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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for *Arctium lappa* for use in plant protection as fungicide in grapevines and vegetables and as insecticide in grapevines[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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 *Arctium lappa* 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 *Arctium lappa* as a basic substance for use in plant protection as fungicide in grapevines and vegetables and as insecticide in grapevines. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.

KEY WORDS

Arctium lappa, basic substance, application, consultation, plant protection, pesticide

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SUMMARY

Arctium lappa 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 (ITAB) 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 of 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 on July 2014, EFSA was asked to organise a commenting on the basic substance application for *Arctium lappa*, 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 3 months of acceptance of the specific request.

A consultation on the basic substance application for *Arctium lappa*, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in July 2014 - September 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by the EFSA on the basic substance application for *Arctium lappa* and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Arctium lappa is an extract of the aerial parts of the plant *Arctium lappa* L. The product is intended to be used as fungicide in grapevines and vegetables and as insecticide in grapevines; however no clear specification has been proposed.

The Regulation states the following "A basic substance is an active substance which is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent". This is not the case for this material as it is extracted by boiling for 45 minutes. It is therefore not a basic substance; it is rather a plant extract and separate guidance document is being prepared for these substances.

The uncertainties on the technical specification and the concerns raised by the available toxicological data do not allow the characterisation of the toxicological profile of *Arctium lappa*.

Since the available data are not sufficient to conclude on the toxicological profile of *Arctium lappa*, a consumer risk assessment could not be completed.

The information provided by the applicant is insufficient to address environmental fate and behaviour or estimate exposure levels in the different environmental compartments from the proposed uses of the extract.

The applicant has not provided any suitable information to allow for a risk assessment for non-target organisms to be performed.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (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.

Arctium lappa 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 (ITAB) for approval as a "basic substance" for use in plant protection as fungicide in grapevines and vegetables and as insecticide in grapevines.

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for *Arctium lappa*, which was conducted via a written procedure in July 2014 - September 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance application for *Arctium lappa* 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 *Arctium lappa* 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 (Institut Technique de l'Agriculture Biologique (ITAB); 2014a, 2014b).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the 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 July 2014, EFSA was asked to organise a commenting on the basic substance application for *Arctium lappa*, 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 prepared by EFSA. The agreed deadline for providing the finalised report is 19 December 2014.

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.

[3] 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.

EVALUATION

The comments received on the basic substance application for *Arctium lappa* and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

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

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. Institut Technique de l'Agriculture Biologique (ITAB), 2014a. *Arctium lappa*. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2014. Submitted by Institut Technique de l'Agriculture Biologique (ITAB). Documentation made available to EFSA by the European Commission.

2. Institut Technique de l'Agriculture Biologique (ITAB), 2014b. *Arctium lappa*. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2014. Submitted by Institut Technique de l'Agriculture Biologique (ITAB). Documentation made available to EFSA by the applicant.

REFERENCES

1. Gökce A. *et al.*, 2011. Ovicidal, larvicidal and anti-ovipositional activities of *Bifora radians* and other plant extracts on the grape berry moth *Paralobesia viteana* (Clemens). Journal of Pest Science, 84(4):pp 487-493.
2. Gökce A. *et al.*, 2014. Behavioral and electroantennogram responses of plum curculio, *Conotrachelus nenuphar*, to selected noxious plant extracts and insecticides. Journal of Insect Science, Vol. 14, article 90.
3. OECD, *Arctium lappa*, tincture. Categorization from Canadian Domestic Substance List Canada.
4. Underwood *et al.*, 2013. Bird behaviour on and entanglement in invasive burdock (*Arctium spp*.) plants in Winnipeg, Manitoba. Canadian Field-naturalist 127(2): 164–174
5. Wang *et al.*, 2009. Bioassay-guided isolation and identification of active compounds from *Fructus Arctii* against *Dactylogyrus intermedius* (Monogenea) in goldfish (*Carassius auratus*). Parasitol Res. 106:pp 247–255.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *ARCTIUM LAPPA* 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		NL did not review this section		Noted.
1(2)		ES: No comments		Noted.

EFSA: No comments.

