TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for approval of willow stem infusion to be used in plant protection as a plant growth regulator

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 willow stem infusion 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 willow stem infusion as a basic substance to be used in plant protection as a plant growth regulator. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: willow stem infusion, basic substance, application, consultation, plant protection, pesticide, plant growth regulator

Requestor: European Commission

Question number: EFSA-Q-2020-00228

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Summary

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

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in March 2020, EFSA was asked to organise a consultation on the basic substance application for approval of willow stem infusion for use in plant protection as a plant growth regulator, 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 approval of willow stem infusion for use as a plant growth regulator was organised by EFSA and conducted with Member States via a written procedure in November 2019 – January 2020. 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 approval of willow stem infusion as a plant growth regulator on herbaceous plants and fruit trees and woody ornamental plants, and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Salix alba is a species of willow native to Europe and western and central Asia. In the updated submission the name of the basic substance was changed from willow bark and stem extract to willow stem infusion. The willow stem infusion is intended to be used in fields for plant protection for root growth stimulation of cuttings.

Salix alba contains derivatives of salicin, flavonoids, condensed tannins and catechins. The active substance willow stem infusion is a complex mixture of natural compounds; the purity of the active substance cannot be defined. The claimed major active components were salicin, indole-3-butyric acid and indole-3-acetic acid. It should be noted that even after the updated submission, the inconsistency remained in what the active components of the extract for the purpose of the claim are.

The active ingredient of the willow stem infusion is a complex mixture of chemical substances, many with pharmacological properties and some adverse effects relating to medicinal use (allergic reactions and gastro-intestinal symptoms). Moreover, the claimed major active components have notified classification for skin sensitisation/irritation and lung irritation properties (ECHA website). The characterisation of the toxicological properties of the willow stem infusion constituents has not been addressed, therefore a qualitative and quantitative consumer risk assessment could not be performed. Based on the available information, it cannot be concluded that willow stem infusion does not pose any toxicological concern.

A consumer risk assessment, or a decision that a quantitative consumer risk assessment might be waived, is not possible with the submitted information. As application to edible crops is intended but a conclusion regarding toxicological properties of the components in willow stem infusion is missing, consumer exposure to potential residues should have been addressed as a further consideration, which was however not provided.

Regarding environmental fate and behaviour, it was considered that the exposure of environmental compartments due to the proposed use of this basic substance might be considered to be within that which might occur considering natural background exposure.

In the area of ecotoxicology, further data were considered necessary to address the risks to terrestrial vertebrates. All other areas of the ecotoxicological assessment are addressed considering the outcome of the fate and behaviour assessment or considering that exposure is expected to be low for the proposed use as a dip.

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1. Introduction

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

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

Willow stem infusion is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique for approval as a 'basic substance' to be used in plant protection as a plant growth regulator. It is noted that in the original application the name of the substance was indicated as Willow bark and stem extract, however, in the updated application the name was changed to Willow stem infusion.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for willow bark and stem extract, which was conducted via a written procedure in November 2019 – January 2020. 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 approval of willow stem infusion as a plant growth regulator on herbaceous plants and fruit trees and woody ornamental plants, 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 willow stem infusion as a 'basic substance' in the context of Article 23 of the Regulation, is key supporting documentation, therefore it is considered as background documentation to this report and will also be made publicly available, excluding their appendices (Institut Technique de l'Agriculture Biologique; 2019, 2020).

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 10 March 2020, EFSA was asked to organise a consultation on the basic substance application for approval of willow stem infusion as a plant growth regulator, 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 10 June 2020.

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

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

2. Assessment

The comments received on the basic substance application for approval of willow stem infusion as a plant growth regulator on herbaceous plants and fruit trees and woody ornamental plants, 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 Appendices C and D, respectively.

Documentation provided to EFSA

1. Institut Technique de l'Agriculture Biologique, 2019. Basic substance application on willow bark and stem extract submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2019. Documentation made available to EFSA by the European Commission.

2. Institut Technique de l'Agriculture Biologique, 2020. Basic substance application update on willow stem infusion submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2020. Documentation made available to EFSA by the applicant.

References

Absalan Godratollah, Akhond Morteza, Sheikhian Leila, 2008. Extraction and high performance liquid chromatographic determination of 3-indole butyric acid in pea plants by using imidazolium-based ionic liquids as extractant. Talanta. Vol. 77, No. 1, pp 407-411.

