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Outcome of the consultation with Member States and EFSA on the basic substance application for Landes pine tar for use in plant protection as protectant and repellent

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, 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 Landes pine tar 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 Landes pine tar as a basic substance for use in plant protection as antifungal, antimicrobial and repellent. 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: Landes pine tar, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00611

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Summary

Landes pine tar 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 Progarein France SAS 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 August 2017, EFSA was asked to organise a consultation on the basic substance application for Landes pine tar, 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 Landes pine tar, organised by EFSA, was conducted with Member States via a written procedure in April-June 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 Landes pine tar and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Landes pine tar is a material produced by the high temperature carbonization of pine wood in anoxic conditions (dry distillation or destructive distillation). The wood is rapidly decomposed by applying heat and pressure in a closed container; the primary resulting products are charcoal and pine tar.

Landes pine tar is proposed to be used as protectant with antimicrobial/antifungal activity and as repellent in vineyard, orchard and shrubs and gardening.

Landes pine tar is a complex mixture and the exact composition is unknown since proper batch analysis is not available. Based on current available information on its composition, the mixture should be considered of concern since it can contain substances of concern (e.g. furfurals, phenols). Furthermore it cannot be excluded the presence of substances of very high concern (e.g. genotoxic carcinogens such as polycyclic aromatic hydrocarbons) that could be of toxicological concern even if formed at low concentration.

The GAP for the uses as antifungal/ antimicrobial and repellent substance was not sufficiently clarified as to exclude with certainty any exposure potential for edible crops. Upon clarification of the exact composition of the basic substance pine tar, it should be demonstrated that substances contained in pine tar are either not of toxicological relevance or not translocated into edible crop parts following application on tree trunks. It can be reasonably assumed that following the proposed use as attractant (i.e. use on trees in the vicinity of crops to be protected) the potential for dietary exposure of consumers or livestock is very low.

The method of application to wounds or to tree bark as a repellent (in both cases by spatula or knife) limits environmental exposure. However the environmental exposure assessment remains open, as it has been confirmed that Landes pine tar is not present naturally in the environment. What is naturally present are resins that are exuded from wounds of pine trees. A comparison of the composition of Landes pine tar and natural resins was not presented.

Data on effects on non-target organisms were not available. However, for the representative uses as protectant and repellent and considering the method of application, exposure to non-target organisms can be assumed to be very low.



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1. Introduction

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

Regulation (EC) No 1107/2009¹ (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.

Landes pine tar is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Progarein France SAS for approval as a 'basic substance' for use in plant protection as antifungal/antimicrobial and repellent.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for Landes pine tar, which was conducted via a written procedure in April-June 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 Landes pine tar 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 Landes pine tar 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 (Progarein France SAS; 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 1 August 2017, EFSA was asked to organise a consultation on the basic substance application for Landes pine tar, 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 1 November 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.

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 Landes pine tar 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. Progarein France SAS, 2017a. Basic substance application on Landes pine tar submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2017. Documentation made available to EFSA by the European Commission.
- 2. Progarein France SAS, 2017b. Basic substance application update on Landes pine tar submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September, 2017. Documentation made available to EFSA by the applicant.

References

SCCNFP (Scientific Committee on Cosmetics Products and non-Food Products), 2003. Opinion of the Scientific Committee on Cosmetics Products and non-Food Products intended for consumers concerning wood tars and wood tar preparations adopted by the SCCNFP during the 23rd plenary meeting of 18 March 2003. SCCNFP/0646/03, final, 12 pp.

European Commission, 2008. Review Report for the active substance blood meal finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of blood meal in Annex I of Directive 91/414/EEC. SANCO/2604/08 – rev. 1-3, 9 March 2012.



Abbreviations

ADI acceptable daily intake

AOEL Acceptable operator exposure level

ARfD acute reference dose

a.s. active substance

GAP good agricultural practice

GC-MS gas chromatography with mass spectrometry

GC- gas chromatography with tandem mass spectrometry

MS/MS

HPLC high performance liquid chromatography

HPLC- high performance liquid chromatography with mass spectrometry

MS

MS Member State

PPP Plant Protection Product



Appendix A — Collation of comments from Member States and EFSA on the basic substance application for Landes pine tar and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

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

No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.1.1	DK: Please explain explicitly in the text why it is, that Landes pine tar produced in a furnace from a temperature of 360° to 480°C will not produce any dangerous substances when it is stated by references further below that pine tar contains polycyclic aromatic		LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	Data gap: The added reference showed that 11 PAHs have been identified and two of them quantified at levels of 0.86% and 0.03% respectively. A specification of the maximum content of the



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2/2)		hydrocarbons (PAHs) classified with Carc. 2.		Defense as and to the board	PAHs in the substance is needed based on quantitative determinations of batch samples, considering that wood tar preparations may contain polycyclic aromatic hydrocarbons which are genotoxic carcinogens. See also comment 4(1)
2(2)	2.1.1.1	DK: We question if the reference Hjulstöm <i>et al.</i> 2006 is relevant for this application.	Remove the mentioned reference from the application, or clarify why it is relevant in this context.	Reference moved to the head of chapter §2.	Addressed.
2(3)	2.1.1.1. Composition	ES: It should be clarified how is guaranteed that no dangerous substances are produced during the Landes pine tar production at 360° to 480°C. In Spain opinion, the formation of dangerous substances is not only dependent of temperature but also other variables such as time, pressure, etc. In this sense, currently, the issue '2.1.4. Method or methods of manufacture of the substance and of the product' is not sufficiently detailed to know how the	ES: No more comments	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See data gap 2(1) The added reference showed that 11 PAHs have been identified and two of them quantified at levels of 0.86% and 0.03% respectively. As a consequence the statement that no dangerous substances are formed is questionable.



