TECHNICAL REPORT

APPROVED: 28 July 2016

Outcome of the consultation with Member States and EFSA on the basic substance applications for *Urtica* spp. for use in plant protection as insecticide, acaricide and fungicide

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 applications for *Urtica* spp. 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 two applications for approval of *Urtica* spp., as a basic substance, with the species considered being *Urtica dioica* L. and *Urtica urens* L. These applications were for use in plant protection as insecticides, acaricides and fungicides. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: *Urtica* spp. *Urtica dioica* L., *Urtica urens* L., basic substance, application, consultation, plant protection, pesticide, insecticide, acaricide, fungicide.

Requestor: European Commission

Question number: EFSA-Q-2016-00233, EFSA-Q-2016-00341

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Summary

Urtica spp. is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received two applications from Institut Technique de l'Agriculture Biologique (ITAB) and Myosotis 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 respectively for applicant ITAB in March 2016 and for Myosotis in May 2016, EFSA was asked to organise a consultation on the basic substance applications for *Urtica* spp., to consult the applicants 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 *Urtica* spp., organised by EFSA, was conducted with Member States via written procedure respectively in December 2015-February 2016 and April-May 2016. Subsequently, EFSA also provided comments and the applicants were 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 applications for *Urtica* spp. and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Urtica spp. folium/herba or nettle leaf/herb is the aerial part of stinging nettle (*Urtica dioica* L., *Urtica urens* L.). It is a complex mixture of chemical substances. The compounds supposed to be involved in the biological activity are: acetic acid, chlorogenic acid, formic acid, lecithin, L-prunasin and rutin. The product to be used is the aerial part of nettle that has been macerated in water during a few days.

The proposed uses of *Urtica* spp. are spray applications as an insecticide on fruit trees, pulses and oilseeds, potato, leaf vegetables, rapeseed, root and tuber vegetables, elder tree, rose, *Spiraea* sp., spray applications as an acaricide on beans and grapevine and spray applications as a fungicide on *Brassicaceae*, cucurbits, fruit trees, grapevine and potato. Proposed uses of *Urtica* spp. are also applications as soil covering included in mulch, as a fungicide in field and protected cucumber, field tomato and field and protected roses and ornamental trees.

Regarding the impact on human and animal health, there is evidence that *Urtica* spp. may have to be classified as a skin sensitiser and eye irritant; additionally developmental toxicity may be an issue considering a notification for classification as Repr 1B, although no toxicological information was found to substantiate these notifications and no harmonised classification according to Regulation 1272/2008 is available. The toxicological profile of the substance needs to be clarified in line with the type of extract proposed; it is also unknown whether harmful compounds may be formed during the fermentation process. It is further noted that *Urtica dioica* L. was considered as a botanical appearing on a negative list or subject to restricted use in at least one European Member State but for which the EFSA Scientific Committee, through the analysis of the data found, could not identify substances of concern, or other data for the inclusion in the compendium (EFSA Scientific Committee, 2012, Annex B). The EFSA Scientific Committee recommended that a systematic literature search should be performed for this species.

A number of data gaps have been identified with respect to the toxicological profile of *Urtica* spp. extracts (classification Repr 1B, harmful compounds may be formed during fermentation) that do not allow concluding that the proposed uses are safe for the consumers.

In the area of environmental risk because a number of data gaps have been identified with respect to identity and the environmental exposure, the following conclusions were drawn:

Regarding the spray uses, the information provided was not sufficient to conclude on the risk to *Urtica* spp. extract and to potentially occurring fermentation products for birds and mammals, aquatic organisms, bees and other non-target arthropods. For soil macro-organisms, soil micro-organisms and terrestrial non-target plants it is considered that a low risk may be concluded considering the nature of the basic substance. Due to the low exposure, a low risk could be concluded for the organisms involved in the sewage treatment.

Regarding the uses in mulch, insufficient information was available to perform a quantitative risk assessment for non-target organisms. However, the risk to birds, wild mammals, aquatic organisms, bees and organisms involved in the sewage treatment processes was assessed as low, considering that representative uses of *Urtica* spp. would lead to a low exposure. The risk to soil organisms and non-target terrestrial plants was considered low, taking into consideration the nature of the basic substance. Due to the potential insecticidal activity of *Urtica* spp. and considering the available information, it was not possible to exclude a high risk to soil dwelling arthropods.

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1. Introduction

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

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

Urtica spp. is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received two applications, one from Institut Technique de l'Agriculture Biologique (ITAB) and one from Myosotis, for approval as a 'basic substance' for use in plant protection as insecticide, acaricide, fungicide.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Urtica* spp., which was conducted via written procedure respectively in December 2015-February 2016 and April-May 2016. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicants were 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 applicants thereon, together with the application update submitted by the applicants, 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 applications for *Urtica* spp. and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The applications and, where relevant, any update thereof submitted by the applicants for approval of *Urtica* spp. as a 'basic substance' in the context of Article 23 of the Regulation, are key supporting documentation, therefore they are considered as background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2016 and Myosotis, 2016).

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 22 March 2016 for the ITAB application and 17 May 2016 for the Myosotis application, EFSA was asked to organise a consultation on the basic substance applications for *Urtica* spp., to consult the applicants 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 31 July 2016.

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

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

2. Assessment

The comments received on the basic substance applications for *Urtica* spp. 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 tables are provided in Appendix A and B (for ITAB and Myosotis respectively) 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 D and E.

Documentation provided to EFSA

1. ITAB, 2015. Basic substance application on *Urticae* folium/herba submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August, 2015. Documentation made available to EFSA by the European Commission.

2. ITAB, 2016. Basic substance application update on *Urticae* folium/herba submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2016.

3. Myosotis, 2016. Basic substance application on *Urtica* spp. folium/herba submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2016. Documentation made available to EFSA by the European Commission.

4. Myosotis, 2016. Basic substance application on *Urtica* spp. folium/herba submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2016.

References

EMA (European Medicines Agency), 2010. Assessment report on *Urtica dioica* L., *Urtica urens* L., folium. EMA/HMPC/508013/2007

EFSA Scientific Committee, 2012. Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663, 60 pp. doi:10.2903/j.efsa.2012.2663.

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance acetic acid. EFSA Journal 2013;11(1):3060, 57 pp. doi:10.2903/j.efsa.2013.3060.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2001. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.1, March 2012.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference SANCO/10058/2005-v. 2.0, 434 pp.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2009. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 1, 604 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.0, January 2011.

Abbreviations

a.s.	Active Substance
DC	Dispersible Concentrate
GAP	Good Agricultural Practice
LD_{50}	Lethal Dose, median; dosis letalis media
LoA	Letter of Access
MRL	Maximum Residue Level
MS	Member State
PEC	Predicted Environmental Concentration
PEC_{sed}	Predicted Environmental Concentration in sediment
PEC_{soil}	Predicted Environmental Concentration in soil
PEC_{sw}	Predicted Environmental Concentration in surface water
RMS	Rapporteur Member State
SC	Suspension Concentrate

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Urtica* spp. (as an insecticide on fruit trees, pulses and oilseeds, potato, leaf vegetables, rapeseed, root and tuber vegetables, elder tree, rose, *Spiraea* sp., as an acaricide on beans and grapevine and as a fungicide on *Brassicaceae*, curcubits, fruit trees, grapevine and potato) and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General

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

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.2.1 Composition of Nettle extract	NL: The final PPP is made by a fermentation process. It is unclear to which degree the composition mentioned here is comparable to the composition of the PPP.	The justification for the fermentation process should be given and any relevant chemical reactions should be described.		Data gap: Information about the composition of the fermented product was not submitted, especially the content of the compounds supposed to be involved in crop protection.
2(2)	General comment	ES: A title of the application with a more restrictive description as "*Urticadioica*	ES: No more comments.	Commission will take final decision in case of approval. "Nettle steeping" could also	Addressed: The applicant agreed on the possible change of the name of the basic

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		and/or *Urticaurens* stalks and leaves" would be more suitable.		be correct title	substance.
2(3)	2.2.1. Common name of the substance and product and their synonyms/plant nomenclature	ES: It might be useful to include the synonym in Spanish (e.g. Substance: "Tallos y hojas de *Urticadioica* y/o *Urticaurens*"; Product: "Extractoacuoso de tallos y hojas de *Urticadioica* y/o *Urticaurens*").	ES: No more comments.	Corrected, synonym added.	Addressed: The synonym in Spanish was added.
2(4)	2.1.2.1 Composition of nettle extract, p.6	EFSA: is there any information available on the content of the compounds supposed to be involved in crop protection after the fermentation of the nettle extract?	The table presented shows the compounds found in the aerial parts of the plants, a similar composition of the fermented extract would be helpful to see that there are no new unidentified compounds, and that the biologically active ones were not degraded.		See data gap 2(1)

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

No comments.