Boeckler A.G. 2011 Phenolic glycosides of the Salicaceae and their role as anti-herbivore defences, Phytochemistry 72, 1497–1509.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and "energy and vitality" (ID 18, 26, 62, 105, 122, 145, 165, 3962, 4054, 4440), "invigoration of the body" (ID 2383, 2386, 2391, 2393, 2409, 2441, 2463, 2488, 3834, 3883), "general health" (ID 1313, 3348, 4182, 4613), "rejuvenation" (ID 3981, 4023), "tonic" (ID 1703, 3462, 3581, 4418), "stimulant" (ID 3190, 3506) and "metabolic benefits" (ID 4438) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1738. [21 pp.]. doi:10.2903/j.efsa.2010.1738. Available online: www.efsa.europa.eu/efsajournal.htm

European Medicines Agency (EMA), 2017. Assessment report on Salix [various species including S. purpurea L., S. daphnoides Vill., S. fragilis L.], cortex. EMA/HMPC/80628/2016.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
BSA	basic substance application
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DC	dispersible concentrate
DE	Germany
DK	Denmark
NL	Netherlands
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
GAP	good agricultural practice
MS	Member State
PG	plant growth
PPP	Plant production products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for willow stem infusion (originally submitted as 'Willow bark and stem extract') and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)	Overall	DK: Please delete template help-text (e.g. text in blue and some in *italics*).		BSA updated	Addressed.
1(2)	Overall	DK: The application sometimes uses the wording "Willow bark extract" only, without the "stem". Please somewhere relevant clearly argue if "Willow bark extract" is the same as "Willow bark and stem extract".		Name changed	Addressed: The name was changed to "willow stem infusion".
1(3)	General	NL: The efficacy of the product is solely based on the presence of indole-butyric acid in the extract (see point 1(2) directly below). Indole-butyric acid is an already authorised active substance under (EC) No 1107/2009.		IBA is chemical with residues of synthesis, not allowed in organic production Find other uses	Addressed: The decision about acceptance as a basic substance submission is a risk management decision.

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**
		With regard to basic substances, (EC) No 1107/2009, recital 18, mentions "*certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited*". This description rules out indole-butyric acid as basic substance, because it is in fact predominantly used in plant protection products and has no other practical uses.			
1(4)	General	NL: Relating to above comment: Although the applicant is very ambiguous on the actual role of indole-butyric acid (IBA), MS NL has strong arguments to support the fact that IBA is in fact the only active component in willow bark and stem extract substantiating the efficacy claims: • The only other major active, salicin, has no apparent plant growth regulating properties. Its function mainly relates to		Find other uses	Addressed: The decision about acceptance as a basic substance submission is a risk management decision.

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**
		plant defence. This (precursor) component is the reason for registration of Salix spp. cortex as basic substance, i.e., as fungicide. • IBA occurs at very low levels, but it also functions at very low levels. The stated natural concentration (10^{-5} M in the extract(?)) is perfectly proportional to the recommended rate for IBA, currently registered under 1107/2009 as chemical active substance.			

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)	2	Please also cite some current uses for this substance, the actual Willow bark and stem extract. Not just historic use.		Willow stems are mainly used as biomass or compost.	Addressed.
2(2)	2.1.2	DK: Please include a comprehensive list of the components of the extract.		Updated in the BSA	Addressed: Additional information was included in the updated submission.
2(3)	2.1.2	DK: Indole-3-Butyric acid is listed as one of the major active components of the extract in section 2.1.2, while it in section 2.1.6, is listed as an inactive component. Please clarify.		Modified	Addressed: The inconsistency remained in the updated submission, too. In 2.1.2 indole-3-butyric acid is listed as one of the active components of the extract in that section, while in section 2.1.6, it is listed as an inactive component for the purpose of the claim. See also comment 2(5)
2(4)	2.1.2	DK: The applicant states: *Willow bark and stem extract is furthermore known on the market.* Please include explicitly if there extracts are also within the scope of this		Name changed Composition updated Mainly home extract since willow stems have no current value.	Addressed: The name was changed to "willow stem infusion".

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**
		application, or if only homemade extract is considered.			
2(5)	2.1.3	EFSA: It seems from this point that the two main active ingredients considered are D-salicin and indole-3-butyric acid, while in 2.1.6 IBA is considered inactive.	Clarification is needed why it is mentioned as active component. This is in contradiction also with 2.5 description of the recipe.	Composition updated Updated in the BSA	Addressed: The inconsistency remained in the updated submission, too. In 2.1.2 indole-3-butyric acid is listed as one of the active components of the extract in that section, while in section 2.1.6, it is listed as an inactive component for the purpose of the claim. In 2.5 it is considered active component. See also 2(3).
2(6)	2.1.5	DK: A reference is missing from the sentence: *was reported in the monographic document from and also from Boeckler, et al.* Please amend.		*Boeckler, et al.* provided	Addressed.
2(7)	2. Predominant uses	NL: It is not clear for what current purposes the particular infusion is predominantly used, if not for plant protection purposes. It is mentioned that willow and		BSA name changed for "Willow stem extract"	See comments 1(4) and 2(4).