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		manufacturing process is performed and how this influences the formation of dangerous substances. Moreover, the table at page 15 show that dangerous substances such as phenol, cresol, etc. are formed at 450°C, below 480°C.			
2(4)	2.1.5. Description and specification of purity of the active substance and product	ES: Landes pine tar contains active substances used in crops protection (e.g. acetic acid, oleic acid). Therefore, a maximum content of these active substances should be established.	ES: No more comments	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible components. Reference included in the updated basic substance application.	Addressed. No specification of these substances were provided, however specifying these two compounds only in such a complex mixture wouldn't be relevant for the product.
2(5)	2.1.5. Description and specification of purity of the active substance and products	ES: Nature of the constituents and their amounts in Landes pine tar should be clearly established according to the pine spp., crop stage, place of the plantation, etc. Both nature and amounts of the constituents can greatly vary attending to these issues. This fact is especially important taking into account that several of Landes pine tar constituents are currently approved as active substances.	ES: No more comments	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible components. Reference included in the updated basic substance application.	Data gap: A specification stating the ranges of the main constituents has not been provided.
				Hjulström, B. Reference	



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	Composition, p.6-7	Isaksson, S., & Hennius, A. 2006 that 'The 4 diterpenoids retene, abietic acid, dehydroabietic acid and methyl dehydroabietate are all major components in pine tar and have been chosen as key compounds in this study'. However, retene and dehydroabietate are not identified in study (with GC-MS) by Egenberg, I. M., Aasen, J. A., Holtekjølen, A. K., & Lundanes, E. 2002/2003, please clarify the statement.		corresponds to old samples. Biomarkers for oldness analysis are different from major components. LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible components. Reference included in the updated basic substance application.	
2(7)	2.1.3 Composition, p.10	NL: The composition in % (by Harmel N 2015) for the main 4 major components retene, abietic acid, dehydroabietic acid and methyl dehydroabietate and the impurity naphthalene are not provided, please clarify.	n.a.	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible components. Reference included in the updated basic substance application.	See data gap 2(5) The referenced study contains only data about the compounds identified in the pine tar, not the quantities. If these compounds are considered the major components, quantitative data of batches are needed in order to support the specification
2(8)	2.1.5 Description and specification of purity of the active substance and product, p.	NL: It is stated in Belliot A, 2007 that 'Pine tar is insoluble in water'. However, in SCCNFP, 2003 it is stated that 'wood tar is soluble in ethanol and ether, slighty	n.a.	Landes pine tar is very slightly soluble, only a few amount	Addressed: Landes pine tar is very slightly soluble in water.



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	13-14	soluable in water'. Please clarify this contradiction.			
2(9)	2.1.7.1 Methods of analysis for the determination of the active substance as manufactured, p. 16.	NL: Identification for the non-volatile compounds is done with HPLC and HPLC-MS (and functional groups by FT-IR), however, no data have been presented in the application, please clarify.	n.a.	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	Addressed: The reference LCE, 2013_2 contains information about the identification of the compounds.
2(10)	2.1.1.1 Composition, p.6	EFSA: It is stated that 'product obtained from the destructive distillation of the wood of <i>Pinus'</i> Polycyclic aromatic hydrocarbons (PAH) and aromatic heterocyclic compounds are formed mainly during the pyrolysis of organic material (heating in the absence of oxygen or incomplete combustion). PAHs form when complex organic substances are exposed to high temperatures or pressures. The destructive distillation is a pyrolytic process that may lead to the formation of such compounds.	It should be explained or proven that under the conditions of production at 480 C no such compounds are formed.	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See data gap 2(1)
2(11)	2.1.1.1 Composition, p.8	EFSA: The PAH values are cited from the Opinion of the Scientific Committee on Cosmetics Products and non-Food Products intended for	It should be explained why this substance is not a 'substance of concern' meaning to have an	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible	See data gap 2(1)



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		consumers concerning wood tars and wood tar preparations (SCCNFP, 2003), which concludes: "SCCNFP is of the opinion that wood tar and wood tar preparations do pose a health risk when used in cosmetic products. Wood tar and wood tar preparations contain polycyclic aromatic hydrocarbons which are genotoxic carcinogens. Wood tar preparations have been found to induce both benign and malignant skin tumours in mouse skin and to form DNA adduct in human skin. The products may represent risk of skin cancer."	inherent capacity to cause an adverse effect on humans animals or the environment. It should be explained why the PAHs concentration in the product is not sufficient to present risks of such an effect.	PAHs are characterised. Reference included in the updated basic substance application. Use as psoriasis treatment, i.e. Belliot A., 2007	
2(12	2) 2.1.1.1 Composition, p.10	EFSA: based on 'Harmel N 2015' the content of the relevant impurities should be maximized		LCE, 2013_2 reference added. Analytical methods are described. Reference included in the updated basic substance application.	Data gap: Maximum levels of PAHs and any other relevant impurities should be set.
2(13	3) 2.1.1.1 Composition, p.15	EFSA: 'LCE 2013' shows that the substance may also contain considerable amount of methanol (12.44%)	Why methanol is not a relevant impurity in this product?	This amount was cited in an internal reference. Doubt is great since pine tars are produce between 450° and 900 °C and methanol boiling point is 64.7 °C	Reference LCE 2013 shouldn't be considered relevant for this submission.



No.	Reference to	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(14	2.2 Proposed trade name, p.17	EFSA: a basic substance cannot be linked to a product with a certain authorization number		This number was an old authorization number listed since 1990. Removed from updated basic substance application.	Addressed.