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

2.1. Identity and physical 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	Identity of the basic substance	EFSA: It is unclear what the specification of the basic substance is. In the application it is unclear: in some places it is aerial parts both dry and fresh and in other places it is powder. Please confirm which form is on the market. The methods are not well described and are not validated.	The same plant can be available from the market fresh or dry, intact or milled into powder. Interesting preparations for plant protection purpose are not only pure synthetic single chemical active substances. Description is restrained to aerial part of the plant, either in the title and the document.	There is still no clear specification for this basic substance. The methods are not validated. See also 2(9), 3(1), 3(5)
2(2)	General comment	ES: A title of the application with a more restrictive description as "*Arctium lappa L* aerial parts extract" would be more suitable.	Modified in BSA	Addressed.
2(3)	General comment	ES: It would be more suitable remove the word "BURDOCK" from the title of the application.	Modified in BSA	Addressed.
2(4)		ES: Another Spanish name could be included "Bardana" (apart from "Lampazo")	Modified in BSA	Addressed.
2(5)		NL : did not review this section		Noted.

2.2. Current, former and in case proposed trade names of substances/ products as put on the market				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)		ES: No comments		Noted.
2(7)	Recipe	EFSA: The Regulation states the following. 'It is not predominantly used for plant protection	The separate guidance document cited, namely Botanicals as of SANCO 11470 2012– rev.	The Regulation states the following. 'It is not predominantly used for plant

2.2. Current, former and in case proposed trade names of substances/ products as put on the market				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling for 45 minutes. It is therefore not a basic substance and is a plant extract. Plant extracts are covered by a separate guidance document.	8 Guidance Document on Botanicals 2014 is mentioning Basic substances (described in article 23) as possible issue. Therefore, botanical extracts are totally entitled for BSA. Following this recurrent comment, we are currently composing a BSA for Water.	protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling for 45 minutes. It is therefore not a basic substance and is a plant extract. Plant extracts are covered by a separate guidance document.

2.3. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		ES: No comments		Noted.

EFSA:No comments

2.4. Type of preparation of the substance/product				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(9)		ES: No comments		Noted.

EFSA: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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(10)	2.5. Description of the recipe for the product to be used	ES: If preparation can be made of fresh plant it might be useful to provide an estimate about % of humidity of aerial parts. ES: Are the efficacy and final yield of this decoction tested? This information should be included.	Aerial green parts of the plants contain 80% of water or more. People know these proportions so with dry plants, the divide by 5 the used weight from wet fresh plants. Reverse calculations are made from the recipe (§2.5) from dry to fresh plants multiply by 5 quantities. In this case, first maceration operation can be suppressed. Corrections included in BSA.	See comment 2(1)

3. Uses of the substance and its product

NL did not review this section

3.1. Field of use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		ES: It should be specified throughout the whole document that the substance is an extract.	Done in the title	See comment 2(1)
3(2)		ES: Vegetable gardening should be included apart from grapevines, which appears in the GAP table.	Corrected	Addressed.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(3)		ES: *Phytophthora infestans and potato late blight* should be included in this point (3.2.1.1), (This information appears in the GAP table)	Corrected	Addressed.

3.3. Usefulness in the framework of plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)		ES: No comments		Noted.

EFSA:No comments

3.4. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)	General comment	ES: How is the concentration of the active ingredient fixed (Conc of a.i. g/kg)? It should be very dependent of the efficacy and final yield of decoction. Therefore, it might be useful to provide both parameters. See above the comments to the issue "2.5. Description of the recipe for the product to be used".	Active(s) ingredient(s) is(are) not completely known. Concept of basic substances is "utility in plant protection" not "single active substances".	See comment 2(1)
3(6)		ES: In the summary of intended uses (GAP table) some rates should be corrected (g a.i./hl; water l/ha; g a.i./ha should be in accordance in fungicide and insecticidal uses). Also in insecticidal uses, the total rate (g a.i./ha) should be reviewed)	Corrected	Addressed.
3(7)		ES: In the "Remarks" the following should be included: "*The preparation has to be used **in the** 24 hours after the preparation because the water extract is sensible to oxygen and or avoiding the potential contamination and multiplication of microorganisms during the storage*."	Added	Addressed.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		NL did not review this section		Noted