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**
		bark extract was historically used for pharmaceutical purposes, although it is unclear whether this mainly concerns ethanolic tinctures (which must be considered a different thing). The point is that the applicant needs to demonstrate that the exact willow bark and stem extract (manufactured as described) is predominantly used for non-PPP purposes. Otherwise, the substance cannot qualify as basic substance.			
2(8)	2.1 Specification	NL: Data relating to the specification are insufficient. Two components are defined as major and under 2.1.5 a number of other substances is provided. Quantitative data are very meagre. No discussion on the relevance of non-active components is included.		BSA updated	Addressed: Modifications were made in the updated submission, however EFSA highlighted that the inconsistency as regards which substances to be considered responsible for the claimed activity remained.
2(9)	2.1.5 Specification of the active substance	EFSA: if "consists of fragments of stems, light green to greenish-grey." It should be	This definition is in line with the proposed use, not in line with the title and contradiction with	BSA name changed for "Willow stem extract"	Addressed: The name was changed to "Willow stem infusion".

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**
		clarified why willow bark is introduced at all in the title.	the composition. (in 2.1.6 "As inactive component for the purpose of our claims, 3-indolebutyric acid (IBA), is also present in *Salix alba* bark"..,)		EFSA notes that in the updated submission the name was changed to infusion and not extract and the inconsistency of what are the active components still remains. See also comment 2(4)
2(10)	2.1.7 Method of analysis	NL: No method is provided for active component indole-butyric acid.		Ref Added	Addressed: The submission was updated with Absalan, et al. 2008.
2(11)	2.5 Description of the preparation for the product to be used	NL: The manufacturing process needs some more detail; no detail is provided regarding extraction time. How long should the clippings be kept in boiling water? What is the recommended temperature of the broth for steeping? What is the recommended steeping time?		name changed for "Willow stem infusion" Recipe is an infusion: modified T° 100°C to room temp	Addressed: The name was changed and the recipe updated in the revised submission.
2(12)	2.5 Description of the preparation for the product to be used	NL: The applicant states that 'Willow bark and stem extract' is similar, but not identical to 'Salix spp. cortex', which is an already registered basic substance. It is noted that the manufacturing process is very		BSA name changed for "Willow stem infusion"	Addressed: The name was changed to "Willow stem infusion" in the revised submission. See also comment 2(4)

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**
		similar. The applicant is requested to state why willow bark and stem extract is exactly different from Salix spp. cortex.			
2(13)	2.1.5, Specification of purity of the active substance	DE: Since indolbutyric acid is important for the mode of action the content of indolbutyric acid in the basic substance should be provided.		Indole butyric acid (IBA) is not a component accumulated in Salix / willow stems in intrinsic way. The process / recipe implemented is the way to force willow stems to produce excess amount of IBA.	Addressed: The recipe was updated in the revised submission. See also 2(11)
2(14)	2.1.7, Methods of analysis	DE: Since indolbutyric acid is important for the mode of action analytical methods should be provided for indolbutyric acid.		Indole butyric acid (IBA) is not a component accumulated in Salix / willow stems in intrinsic way. The process / recipe implemented is the way to force willow stems to produce excess amount of IBA. So analytical method is not consistent.	Addressed: The submission was updated with Absalan, et al. 2008. See also 2(10)

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(15)	2.2	DK: It is not clear from the overall application is "Willow bark extract", as stated here, is in fact the same as "willow bark and stem extract". Why the difference? If not, then all references for "Willow bark extract" are (mostly) not relevant in this application.		BSA name changed for "Willow stem infusion"	Addressed: The name of the application was changed to "Willow stem infusion". See also 2(4)

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(16)	2.3	DK: Does this mean that all botanical resellers's Willow bark and stem extracts are considered for this application?		Yes, but stems are tree shoots mainly collected by people. Salix / willow emit tree shoots yearly.	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**

No comments.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(17)	2.5	DK: Please deleting the sentence about consumption of infusions: *Unless the infusion is to be consumed immediately, it may then be bottled and refrigerated for future use.* This is not relevant for this application.	DK: Delete the first part of a sentence: *Unless the infusion is to be consumed immediately.*	Modified	Addressed: The submission was updated.
2(18)	2.5 (Step 4)	DK: Please specify a time for the steeping, at least give an interval. As it is it says that the longer time the stronger the infusion. This is logical, however there should be a max level to insure that the infusion is not stronger than		Recipe updated	Addressed: The recipe was updated in the revised submission. See also 2(11)

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
		what is justified to use based on the risk assessment.			
2(19)	Overall	DK: Is this proposed basic substance an "extract" or an "infusion"?		BSA name changed for "Willow stem infusion"	Addressed: The name was changed to "Willow stem infusion". See also 2(4)
2(20)	Recipe Step five	DE: Please describe in the recipe whether the willow stems stay in the stored extract or whether the stems are filtered off before storage of the extract.		BSA name changed for "Willow stem infusion" Recipe updated	Addressed: The recipe was updated in the revised submission. See also 2(11)
2(21)	2.5 Description of the recipe	EFSA: The description of the recipe says that willow bark and stem are chopped and in the next sentence talks about extension of use, while in the detailed description only willow stems appear.	If the proposed use is as plant growth regulator, i.e IBA is considered the active substance, why the bark is introduced at all in the title. Does the preparation work as plant growth regulator only using bark? Is the bark also needed for the plant growth regulator effect? It seems that the willow bark use is for the fungicidal effects, this one is different from that, especially as IBA, mostly being in the stem, is the active. This seems not to be an extension of the *Salix* spp cortex, but a different	BSA name changed for "Willow stem infusion" Recipe updated	Addressed: The name was changed to "Willow stem infusion" and the recipe was updated in the revised submission. See also 2(11)

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**
			basic substance. The contradiction between the considered active substance(s), effects, preparation, extension/new should be resolved.		