2.3.	2.3. Manufacturer of the substance/products								
No.	Column 1	Column 2	Column 3	Column 4	Column 5				
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	applicant .	EFSA's scientific views on the specific points raised in the commenting phase				
					conducted on the application				

2.4. Type of preparation

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



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)		ES: intended as protection sizes wounds. No application rate defined. Needed		GAP corrected Application rate added.	Addressed: The GAP was updated in the revised submission.
3(2)		ES: In the point 3.1 it is indicated the field of use (vineyard, shrubs and orchard) but in the table 3.4 are also included: gardening, field crops like maize and cereals.		GAP uses for field crops like maize and cereals are attractant (AT). No spray on theses crops! Landes pine tar is coated on trees in the vicinity not on field crops.	Addressed: The GAP was updated in the revised submission.
3(3)		NL: No comments		-	Addressed.
	3 Uses	EFSA: a basic substance shouldn't have been registered as a pesticide, while it is stated that "Pine tar oil has been registered for pesticide use in the USA, Australia, New Zealand, Hungary, and Canada"		Pine tar oil is different from Landes pine tar (solid) and local, national or foreign registrations are independent from this application. i.e. some non-approved basic substances are registered in Germany!	Addressed.
3(5)	3.2.1.2 Antifungal activity, p.19	EFSA: How can this substance be used in combination with nicotine?		Reference removed	Addressed: The reference was removed from the updated submission.



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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(6)	3.2.1.5	DK: Please clarify why these references are placed here and not further below in e.g. 8.3.2 (Other Arthropods). As the basic substance is not applied for as an insecticide (according to 3.4 Summary of intended uses), this information is more relevant for risk assessment of nontarget arthropods.	Either justify why the references are placed here or move them to 8.3.2.	Landes pine tar is not applied fas an insecticide (IN) but repellent (RE). Reference removed. Formulation Code adjusted to PC Paste Landes pine tar is applied forming a dry layer (i.e. on wounds)	Addressed: The references were removed from the application.
3(7)		NL: No comments		_	Addressed.

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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(8)		DE: In the Application this chapter has the number 3.4. General comment to the uses: The type of formulation in the GAP table is given as paste or any other liquid. This matches to chapter 2.4 (Type of preparation of the substance/product) "paste or liquid undiluted", however	Please clarify and give more details in the use in chapter 2.5 Please check whether the application as aerosol would require figures for the application rate per ha. Please check whether this use falls	GAP corrected Application rate added. Point §2 is also corrected No aerosol Formulation Code adjusted to PC Paste Application rate provided. Clearly this substance is not	Addressed: The GAP was updated in the revised submission. Application rate was added. The substance is not rodenticide but acts as repellent.



3.3. Summary of intended uses

No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		in chapter 2.5 (Description of the recipe for the product to be used) only reference to the use of a paste is given. If the basic substance shall be applied as a liquid, please clarify the use (it seems a rope or a string should be soaked with the liquid). Moreover, application as aerosol is mentioned in column "interval between applications". Would the repellent activity on rats and snakes fall under the scope of regulation?	under the scope of regulation, especially regarding snakes and biodiversity.	rodenticide (RO) but act as repellent for these bioaggressors.	
3(9)		DE: According to the GAP table (please see third use) it is planned to use Landes pine tar also as attractant for game like wild boar. This use does not fall under the scope of the plant protection legislation.	It should be withdrawn.	Game repellent activity is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1 Even PPP in DE	Data gap: The use as attractant should be removed from the GAP table. There weren't any data to support this use.
3(10)3.4	DK: Please change `France & All Member States' to `All Member States'.	Change the wording of the GAP tables in section 3.2	Basic substance application modified as requested	Addressed: The GAP was updated in the revised submission



	Summary of inte				
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(11) 3.4	DK: On the GAP tables where the interval between applications is indicated to be "6-10 week (4 weeks if in aerosol"; where in the application is it stated that it would be acceptable to apply the pine tar as an aerosol? The method of application is described as "Spread with a spatula".	Please correct the GAP so that the application method and the intervals etc. are in accordance. It may give a better overview to have the liquid and the aerosol application in different rows in this case. Note that the formulation type is PA or AL, and not AE, thus different rows would be more appropriate for the AE formulation type. However, the use in aerosol form may not be acceptable (human tox etc.), thus the wording "(4 weeks if in aerosol) should likely be deleted in GAP table 3.4.1 and 3.4.2.		Data gap: The GAP was not updated concerning the use as an aerosol. The wording '(4 weeks if in aerosol)' should be deleted from the GAP table 3.4.1 and 3.4.2.
3(12) 3.4	DK: Please describe somewhere in section 3 how to use "coated string stretched tar" as mentioned on the GAP tables in 3.4.	Add a description on how to use the pine tar, maybe include an illustration.	GAP corrected Application rate added. Formulation Code adjusted to PC Paste. Point §3 is also corrected	Data gap: The use 'coated string stretched tar' wasn't described in the updated submission.
3(13	3.4.3	DK: The use as an attractant is not included in the argumentation in 3.1 or 3.2, therefore it is confusing to include it on the GAP table	Delete table 3.4.3.	More references added GAP uses for field crops like maize and cereals are AT Attractant. No spray on theses crops! Landes pine tar	See data gap 3(9)

assessment if the application

rate is not defined

NL: No comments



No.	. Column 1 Column 2	Column 3	Column 4	Column 5	
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		in 3.4.		is coated on trees in the	
		The use as an attractant becomes more confusing as the GAP instructs the user to apply the pine tar with a spatula on cereal stems (?). Furthermore, how does attracting game like wild boar protect field crops like cereal? This becomes clearer when reading 8.1.2 where the applicant writes: "Pine tar is used to simplify the hunt of wild boar." DK strongly disagree that this purpose should be included in a plant protection scheme.		vicinity not on field crops.	
3(14	3.4. SUMMARY OF INTENDED USES	ES: It should be provided some kind of application rate, for example kg a.i. per plant.	ES: No more comments	GAP corrected Application rate added.	Addressed: The GAP table was updated in the revised submission.
3(15	5)	ES: it is not possible to conduct an environmental risk		GAP corrected Application rate added.	Addressed: The GAP table was updated in

3(16)

the revised submission.

Addressed.