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

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(6)		ES: No comments.			Addressed.
2(7)	Type of product, p.14	EFSA: clarification is needed what is considered as preparation: the fermentation mixture as such, the filtrated mixture or the diluted filtrated mixture? A DC is a liquid homogeneous formulation to be applied as a solid dispersion after dilution in water.		Diluted filtrated mixture. Type of product may be considered as SC Suspension concentrate.	Addressed: The preparation is the diluted filtrated mixture.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(8)		NL: See 2.1 identity.			See data gap 2(1)
2(9)		ES: No comments.			Addressed.

2.5. Description of the recipe for the product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(10)	2.5 Description of the recipe, p. 15	EFSA: it seems that the way the product to be used is prepared is relevant to avoid enzymatic degradation and to have the right fermentation. Are there any means of controlling the extraction and fermentation? Is the efficiency influenced by the fermentation process?	A more clear and unequivocal description of the preparation of the product to be used would be important.	Recipe re-written.	Addressed: The description of the recipe was updated.
2(11)	2.5 Description of the recipe, p. 15	EFSA: how is the pH controlled?		Since fermentation is operated in water, pH paper or strips.	Addressed: The pH is controlled with pH paper.
2(12)	2.5 Description of the recipe, p. 15	EFSA: are there any quality control possibilities to control that no enzymatic degradation occurred and no harmful compounds formed if the fermentation process went wrong?		T°C control is necessary. When no more bubbles appear, the product of fermentation is ready. Further maceration may generate bad smelling.	Addressed: The quality control is done by the control of the temperature and observation of bubbles during the fermentation process.
2(13)	2.5 Description of the recipe, p. 15	EFSA: are there data proving the storage stability claimed?	It is stated that the mixture can be preserved in a dark place during one year, however shelf life study or an accelerated storage stability study would be required to support this.(at high and low temperatures, too)	When fermentation is finished, all oxygen is consumed. Storage under anaerobic conditions is possible. If evaluator wants to reduce storage possibility to few weeks, we acknowledge.	Addressed: The claim of storage for one year has been removed.

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)		DE: No specific data were provided which allow a detailed description of the cited GAPs.		Many pages of references are cited.	Addressed: The proposed uses were supported by the cited scientific literature.
3(2)		ES: Apart from include the pest or group of pest controlled, it should be indicated the intended crops.		Crops are mentioned.	Addressed: The proposed crops are mentioned in the summary of intended uses.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(3)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in the uses described should be expected.	In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exist.	Utility is the only concept for basic substance. If DE MS estimates that nettle extract is not useful in plant protection, it should remove the product from "Pflanzenstärkungsmittel" list!	Addressed: Based on the cited literature only limited effects in the uses described are expected.

3.2. Effects on harmful organisms or on plants

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

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Please provide reasons for your opinion that no phytotoxicity must be expected.		Data gap: No reasoning was provided to allow the exclusion of potential phytotoxic effects.
3(6)	3.4 Summary of intended uses	ES: It should be corrected the units appearing in the headlines (titles). Eg. -Formulation (Conc. of a.i.): g/L -Application rate per treatment: g instead of kg -Total rate: g instead of kg		Corrected.	Addressed: The units were corrected in the revised submission.
3(7)	3.4 Summary of intended uses	ES: Some values in the table are wrong. Please review *Application rate per treatment* and *Total rate* for: -potato -leaf vegetables -brassicaceae (flea beetle and		Corrected.	Addressed: The values were corrected in the revised submission.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		diamondback moth) -apple/pear tree (min and max values)			

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)		DE: We do not agree to approve a substance with sensitising (Skin Sens. 1/H317) and eye irritating (Eye Irrit. 2/H319) properties that may cause a risk mainly for operators as a basic substance. With regard to the sensitising and eye irritating properties it has to be concluded, that the condition laid down in Article 23(a) of Regulation (EC) No 1107/2009, that a basic substance is not a substance of concern, is not meet.	Applications for authorisations of plant protection products containing *Urticae folium* as "active ingredient (mixture)" should be made in accordance with the EU Guidance Document on Botanical Active Substances (SANCO/11470/2012).	So why it is sold as "Pflanzenstärkungsmittel" in Germany? Be consistent! EU Guidance Document on Botanical Active Substances (SANCO/11470/2012 rev 8) refers to basic substance in§ 15. Note that this product is sold in all Europe under special national regulations (illegal or not) for years!	Data gap: There is evidence that *Urtica* spp. may have to be classified as a skin sensitiser and eye irritant; additionally developmental toxicity may be an issue considering a notification for classification as Repr 1B, although no toxicological information was found to substantiate these notifications and no harmonised classification according to Regulation 1272/2008[2] is available. The toxicological profile of the substance needs to be clarified in line with the type of extract proposed. See also 4(2, 3, 4, 5) and 5(5, 6, 7), and Appendix B, 1(2), 4(1, 2, 3, 4), 5(1, 2, 3)
4(2)	4. Classification and labelling	NL: *Urticaurens* has a notification for classification with H360D. The applicant indicates that they could not find	We suggest contacting ECHA to try and obtain the background information on the notification for classification with H360D.	Dossier is empty, no data. We are looking for the applicant in order to ask the question of deposit with H360D with no data.	See data gap in 4(1)

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		the source related to the reprotoxicity of *urticaurens*. However, this is essential information as substances classified with H360D cannot be approved as a basic substance. More information on the background of this notification is required.		We take note of the applicant provided no proof, in order to envisage later legal action.	
4(3)	Table on *Urticaurens*, extract classification and labelling	PL: The proposal of *Urticaurens*, ext. classification as Repr. 1B was applied by over 747 applicants to ECHA. The final decision about classification has not been taken yet. It is a standard procedure that ECHA or applicants do not provide justification of proposed classification as long as it is not approved.	The applicant should wait for the final approval or rejection of proposed classification and only then correct the data of classification and labelling of *UrticaUrens*, ext. appropriately.	Dossier at ECAH is empty, no data. ECHA need no data and EFSA need data? No justification of proposed classification is needed? Should we pay a LoA if no data are available? We have no data corresponding to any reprotoxic properties.	See data gap in 4(1)
4(4)	Conclusion §4	PL: Since *Urticadioica*, ext. is classified as Skin Sens. 1 and Eye Irrit. 2, i.e. it is classified in regards to acute toxicity, it is a mistake to report that	The comment should be considered in the updated version of the application.	Sentence supressed and text completed.	See data gap in 4(1)

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		"*Urtica folium/herba* **does not show toxicity".**			
4(5)			PL: **Classification for products** should depend on the type of extract **Description of EC Inventory:** Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Urticadioica*, Urticaceae.		See data gap in 4(1)

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	Impact on human and animal health General	EFSA: references are given from uses in human medicine of different ethanolic extracts of *Urtica dioica* L., and *Urtica urens* L. These products are not comparable to the one proposed as basic substance (fermentation product of *Urtica* spp.). Other articles refer to single compounds present in the fermentation products; other articles refer to use as herbal tea; overall there is no toxicological information on the product proposed as basic substance. Furthermore, it is unknown whether harmful compounds are produced during the fermenting process reported (see 2(19) above).	Toxicological information should be provided on the product as proposed as a basic substance or give evidence of the similarity of the product as reported in the literature and the one proposed as a basic substance.	No overall toxicity tests.	Data gap: Since it is unknown whether harmful compounds may be formed during the fermentation process, toxicological information on the preparation should be provided.

5.2. Acute toxicity

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

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	European Medicines Agency. Assessment report on *Urtica dioica* L., *Urtica urens* L., folium. EMA/HMPC/508013/2007 and references therein.	PL: Both quoted studies do not fulfil criteria set for short-term toxicity studies as presented in the Commission Regulation (EU) No 544/2011[3] (both studies had too short duration).	The reference presented in this paragraph should be removed since it does not refer to short-term toxicity.	Ref removed.	Addressed.

5.4. Genotoxicity

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

[3] Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)	DaherCostantine F., BaroodyKarmen G., George M. Baroody 2006 Effect of Urtica dioica extract intake upon blood lipid profile in the rats Fitoterapia 77 pp 183–188	PL: The summarized study does not fulfil criteria set for long-term toxicity studies as presented in the Commission Regulation (EU) No 544/2011 (the study had too short duration).	The information should be removed from the subchapter 5.5 Long-term toxicity. However, it can be used to provide information on short-term toxicity, i.e. it could be shifted to the subchapter 5.3.	Ref. moved.	Addressed.
5(4)	European Medicines Agency. Assessment report on *Urtica dioica* L., *Urtica urens* L., folium. EMA/HMPC/508013/ 2007 and references therein	PL: The summarized study does not fulfil criteria set for long-term toxicity studies as presented in the Commission Regulation (EU) No 544/2011 (the study had too short duration).	The information should be removed from the subchapter 5.5 Long-term toxicity. However, it can be used to provide information on short-term toxicity, i.e. it could be shifted to the subchapter 5.3.	Ref. moved.	Addressed.