EFSA:No comments

5. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	General comment	EFSA: from the application: "Burdock is known to contain up to 45 % inulin, up to 3.5 % polyphenols, including chlorogenic and caffeic acid, phytosterols, tannins, about 0.1 % volatile oil and many other compounds". The uncertainties on the technical specification do not allow making efficient use of the available toxicological information presented on some of the identified components.	Composition is depending on environmental natural growing conditions. Ranges are indicated. chlorogenic and caffeic acid are present in various food products (coffee, potatoes)	The uncertainties on the technical specification do not allow characterising the toxicological profile of *Arctium lappa*.
5(2)		EFSA: *Arctium lappa* seems to have several pharmacological activities, also depending on the type (e.g root, leaves, extract, seeds..); however it is unclear what is the safe level compared to the pharmacologic/toxic one. Based on this it is not possible to derive reference values to perform a risk assessment; it is not possible to conclude whether it is a basic substance.	Title corrected to aerial parts extract.	Based on the available data indicating some possible toxicological concerns it is not possible to conclude whether *Arctium lappa* is a basic substance.
5(3)	5.1 General comment p22ff	DE: All endpoints concerning human health should be addressed by evaluation of possible adverse health effects followed by a risk assessment whether these effects are relevant for the extract applied for. Furthermore, the extract should not contain substances of concern, which have inherent capacity to cause adverse effects to humans. Some endpoints are only addressed by citation of abstracts derived from publications but	Chlorogenic and caffeic acid are present in various food products (coffee, potatoes). Inulin is increasingly used in processed foods because it has unusually adaptable characteristics. Its flavour ranges from bland to subtly sweet (approx. 10% sweetness of sugar/sucrose).	See 5(1) and 5(2)

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		evaluation is lacking. We suggest amendment of the report.		

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	5.5. p 27 ff	DE:Concerning genotoxicity and carcinogenicity of chlorogenic acid and caffeic acid: Article 23 of Reg (EC) No 1107/2009 clearly states that a basic substance is not a "substance of concern". Chlorogenic acid and caffeic acid are both genotoxic and carcinogenic but are expected to be present in low but not reported concentrations in the decoction. Consequently, it should be clearly pointed out which concentrations of these substances of concern are to be expected and this should be integrated in a risk assessment.	Chlorogenic and Caffeic acid are contained in coffee and potatoes. Publications added	See 5(1) and 5(2)

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)	5.7 Reproductive toxicity, page 29	NL: Minor remark. It is stated that there is no data for *Arctium lappa* plant extract on reproductive toxicity. However, in the	EMEA ref was not cited although it is in favour because it cannot be extrapolated to aerial parts.	Addressed

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment report on *Arctium lappa* L. from the European Medicine Agency a study is mentioned for *Arctium lappa* L. extract reporting no effect on fertility.		

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.11. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.13. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA:No comments

5.14. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)	5.14 p 37 ff	DE: Potential allergic reactions including description of human cases of contact dermatitis must be included in this chapter.	References added	Addressed
5(7)	5.14.General conclusion §5, p39	DE: A comprehensive summary and evaluation of all critical effects of substances must be	As Chlorogenic and Caffeic acid are contained in coffee and potatoes, these natural compounds	See 5(1) and 5(2)

5.14. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		given here followed by an evaluation demonstrating that criteria in Article 23 of Reg (EC) No 1107/2009 are met. For example, the genotoxic and carcinogenic potential of chlorogenic and caffeic acids, the neurotoxic potential with regard to acetylcholinesterase inhibition by arctigenin, the endocrine disrupting potential based on the aphrodisiac and uterine stimulation effects of the extract must be evaluated in context of the intended use. An estimation might be helpful which concentrations of critical ingredients of the extract are to be expected (might also be compared to other intakes e.g. medicine, food). A final comprehensible conclusion based on the evaluation of the information given in the BSA must be drawn. Evaluation given by e.g. EFSA and EMA should be integrated here.	may be waived from fears. Situation for arctigenin is also not clear since it is use as anticancer drug. Inulin is increasingly used in processed foods because it has unusually adaptable characteristics. Its flavour ranges from bland to subtly sweet (approx. 10% sweetness of sugar/sucrose).	