4. Classification and labelling of the substance

Class		elling 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	DE: The composition (specification) of the technical material is unclear. Apparently, benzo[a]pyrene is present, which has a harmonised C&L with Muta 1B, Carc 1B, Repr. 1B and Skin sens 1. For Carc there is a SCL of 0.01 %.	The specification of the technical material should be clarified. The impact of impurities on the classification should be determined.	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See data gap 2(1)
4(2)	4 –Classification and labelling of the substance	DK: We question that Landes pine tar fulfils the criteria laid down in Article 23 (1a) and Article 23 (1b). Landes pine tar contains substances that are classified is as mutagent cat. 2 and others that are classified carcinogenic cat. 2. As not all seem to have threshold values even a low content does not necessarily indicate a low/acceptable risk, and thus the substance may be perceived as a substance of concern.	Justify explicitly how it is that Landes pine tar is not a substance of concern (wide spread use alone is not a justification).	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See data gap 2(1)
4(3)		NL: No comments			Addressed.



5. Impact on Human and Animal Health

No.	Column 1 Reference to Application	Column 2 Comments from Member States / EFSA	Proposal by Member States/EFSA Fo	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the
	Template		updated to address the comment		commenting phase conducted on the application
5(1)	5.2	DE: The listed toxicological properties lead to a classification of pine tar, which is corroborated by the classification listed in section 4. Hence, pine tar fulfils the criteria of a substance of concern.			Landes pine tar is a complex mixture. Proper batch analysis is not available. Based on current available information on its composition (considering proposed temperatures from 360 to 480°C) the mixture should be considered of concern since it can contain substances of concern (e.g. furfurals, phenols). Furthermore, the presence of substances of very high concern (e.g. polycyclic aromatic hydrocarbons) that could be of toxicological concern even if formed at low concentration (considering proposed temperatures from 360 to 480°C), cannot be excluded.
5(2)		NL: No comments		-	See comment 5(1).



5.2.	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	applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application		

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

No comments

5.4.	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	applicant .	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application		



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)	5.5 Carcinogenicity	NL: Several literature references are included describing a possible link to carcinogenicity. This seems to arise from the presence of PAHs in the tar. For this dossier, the following is concluded by the applicant: However, Landes pine tar is produced in furnace from a temperature 360° to 480°C, therefore, no dangerous substances is produced.' Could you please indicate what the level of PAHs is in Landes pine tar compared to the level of PAH in the literature describing a link to carcinogenicity? Is it indeed the case that the level of PAHs is (much) lower in Landes pine tar?		LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See comment 5(1).



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

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

No comments

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



5.9.	5.9. Medical Data: adverse effects reported in humans							
No.	Column 1	Column 2	Column 3	Column 4	Column 5			
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			

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

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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	5.11	DE: Where relevant, please provide more evidence that pine tar (as applied for) fulfils the criteria of a foodstuff (as defined in Art. 2 of reg. (EC) No 178/2002).	Please provide more evidence that pine tar (as applied for) fulfils the criteria of a foodstuff.		Addressed: Pine tar doesn't fulfil the criteria of a foodstuff.
5(5)	5.11 flavouring	NL: Looking at the literature included in the dossier, pine tar is mainly used in the		Applicant confirms flavouring agent status.	Data gap Authorisation as food flavouring substance is not



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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		treatment of skin diseases. However, in this section two references state the use as flavouring agent (Parchem fine as of 2015; Cervia as of 2015). Is pine tar indeed assessed/authorised as a flavouring agent?		See reference in the basic substance application	provided.

5.12	Acceptable daily	intake, acute reference dose, ac	cceptable operator exposure lev	<i>r</i> el	
No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)	Conclusion §5	DE: Following conclusion is listed: "PAHs compounds like phenanthrene and anthracene are classed like carcinogenic compounds. Wood tar and wood tar preparations contain genotoxic carcinogens. Wood tar preparations are demonstrated to induce both benign and malignant skin tumours in mice. In humans, tars are		LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application. Use as psoriasis treatment,	See comment 5(1).



5.12	. Acceptable dai	ly intake, acute reference dose, a	cceptable operator exposure lev	/el	
No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		responsible for developing		i.e.	
		lung cancer, lung cancer commonly known. The allergic potential of pine tar has been shown by several studies. Some of cases show the carcinogen effect of tar in human for short or long term during treatment for skin disease like eczema. Also treatment of psoriasis patients with a wood tar preparation has induced DNA adducts in the skin." This places doubt on the conclusion that the approval criteria (especially Art.		Belliot A., 2007	
5(7)		23(1)(a) and (b)) are met. NL: No comments			Noted

5.13.	5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it								
	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	applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application				
5(8)		EFSA: The assessment as	EFSA: a detailed and specific	LCE, 2013_2 reference	See comment 5(1).				



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		presented by the applicant was focussed on substances of very concern as PAHs compounds. However, as indicated by the applicant the presence of these compounds would be very low at temperatures of 450° C. The assessment of lands pine tar should have been focussed on the toxicological profile of the components of the mixture at 450° C. The applicant considered that substances present at 450° C are of no concern. EFSA did not agree with the applicant. Landes pine tar should be considered a mixture of concern on the basis of its composition at 360° to 480° C.	analysis of landes pine tar should be done including all the substances of concern as described on page 15. The applicant should provide an assessment of the toxicological profile of the different components of the mixture at 450° C.	added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		concern as PAHs compounds but EFSA would not disregard as substances of human health concern the list of substances or groups of substances described on page 14 (i.e."Conventional Flash Pyrolysis (450°-500° C) composition") and the following table at page 15 (composition at 450 C, 30 minutes). Substances like furfurals, methoxyphenols, phenolics present at 450° C are			
5(9)		substances of concern. NL: No comments			Noted