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		DE: The advice not to use "nettle leaf/herb" during pregnancy and lactation is a further argument for not considering *Urticae folium*		This refers to medicinal uses. Plant extract may not considered as basic substance, although plant extract approved as basic	See data gap in 4(1)

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		as a basic substance.		substance are accepted by DE https://www.umwelt-online.de/recht/eu/11/11_0540vc.htm	
5(6)		NL: see the comment on the classification of *Urticaurens* for developmental toxicity.			See data gap in 4(1)

5.7. Neurotoxicity

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

No comments.

5.8. Toxicity studies on metabolites

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

No comments.

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)		DE: A number of side effects are mentioned. A "basic substance" should be devoid of such effects.			See data gap in 4(1)
5(8)	Singh, D., Gupta, R., &Saraf, S. A. 2012 Herbs–are they safe enough? An overview. Critical reviews in food science and nutrition 52(10) pp 876-898	PL: The proposed basic substance, *Urticae folium/herba*, *i.e.* aerial part of nettle, is a food stuff and a medicinal herb. It has no significant adverse effect nor toxic action. It is not genotoxic, not reprotoxic, not neurotoxic neither immunotoxic. Therefore it meets the requirements of basic substance. The reference does not indicate toxicity caused by *Urticadioica*. The manuscript of Scholz et al., 1980 explains that the signs of poisoning observed after exposure to a health tea containing *Urticadioica* were caused by *Atropa belladonna* that contaminated the tea.	The reference should be removed since it does not refer to the adverse effects caused by *Urticadioica*.	Ref removed. Contamination by other plant is corresponding to misuses. Farmers should be aware of possible contamination. Sales of dry nettle are a guaranty of consistency of the active substance with §2. Applicant is not concern by misuses of the a.s. Many suicides are committed with pesticides without trial of the corresponding applicant, fortunately.	Addressed.

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

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

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
No comments.					

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

6. Residues

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
6(1)		ES: No comments			Addressed.
6(2)		EFSA: No data provided and not required as long as toxicological concerns are not identified in the section on toxicology.		No long term toxicity assays or references provided.	The data gaps identified under point 4.1 and 5.1 do not allow concluding that the proposed uses are safe for the consumers.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(1)		ES: No comments.			Addressed

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(2)		NL: on page 47 it is written Reliable data for environmental fate and	Acetic acid is an approved active substance in the EU, therefore the endpoints of	Normal application is equivalent to 120 g acetic acid per ha, compare to 40-100 kg	See data gap in 7(5)

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		transport behavior are available for acetic acid and its salts (see Appendix 1)." Appendix list he reference list, there is no reference for the fate and behaviour of acetic acid. Acetic acid is an approved active substance in the EU therefore the endpoints of that assessment should be referred to.	that assessment should be referred to.	for acetic acid uses, and MRLs are in Annex IV of 396/2005 Reg, so assessment of Urtica is covered for acetic acid.	
7(3)		ES: No comments.	-	-	Addressed
7(4)	2.1.2.1 Composition of nettle extract. 2.5 Description of the recipe for the product to be use	EFSA: A number of components, including the assumed to have pesticide activity, are listed under 2.1.1.1 section. It seems these components are identified in crude extracts of nettle. However, according the description in 2.5, it is clear that what it is proposed to be used as plant protection product is a fermented extract. Also it is clear from the references provided that fermentation is needed to obtain the desired	Information on the components found in the fermented extracts of nettle (*Urtica dioica* L. and *Urtica urens* L.), specially on the biologically active ones, need to be provided and assessed with respect to their fate and behaviour into the environment (information currently available in the application seems to be limited to compounds found in the fresh leaves, these may suffer significant changes during the fermentation	Mode of action and active components are not clear.	Data gap: Applicant would need to clarify if fermented extract is intended to be used and what makes the difference in terms of active components with crude extract. Depending on this information the need for further environmental assessment could be decided.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		fungicidal/insecticidal effect. Environment will be exposed to the products of fermentation of nettle extract, not to nettle extract itself. Therefore, information on the components found in the fermented extracts of nettle (*Urtica dioica* L. and *Urtica urens* L.), specially on the biologically active ones, need to be provided and assessed with respect to their fate and behaviour into the environment. In addition, it is noted that most of the limited uses of nettle leaves as food reported in the application are based on cooked fresh nettle leaves not on fermented dry ones.	process)		
7(5)		EFSA: Maximum seasonal application rate proposed is equivalent to 81 Kg dry a.i / ha. Taking into account the composition presumed (assuming no transformation of these	Environmental exposure assessment including PEC soil, PEC SW and PEC GW is needed for at least the identified active components of nettle extract covering the worst case maximum	Normal application is equivalent to 120 g (2.187 Kg / ha max) acetic acid per ha, compare to 40-100 kg for acetic acid uses, and MRLs are in Annex IV of 396/2005 Reg., so assessment of Urtica is	Data gap: As acknowledged by applicant some of the known active components of *Urtica* spp. extract are intrinsically hazardous compounds. Risk for the environment is not driven by the natural or artificial origin of the

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		compounds occur during fermentation), this is equivalent to an application of: - 1.3 Kg / ha of 2-O-caffeoylmailic acid - 405 g / ha of chlorogenic acid - 79 g / ha of rutin - 2.187 Kg / ha of acetic acid Plus unknown quantities of formic acid, lecithin, lectines, L-prunasin and other potentially biologically active substances. It is noted that acetic acid has been assessed as authorized in EU as a PPR a.s. *per se* and that an available EFSA conclusion (EFSA, 2013).	application rate proposed (if it is confirmed that they are present in the fermented product). It is suggested that at least the following compounds and application rates should be considered: - 1.3 Kg / ha of 2-O-caffeoylmailic acid - 405 g / ha of chlorogenic acid - 79 g / ha of rutin - 2.187 Kg / ha of acetic acid For this the applicant is advised to use current available FOCUS guidance (FOCUS, 2001; 2006; 2009) and, for the particular case of acetic acid, to take into consideration available EFSA conclusion (EFSA, 2013).	covered for acetic acid. Other compounds are natural occurring compounds, which may be forbidden by EFSA but still present in nature, transferable in atmosphere and rivers by any means (rain, wind…). By instance, chlorogenicacid is a highly flammable liquid and vapour, is harmful if swallowed, is harmful in contact with skin, causes serious eye irritation and is harmful if inhaled, and still present in nature (is one of the major phenolic compounds identified in peach and present in prunes potatoes…).	substances released to it, but by the combination of the specific levels of exposure with respect to the hazard of the substance. Therefore, appropriate exposure assessment to the environment is needed for those substances present in the *Urtica* spp. extract (or its fermentation products, see above) with biological activity. **Note**: authorisation or not of the use of a specific substance as plant protection product is a risk management issue out of the scope of EFSA competences.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1.1 Birds	DE: Nettle may be used to feed chickens and poultry. But the amounts of nettle in the intended uses are very high, and is it not shown in the application that these amounts will not cause an unacceptable risk for wildlife birds.	Show in a sound risk assessment that the intended uses cause no unacceptable risk for wildlife birds.	Such Evaluation may be found in "Brenessel" dossier corresponding to allowed and sold product as "Pflanzenstärkungsmittel" in Germany	See 8(4)
8(2)	8.1.2 Mammals	DE: In the study of Ahmad *et al.* rats showed diarrhoea and diuresis at 2000 mg nettle extract/kg bw. The European Medicines Agency determined a LD_{50} of 1928 mg/kg bw for rats. The application does not show whether these amounts can be reached in wildlife mammals in the intended uses.	Show in a sound risk assessment that the intended uses cause no unacceptable risk for wildlife mammals.	Such Evaluation may be found in "Brenessel" dossier corresponding to allowed and sold product as "Pflanzenstärkungsmittel" in Germany	See 8(4)
8(3)		ES: No comments.			Noted
8(4)	8.1.1 and 8.1.2 Birds and mammals	EFSA: The information provided does not allow for a risk assessment of *Urtica dioica* extract.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk to birds and mammals (acute		Data gap: Not enough information was available to perform a quantitative/qualitative risk assessment for birds and mammals to *Urtica* spp. extract and

