it is there is no relevant references or risk assessment from other authorities etc.	with a Predicted non effect concentration in water to fix some value and propose management possibilities.	
8(8)	The reference Becker *et al.* (1999)	DK: This reference is not relevant here as it is about tannins in fish feed, and not from exposure to tannins in water bodies from use in e.g. agriculture.	Exclude reference or move it to somewhere else in the application for perspective purposes only.	It is clear this publication is not appropriate in context of Tannins exposure to fish, but this gives general background as feeding fish is done in water. Reference is moved not to be in core of this part of the basic substance application.	Addressed
8(9)		PL: Actually, one can argue that the substance should not be hazardous according to (Reg. (EC) No. 1272/2008)[5] (CLP) criteria for aquatic chronic toxicity classification.	No objections	Noted.	Noted
8(10)		PL: Quebracho extract based on a read-across approach, are not considered harmful to fish, according to (Reg. (EC) No. 1272/2008). Tannin is considered to be moderately toxic to pratically non-toxic to aquatic		Noted.	See comments 8(3) and 8(6)

[5] 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.

8.2. Effects on aquatic organisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		organism. Quebracho tannin can be used as fish meal substitutes in carp diets.			

8.3. Effects on bees and other arthropods species					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(11)		DE: There is no proof that tannins are harmless to arthropods.	Please provide evidence.	Through literature Tannins and read across substances are key elements in Nature for plants to adapt their ecosystem. Including arthropods populations. Then it is not possible to prove in general that Tannins are not harmless to arthropods, but in the context of product application no evidence of harmless to arthropods is noticed.	See comment 8(6)
8(12)		PL: These compounds are responsible for the antioxidant activity. So hydrolysable tannins included chestnut tannin are used by metabolism of Bee	Tannins including chestnut tannin and quebracho tannin have properties that can be responsible for antimicrobial properties against Paenibacillus larvae.	Noted.	See comment 8(6)

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		and might be a natural alternative for the prevention/control of afb american foulbrood - see Pilot project			
8(13)		PL: For the negative effect, the concentration of extra tannin in food could be approximatively is near to 10 % - Pilot project.	Suggestions for research needs.	Noted.	See comment 8(6)

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)		PL: Modifications of soil fauna communities may lead to loss- of diversity and result in losses of functions when specific structural pat- terns or regulation mechanisms are lost.	Use dosage no change soil properties	In line with calculation added in the basic substance application to compare potential concentration in environment and added by the product application according uses.	See comment 8(6)

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)		PL: Important soil bacteria such as Nitrobacter species and Nitromonas species were inhibited by chestnut tannin - Pilot project		Noted.	See comment 8(6)

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(16)		DE: Effects on non-target beneficial organisms are not discussed.	Please provide evidence that they are not harmed.	Massive input of Tannins may affect plant environment and population as shown in literature added to the basic substance application. Studies were conducted in specific environment non cultivated and forestry soils with higher organic matter content than usual cultivated soil. Argumentation in context of product application added to the basic substance application.	See comment 8(6)
8(17)		DE: There are no documents proving the harmlessness towards plants.	Please provide evidence that the tannins if applied on plant surfaces are not phytotoxic.	As mentioned in 8(3) Tannins can be already applied on fodder crop with compatible	See comment 8(6)

8.6. Effects on other non-target organisms (flora and fauna)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
				dosage with that of the product, without any crop damages. Molecules are big polymers with hydrophilic properties and little ability to interact with plant cuticle. Main effect noticed can be brown dye coloration on plants after application, which can be washable.	
8(18)		PL: At proposed dose the mixture of these two tannins is not considered toxic for non-target organisms - Pilot project		Noted.	See comment 8(6)

8.7. Effects on biological methods of sewage treatment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(19)		PL: Tannin is a biodegradable anionic polymer. Tannin as a coagulant aid can be a potential substitute for synthetic anionic polyelectrolytes in water treatment because it can :		Noted.	See comment 8(6)

8.7. Effects on biological methods of sewage treatment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		(1) avoid the health effects from residual aluminum(III) and synthetic polymers, and (2) produce biodegradable sludge - Pilot project.			

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		DE: According to the classification provided to ECHA in CLP notifications tannins cause serious eye irritations and skin irritation. Furthermore, ECHA submitted the following information: tannins are 'Suspected mutagen: the toolbox profiler protein binding alerts for chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity' and 'Suspected respiratory sensitizer: the toolbox profiler respiratory sensitisation gives an alert for respiratory sensitisation.' According to IARC (Vol. 10, 1976) tannic acid is carcinogenic in rats and mice following its subcutaneous application. According to the submitted application template there are also further indications of mutagenicity, carcinogenicity and organ	It is proposed to regulate *Castanea* and *Schinopsis* sp. Tannins according to Guidance Document SANCO/11470/2012.	Argumentation according DE comments is detailed in the basic substance application, part 9. Therefore, we consider than *Castanea* and *Schinopsis* sp. Tannins do meet the criteria of article 23(a) and (b) of Regulation (EC) No 1107/2009. (c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and For point (c) the substance is today broadly used in leather tanning, as animal feeding or food additive, not used in plant protection market (point d) (d) is not placed on the market as a plant protection product Product proposed is a water dilution of the substance to be handled on an easier way in plant protection purpose. We consider that Basic substance application is appropriate.	See comment 4(2)

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		toxicity (salivary glands) reported in the available literature. Therefore, *Castanea* and *Schinopsis* sp. Tannins do not meet the criteria of article 23(a) of Regulation (EC) No 1107/2009.			