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DK: We question if "root growth stimulation" is within the scope of the Regulation (1107/2009). It is likely that this use is to be considered a kind of fertilisation (different regulation).	DK: **EFSA**, please ask the Standing Committee (Scope and borderline issues) to discuss whether the use of 'Willow bark and stem extract' as 'root growth stimulation for various crops tree cuttings' is within the scope of the Regulation (1107/2009). Please see the case about a growth stimulant called "EURECA" where the standing Committee (Legislation 28 June 2004) discussed a growth stimulant containing plant extract and concluded not a PPP.	Applicant found this question strange: As IBA was mentioned as approved active substance and some other auxins (MAD, MAA, as well as gibberellins) are also present in the EU pesticide data base as PG plant growth regulator.	Addressed: This is a management decision out of the remit of EFSA.

3.2. Effects on harmful organisms or on plants					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
3(2)	3.2.2.	DK: The majority of the references regarding the mode of action consider effects of indole-3-butyric acid which was listed as an inactive substance in section 2.1.6 please clarify.		Other compounds are included in the updated version	Addressed: The inconsistency between different parts of the submission as regards what substance to be considered active still remains.
3(3)		DK: D-(-)-Salicin is listed as an active substance in section 2.1.2, but is not considered in this section, please clarify.		Component, not active matter in this application	Addressed: The inconsistency between different parts of the submission as regards what substance to be considered active still remains. See also 3(2)
3(4)	3.2.1	DK: Please delete the sentence: *No Effects on harmful organisms: plant growth regulator*. It is redundant here.		Sentence removed.	Addressed.

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(5)	3.4 Summary of intended uses	DK: The method is listed as "manually". Please write "dipping" of something like it to better state how the proposed basic substance is to be applied. "Manually" alone does not give a notion on how to manually apply the substance.		GAP modified	Addressed: The GAP table was updated in the revised submission.
3(6)	3.4, summary of intended uses, GAP table.	NL: The table of intended uses is only partially completed. Please try to complete as many of the columns as possible. The method of application is listed as "manually" but is more relevant to include if it is done by dipping of cuttings, foliar spray or by another application method. An indication of the duration of dipping may also be relevant. No attempt was made to quantify the dose rate of the solution in the table of uses. This information should be added.		GAP updated	Addressed: The GAP table was updated in the revised submission. See also 3(5)

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(7)	3.4, summary of intended uses, GAP table.	The active component of the willow extract is claimed to be indole-butyric acid, which is an existing active substance in PPP products. The table of uses currently does not give any indication of how much indole-butyric acid is present.		Now plant growth regulators are PPP? Above it is not. All means are used to discriminate between sustainable, renewable and natural basic substances used in the field.	Addressed: This is a management decision out of the remit of EFSA.
3(8)	3.4.1	DE: If the use was restricted to cuttings before planting, harmful effects on certain groups of organisms may be ruled out.	Specify the intended use/application.	Only dipping described in GAP	Addressed: The GAP table was updated. See also 3(5)

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)	4	DK: As basic substances are to be used by amateurs and professionals alike DK does not consider it acceptable if the use of the proposed basic substance has risk mitigation such as 'wearing gloves'. If the risk mitigation measure 'wearing gloves' is required, then please base it on a risk assessment. DK question if it is relevant in this chapter (classification and labelling) to advise the user to wear gloves due the risk of coloration.		Gloves are good way to avoid coloration of hands We use gloves for dishes as well.	It is noted that the use of gloves is proposed in order to avoid coloration of hands and not as risk mitigation measure.
4(2)	4	DK: As there are many components in this extract (according to chapter 2 application) please include/list their classifications according to ECHA in this chapter. It does not follow that the proposed active substance is classified, however there should be an overview here. Without such an overview it cannot be ruled out if this		Of course, especially when some are approved as active substance they are for sure dangerous since they have to pay to be approved! And natural extract is naturally more dangerous than chemicals by essence…	Information on the notified classification for the claimed major active components of willow stem infusion was not provided by the applicant. Willow stem major active components have skin sensitisation/irritation and lung irritation properties, as from notified classification (ECHA website).