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			and reproductive). The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.		to potentially occurring bioactive fermentation products of nettle leaves.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)		ES: No comments.			Noted.
8(6)	8.2 Effects on aquatic organisms	EFSA: The information provided does not allow for a risk assessment of *Urtica dioica* extract.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk to aquatic organisms (acute and reproductive). The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.	No data.	Data gap: Not enough data were available to perform a quantitative/qualitative risk assessment for aquatic organisms to *Urtica* spp. extract and to potentially occurring bioactive products of fermentation of nettle leaves.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(7)	8.3 Effects on bees and other arthropods species	DE: Nettle is used against aphids, moths and *Chrysomelidae*. Nettle has an insecticidal effect. The submitted studies are not sufficient to clarify whether there is an unacceptable risk for non-target arthropods by the intended uses. DE: The presented data are not appropriate to assess the risk to bees from the use of nettle extract as foliar spray.	DE: Provide a sound risk assessment for non-target arthropods and show that there is no unacceptable risk caused by the intended uses for nettle. Please indicate in dossier.	Such Evaluation may be found in "Brenessel" dossier corresponding to allowed and sold product as "Pflanzenstärkungsmittel" in Germany.	Data gap: No quantitative/qualitative risk assessment for bees and other non-target organisms to *Urtica* spp. extract and to potentially occurring bioactive fermentation products of nettle leaves was performed. It should be noted that the nettle extract has been reported to have insecticidal properties. A low risk to bees and other non-target arthropods cannot be concluded on the basis of the available information.
8(9)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Please indicate in dossier.	Such Evaluation may be found in "Brenessel" dossier corresponding to allowed and sold product as "Pflanzenstärkungsmittel" in Germany.	See 8(7).
8(10)		ES: No comments.			Noted
8(11)	8.3.1 Effects on bees	EFSA: The exposure of the bees in the referenced studies should be included in the study summary. The exposure should then be compared to the likely exposure to following the representative uses of *Urtica dioica* extract in a risk assessment.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk to bees. The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.		See 8(7)

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(12)	8.3.1 Effects on other arthropods	EFSA: Please include the tested rate in the study of Gaspari *et al.* (2007). Moreover, the exposure should then be compared to the likely exposure to following the representative uses of *Urtica dioica* extract in a risk assessment.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to non-target arthropods. The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP. The assessment should cover several species of non-target arthropod.	Gaspari et al. (2007) rate is 200 g / L and our concentration is lower 75 g / L.	Addressed In Gaspari *et al.* (2007) rate is 200 g / L and the concentration in the application is lower (75 g / L). See 8(7)

8.4. Effects on earthworms and other soil macro-organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)	8.4 Effects on earthworms and other soil macro-organisms	DE: In section 8.5 it is said that the use of nettle may modify the ecology of the soil. This may cause an unacceptable effect on earthworms and other soil macroorganisms. Robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm *Eiseniafetida*) were not	DE: Provide a sound risk assessment for earthworms and soil macroorganisms and show that there is no unacceptable risk caused by the intended uses for nettle.	Such Evaluation may be found in "Brenessel" dossier corresponding to allowed and sold product as "Pflanzenstärkungsmittel" in Germany	Not enough data were available to perform a quantitative/qualitative risk assessment for earthworms and other soil macro-organisms to *Urtica* spp. extract and to potentially occurring bioactive fermentation products of nettle leaves. Due to the nature of the basic substance it may be reasonable to conclude a low risk to earthworms

8.4. Effects on earthworms and other soil macro-organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		submitted.			and other soil macro-organisms.
8(14)		ES: No comments			Noted
8(15)	8.4 Effects on earthworms and other soil macro-organisms	EFSA: No information has been provided to perform a risk assessment for earthworms.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to earthworms. The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.	Nettle extract is allowed in Germany. Risk evaluation may be found in the corresponding Dossier although it was considered as plant strengthener, but Guideline 1003/2000 rev.3 from DG Sanco specifies that plant strengthener are PPPs.	See 8(13)

8.5. Effects on soil micro-organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(16)	8.5 Effects on soil micro-organisms	DE: In the application it is said that the use of nettle may modify the ecology of the soil. This may cause an unacceptable effect on soil microorganisms. Robust experimental reports were not submitted; information on effects on soil micro-organisms cannot be derived.	DE: Provide a sound risk assessment for soil microorganisms and show that there is no unacceptable risk caused by the intended uses for nettle.	No comment from applicant.	Not enough data were available to perform a quantitative/qualitative risk assessment for earthworms and other soil macro-organisms to *Urtica* spp. extract and to potentially occurring bioactive fermentation products of nettle leaves. However due to the nature of the basic substance it might be considered reasonable to conclude a low risk to

8.5. Effects on soil micro-organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					soil micro-organisms.
8(17)		ES: No comments			Noted.
8(18)	8.5 Effects on soil micro-organisms	EFSA: No information has been provided to perform a risk assessment for soil micro-organisms.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to soil micro-organisms. The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.	Same extract is used in fertilization at higher rate. No negative impact is observed.	See 8(16)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(19)		ES: No comments			Noted
8(20)	8.6 Effects on other non-target organisms	EFSA: No information has been provided to perform a risk assessment for non-target plants.	Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to non-target plants. The assessment should consider the risk from the extract of *Urtica dioica* when used according to the GAP.	Idem 8.5	No information has been provided to perform a risk assessment for non-target plants. The extracts from *U. dioica* might have allelopathic effects (Dziamski, Andrzej, and Z. Stypczynska. "Allelopathic effect of preparations of *Betula pendula* Roth., *Chamomilla recutita* L. and *Urtica dioica* L. on the initial growth of *Hordeum vulgare* L." Acta

8.6. Effects on other non-target organisms (flora and fauna)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					Agrobotanica 68.1 (2015).) however, as Urtica is a nitrophilic weed, and can be used as an organic fertiliser as the mulch is placed on the soil surface. Overall it is considered reasonable to conclude a low risk to NTTPs.

8.7. Effects on biological methods of sewage treatment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(21)	B.8.7 page 52	NL: it is said 'no references were found'. Because nettle extract has antifungicidal and antibacterial activities, it may modify the microbial population of the sewage sludge. However, based on the intended use the amount of nettle extract reaching an STP will be very low. Furthermore, based a thehughe numbers of microbes in active sludge some potential modification will not influence the performance of the STP.		This extract is only from vegetal origin, totally biodegradable.	Addressed. A low risk can be concluded due to low exposure.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(22)		ES: No comments.			Noted.

General:

NL:
The nettle that is used as food and herbal medicine seems to be of different composition as the nettle that is proposed as basic for plant protection purposes.
The extract for PPP uses is prepared by the following recipe:
The proposed basic substance is *Urticae* spp. folium/herba, *i.e.* aerial parts of nettle. The product is aerial parts of nettle that have been macerating in water during a few days.
Young shoots of nettle are cut in little pieces. Put them in water at a concentration of 75 g/l.* Choose preferably rainwater or spring water. If not, using tap water is also possible. Let the nettle steep, in a container in plastic or stainless steel, for:
- Up to 2 days at 30 °C
- Up to 5 days at 20 °C **
- Up to 10 days at 5 °C

Mix it a few minutes every day. Little bubbles appear on the surface during mixing, it is the sign that fermentation occurs. When no more bubbles appear, the product of fermentation is ready. Use it or stock it before the beginning of putrefaction. The pH must range between 6 and 6.5 approximately. Filter it, and dilute 1L of fermentation mixture in 5L of water. Spray it on the crops.
This mixture can be preserved in a dark place during one year, in a closed recipient at fresh temperature.

*If dry pieces of nettle are used, the concentration is 15 g/l.
** The ideal temperature range between 15°C and 25°C. Below 15°C, the fermentation is difficult, over 25°C, enzymatic degradations occur.
APPL: This procedure is largely different from a simple tea brew, (dry) leafs used in food or extracts used for homeopathic medicine.

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

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
9(1)	Final conclusion	PL: The results of experiments on laboratory animals (e.g. used for toxicity studies) and epidemiological data indicate clearly that *Urtica* may show toxicity for animals. The massive exposure to nettle may cause salivation, itching of pawns, scratching of the body, vomiting, laboured respiration, depression, ataxia (Burrows and Tyrl, 2013, "Toxic plants of North America).	The comment should be considered in the updated version of the application.	These extracts are already sold as fertilisers, legally at high level input per ha. These uses are considered as illegal PPP uses in certain cases, we provided the most complete accurate and filled Dossier in order to ask for basic substances approval for known uses, in order to regularize this extract. If considered literature provided acknowledges environmental risk (aquatic, non-target) and even human risk, conclusion of Commission will be non-approved. Later, the Commission should operationalize this result on the field and throughout Europe. We will comply with this result as we have always did and will ensure that this prohibition is respected throughout Europe using, if necessary, a complaint to the European courts to prevent the current concurrency distortion between farmers,	A number of data gaps have been identified with respect to identity, impact on human and animal health, and the environmental risk assessment of *Urtica* spp. (including exposure and hazard characterisation) that do not allow concluding on the safety of the uses proposed.

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
				maintained by some countries in the Union!	

10. Other comments

Other comments					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
10(1)		DE: General comment on the efficacy evaluation in the dossier: The idea of the authorisation of basic substances is that no product approval takes place after the final decision on the as.	Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	Such product approval may be already found as "Brenessel" products allowed and sold product as "Pflanzenstärkungsmittel" in Germany, and this substance is now approved as basic substance in Switzerland.	See comment 3(3)
10(2)		ES: No comments.			Addressed.