6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		EFSA: No comments. However, if toxicological concerns are indentified in the Phys-Chem or Tox. sections, the possible impact on the consumers safety should be addressed.		Since the available data are not sufficient to conclude on the toxicological profile of *Arctium lappa* (see 5(1) and 5(2)), the consumer risk assessment could not be finalised.
6(2)		NL : no comments ES : no comments		Noted.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7. Fate and behaviour in the environment	EFSA: The information presented is considered inadequate to make any assessment. Though it is agreed that it can be expected 'that these different natural substances are degraded in the environment in accordance with the known metabolic pathways of 'organic matter.' No information on the rate of degradation of the different constituents that might be present in the extract has been presented. No information on their soil mobility has been presented. No information on levels of occurrence, natural as well as after the use of *Arctium lappa*, are provided. Such information is required as a minimum, for estimation of possible effects on the environment.	No crucial information was found on negative effect neither from either *Arctium lappa* extract use (spilling) nor as soil effect from *Arctium lappa* as entire plant form.	Usable information has not been provided by the applicant to address environmental fate and behaviour or estimate exposure levels in the different environmental compartments from the proposed use of the extract.
7(2)	7.1 Fate and behaviour in the environment	DE: No information has been provided by the applicant.		See Comment 7(1).
7(3)	7.1 fate and behaviour in the environment	NL: the OECD document provided does not bring much help to address this point. It says with regard to persistence in the environment 'uncertain' the same as to biodegradable potential. To address the fate in the environment with 'low ecotoxicological concern' is also not elucidating the fate. NL is of the opinion that with regard to the basic substance *Arctium lappa* being a natural occurring plant no major issues are to be expected		See Comment 7(1).

7.1. Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		with regard to environmental fate. However, we would like to see this addressed in another more proper way referring to natural occurrence and background levels from various uses for the complete extract and the identified components.		
7(4)		ES: Some justification regarding this point should be included.		See Comment 7(1).

7.2. Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(5)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water)	DE: No information has been provided by the applicant.	No crucial information was found on negative effect neither from either *Arctium lappa* extract use (spilling) nor as soil effect from *Arctium lappa* as entire plant form.	See Comment 7(1).
7(6)	7.2	NL: not addressed in the application template. See comment above		See Comment 7(1).

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: no comments		See comments 8(3) and 8(4).
8(2)		NL: no comments		See comments 8(3) and 8(4).
8(3)	8.1.1. Birds	DE: No sufficient information has been provided by the applicant regarding the effects of *Arctium lappa* on birds. The cited study does not provide information about the toxicity of *Arctium lappa* to birds. In section 5 adverse reproductive effects and a contraindication during pregnancy for mammals are described. It cannot be reasoned that the substance does not show these effects on birds.	*Arctium lappa* (burdock) is more dangerous by physical adverse effect: *Arctium lappa* (burdock) produce their seeds within large burrs, small animals may become entangled in these burrs and die.	An additional paper was provided by the applicant (Underwood and Underwood, 2013) who discusses the effects of invasive Burdock (*Arctium* spp.) in America. However, the cited paper does not provide any information of the toxicity of *Arctium lappa* L. aerial parts extract. Furthermore, it is noted that there are uncertainties regarding the technical specification (see comment 2(1)). Consequently, a risk assessment cannot be performed. See also comment 8(4).
8(4)	8.1.2. Mammals	DE: No sufficient information has been provided by the applicant regarding the effects of *Arctium. lappa* on mammals. The cited study does not provide information about the toxicity of *Arctium lappa* to mammals. In section 5 adverse reproductive effects and a contraindication during pregnancy for mammals are described. It cannot be reasoned that the substance is harmless to mammals.		The available data presented in Section 5 indicate a possible toxicological concern (see comment 5(2)). Furthermore, it is noted that there are uncertainties regarding the technical specification (see comment 2(1)). Consequently, a risk assessment cannot be performed.
8(5)		EFSA: considered and substantiated that the substance has "neither an immediate or	No study provided. No bibliography available.	See comments 8(3) and 8(4).

8.1. Effects on terrestrial vertebrates				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		delayed harmful effect on animal health nor unacceptable effects on environment"		

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	8.2 Effects on aquatic organisms	DE: The classification of the OECD that *Arctium lappa* is not inherently toxic to aquatic organisms cannot be followed because it is not clear on which information the classification was based. The underlying studies should be submitted with this application.	No study provided. More bibliography founded: uses of *Arctium lappa* extract on aquatic organisms for beneficial effects.	A paper has been provided (Wang *et al.*, 2009) which investigates the toxicity of arctigenin and arctiin to goldfish (*Carassius auratus*). The resulting LC_{50} values were 8.47 mg/L for arctigenin and 14.14 mg/L for arctiin. The tested substances in Wang et al. (2009), arctigenin and arctiin, were derived from a chloroform extract. *Arctium lappa* L. aerial parts extract is a water extract and therefore it is not known whether the tested substances are present in the active substance under consideration. The toxicity data are therefore not useful to the current assessment. The applicant has also referred to the OECD categorisation from the Canadian Substance List in which it is stated that *Arctium lappa* tincture is not inherently