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**
		substance does not meet the criteria of article 23 of Regulation (EC) No 1107/2009.			
4(3)	4. Classification and labelling.	NL: Willow bark and stem extract contains salicin (CAS 138-52-3) which according to the notifications under REACH should be classified as a skin sensitiser. It is unclear what the level of salicin is in the extract and whether or not the extract as a whole should be regarded as a sensitiser.		Salicin is less toxic than aspirin, and aspirin (legal) exhibit high death rate! Am J Gastroenterol. 2005 Aug;100(8):1685-93. A nationwide study of mortality associated with hospital admission due to severe gastrointestinal events and those associated with nonsteroidal antiinflammatory drug use.	Please, refer to 4(2).
4(4)		DE: According to the submitted application major active components of willow bark stem extract are D-(-)-salicin (CAS: 138-52-3) and indole-3-butyric acid (CAS: 133-32-4). According to the classification provided by companies to ECHA in CLP notifications indole-3-butyric acid (CAS: 133-32-4) is toxic if swallowed (H301), causes serious eye irritation (H319), causes skin		Therefore, withdraw indole-3-butyric acid from PPP!	Please, refer to 4(2).

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**
		irritation (H315) and may cause respiratory irritation (H335). D-(-)-salicin (CAS: 138-52-3) may cause an allergic skin reaction (H317).			

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5, in general	DK: The inserted abstracts are not considered sufficiently comprehensive to describe health effects of the extract. Please provide summaries based on the abstracts and conclusions as well.		Applicant agree	Literature abstracts only have been provided without any further assessment/consideration by the applicant.
5(2)	General remark	NL: The details provided on the toxicity of willow bark is very limited. Only reference is made to the EMA evaluation without providing details. It would have been helpful if a summary of the available information had been provided for each endpoint in the report.		EMA removed	Please refer to 5(14).
5(3)	5.2 Acute toxicity	NL: Willow bark and stem extract contains salicine (CAS 138-52-3) which according to the notifications under REACH should be classified as a skin sensitiser. The EMA report also states that side effects with willow bark medicines include allergic reactions.		Therefore, to be consistent withdraw indole-3-butyric acid from PPP!	Please, refer to 4(2) and 5(14).

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	5.2	DK: Salicin is suspected to have skin sensitizing properties, it is therefore very important to know the content of this in the extract, to know whether such effects could be expected from the extract.		Infusion is not intended to be used as shower. Infusion is directly transferred into plant system (dipping).	Please, refer to 4(2).
5(5)	General remark	NL: The details provided on the toxicity of willow bark is very limited. Only reference is made to the EMA evaluation without providing details. It would have been helpful if a summary of the available information had been provided for each endpoint in the report.		EMA reference was corresponding to bark, removed.	Please, refer to 5(1) and 5(14).
5(6)	5.2 Acute toxicity	NL: Willow bark and stem extract contains salicine (CAS 138-52-3) which according to the notifications under REACH should be classified as a skin sensitiser. The EMA report als states that side effects with willow bark medicines include allergic reactions.		Only plant growth regulators are needed to be extracted with infusion, polyphenols are slightly extracted.	Please, refer to 5(1) and 5(14).

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)	5.3 short term toxicity	NL: The EMA evaluation of willow bark states that willow bark medicines should not be taken by people with asthma, active stomach ulcers, severe liver or kidneys dysfunction, clotting disorders and glucose-6-phophate dehydrogenase deficiency, woman in the third trimester, children and adolescents. Possible exposure of these sensitive groups does not appear to be addressed in the report.		Willow stems infusion is not intended to be drunken. Suicidal comportment are not covered by PPP applications, although some people does.	Please, refer to 5(14).

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**
5(8)		DK: The risk of teratogenic effects of salicylates should be considered in this application.		Applicant agree, still 22 Carc. 2 proven as active substance, 175 classified a.s. and 31 candidates for substitution…	Please, refer to 5(1).
5(9)	5.6 Reproductive toxicity	NL: As indicated in our previous comment the EMA evaluation indicates that willow bark extract should not be used by women in their third trimester. No justification is made on why pregnant women would not be at risk due to willow bark extract use as plant protection product. It is also noted that full evaluation of EMA (EMA/HMPC/80628/2016) mentions that salicylates in		EMA ref removed	Please, refer to 5(14).

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**
		breast milk have been reported to cause macular rashes in babies. These concern should also be addressed.			

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**
5(10)	5.9 Medical data	NL: Several adverse effects are reported by EMA relating to medicinal use of willow bark including, allergic reactions and stomach and gut symptoms. On the basis of the evaluation provided in the report it cannot be excluded that these adverse effects may also occur due to PPP use of willow bark extract.		EMA ref supressed	Please, refer to 5(14).

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

No comments

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

No comments

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(11)	5.12	DK: Please provide a detailed comparison between extracts of Salix alba and extracts of Willow bark and stem, to support the weight of the argument.		Applicant disagree, different recipe, different extract, not comparable.	Comparison between extracts of Salix alba and extracts of Willow bark and stem is not provided, therefore the applicant conclusions that *Willow stem infusion a plant extract which can be fully characterized and similar to Salix cortex extract* cannot be supported.
5(12)	5.12 ADI, AOEL, ARfD	NL: The EFSA panel outcome only relates to the health claims made on willow bark (maintenance of joints). It does not contain a safety evaluation and therefore this report does not appear to be relevant for setting an ADI, ARfD or AOEL.		No data. But EFSA outcome as food.	The scientific opinion by the EFSA Panel EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) (EFSA NDA Panel, 2010) reported by the applicant is referring to the health claims related to various food(s)/food constituent, including Salix alba (Willow). It does not address the risk assessment for Salix alba (Willow).