10. Other comments

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

No comments

Appendix B – Identity and biological properties

Common name (ISO)	*Castanea* and *Schinopsis* sp. Tannins (not ISO)
Chemical name (IUPAC)	n.a. (complex mixture)
Chemical name (CA)	n.a. (complex mixture)
Common names	Chestnut extract, *Castanea Sativa* extract, Chestnut wood extract, chestnut tannin, sweet chestnut tannin extract, European chestnut. Quebracho extract, Quebracho colorado tannin extract, *Schinopsis* Quebracho-Colorado Wood Extract *Schinopsis* balansae: quebracho colorado condensed tannins extract
CAS No	none
CIPAC No and EEC No	n.a.
FAO specification	none
Minimum purity	*Castanea sativa* extract: tannins min. 75% (ISO14088 method) *Schinopsis lorentzii* extract: tannins min. 70% (ISO14088 method)
Relevant impurities	n.a.
Molecular mass and structural formula	n.a. (complex mixture)
Mode of Use	Spraying, application on soil by watering
Preparation to be used	Soluble concentrate (SL)
Function of plant protection	Bactericide, fungicide, nematicide, plant elicitor

Appendix C – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Tomatoes *Solanum lycopersicum L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24kg		
Tomatoes *Solanum lycopersicum L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Phytosphtora root rot** *Phytophtora sp* **White mold** *Sclerotinia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with lance)	From emergence to fruit maturation (BBCH 12 – BBCH 79)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		
Tomatoes *Solanum lycopersicum L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins	G	**Pseudomonas** *Pseudomonas sp*	SL	400 g/L	Spraying (Field crop sprayer or	From emergence to fruit maturation (BBCH	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		

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			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
		IAZ08					Knapsack or tank with lance)	12 – BBCH 79)								
Aubergine *Solanum melongena L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Aubergine *Solanum melongena L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Phytosphtora root rot** *Phytophtora sp* **White mold** *Sclerotinia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with lance)	From emergence to fruit maturation (BBCH 12 – BBCH 79)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		
Aubergine *Solanum melongena L.*	FR, All MS	*Castanea & Shinopsis* Natural	G	**Pseudomonas** *Pseudomonas sp*	SL	400 g/L	Spraying (Field crop sprayer	From emergence to fruit maturatio	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		

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			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
		Tannins IAZ08					or Knapsack or tank with lance)	n (BBCH 12 – BBCH 79)								
Potatoes *Solanum tuberosum*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Collar rot, toot rot** *Rhizoctonia solani*	SL	400 g/L	Application in furrow	Plantation	1	10 days	0,4 to 2	200 to 1000	4	4 kg		
Potatoes *Solanum tuberosum*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Phytosphtora root rot** *Phytophtora sp* **Early blight** *alternaria solani*	SL	400 g/L	Spraying (Field crop sprayer)	From emergence to end vegetation (BBCH 12 – BBCH 89)	1 to 8	10 days	0,8 to 4	100 to 500	4	4 kg to 32 kg		
Lettuce and salad plant *(LACSA) Lactuca spp.* (CICEL),	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
(CICEG), (VILLO), (ERUVE)And other								30)								
Lettuce and salad plant *(LACSA) Lactuca spp.* (CICEL), (CICEG), (VILLO), (ERUVE)And other	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**White mold** *Sclerotinia sp* **Rhizoctonia** *Rhizoctonia sp*	SL	400 g/L	Application on soil watering or drop by drop	From emergence to main development (BBCH00 to BBCH 49)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		
Lettuce and salad plant *(LACSA) Lactuca spp.* (CICEL), (CICEG), (VILLO), (ERUVE)And other	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Lettuce downy mildew** *Bremia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with lance)	From emergence to fruit maturation (BBCH 12 – BBCH 79)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Turnips *Brassica rapa var. Rapa L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Turnips *Brassica rapa var. Rapa L.*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Rhizoctonia** *Rhizoctonia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with lance)	From emergence to main development (BBCH00 to BBCH49)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 kg to 24 kg		
Rutabagas (BRSNA) *Brassica napus* subsp. *rapifera*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Rutabagas (BRSNA) *Brassica napus* subsp. *rapifera*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Rhizoctonia** *Rhizoctonia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with lance)	From emergence to main development (BBCH00 to BBCH49)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 kg to 24 kg		
Radishes (RAPSN) *Raphanus sativus*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Radishes (RAPSN) *Raphanus sativus*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Rhizoctonia** *Rhizoctonia sp*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with	From emergence to main development (BBCH00 to BBCH49)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 kg to 24 kg		