6. Residues

Resi	dues					
No.	Column 1 Reference to Application Template	ence to Comments from Member States / EFSA	Column 3 From Member States 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)		ES: Please, review the sentence included in the point 5.12 (ADI, AOEL, ARfD)		Applicant acknowledges. Modified	Addressed. ADI, AOEL or ARfD are not determined.	
6(2)	2.1.7.3	NL: When reading the sentence, it seems that it is not being understood what is meant with residues.	If it can be concluded that residues are indeed not of importance (see also comment 6(2)), then this paragraph 2.1.7.3 can be considered as not relevant.	Residues are not expected on crop or crop products.	Refer to comments 6(6) and 6(7)	
6(3)	6.	NL: Although no residues are probably expected, this should be better described.	It is assumed that the product is only being used on wounds or the stems of plants, and therefore it does not touch the parts of the plants which will be used for food or feed? Furthermore, the product should not be systemic? If indeed the above is true, then a case can be made that residues are not of importance.	Residues are not expected on crop or crop products. No movement or systemic properties	Refer to comments 6(6) and 6(7)	
6(4)		PL: No comments – no expected residue, only use as repellent or attractant no residues will occur in plant. There's no need determination of residues in products		-	Noted.	



	dues				
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(5)	3.4. Summary of intended uses	EFSA: The GAP is listing 'field crops like maize, cereals' This should be specified (which field crops specifically?) and the application of pine tar in such crops including cereals should be explained in more detail, including the growth stage of application and/or PHI as appropriate in order to assess the potential for consumers getting exposed to residues/contamination.		Residues are not expected on crop or crop products. GAP uses for field crops like maize and cereals are Attractant (AT). No spray on theses crops! Landes pine tar is coated on trees in the vicinity not on field crops.	The GAP table has been updated as to clarify that the basic substance when used as attractant is applied on
6(6)	3.4. Summary of intended uses	EFSA: For the uses in orchards, vineyards the growth stage of application should be specified in order to assess the potential for consumers getting exposed to residues/ contamination.		GAP uses for field crops like maize and cereals are Attractant (AT). No spray on theses crops! Landes pine tar is coated on trees in the vicinity not on field crops.	Refer also to comment 6(7) The request is not relevant for the use as attractant according to the GAP table. The request is not addressed for the uses as antifungal/antimicrobial and repellent substance. Although a season in the year is roughly specified in the GAP table (e.g. 'Nov-Feb', 'spring') a growth stage of treatment was not specified, which may help excluding that some



Resid	Residues							
No.	Column 1	Column 2	Column 3	Column 4	Column 5			
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
					orchard trees might still be carrying fruits (e.g. citrus, quinces, treenuts) when treated or fruits are already about to form for some crops (spring)			
6(7)	6. Residues	EFSA: Pine tar contains multiple substances like e.g. furfurals, methoxyphenols, phenolics deemed substances of concern, and no information is available regarding potential uptake and translocation in the plant when applied to the stems or fresh wounds of crops, shrubs and trees. If there is no information on both the growth stage of application and the potential for transfer of residues into edible crop parts and their significance for the consumer cannot be assessed. The requested information is		GAP uses for field crops like maize and cereals are AT Attractant. No spray on theses crops! Landes pine tar is coated on trees in the vicinity not on field crops.	Applicant's answer is not addressing the comment. Data gap: Upon clarification of the actual composition and impurities of the basic substance pine tar (see data gaps 2(5) and 2(12)) it should be demonstrated that substances potentially contained in pine tar like e.g. furfurals, methoxyphenols, phenolics, polycyclic aromatic hydrocarbons are not translocated into edible crop parts following application. Alternatively it should be demonstrated that the active substance pine tar (i.e. the substances it is composed of and its impurities) are not of toxicological relevance (see also data gap 5(5) and 5(1).			



Res	Residues								
No.	Column 1	Column 2	Column 3	Column 4	Column 5				
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application				
		only non-relevant if the active substance pine tar (the substances it is composed of) is demonstrated to be void of toxicological relevance.			If this cannot be achieved, mitigation should be considered. If appropriate, the GAP could be specified in terms of the application window (e.g. dormancy + removal of the coated strings when growing fruits) or crops to be protected (non-food uses), as to exclude that edible crop parts are present or are about to form when the basic substance pine tar is attached to orchard trees/shrubs with relevance for consumers or livestock, and to grapevines. See also comment 6(6) This data gap is considered relevant for the applied for uses as antifungal/antimicrobial and repellent substance. It can be reasonably assumed that after the use as attractant (use in the vicinity of crops -similar to a bait use)				



Resid	dues				
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
					dietary exposure is considered unlikely (provided this use can be maintained, see data gap 3(9))



7. Fate and Behaviour in the environment

7.1 F	ate and Behavi	our 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)		ES: it will be desirable to know if how long the residue is above the background concentration in each of the environmental compartments		Tars are not usually present in environment, although resins are similar.	It has been confirmed that pine tar is not present naturally in the environment, but rather resins. A comparison of the composition of pine tar and natural resins (that are exuded from pine trees when bark is damaged) was not presented.
7(2)	7.1	NL: The fact that pine tar is produced naturally cannot be used to waive the assessment of its environmental fate and behaviour.	NL: For the assessment of environmental fate and behaviour, the environmental concentrations resulting from application should be compared to natural background concentrations. For example, if the compounds present in Landes pine tar are identical to those in pine wood or natural pine resin (and are not altered due to the extraction process), a comparison can be made between the environmental concentrations expected to result from natural degradation of pine wood or		The dose rate has now been specified but it has also been confirmed that pine tar is not present naturally in the environment.