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				toxic to aquatic organisms. However, the underlying data used to reach this conclusion have not been provided. No information was available regarding the toxicity of *Arctium lappa* L. aerial parts extract to aquatic invertebrates or algae. Furthermore, as discussed in comment 7(1) there are no available surface water exposure estimates available. In addition, it is noted that there are uncertainties regarding the technical specification (see comment 2(1)). Currently a risk assessment for aquatic organisms cannot be performed.
8(7)	8.2 effects on aquatic organisms	NL: the OECD document provided does not bring much help to address this point. It indicates that it is not toxic to aquatic organisms but this has no reference. Further information referring to e.g. natural occurrence and background levels from various uses for the complete extract and the identified components or literature information on (absence of) effects would be required.	More bibliography founded: uses of *Arctium lappa* extract on aquatic organisms for beneficial effects.	See comment 8(6).
8(8)		ES: no comments		See comment 8(6).

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)		ES: no comments		
8(10)		EFSA: No specific information or assessment was provided for non-target arthropods. The insecticidal mode of action is claimed to be via repellent effects. However a paper summarised in point 3.2.1.2 (Gökce A. Isaacs R. Whalon M.E. 2011) indicated larval mortality of the North American grape berry moth in response to the methanol extract of *Arctium lappa.* The possible effects of the use of *Arctium lappa* extract to non-target arthropods should be addressed.	Reference added show that action is mainly antifeedant activity.	Gökce A. *et al.* (2011) and Gökçe A., *et al.* (2014) investigated the effects of extracts of *Arctium lappa* to the grape berry moth (*Paralobesia viteana*) and plum curculio (*Conotrachelus nenuphar*). Reproduction and feeding activity of the moth were significantly affected. Both these effects could be considered as relevant for the risk assessment of non-target arthropods. Furthermore, it is noted that there are uncertainties regarding the technical specification (see comment 2(1)). Further information and a risk assessment are needed in order to demonstrate a low risk to non-target arthropods.
8(11)	8.3.2. Effects on other arthropods	DE: No information has been provided by the applicant regarding the effects on other arthropods than bees. It has not been reasoned that the substance is harmless for other arthropods than bees.		See comment 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(12)	8.4. Effects on earthworms and other soil macro-organisms	DE: If *Arctium lappa* has a toxic effect on human worms, an unacceptable risk on earthworms and other soil macro-organisms caused by an application of *Arctium lappa* cannot be excluded.		No information was provided in order to perform a risk assessment for earthworms and other soil macroorganisms.

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)	8.5. Effects on soil micro-organisms	DE: *Arctium lappa* is known for its antibacterial properties. An unacceptable risk for soil micro-organisms caused by an application of *Arctium lappa* cannot be excluded.		No information was provided in order to perform a risk assessment for soil microorganisms.
8(14)		ES: no comments		See comment 8(13).

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)	8.6 Effects on other non-target organisms	NL:. Further information referring to e.g. natural occurrence and background levels from various uses for the complete extract and the identified components would be helpful.	As Chlorogenic and Caffeic acid are contained in coffee and potatoes, these natural compounds may be waived from fears. However this is not a criteria since raw potatoes are dangerous for consumption.	No information was provided to compare the expected exposure of non-target organisms to that of natural background levels.
8(16)		ES: no comments		Noted.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(17)	8.7 Effects on biological methods of sewage treatment	NL: *Arctium lappa* extract is known for its antibacterial properties therefore further information is required for the relevant proposed uses where exposure can be expected. Information referring to e.g. natural occurrence and background levels from various uses for the complete extract and the identified components could be useful to address this.	No study provided. No bibliography available.	No information was provided to compare the expected exposure of non-target organisms to that of natural background levels.
8(18)		ES: no comments	No study provided. No bibliography available.	See comment 8(17).

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)	General comment.	DE: In consideration of the genotoxicity and carcinogenicity of chlorogenic acid and caffeic acid max. limit values should be derived for the extract.	As Chlorogenic and Caffeic acid are contained in coffee and potatoes, these natural compounds may be waived from fears. § 9 modified according to these new elements.	See 5(1) and 5(2)
9(2)		NL did not review this section.		Noted.

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		NL did not review this section. ES : no comments		Noted.

EFSA:No comments

ABBREVIATIONS

µg	microgram
a.s.	active substance
DG SANCO	European Commission Directorate General Health and Consumers
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
g	gram
GAP	good agricultural practice
ha	hectare
hL	hectolitre
kg	kilogram
L	litre
LC_{50}	lethal concentration, median
mg	milligram
OECD	Organisation for Economic Co-operation and Development