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(13)		NL: The EMA evaluation of willow bark states that willow bark medicines should not be taken by people with asthma, active stomach ulcers, severe liver or kidneys dysfunction, clotting disorders and glucose-6-phophate dehydrogenase deficiency, woman in the third trimester, children and adolescents. Since no risk assessment is carried out a risk cannot be excluded for these sensitive groups.		EMA ref removed	See 5(14).
5(14)		EFSA: no assessment has been provided on the impact of willow bark and stem extract on human health. The active ingredient of the product is a complex mixture of chemical substances, many with pharmacological properties. Some of them have also notified classification for acute toxicity (ECHA website). The reference to the EMA assessment report (EMA, 2017) only is provided in the	Applicant to provide an updated report including characterisation of the toxicological properties of chemical substances in the willow bark and stem extract.	More ref added Some genotoxicity are exhibited.	The active ingredient in the product is a complex mixture of chemical substances, including salicylates. These are known to have pharmacological properties and some adverse effects relating to medicinal use (allergic reactions, gastro-intestinal symptoms; use contraindicated during pregnancy and in children and adolescents under 18 years of age) (EMA, 2017). Moreover, willow stem major active components have skin

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**
		tox section, without any information/summary/detail. An updated report including characterisation of the toxicological properties of the chemical substances in the extract should be provided.			sensitisation/irritation and lung irritation properties, as from notified classification (ECHA website). The reference to the EMA assessment report has been removed by the applicant. A study (abstract only) investigating the cytotoxic and genotoxic potential of Salix Alba bark extract on human cultured leukocytes has been provided. In the study, cytotoxicity (viability decreases) is observed at the high doses. It is also reported that data suggest that the genotoxic effects of Salix Alba bark extract occur when it is not metabolised by liver enzymes. Very limited information (literature abstracts only) have been provided, without details and considerations by the applicant. The evaluation of toxicological properties of the willow stem infusion has not been sufficiently investigated.

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**
					The characterisation of the toxicological properties of the willow stem infusion constituents has not been addressed, therefore a qualitative and quantitative consumer risk assessment could not be performed. Based on the available information, it cannot be concluded that willow stem infusion does not pose any toxicological concern.

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)	6. Residues	NL: It is only mentioned that willow bark and stem extract is similar to *Salix* spp. cortex infusion. Please include a reasoning why residues are not relevant for willow bark and stem extract.	EFSA: It is suggested the applicant provide a reasoning whether the intended GAP could lead to residues in edible commodities and why/why not. Cross-referencing to other applications is indeed insufficient as the proposed uses may not be comparable and the application on Willow bark and stem extracts has to be a complete stand-alone document.	Rooting is applying to any kind of transplanted plant, mainly horticulture. GAP more precise.	Refer to 6(2).
6(2)		ESFA: In line with comments under section 3.3 the scope of the GAP is not totally clear. Can the applicant please specify which crops would fall in their opinion into the category "herbaceaous trees"? If the GAP refers to herbaceaous plants instead, these include a wide range of edible crops and further details are needed for an assessment of the proposed use.	EFSA: Applicant to specify in more detail the crop categories in which application of Willow bark and stem extracts is intended.	Rooting is applying to any kind of transplanted plant/trees, mainly horticulture. GAP more precise.	The applicant clarified that the application is intended to "any kind of transplanted plant/trees". It is therefore assumed that application to edible crops is intended and the relevance of residues for consumers should be addressed by the applicant, which was not the case. A consumer exposure and risk assessment or the decision that a quantitative consumer risk assessment could be waived is

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**
					currently not possible, specifically in view of the unclear information regarding the active components and the purity (see section 2.1) and the characterisation of the toxicological properties of components in willow stem infusion (see section 5.13.).

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)	Chapter 7	NL: In view of the recipe for this basic substance (willow bark and stem extract in water), the proposed use and the fact that the basic substance *Salix* cortex is already approved in the EU, NL does not consider it necessary to provide further information on the environmental fate and behaviour of this basic substance. The exposure of environmental compartments due to the proposed use of this basic substance is considered to be within the natural background exposure.		Willow stem extract similar to *Salix cortex*.	The only commenter considered that the exposure of environmental compartments due to the proposed use of this basic substance might be considered to be within the natural background exposure. This appears to be a qualitative expert judgement.
7(2)	Chapter 7	EFSA: Minor comment. The reference included in chapter 7 relates more to the hazard characterisation of a transformation product of components of willow bark and stem extract (salicin), so is better placed in chapter 8. It is noted that the	The hazard information included in chapter 7 might be removed.	No comment from applicant	The applicant did not make any change in the application.

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**
		information was also already included in chapter 8.			