7	'.1	Fate	and	Beha	viour	in t	the	envi	ronn	nent

No.	Column 1	Column 2	Column 3	Column 4	Column 5	
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application	
			to the natural occurrence of pine resin and the concentrations resulting from application. To be able to compare the exposure resulting from use of the product to natural concentrations, an application rate of the product has to be given. Only when concentrations resulting from application are lower than natural background concentrations, no further assessment of environmental fate is necessary. If the estimated exposure levels resulting from application are higher than natural background levels, it should be demonstrated that the higher exposure levels will not have an unacceptable effect on the environment.			
7(3)		PL: According to accessible literature on pine tar this product does not present any specific risk to the environment. The pine tar compounds are naturally produced by the environment.		Majority of Pine tar compounds are naturally present in environment as pine resins are the main natural provider. Those resins act similarly to	It has been confirmed that pine tar is not present naturally in the environment, but rather resins. A comparison of the composition of pine tar and natural resins was not	

for application of basic

of Regulation (EC) No

1107/2009

provided

substances to be approved

in compliance with Article 23

(SANCO/10363/2012 rev. 21

March 2014) an assessment of the fate and behavior of landes pine tar in the environment should be

7 1 Fate and Rehaviour 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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Pilot project: Proposal for approbation of basic substances, in the context of Regulation (EC) N°1107/2009 December 2015		pine tar for wound protection.	presented.
7(4)		EFSA: in accordance with the guidance on the procedure		Majority Pine tar compounds are naturally present in	It has been confirmed that pine tar is not present

natural resins was not

comparison of the

presented.

naturally in the environment,

environment as pine resins

Those resins act similarly to

are the main natural provider. but rather resins. A

pine tar for wound protection. composition of pine tar and



7.2 E	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application		
7(5)	7.2	NL: The information provided is not sufficient for the assessment of the exposure of the environmental compartments.	NL: Please see previous comment.	Majority Pine tar compounds are naturally present in environment as pine resins are the main natural provider. Those resins act similarly to pine tar for wound protection.	It has been confirmed that pine tar is not present naturally in the environment, but rather resins. A comparison of the composition of pine tar and natural resins was not presented.		
7(6)		PL: Because of point application on wounds by spatula or knife its harmless for soil, surface and ground water		No comment from applicant Landes pine tar is not intended to be spray on crops.	Addressed		

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8. Effects on non-target species

No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8. Effects on non-target organisms	DE: Data on effects of pine tar on non-target organisms is not available. The overall conclusion that pine tar has no unacceptable effects on the environment is therefore only related to the specific use as wound protection of wooden plants (vine, fruit trees) applied as a paste or viscous liquid with a tool like spatula. In this case no significant exposure of the environment and non-target organisms can be assumed. It should therefore clarified that no other methods of application are intended (e.g. no spray application). The table of intended uses should therefore be revised. Any 'uses' which are not related to plant protection should be removed (repellent for snakes; game attractant etc.)		Game repellent is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1	Data on effects on non-target organisms were not available. However, for the representative uses as protectant and repellent and considering the method of application, exposure to non-target organisms can be assumed to be very low. The use as attractant should be removed from the GAP table. See also comment 3(9)
8(2)		NL: In this section the applicant	The applicant should provide a risk	LCE, 2013 2 reference	See comment 8(1)



	8.1. Effe	cts on terr	estrial ver	tebrates
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No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		describes the potential uses of the product. However no risk assessment is provided or a justification why birds and mammals are not exposed to the product. Since Poly Aromatic Hydrocarbons can be carcinogenic to humans they may also pose a danger to birds and mammals	assessment or a justification why birds and mammals are not exposed to the product. Since Poly Aromatic Hydrocarbons can be carcinogenic to humans they may also pose a danger to birds and mammals	added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	
8(3)		PL: Due to its pungent smell it is used as a repellent against rabbits, rats and snakes and also horse bites on tree stems/trunks		Exact GAP claims. No comment from applicant	Addressed
8(4)		PL: Prevents attacks of rodents and repels snakes and lizards		Exact GAP claims. No comment from applicant	Addressed
8(5)	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 pine tar on non-target		Landes pine tar is not intended to be spray on crop in any case. Deposits occurs at tree trunks and branches for wound protection, or attractant/repellent activity	See comment 8(1)



8.1.	8.1. Effects on terrestrial vertebrates							
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
		organisms should be provided.						

No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	8. Effects on non-target organisms	DE: Data on effects of pine tar on non-target organisms is not available. The overall conclusion that pine tar has no unacceptable effects on the environment is therefore only related to the specific use as wound protection of wooden plants (vine, fruit trees) applied as a paste or viscous liquid with a tool like spatula. In this case no significant exposure of the environment and non-target organisms can be assumed. It should therefore clarified that no other methods of application are intended (e.g. no spray application).		Game repellent activity is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1 Even PPP in DE	See comment 8(1)



No.	Effects on aqua	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		The table of intended uses should therefore be revised. Any "uses" which are not related to plant protection should be removed (repellent for snakes; game attractant etc.)			
8(7)		NL: No risk assessment or justification is provided for the product. Although Polyaromatic Hydrocarbons have a low solubility, they may still dissolve or disperse in water. From public literature, aquatic ecotoxicity data are available on PAH's.	NL: Please submit aquatic ecotoxicity data and perform a risk assessment	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See comment 8(1)
8(8)		NL: In addition, according to classification and labelling table of ECHA, Pine tar CAS 8011-48-1 is classified H412 (Harmful to aquatic life with long lasting effects) and the compounds phenol is classified as H411 (Toxic to aquatic life with long lasting effects) and Anthracene as h410 (Very toxic to aquatic life with long lasting effects).	Since the product itself and its compounds are classified as toxic to aquatic life, aquatic ecotoxicity data should be submitted and a risk assessment should be performed. Or a justification should be submitted why aquatic life will not be exposed to the product or other reasoning why the product is not harmful to aquatic life.	LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application.	See comment 8(1)



8.2.	.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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
8(9)		PL: No acute aquatic ecotoxicity data available		Pine tar was never approved under biocide regulation (Regulation (EU) No 528/2012²) because no applicant was found and it is still under derogation for aquatic antifouling. These uses are still claimed by some MS to be 'traditional' or 'ancestral', especially in chapter §4iii and §5iv of this document although skin diseases and dermal exposure concerns are mentioned. Therefore, some EU MS requested in 2006 the renewal of this derogation agreement under biocide regulation notwithstanding some concerns until 2016, without any application submission.				