Appendix B – Collation of comments from Member States and EFSA on the basic substance application for *Urtica* spp. (as a fungicide on cucumber roots, tomato and ornamental trees) and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)		NL: No comments.			Addressed.
1(2)	4. Classification	DK: The classifications of Urticadioixa is only noted by a single notifier, thus the reliability is uncertain. The repro 1B classification of UrticaUrens is notified by 747 notifiers, but as the evidence for this classification is not available, the reliability is uncertain.	DK: For the stated classifications, it should be clearly emphasized that the classifications are not harmonised but only notified classifications, and neither should be used to support the classification of Nettle.	Classification by ECHA notifiers has no report or publication as support. EFSA has access to ECHA database.	See data gap 4(1) in Appendix A
1(3)	2. Identification	DK: Why is 'folium/herba' written in italics? It is not a species name like e.g. Urticaurens.	DK: Propose to change the Urtica folium/herba to Urtica spp. Folium/herba, or maybe Urticadioica, Urticaurens folium/herba.	*Urtica* spp. folium/herba approved by applicant. BSA updated.	Addressed. Application was updated.
1(4)	3. Identification 3.1 Field of use (and 3.4 intended use)	DK: Spelling error. 'Cryptogrammic' should probably have read 'cryptogamic'.	DK: Replace 'cryptogrammic diseases' with 'cryptogamic diseases'.	Corrected in BSA.	Addressed. The updated application is still incorrect.
1(5)	3. Identification 3.2.1 mode of action	DK: The Mode of action is not fully mentioned here.	DK: Please explicitly mention if nettle extract has a fungicide effect, or if nettle extract has repellent and antifeedant activities only.	All effects are claimed.	Addressed.

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.2.1 Composition of nettle extract	DE: For several substances listed in the table of substances involved in crop protection no information about the content of these substances in nettle has been provided.		Composition with amounts is described in BSA p. 6	Addressed, however the sambunigrin content is still missing.
2(2)		NL: No comments.			Addressed.
2(3)	Section 2, page 5	UK: The identity of the active substance is not fully addressed, the reason for the fermentation process in the method of manufacture is unclear, as this is a botanical composition consideration should be in accordance with EU Guidance document on Botanical active substances SANCO/11470/2012–rev. 8		The identity of the active substance is not clear. Some carboxylic acids are known to be repulsive. Although mode of action is not compulsory, we try to understand more of the utility of these substances, however, to our point of view this could never be reduce to unique synthetic chemicals.	See data gap 2(4)
2(4)	2.1.2.1 Composition of nettle extract, p.9	EFSA: is there any information available on the content of the compounds supposed to be involved in crop protection after the fermentation of the nettle?	The table presented shows the compounds found in the aerial parts of the plants, a similar composition of the fermented extract would be helpful to see that there are no new unidentified compounds, and that the biologically active ones were not	This way of pursuing active components from active principles is not our goal. Reduction to single active molecule is not to our point of view a meaningful goal. We have no wish to reduce this	Data gap: Information about the composition of the fermented product was not submitted, especially the content of the compounds supposed to be involved in crop protection.

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
			degraded.	natural action to chemical concepts.	See also 5(5)

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

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(6)		NL: No comments.			Addressed.

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(7)		NL: No comments.			Addressed.

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		ES: Perhaps, it could be better to consider the *Urticae folium* "extract" as the basic substance.		Agree, see 1(3). This point was already mentioned by ES M.S. previously for other plant extracts and we totally agree that point for decoction but this product is dry leaves of nettle.	Addressed. The decision on what is considered the basic substance is a risk management decision.
2(9)	Type of preparation of the substance/product, p.14	EFSA: clarification is needed what is considered as preparation: the fermentation mixture as such, the dried aerial parts of the nettle or something else? A formulation code D does not exists.	The product is said to be the aerial parts of nettle that have been submitted to rain, liberating phenolic compounds, meaning that the fermentation process started. This cannot be dry. It is not clear what is happening before and after submitting to rain. What is the basic substance and what is used as plant protection product? A more precise description would be needed.	It is included in mulch as dry leaves. We believed "Dry" formulation code is accurate as used for Equisetum previously and accepted by DG Santé.	Data gap: The type of preparation is still not clearly defined. See also 5(5)

2.5. Description of the recipe for the product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(10)		NL: No comments.			Addressed.
2(11)	Description of the	EFSA: it is not clear how the		Dry leaves of Nettle are	Addressed.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
	recipe for the product to be used, p. 15	dry parts are "produced"? If the aerial part is submitted to rain, it is dried and after that mixed with mulch?		commercially available for botanic preparations, fertilization, and Pharmacopeia as herbal tea preparations.	

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)		DE: It is known that extracts from nettles might have phytotoxic effects. However no specific data were provided which allow the exclusion of potential phytotoxic effects.	Please provide reasons that no phytotoxicity is expected.	Nettle extract is not spray on crops.	Addressed.
3(2)		NL: No comments.			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** **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(3)		NL: No comments.			Addressed.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)		NL: No comments.			Addressed.
3(5)	3.4 Summary of intended uses	EFSA: the mode of application is covering the soil with mulch only?		The mode of application is covering the soil with mulch AND nettle leaves.	Addressed.
3(6)	3.4 Summary of intended uses	ES: In the headline of the GAP table, the units of Application rate per treatment and Total rate are wrong (kg/ha and g/ha)		Corrected.	Addressed.
3(7)	3.4 Summary of intended uses	ES: For potato, the total rate is wrong taking into account the application rate per treatment.		Corrected.	Addressed. GAP table does not contain use on potato.
3(8)	3.4 Summary of intended uses	ES: For Brassicaceae (for the two pest), the total rate (min) is wrong taking into account the application rate per treatment.		Corrected.	Addressed. GAP table does not contain use on Brassicaceae.
3(9)	3.4 Summary of intended uses	ES: For apple tree, three applications have been proposed, so the total rate (min) is wrong, taking into account the application rate per treatment.		Corrected.	Addressed. GAP table does not contain use on apple trees.
3(10)	3.4 Summary of intended uses	ES: For Brassicaceae (for the two pest) and potato, the maximum application rate per treatment (kg/ha) is wrong (10 kg/ha); if we consider 1500 g/hl and 500 l/ha.		Corrected.	Addressed. GAP table does not contain use on Brassicaceae.
3(11)	3.4 Summary of intended uses	EFSA: in the heading of the GAP table, under Growth stage, there	Please update the GAP table, taking into account all remarks.	Corrected.	Addressed:

3.3. Summary of intended uses					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		is a sign ** for a note, which is not found under the table.			GAP table still incorrect, correction not made.

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)	4. Classification and labelling	NL: *Urticaurens* has a notification for classification with H360D. The applicant indicates that they could not find the source related to the reprotoxicity of *urticaurens*. However, this is essential information as substances classified with H360D cannot be approved as a basic substance. More information on the background of this notification is required.	NL: We suggest contacting ECHA to try and obtain the background information on the notification for classification with H360D.	Literature and ECHA folder do not provide any information or proof of this classification.	See data gap 4(1) in Appendix A

4(2)		DE: We do not agree to approve a substance with sensitising (Skin Sens. 1/H317) and eye irritating (Eye Irrit. 2/H319) properties that may cause a risk mainly for operators as a basic substance. With regard to the sensitising and eye irritating properties it has to be concluded that the condition laid down in Article 23(a) of Regulation (EC) No 1107/2009, that a basic substance is not a substance of concern, is not met.	DE: Applications for authorisations of plant protection products containing Urticae folium as "active ingredient (mixture)" should be made in accordance with the EU Guidance Document on Botanical Active Substances (SANCO/11470/2012).	Degradation transformation of nettle known active components in mulch is the same as degradation of nettle in nature, or as nettle use as fertilizer. Nettle is authorized as biostimulantin DE, FR. Information may be found in: - Pflanzenstärkungsmittel liste asNettel / Brenessel, - Décret no 2008-841 du 22 août 2008 relatif à la vente au public des plantes médicinales inscrites à la Pharmacopée et modifiant l'article D. 4211-11 du code de la santé publique NOR: SJSP0816560D.	See data gap 4(1) in Appendix A
4(3)	Section 4, p. 10	UK: Self-classification as skin Sens. 1 and eye Irrit. 2 has not been sufficiently addressed in document. This has also been contradicted later as it is stated that "It has no adverse nor toxic action" in section 5.13	EFSA: Irritation properties to eyes and skin and skin sensitisation potential of the substance need to be clarified.	Nettle leaves as plant part are indeed skin irritant. This fact is well known and felt all around the world by every people who touched the plant. This is why the plant itself is called "Stinging Nettle".	See data gap 4(1) in Appendix A
4(4)	4. Classification and labelling of the substance, p. 26	EFSA: Classification as Repro 1B for *Urtica urens*, extract is a criteria for non-approval. Although not a harmonised classification, the basis for this proposal has to be clarified, is it a component of the mixture, result of modification of the plant (extract, fermentation, other)?	EFSA: Agreement with NL proposal to obtain the background information on the notification for classification with H360.	Literature and ECHA folder do not provide any information or proof of this classification.	See data gap 4(1) in Appendix A

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

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

5.2. Acute toxicity

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

5.3. Short-term toxicity

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

5.4. Genotoxicity

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

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

5.6. Reproductive toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(1)		NL: see the comment on the classification of Urticaurens for developmental toxicity.		Applicant agree if ECHA folder is not empty.	See data gap 4(1) in Appendix A
5(2)		ES: It should be included in the label: *"The product should be not used during pregnancy and lactation without medical advice."*	EFSA: See 4(1), 4(4)	Applicant agree if ECHA folder is not empty.	See data gap 4(1) in Appendix A
5(3)	See 4(4)	EFSA: Classification as Repro 1B for *Urtica urens*, extract is a criteria for non-approval. The basis for this proposal should be checked.	See 4(4)	Applicant agree if ECHA folder is not empty.	See data gap 4(1) in Appendix A

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

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

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

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

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

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
No comments.					