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

No comments

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1	NL: Only toxicity values are presented. In the context of this application, are there any harmful effects expected on birds and mammals? If, for example, the current exposure is lower or similar to the background concentration this point can be waived. Also information from chemicals that are structurally similar can be used.		Toxicity is similar to other auxins. Useful concentration of active substances is usually low (10^{-5} to 10^{-4} mol/L)	Only one study has been provided for effects on terrestrial vertebrates, stating only the toxicity values. Additional studies and detailed explanations are required.
8(2)		EFSA: Applicant to provide study or literature review on toxicity to birds and mammals.		More ref added	See 8(1).

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)	8.2	NL: the information presented should be summarized. For the purpose of the evaluation, presenting only the endpoints it is not considered sufficient. Please introduce the study objective, the test organism, exposure concentrations, results and discussion, conclusions. According to SANCO/10363/2012 rev.9, "based on the description of the intended uses, the potential consequences of increased exposure with respect to natural exposure levels or to exposure due to other uses should be considered and substantiated that the substance has "neither an immediate or delayed harmful effect on animal health nor unacceptable effects on environment"".		No explicit data	Addressed: Three papers have been provided that do not give enough details about toxicity to aquatic organisms. One of them mentions slight toxicity of salicylic acid to fish. However, on the basis of the judgement made in comment 7(1) no aquatic risk assessment is necessary.
8(4)	8.2	NL: the intended use of the product is as a plant growth regulator. According to the EC 283/2013, for plant growth		No explicit data	See 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
		regulators, information on aquatic macrophytes should be provided			
8(5)	8.2.	EFSA: Agree with MS. Studies or literature reviews regarding toxicity to aquatic organisms should be provided. Influence on aquatic macrophytes should also be provided.		No explicit data	See 8(3).

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	8.3.1	NL: the information presented should be properly summarized (see also comment 8.2 above)		Soil treatment (dipping) for roots.	Addressed: Two studies have been provided that give some information about the effect on bees, but they should be more detailed. There is no information about the toxicity on other arthropod species. It is anticipated that there is limited potential for exposure

8.3. Effects on bees and other arthropods species					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					to bees and foliar arthropods for the proposed use (dipping). Furthermore, on the basis of the judgement made in comment 7(1) no risk assessment for soil dwelling arthropods is necessary.
8(7)	8.3.1	NL: Only if no effects on bees were observed at concentrations similar or higher than the current application rate, then it can be concluded that Salix alba it has no effects on bees. A sentence such as "no risk assessment is necessary" is only applicable if the exposure of bees does not occur.		Soil treatment (dipping) for roots.	See 8(6).
8(8)	8.3.1	NL: No information on non-target arthropod species is available. If, for example, the current exposure is lower or similar to the background concentration this point can be waived. Also information from chemicals that are structurally similar can be used.		Soil treatment (dipping) for roots.	See 8(6).
8(9)	8.3.1, Honeybees	DE: The provided references are not appropriate.	Please refer to studies that meet scientific standards, preferably	Soil treatment (dipping) for roots.	See 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**
			published in independent peer-reviewed journals.		

8.4. Effects on earthworms and other soil macroorganisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(10)	8.4	NL: the information presented should be properly summarized (see also comment 8.2 above)		Used as fertilizer.	Addressed: On the basis of the judgement made in comment 7(1) no risk assessment for soil organisms is necessary.
8(11)	8.4	NL: No information on other soil macro-organisms is available. If, for example, the current exposure is lower or similar to the background concentration this point can be waived. Also information from chemicals that are structurally similar can be used.		Used as fertilizer.	See 8(6).
8(12)		EFSA: Applicant to provide additional information on		Used as fertilizer.	See 8(10).

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
		toxicity to bees and non-target arthropods.			

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)	8.5	NL: the information presented should be properly summarized (see also comment 8.2 above)		Used as fertilizer.	Addressed: On the basis of the judgement made in comment 7(1) no risk assessment for soil organisms is necessary.

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(14)	8.6	NL: the information presented should be properly summarized (see also comment 8.2 above)		Used as fertilizer.	Addressed: Out of the three studies presented by the applicant only one deals with soil microorganisms and the other

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
					two are more general. However, on the basis of the judgement made in comment 7(1) no risk assessment for soil organisms is necessary.
8(15)	8.6	NL: According to 283/2013 For active substances that exhibit herbicidal or plant growth regulator activity, vegetative vigour and seedling emergence concentration/response tests shall be provided for at least six species representing families for which herbicidal/plant growth regulatory action has been found. Where, from the mode of action, it can be clearly established that either seedling emergence or vegetative vigour is effected, only the relevant study shall be conducted". If, for example, the current exposure is lower or similar to the background concentration this point can be waived. Also		Used as fertilizer.	Addressed: On the basis of the judgement made in comment 7(1) no risk assessment for seedling emergence, following contamination of the soil, is necessary.

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**
		information from chemicals that are structurally similar can be used.			
8(16)		EFSA: Applicant to provide additional data on influence of willow on non-target organisms.		Used as fertilizer.	See 8(14).