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² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123.



No.	Column 1		Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment	Follow up response from applicant	EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(10	8. Effects on non- target organisms	DE: Data on effects of pine tar on non-target organisms is not available. The overall conclusion that pine tar has no unacceptable effects on the environment is therefore only related to the specific use as wound protection of wooden plants (vine, fruit trees) applied as a paste or viscous liquid with a tool like spatula. In this case no significant exposure of the environment and non-target organisms can be assumed. It should therefore clarified that no other methods of application are intended (e.g. no spray application). The table of intended uses should therefore be revised. Any "uses" which are not related to plant protection should be removed (repellent for snakes; game attractant etc.)		GAP Table is clear, no spray Game repellent is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1	See comment 8(1)
8(11)	NL: No risk assessment is provided or a justification why bees and Non-Target Arthoprods are not exposed		GAP Table is clear, no spray	See comment 8(1)



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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application				
		to or harmed by the product. Please submit							
8(12)	PL: No data found for bees and other arthropods species		GAP Table is clear, no spray on crops.	See comment 8(1)				

No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13) 8. Effects on non- target organisms	DE: Data on effects of pine tar on non-target organisms is not available. The overall conclusion that pine tar has no unacceptable effects on the environment is therefore only related to the specific use as wound protection of wooden plants (vine, fruit trees) applied as a paste or viscous liquid with a tool like spatula. In this case no significant exposure of the environment and non-target organisms can be assumed. It should therefore clarified		GAP Table is clear, no spray Game repellent is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1	See comment 8(1)



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		that no other methods of application are intended (e.g. no spray application). The table of intended uses should therefore be revised. Any "uses" which are not related to plant protection should be removed (repellent for snakes; game attractant etc.)			
8(14)	NL: No risk assessment is provided or a justification why soil macro-organisms are not exposed to or harmed by the product. Please submit		GAP Table is clear, no spray on crops.	See comment 8(1)
8(15	5)	PL: No data available.		GAP corrected, no spray on	Addressed

8.5.	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
8(16)8. Effects on non- target organisms	DE: Data on effects of pine tar on non-target organisms is not available. The overall		GAP Table is clear, no spray	See comment 8(1)			

crops



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		conclusion that pine tar has no unacceptable effects on the environment is therefore only related to the specific use as wound protection of wooden plants (vine, fruit trees) applied as a paste or viscous liquid with a tool like spatula. In this case no significant exposure of the environment and non-target organisms can be assumed. It should therefore clarified that no other methods of application are intended (e.g. no spray application). The table of intended uses should therefore be revised. Any "uses" which are not related to plant protection should be removed (repellent for snakes; game attractant etc.)		Game repellent is fully PPP compliant see SANCO/2604/08 – rev. 4 or SANCO/2629/08 – rev. 1	
8(17	7)	NL : no comment		-	Noted
8(18		PL: Pine tar resin induced a non- statistical increase of mutations of some microorganisms (Pilot project: Proposal for approbation of basic		GAP Table is clear, no spray No spray on soil or crops. HPA are at lowest concentration possible.	See comment 8(1)



8.5.	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
		substances, in the context of Regulation (EC) N°1107/2009 December 2015).						

8.6. E	ffects 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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(19)		PL: Not enough information. According to Pilot project 2015 (see above) pine tar inhibited the germination of downy brome.		Landes pine tar is not spray on soil, crop or weeds. No effect on weeds (i.e. herbicide) is expected.	See comment 8(1)
8(20)		NL: no comment		-	-

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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(21))	PL: No comments. Not enough information.		As solid paste, Landes pine tar is not supposed to practically reach sewage	See comment 8(1)

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8.7. I	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	applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application				
				treatment units.					
8(22))	NL : no comment		-	Noted				

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

No.	Column 1	rith respect of eligibility of the su Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		DK: Based on the argumentation and listed references in section 5; we are of the opinion that the use in 3.4.1 (for healing in orchards, vineyards and shrubs) is not unacceptable with regard to human and animal health (non-target organisms included) due to the expected spot treatment. However due to the inherent properties of Landes pine tar (see DK comment on section 4 above) the use as a repellent is not acceptable	Please update GAP table 3.4.1 to include the wording 'spot treatment' either as an addition to the 'Method kind' or 'Remarks'. Also, please reconsider the use as a repellent, it may not be acceptable as a use for a basic substance, and furthermore may not be acceptable in all MSs.	GAP Table is clear, no spray Treatments are really spot treatments regarding maximum amount of 20g/tree. Repellent (RE) is one officially recognised use in EU for pesticide substance, why it would not be allowed for basic? Basis are plant strengtheners, insecticides, fungicides, attractant, elicitors and seed treatments	



No.	Column 1	Column 2	Column 3	Column 4	Column 5
	Reference to Application Template	Comments from Member States / EFSA	Proposal by Member States/EFSA on how the application should be updated to address the comment		EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		due to the expected necessity to treat whole stems and tree trunks (considerably larger areas compared to spot treatment). Also, the use as an attractant is not appropriate (see DK			
0(2)	0	comment to 3.4.3 above).	EC. N		C + 2/4)
9(2)	General comment	ES: The fulfilment of the criterion "(d) is not placed on the market as a plant protection product" is questionable, because Landes pine tar contains approved active substances (e.g. acetic acid, oleic acid) (please, see comments for issue 2.1.5). This criterion should be guaranteed by establishing requirements that assurance the absence of these substances in the Landes pine tar.	ES: No more comments	Cited active substances are minor components and are not extractible from the Landes pine tar. They have also other properties and uses i.e. herbicide	See comment 2(4)
9(3)		NL: No comments		-	Noted
9(4)		PL: The landes pine tar has no harmful effect, immediate or delayed, on animal health and neither any unacceptable effects on the		No comment from applicant. Pine tar under derogation for many MS as biocide without evaluation.	Noted



Over	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application				
		environment.							