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(4)		ES: It should be highlighted in the information about the substance that: the aerial parts of stinging nettle must be collected in an unpolluted area because nettle is able to accumulate metals in its tissues. It is important to avoid industrial wasteland and mining sites.		Pharmacopeia is clear about these specifications. Applicant agrees requested restriction to clean lands.	Addressed.
5(5)	See 2(9)	EFSA: As clarification is needed on what is	EFSA: pending on the clarification given regarding the preparation,	No fermentation is occurring in the process, Nettle leaves	See data gap in 2(4, 9)

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		considered as preparation: the fermentation mixture as such, the dried aerial parts of the nettle or something else, further toxicological data may be necessary. For instance if a fermentation process is required, it has to be demonstrated that no toxic compounds are formed.	further toxicological considerations may be necessary.	are included in mulch no maceration is processed, no fermentation in water occurs.	

6. Residues

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
6(1)		NL: No comments.			Addressed.
6(2)		EFSA: No data provided and not required as long as toxicological concerns are not identified in the section on toxicology.		More paper added about toxicological concern in Point §5 Johnson 2013 Akbari 2015 Mohammadi 2016 Doukkali 2016	The data gaps identified under point 4.1 and 5.1 in Appendix A do not allow concluding that the proposed uses are safe for the consumers.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7.2. ESTIMATION OF THE SHORT AND LONG-TERM EXPOSURE OF RELEVANT ENVIRONMENTAL MEDIA (SOIL, GROUND WATER, SURFACE WATER)	NL: The reference Doman, N. G., & Romanova, A. K. (1962). Transformations of labelled formic acid, formaldehyde, methanol, & CO2 absorbed by bean & barley leaves from air. Plant physiology, 37(6), 833 used to justify the degradation of formic acid by plants contains many citations.	The citation should also be provided by the applicant and added to the dossier.	Reference was already cited and included in BSA by applicant in Point §7.	Addressed

7(2)	2.1.2.1 Composition of nettle extract 2.5 Description of the recipe for the product to be use	EFSA: A number of components, including the assumed to have pesticide activity, are listed under 2.1.1.1 section. It seems these components are identified in crude extracts of nettle. Nettle is proposed to be mixed to mulch added to the crops. Possible transformation of nettle components in mulch would need to be investigated.	Degradation transformation of nettle known active components in mulch would need to be investigated.	Degradation transformation of nettle known active components in mulch is the same as degradation of nettle in nature, or as nettle use as fertilizer. Nettle is use as biostimulant also and authorized in: DE, FR. Information may be found in: - Pflanzenstärkungsmittel liste as Nettel / Brenessel, - Décret no 2008-841 du 22 août 2008 relatif à la vente au public des plantes médicinales inscrites à la Pharmacopée et modifiant l'article D. 4211-11 du code de la santé publique NOR : SJSP0816560D	Data gap: Applicant would need to clarify the effect of mixing nettle with mulch in terms of active components that might result (eg. fermentation / compost products may be formed with different biological properties). Depending on this information the need for further environmental assessment could be decided.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(3)		NL: No comments.			Addressed
7(4)		EFSA: Maximum seasonal application rate proposed is equivalent to 100 Kg dry a.i / ha. Taking into account the composition presumed (assuming no transformation of these compounds occur during fermentation), this is	Environmental exposure assessment including PEC soil, PEC SW and PEC GW is needed for at least the identified active components of nettle extract covering the worst case maximum application rate proposed (if it is confirmed that they are present in the fermented	Quantities corrected in BSA, GAP table corrected. Values provided need to be divided by 6.7, i.e.. - 0.24 kg / ha of 2-O-caffeoylmailic acid - 75 g / ha of chlorogenic acid	Data gap: Some of the known active components of *Urtica* spp. extract (nettle extract) are intrinsically biologically active compounds. Risk for the environments is not driven by the natural or artificial origin of the substances released to it, but on the

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		equivalent to an application of: - 1.6 Kg / ha of 2-O-caffeoylmailic acid - 500 g / ha of chlorogenic acid - 98 g / ha of rutin - 2.7 Kg / ha of acetic acid Plus unknown quantities of formic acid, lecithin, lectines, L-prunasin and other potentially biologically active substances. It is noted that acetic acid has been assessed as authorized in EU as a PPP a.s. *per se* and that an EFSA conclusion is available (EFSA, 2013).	product). It is suggested that at least the following compounds and application rates should be considered: - 1.6 Kg / ha of 2-O-caffeoylmailic acid - 500 g / ha of chlorogenic acid - 98 g / ha of rutin - 2.7 Kg / ha of acetic acid For this the applicant is advised to use current available FOCUS guidance (FOCUS, 2001, 2006, 2009) and, for the particular case of acetic acid, to take into consideration available EFSA conclusion (EFSA, 2013).	- 14.7 g / ha of rutin - 0.405 kg / ha of acetic acid Alternatively, some of them are generic plant metabolites largely released in environment by plants, plant parts and crop/field residues (stalks and stubble (stems), leaves, and seed pods) without any control, and acetic acid has no MRL at all.	combination of the specific levels of exposure with respect to the hazard of the substance. Therefore, appropriate exposure assessment to the environment is needed for those substances present in the *Urtica* spp. extract (or the products produced when mixed with mulch, see above) with biological activity.

8. Effects on non-target species

NL: No comments.

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1. effects on terrestrial vertebrates	EFSA: please, provide study summaries of the cited papers including experimental details and results to allow an evaluation.		Nettle leaves intended for use in mulch are not dedicated to large field areas (ha level). Effect on terrestrial is not different from mulch itself at 83 g/kg rate.	No additional information has been included in the study summaries of the application.

8(2)	8.1. effects on terrestrial vertebrates	EFSA: Note that, at the present stage, any form of risk assessment/ scientific justification was not presented. It's, therefore, not possible to conclude on the risk for bids and wild mammals.it is deemed reasonable to consider the dietary exposure to birds and wild mammals following the application of the basic substance according to the representative uses to be low. However, it should be better clarified how the product is intended to be applied to mulch (i.e., whether the premixed nettle+mulch is directly applied in the field or the dry nettle leaves and, if so, how).	EFSA: Some form of risk assessment and or a scientific justification should be submitted in order to demonstrate a low risk to birds and wild mammals. The assessment should consider the risk from the BS when used according to the GAP. The applicant may wish to include in the BSA document clear details on the method of application together with (in case it's deemed relevant) a justification for the low exposure of terrestrial vertebrates.	Method kind is clearly described in GAP table, dry nettle leaves (Type) are applied inside mulch. Definition of mulch is given in BSA.	Not enough information was available to perform a quantitative/qualitative risk assessment for birds and mammals to *Urtica* spp. However, it is considered that the dietary exposure of birds and mammals to the basic substance when applied according to the representative uses (i.e., mixed with mulch) would be low. Therefore, a low risk can be concluded.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)	Section 8, page 49	UK: There are no clearly presented conclusions on the risk to aquatic organisms		In Point §8 Nettle is given as feed additive (supplementation) to diverse fish species in order to prevent	See 8(4)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				infections. Binaii et al. 2014 Awad E. 2010 Sabzar 2013	
8(4)	8.2. Effects on aquatic organisms	EFSA: Note that, at the present stage, any form of risk assessment/ scientific justification was not presented. It's, therefore, not possible to conclude on the risk to aquatic organisms. Taking into consideration the representative use (application in mulch) it is considered that the exposure to aquatic organisms might be considered low. However, it should be better clarified how the fungicidal activity is exerted. Moreover, comments 7(2) and 7(4) should be taken into consideration.	EFSA: Some form of risk assessment and or a scientific justification should be submitted in order to demonstrate a low risk to aquatic organisms. The assessment should consider the risk from the BS when used according to the GAP.	Nettle does not show any adverse effect to fish and even serve as feed additive.	Not enough information was available to perform a quantitative/qualitative risk assessment for aquatic organisms to *Urtica* spp. However, it is considered that the exposure to the basic substance when applied according to the representative uses (i.e., mixed with mulch) would be low. Therefore, a low risk can be concluded.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)	Section 8 page 51	UK: There are no clearly presented conclusions on the risk to non-target arthropods		Nettle uses described in this application do not differ from natural Nettle situation in nature. Only targeted use on soil/roots contact with Nettle as it can occurs in nature (spilling, rains...).	See 8(6) and 8(7)
8(6)	8.3.1. Effects on bees	EFSA: Note that, at the present stage, any form of risk assessment/ scientific justification was not presented. It's, therefore, not possible to conclude on the risk to bees. However, taking into consideration the representative use (application in mulch) it is considered that the exposure to bees can be considered low.	EFSA: Some form of risk assessment and or a scientific justification should be submitted in order to demonstrate a low risk to bees. The assessment should consider the risk from the BS when used according to the GAP. The applicant may wish to include in the BSA document clear details on the method of application together with (in case it's deemed relevant) a justification for the low exposure of bees.	Nettle extract does not show any bee toxicity. Pohorecka 2004 Components like acids are used commonly in beehives. Further, Nettle used in mulch won't be in contact with bees and not intended for spray on crops.	Not enough information was available to perform a quantitative/qualitative risk assessment for bees to *Urtica* spp. However, it is considered that the exposure to the basic substance when applied according to the representative uses (i.e., mixed with mulch) would be low. Therefore, a low risk can be concluded.
8(7)	8.3.2. Effects on other arthropods	EFSA: Note that, at the present stage, any form of risk assessment/ scientific justification was not presented. It's, therefore, not possible to conclude on the risk to non-target arthropods other than bees.	EFSA: Some form of risk assessment and or a scientific justification should be submitted in order to demonstrate a low risk to NTAs other than bees. The assessment should consider the risk from the BS when used according to the GAP.	Nettle as leaves is not used in different situation for non-target than usual plant natural spills. Regarding amounts per ha and small targeted areas we believe that assessment is not relevant and would not end-up	Data gap: No quantitative/qualitative risk assessment was performed. The basic substance *Urtica* spp. is reported to have insecticidal properties. The exposure to ground dwelling arthropods cannot be excluded when