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**

No comments.

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)	9	DK: Please delete the sentence: *Willow bark and stem extract has an **extremely** low toxicological profile.* Based on the sparse listing in this application of composition of the proposed extracts and the classification of the components, this is not documented.	DK: Delete: *"Willow bark and stem extract has an **extremely** low toxicological profile."*	Sentence modified as requested.	The characterisation of toxicological properties of the willow stem infusion components has not been addressed. Based on the available information, it cannot be concluded that willow stem infusion does not pose any toxicological concern. Please refer also to 5(14).
9(2)	9	DK: We question if this use is within the scope of the regulation (1107/2009. If the use is within the scope of the Regulation, then this application needs to be specific regarding components of the proposed extract, the classification range of the proposed extract for use. If the proposed basic substance does not meet the criteria in Article 23 then we suggest an application for approval as an active substance (botanical).		Other auxins are PPP.	The decision about acceptance as a basic substance submission is a risk management decision, out of the remit of EFSA.

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(3)	9	DK: If a risk assessment show that gloves are needed as risk mitigation measure, then DK is against this substance as a basic substance on principle, as it should lead to this proposed basic substance to be approved for professional users only.		Gloves are used everywhere daily.	See 9(2).
9(4)	Eligibility of willow bark and stem extract to be approved as basic substance	DE: It is not agreed to approve willow bark and stem extract as basic substance. According to the submitted application major active components of willow bark stem extract are D-(-)-salicin (CAS: 138-52-3) and indole-3-butyric acid (CAS: 133-32-4). According to the classification provided by companies to ECHA in CLP notifications indole-3-butyric acid (CAS: 133-32-4) is toxic if swallowed (H301), causes serious eye irritation (H319), causes skin irritation (H315) and may cause respiratory irritation (H335). D-(-)-salicin (CAS: 138-52-3) may cause an allergic skin reaction		Some component are approved at other regulation or PPP regulation, if indole-3-butyric acid is so toxic please remove it from PPP regulation. D-(-)-salicin is still allowed at EU Pharmacopeia.	See 9(2).

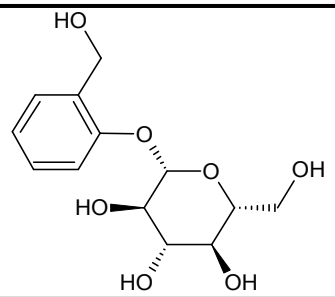
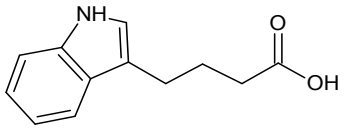
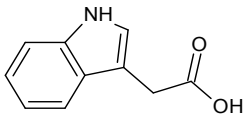
Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to 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**
		(H317). Therefore, willow bark and stem extract does not meet the criteria of article 23 of Regulation (EC) No 1107/2009. It is proposed that the application for approval of willow bark and stem extract should be based on the guidance document on botanical active substances (SANCO/11470/2012).			

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 – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation[b]	Structural formula[c]
salicin	2-(hydroxymethyl)phenyl β-D-glucopyranoside OCc1ccccc1O[C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O NGFMICBWJRZIBI-UJPOAAIJSA-N	
indole-3-butyric acid IBA	4-(1*H*-indol-3-yl)butanoic acid O=C(O)CCCc1c[NH]c2ccccc21 JTEDVYBZBROSJT-UHFFFAOYSA-N	
indole-3-acetic acid	1*H*-indol-3-ylacetic acid O=C(O)Cc1c[NH]c2ccccc21 SEOVTRFCIGRIMH-UHFFFAOYSA-N	

(a): The compound name in bold is the name used in the technical report.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019)
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019)

Appendix C – Identity and biological properties

Common name (ISO)	willow stem infusion (not ISO)
Chemical name (IUPAC)	not applicable (complex mixture)
Chemical name (CA)	not applicable (complex mixture)
Common names	white willow; *Salix alba*
CAS No	willow stem infusion: not applicable salicin: 138-52-3 indole-3-butyric acid: 133-32-4 indole-3-acetic acid: 87-51-4
CIPAC No and EEC No	willow stem infusion: not applicable salicin: 205-331-6 indole-3-butyric acid: 205-101-5 indole-3-acetic acid: 201-748-2
FAO specification	none
Minimum purity	not applicable (complex mixture)
Relevant impurities	none
Molecular mass and structural formula	not applicable (complex mixture)
Mode of Use	willow stem is used to prepare a water infusion
Preparation to be used	Dispersible concentrate (infusion) (DC).
Function of plant protection	plant growth regulator

Appendix D – List of uses

Crop and/or situation (a)	Member State for use	Example product name as available on the market	FGI (b)	Target (c)	Product		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
herbaceous plants and fruit trees and woody ornamental plants	All Member States	Willow stem infusion	FGI	Root growth stimulation of cuttings	Dispersible concentrate (DC)	50 to 75 eq. g/L	Dipping	BBCH 00 to 06	1	-					None	

(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