10. Other comments

Othe	r comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)8.8. overall conclusion on the effects on non- target species	NL: In the conclusion it is stated that:" To conclude, Landes pine tar have no harmfull effect, immediate or delayed, on animal health and nor any unacceptable effects on the environment" This is not supported by data, a risk assessment or a justification. Please submit		Landes pine tar is not spray on soil, crop or weeds, nor crop productions. Pine tar under derogation for many MS as biocide without evaluation.	Noted. See also comment 8(1)
10(2	8.8. overall conclusion on the effects on non-target species	NL: in addition it is mentioned that "Landes pine tar is produced in furnace from a temperature 360 to 480°C, therefore no dangerous substances is produced." It is not clear if this is a statement to support the claim that there are no unacceptable effects on the environment. It is also unlikely that this is a valid claim, since in chapter 2 it is demonstrated by several tables that ecotoxic compounds like Polyaromatic hydrocarbons, phenol etc. are still present and the classification of the		LCE, 2013_2 reference added. Analytical methods, concentrations and identifications of possible PAHs are characterised. Reference included in the updated basic substance application. Final conclusion from applicant Pine tar under derogation for many MS as biocide without any evaluation. Our GAP is clear: no spray on crops, no water contact supposed instead of biocide derogation as antifouling	Noted See also Comment 8(1)



Othe	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 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application			
		product pine tar on the ECHA website as H412		substance.				



Appendix B – Identity and biological properties

Common name (ISO)	there is no ISO common name for this substance
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Not applicable
Common names	Landes pine tar
CAS No	8011-48-1
CIPAC No and EEC No	232-374-8 (EINECS)
FAO specification	none
Minimum purity	Not applicable (complex mixture)
Relevant impurities	Polyaromatic hydrocarbons, open
Molecular mass and structural formula	Not applicable (complex mixture)
Mode of Use	Spread with a spatula or a knife directly on the cleaned and fresh wounds or on stem
Preparation to be used	Paste (PA) Any other liquid (AL)
Function of plant protection	Protectant with antimicrobial activity, repellent



Appendix C – List of uses

Antifungal and antimicrobial activity

Crop and/or situatio n (a)	Membe r State or Countr y	Exampl e	F G	Pests or group of	Formulatio n		Application				Applicat treatme		e per	Total rate	PHI (days	Remark s
		product name as availabl e on the market	I (b)	pests controlled (c)	Type (d-f)	Con c of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Numbe r min max (k)	Interval between applicatio ns (min)	kg a.i./hl min max (g/hl)	Wate r I/ha min max	kg a.i./h a min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)	kg) a.i./ha (m) min max (g/ha)	
Orchard, vineyard, shrubs	All Member States	Landes pine tar	F	For healing, prevents fungi like Nectria galligena, Endothia parasitica and microbes and bacterias development like Pseudomon as fluorescens	Past e PA, Any other Liqui d AL	Use d pure	Spread with a spatula or a knife directly on the cleane d and fresh wound s.	During the size period from Novemb er to February	1 to 2	6-10 Weeks	to 20 g per wounde d tree	-	-	Depend s on the diamete r of the size to cover. average 15 to 20 g per wounde d tree	n.a	none

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Repellent activity

Crop and/or situatio n (a)	Membe r State or Country	Example product	F G	Pests or group of	Formulation		Application				Application rate per treatment			Total rate	PHI (days	Remark s
		name as availabl e on the market	I (b)	pests controlled (c)	Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growt h stage and season (j)	Numbe r min max (k)	Interval between application s (min)	kg a.i./h l min max (g/hl	Wate r I/ha min max	kg a.i./h a min max (g/ha)	kg a.i./h a min max (g/ha)) (m)	
Orchard, vineyard, shrubs, gardenin g	All Member States	Landes pine tar	F	Rabbit Rabbits and rats, snakes. Horse bites on tree stems/trunk s mice and rats, snakes	Paste PA, Any other Liqui d AL	Use d pure	Spread with a spatula or a knife in stem Coated string stretche d tar	Spring	1 to 2	6-14 Weeks (3 weeks if in aerosol)	15 to 20 g per stem or tree	-	-	-	n.a	none

Attractant activity

Crop and/or situatio n (a)	Membe r State or Country	Example product name as availabl e on the market	F G I (b)	Pests or group of pests controlle d (c)	Formulation			Application rate per treatment			Total rate	PHI (days	Remark s			
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Numbe r min max (k)	Interval between application s (min)	kg a.i./h I min max (g/hl)	Wate r I/ha min max	kg a.i./h a min max (g/ha) (I)	kg a.i./h a min max (g/ha) (l)) (m)	(*,**)
Field crops like maize, Cereals,	All Member States	Landes pine tar	F	Game like Wild boar	Paste PA, Any other	Use d pure	Spread with a spatula or a	Not relevan t	1	2-4 weeks	15 to 20 g per stem	-	-	-	n.a	none



Crop and/or situatio n (a)	Membe r State or Country	Example product	F G	Pests or group of pests controlle d (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days	Remark s
		name as availabl e on the market	I (b)		Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Numbe r min max (k)	Interval between application s (min)	kg a.i./h I min max (g/hl)	Wate r I/ha min max	kg a.i./h a min max (g/ha) (l)	kg a.i./h a min max (g/ha) (l)) (m)	(*,**)
Vineyard s					Liqui d AL		knife in stem in the vicinity Coated string stretche				or tree		V	C/		

- (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,
- (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
- (I): 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 between the plant type of equipment used must be indicated