8.3. Effects on bees and other arthropods species					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		Note that Nettle has insecticidal effect (see Gaspari *et al.*, 2007).		with risk. Again no spray on crop is developed in this application.	the basic substance is applied according to the representative uses (i.e., mixed with mulch). Overall, a low in-field risk cannot be concluded for ground dwelling arthropods.
8(8)	8.3.1 Effects on other arthropods	EFSA: Please include a more detailed study summary of Gaspari *et al.* (2007).	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to non-target arthropods.	Gaspari et al. (2007) are direct spray on crops largely different from our static uses.	See 8(7)

8.4. Effects on earthworms and other soil macro-organisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(9)	8.4. Effects on earthworms and other soil macro-organisms	EFSA: No information has been provided to perform a risk assessment for earthworms.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to earthworms.	Nettle is considered as weed for some people, although included in Pharmacopeia. Described uses are not different from natural decomposition of this plant.	No quantitative/qualitative risk assessment was provided. Taking into account the nature of the substance and the representative uses a low risk to soil organisms can be concluded. See also 8(7)

8.5. Effects on soil micro-organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(10)	8.4. Effects on earthworms and other soil macro-organisms	EFSA: No information has been provided to perform a risk assessment for soil macro-organisms.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to soil macro-organisms.	Nettle leaves are part of natural plant or weed, decomposition of this plant part is not considered as dangerous for environment and non-target macro-organisms.	See 8(9)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)	8.6 Effects on other non-target organisms	EFSA: No information has been provided to perform a risk assessment for non-target plants. However, taking into consideration the representative use (application in mulch) it is considered that the exposure to NTTPs may be considered low.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk to non-target terrestrial plants. The applicant may wish to include in the BSA document clear details on the method of application together with (in case it's deemed relevant) a justification for the low exposure of NTTPs.	Nettle in this application is not intended to be sprayed on crops. This application is not different from natural Nettle decomposition in fields as "weed".	No quantitative/qualitative risk assessment was provided. Taking into account the nature of the substance and the representative uses a low risk to NTTPs can be concluded.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(12)	8.7 Effects on biological methods of sewage treatment	EFSA: No information has been provided to perform a risk assessment for organisms involved in the sewage treatment.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk for organisms involved in the sewage treatment.	Although Mulch is intended to be recycled, nettle leaves may be left on place to serve as further fertilizer. Nettle dispersion is not different from natural plant spilling.	No quantitative/qualitative risk assessment was provided. Taking into account the nature of the substance and the representative uses a low risk to organisms involved in the sewage treatment can be concluded. See also 8(7)

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

NL: No comments.

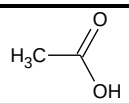
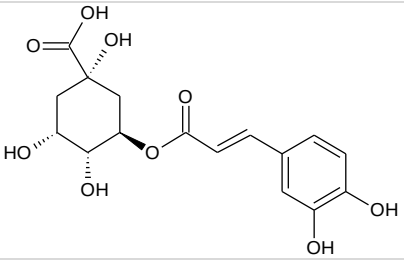
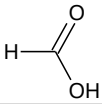
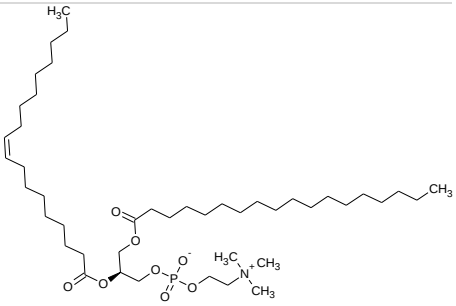
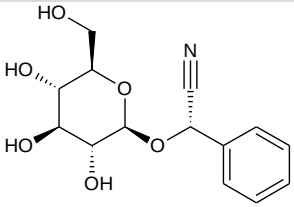
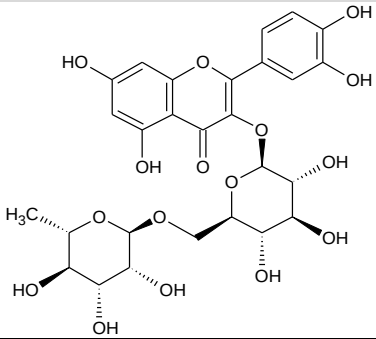
Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)	Section 9, page 53	UK: The UK does not believe this substance fits the definition of substance of no concern – specifically Article 23 (a) Regulation 1107/2009 is not met.		Nettle use as describe in the GAP table is not a substance of concern. Although nettle urticates, it is either eaten raw in salad or used as extract (soup) for centuries. At this stage a little common sense is required. Eating raw potatoes is dangerous, deadly-even, but overall consumption of megatons of potatoes do not kill so many people over the world!	A number of data gaps have been identified with respect to identity, impact on human and animal health, and the environmental risk assessment of *Urtica* spp. extract (including exposure and hazard characterisation) that do not allow concluding on the safety of the uses proposed.

10. Other comments

Other comments					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
10(1)		NL: No comments.			Addressed

Appendix C – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
acetic acid	acetic acid CC(=O)O	
chlorogenic acid	(1*S*,3*R*,4*R*,5*R*)-3-{[(2*E*)-3-(3,4-dihydroxyphenyl)prop-2-enoyl]oxy}-1,4,5-trihydroxycyclohexanecarboxylic acid O[C@@H]2[C@H](O)C[C@](O)(C[C@H]2OC(=O)/C=C/c1ccc(O)c(O)c1)C(=O)O	
formic acid	formic acid O=CO	
lecithin	(2*S*)-2-[(9*Z*)-octadec-9-enoyloxy]-3-(stearoyloxy)propyl 2-(trimethylammonio)ethyl phosphate C[N+](C)(C)CCOP([O-])(=O)OC[C@H](COC(=O)CCCCCCCCCCCCCCCCC)OC(=O)CCCCCCC/C=C\CCCCCCCC	
L-prunasin	(2*S*)-(β-D-glucopyranosyloxy)(phenyl)acetonitrile N#C[C@@H](O[C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)c2ccccc2	
rutin	2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4-oxo-4*H*-chromen-3-yl 6-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranoside Oc1ccc(cc1O)C=4Oc5cc(O)cc(O)c5C(=O)C=4O[C@@H]3O[C@H](CO[C@@H]2O[C@@H](C)[C@H](O)[C@@H](O)[C@H]2O)[C@@H](O)[C@H](O)[C@H]3O	

Appendix D – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture
Chemical name (CA)	Not relevant, the substance is a complex mixture
Common names	Nettle, nettle aqueous extract nettle leaf/herb
CAS No	84012-40-8 (*Urtica dioica* extract) 90131-83-2 (*Urtica urens* extract)
CIPAC No and EEC No	Not available
FAO specification	Not available
Minimum purity	Not relevant Purity is depending on the origin
Relevant impurities	None
Molecular mass and structural formula	Not relevant, the substance is a complex mixture
Mode of Use	Spray applications Soil covering (mulch)
Preparation to be used	Suspension concentrate (SC) Dispersible concentrate (SC) Dry aerial part left in the rain and added to mulch (data gap)
Function of plant protection	Insecticide, acaricide, fungicide