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			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
							lance)									
Cucurbits with edible peel (cucumbers, (CUMSA)*Cucumis sativus*, courgetlte (CUUPG) *Cucurbita pepo L.*, gherkins and others (CUMSG))	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Cucurbits with edible peel (cucumbers, (CUMSA)*Cucumis sativus*, courgetlte	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Powdery mildew** *Podosphaera xanthii*	SL	400 g/L	Spraying (Field crop sprayer or Knapsack or tank with	From emergence to fruit maturation (BBCH 12 – BBCH 79)	1 to 6	10 days	0,4 to 2	200 to 1000	4	4 kg to 24 kg		

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			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
(CUUPG) *Cucurbita pepo L.*, gherkins and others (CUMSG))							lance)									
Oat (AVESA) *Avena sativa*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	Elicitor	SL	400 g/L	Spraying (Field crop sprayer)	From end tillering to flowering (BBCH 29 – BBCH 47)	1 to 3	10 days	1 to 4	100 to 400	4	4kg to 12 kg		
Wheat (TRZSS) *Triticum spp*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	Elicitor	SL	400 g/L	Spraying (Field crop sprayer)	From end tillering to flowering (BBCH 29 – BBCH 47)	1 to 3	10 days	1 to 4	100 to 400	4	4kg to 12 kg		
Barley (HORVX) *Hordeum vulgare*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	Elicitor	SL	400 g/L	Spraying (Field crop sprayer)	From end tillering to flowering (BBCH 29 – BBCH	1 to 3	10 days	1 to 4	100 to 400	4	4kg to 12 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
								47)								
Rye (SECCE) *Secale cereale*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	Elicitor	SL	400 g/L	Spraying (Field crop sprayer)	From end tillering to flowering (BBCH 29 – BBCH 47)	1 to 3	10 days	1 to 4	100 to 400	4	4kg to 12 kg		
Almonds (PRNDU) *Prunus dulcis*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Bacterial blight** *Xanthomon ascampestris pv. Juglandis*	SL	400 g/L	Spraying (Ochard)	From bud emergence to fruit development (BBCH 03 to BBCH 79)	1 to 6	10 days	0,4 to 0,8	500 to 1000	4	4 kg to 24 kg		
Walnuts (IUGRE) *Juglans*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Bacterial blight** *Xanthomon ascampestris pv. Juglandis*	SL	400 g/L	Spraying (Ochard)	From bud emergence to fruit development (BBCH 03 to BBCH 79)	1 to 6	10 days	0,4 to 0,8	500 to 1000	4	4 kg to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Chestnuts (CSNA) *Castanea sativa*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Bacterial blight** *Xanthomonascampestris pv. Juglandis*	SL	400 g/L	Spraying (Ochard)	From bud emergence to fruit development (BBCH 03 to BBCH 79)	1 to 6	10 days	0,4 to 0,8	500 to 1000	4	4 kg to 24 kg		
Hazelnuts (CYLAV) *Corylus avellana*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Bacterial blight** *Xanthomonascampestris pv. Juglandis*	SL	400 g/L	Spraying (Ochard)	From bud emergence to fruit development (BBCH 03 to BBCH 79)	1 to 6	10 days	0,4 to 0,8	500 to 1000	4	4 kg to 24 kg		
Stone fruits: Peaches (PRNPS), Abricots(PRNAR), Cherries (PRNCE), Plums (PRNDO), Nectarine (PRNPN),M	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F	**Bacterial blight** Xanthomonas arboricola pv. pruni	SL	400 g/L	Spraying (Ochard)	After harvest at leave fall, from bud emergence to fruit development (BBCH 03 to BBCH 79)	1 to 6	10 days	0,4 to 0,8	500 to 1000	4	4 kg to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
irabelliers (PRNDS), *Prunus spp*																
Carrots (DAUCS) *Daucus carota subsp sativus*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Horseradishs (RAPSN) *Armoracia rusticana*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Jerusalem artichokes (HELTU) *Helianthus*	FR, All MS	*Castanea & Shinopsis* Natural	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil waterin	From plantation to early developm	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pest controlled (C)	Formulation		Application				Application rate per treatment			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
tuberosus		Tannins IAZ08					g or drop by drop	ent (BBCH 00 to BBCH 30)								
Parsley roots (PARCT) *Petroselinum crispum subsp. tuberosum*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Salsifies (SCVHI) *Tragopogon porrifolius*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Celeriacs (APUGR) *Apium graveolens L. subsp rapaceum*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		

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			Total rate	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) a) per use b) per crop/ season	Interval between applications (min)	kg a.i./hl min max (kg/hl	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
								30)								
Parsnip (PAVSA) *Pastinaca sativa*	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		
Sugar beets (BEAVC) Beta vulgaris	FR, All MS	*Castanea & Shinopsis* Natural Tannins IAZ08	F,G	**Nematods** MELGSP *Meloidogyne sp*	SL	400 g/L	Application on soil watering or drop by drop	From plantation to early development (BBCH 00 to BBCH 30)	1 to 3	10 days	0,16 to 1,6	500 to 5000	8	8 kg to 24 kg		

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f): All abbreviations used must be explained
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k): Indicate the minimum and maximum number of application possible under practical conditions of use
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m): PHI - minimum pre-harvest interval