Appendix E – List of uses

Applicant: Institut Technique de l'Agriculture Biologique (ITAB)
Uses against insects

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc ofa.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	g a.i./ha min max (g/ha) (l)		
Fruit trees Apple tree *Malusdomestica*, Plum tree *Prunusdomestica*, Peach tree *Prunuspersica*, redcurrant *Ribesrubrum,* Walnut tree*Juglans sp.,* Cherry tree *Prunus sp.*	Proposed by France All member states	Nettle extract	F	peach-potato aphid *Myzuspersicae*, *Macrosiphum rosae,* wolly apple aphid *Eriosoma Lanigerum,* Currant aphid *Cryptomyzusribis,* Walnut aphid *Callaphisjuglandis,* Black cherry aphid *Myzuscerasi*	Dispersible Concentrate (DC)	Up to 75 g/L (fresh nettle) Or 15 g/L (dry matter) Filtration	Foliar spraying or Shoot spraying Directly on aphids	Spring Summer until BBCH87 (fruit ripe for picking)	1 to 5	Min. 7 days Commonly 15 days	1500 g/hl (dry matter)	300 to 900 l/ha	4500 to 13500 g/ha	1500 to 67500 g/ha	none	Preventive treatment is inefficient 24h of maceration at 20°C is enough
Bean, for example french bean *Phaseolus vulgaris*				Black bean aphid *Aphis fabae*				Spring Summer until BBCH89 (fully ripe)				300 to 500 l/ha	4500 to 7500 g/ha	4500 to 37500 g/ha		
Potato *Solanumtuberosum*			F	Peach-potato aphid *Myzuspersicae*				Spring Summer until BBCH49 (end of tuber formation)				300 to 500 l/ha	4500 to 10000 g/ha	1500 to 60000 g/ha		

Leaf Vegetables: Lettuce*Lactuca sativa*, Cabbage *Brassica olaeraceae*	Proposed by France All member states	Nettle extract	F	Aphids, for example: cabbage aphid *Brevicorynebrassicae, Nazonoviaribisnigri*	Dispersible Concentrate (DC)	Up to 75 g/L (fresh nettle) Or 15 g/L (dry matter) Filtration	Foliar spraying or Shoot spraying Directly on aphids	Spring Summer until BBCH19 (9 or more true leaves unfolded)	1 to 5	Min. 7 days Commonly 15 days	1500 g/hl (dry matter)	300 to 500 l/ha	4500 to 7500 g/ha	4500 to 37500 g/ha	none	Preventive treatment is inefficient 24h of maceration at 20°C is enough
Elder tree *Sambucusracemosa*				Elder aphid *Aphis sambuci*				Spring Summer				400 to 800 l/ha	6000 to 12000 g/ha	6000 to 60000 g/ha		
Rose *Rosa sp.*				Rose aphid *Macrosyphumrosae*								300 to 600 l/ha	4500 to 9000 g/ha	4500 to 45000 g/ha		
Spiraea sp.				*Aphis spiraephaga*												
Brassicaceae (cabbage *Brassica olaeraceae*, Rapeseed *Brassica napus*, Radish *Raphanussativus*)				fleabeetle *Phyllotretanemorum,*			Foliar spraying	Spring Summer until BBCH19 (9 or more true leaves unfolded)	1 to 6	Min. 7 days Commonly 15 days		300 to 500 l/ha	4500 to 10000 g/ha	4500 to 60000 g/ha		-
				diamondbackmoth *Plutellaxylostella*				Spring Summer until BBCH49 (typical leaf mass reached)	1 to 6	Min. 7 days Commonly 15 days		300 to 500 l/ha	4500 to 10000 g/ha	4500 to 60000 g/ha		-
Apple tree *Malusdomestica* Peer tree *Pyruscommunis*				Codlingmoth *Cydiapomonella*				2 Treatments in April, 1 treatment in May	3	15 days		300 to 900 l/ha	4500 to 13500 g/ha	13500 to 40500 g/ha		-

NB: the quantities of fresh nettle (or dry matter) (a.i.) written represents the quantities of nettle used in the recipe, but not the quantities that are effectively put in field – there is a filtration before.

Uses against acarids

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc ofa.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max	Water l/ha min max	g a.i./ha min max (l)	g a.i./ha min max (l)		
Bean, for example french bean *Phaseolus vulgaris*	Proposed by France All member states	Nettle extract	F	two-spotted spider mite *Tetranychusurticae*	Dispersible Concentrate (DC)	Up to 75 /L (fresh nettle) Or 15 g/L (dry matter) Filtration	Foliar spraying	Spring Summer until BBCH89 (fully ripe)	1 to 6 (commonly 3)	7 to 21 days (Commonly two or three weeks)	1500 g/hl (dry matter)	300 to 500 l/ha	4500 to 7500 g/ha	4500 to 45000 g/ha	none	24h of maceration at 20°C is enough
Grapevine *Vitisvinfera*				two-spotted spider mite *Tetranychusurticae* Red spider mite *Tetranychustelarius*				Spring Summer until BBCH89 stage	1 to 6 (three before flowering, three after flowering)			300 to 600 l/ha	4500 to 9000 g/ha	4500 to 54000 g/ha		

NB: the quantities of fresh nettle (or dry matter) (a.i.) written represents the quantities of nettle used in the recipe, but not the quantities that are effectively put in field – there is a filtration before.

Uses against fungi

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc ofa.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max	Water l/ha min max	g a.i./ha min max (l)	g a.i./ha min max (l)		
Brassicaceae (mustard family *Brassica sp*, *Sinapissp*, radish *Raphanussativus)*	Proposed by France All member states	Nettle extract	F	*Alternariasp*	Dispersible Concentrate (DC)	Up to 75 /L (fresh nettle) Or 15 g/L (dry matter) Filtration	Foliar spraying	Spring Summer until BBCH49 (typical leaf mass reached)	1 to 6	7 days – 15 days	1500 g/hl (based on dry matter)	300 to 500 l/ha	4500 to 7500 g/ha	4500 to 45000 g/ha	none	-
Cucurbitacea (cucumber *Cucumissativus)*				Powderymildew*Erysiphepolygoni, Alternaria alternata f. sp.cucurbitae*			Foliar spraying	until BBCH89 (typical fully ripe colour)				300 to 500 l/ha	4500 to 7500 g/ha	4500 to 45000 g/ha		
Fruit trees (Apple trees *Malusdomestica*, Plum trees *Prunusdomestica*, Peach trees *Prunuspersica*, Sweet cherry tree *Prunusavium*				Leaf spot *Alternariaalternata*, Brown Rot Blossom Blight *Monilinialaxa*, *Botrytis cinerea*,black bread mold*Rhizopusstolonifer*			Foliar and Fruit spraying	Spring Summer until BBCH87 (fruit ripe for picking)				300 to 900 l/ha	4500 to 13500 g/ha	4500 to 81000 g/ha		
Grapevine *Vitisvinfera*	Proposed by France	Nettle extract	F	Mildew *Plasmoparaviticola*	Dispersible Concentrate (DC)	Up to 75 /L (fresh nettle) Or	Foliar spraying	Spring Summer until BBCH89 stage	1 to 6	7 to 15 days	1500 g/hl (dry matter)	300 to 600 l/ha	4500 to 9000 g/ha	4500 to 54000 g/ha	none	

Potato *Solanumtuberosum*	All member states			Potato blight *Phytophthorainfestans*		15 g/L (dry matter) Filtration		Spring Summer until BBCH49 (end of tuber formation)				300 to 500 l/ha	4500 to 7500 g/ha	4500 to 45000 g/ha		

NB: the quantities of fresh nettle (or dry matter) (a.i.) written represents the quantities of nettle used in the recipe, but not the quantities that are effectively put in field – there is a filtration before.

*** e.g. The product cannot be applied in case of hot temperature. It is used in case of rainy period**
**** e.g. The product is a plant homogenate extracted with hot water and filtered (decoction)**

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

Applicant: Myosotis
Uses against fungi

Crop and/or situation (a)	Member State	Example product name as available on the market	F G I (b)	Target (c)	Product		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth Stage and season** (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (kg/hl)	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Cucumber roots *Cucumis sativus*	France (MS) Not relevant	*Nettle (i.e. aerial parts of stinging nettle*	G/F	Powdery mildews *Podosphaera xhantii* Root fungi like common root rot seedling blight *Pythium* spp.	Dry (D) ***	83	Included in mulch	Not relevant	1	-	-	-	15	15	Not relevant	Dry Plant aerial parts
Tomato *Lycopersicum esculentum*			F	Early blight *Alternaria solani* Septoria blight *Septoria lycopersici*												
Ornamental trees uses of which *Prunus spp.* Roses *Rosa spp.*			F/G	Ornamental Cryptogramic diseases Rose Black spot *Marsonia spp.* Rose rust *Phragmidium mucronatum* Leaf curl diseases, Monilioses, Oidium and Mildew												

*** **The product is mixed/included in mulch**

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(m) PHI - minimum pre-harvest interval