



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance

Urtica spp.

SANTE/11809/2016– rev. 0.1

24 January 2017

Final Review report for the basic substance *Urtica* spp.

Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on
24 January 2017

in view of the approval of *Urtica* spp. as basic substance in accordance with Regulation (EC)
No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Urtica* spp. made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 18 August 2015 an application from Institut Technique de l'Agriculture Biologique (ITAB), hereafter referred to as the applicant, for the approval of the substance *Urtica* spp. as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application.

In addition, the Commission received on 5 January 2016 an application from Myosotis for the approval of Nettle as a basic substance. Considering that this application also regards *Urtica* spp., but with a different proposed use, the Commission merged the assessment of both applications.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the applications to EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for *Urtica* spp. on 28 July 2016³.

The Commission examined the applications, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 24 January 2017.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2017/419**⁴ concerning the approval of *Urtica* spp. as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of *Urtica* spp. as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

³ European Food Safety Authority, 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, fungicide and acaricide. EFSA supporting publication 2016:EN-1075. 72 pp.

⁴ OJ L 64, 10.3.2017, p. 4–6.

⁵ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that *Urtica* spp. fulfils the criteria of Article 23.

Urtica spp. fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA conclusions on the basic substance application for *Urtica* spp., the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of *Urtica* spp. would not lead to concerns for human health. Furthermore, the conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

Urtica spp. does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation (EC) No 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water (depending on the intended use). Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicants and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

The following points were considered as open by EFSA (2016) for *Urtica* spp, reasons follow to explain why the risk is considered negligible:

Chapter 5: Impact on human and animal health

- *Regarding the impact on human and animal health, there is evidence that Urtica spp. may have to be classified as a skin sensitizer and eye irritant;*

The EFSA technical report refers to one notification for classification by third parties for *Urtica dioica* as skin sensitizer and eye irritant. However, the majority of notifications do not classify *Urtica dioica* as such. Moreover, there is no harmonized classification according to Regulation 1272/2008.

- *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 harmonized classification according to Regulation 1272/2008 is available.*

The notification for classification as Repr 1B for *Urtica urens* referred to was done by a third party and has not yet been assessed by the European Chemicals Agency. According to the EFSA technical report, it does not seem to be supported with toxicological information. Moreover, the review of the European Medicines Agency on *Urtica urens* states that no information on reproductive toxicity was available⁶. Since no harmonized classification according to Regulation 1272/2008 is available and no classification is proposed by EFSA, there is insufficient indication that the notification indicates an actual concern that would preclude an approval.

- *It is also unknown whether harmful components may be formed during the fermentation process.*

Urtica spp. and their extracts are used as a foodstuff and as a traditional medicine. Diluted fermented steepings of *Urtica* spp. have an extended history of use as a liquid foliar fertiliser. No reports are available to indicate that diluted steepings of *Urtica* extracts contain harmful components at such levels that have an adverse effect on human or animal health. However, there are reports indicating that unhygienic conditions may lead to contamination with and growth of pathogenic organisms, such as *E. coli*, during the steeping process. This constitutes a food safety risk when the liquid is sprayed on edible parts of the crop. Good hygienic practices and quality control in accordance with Regulation (EC) No 852/2004⁷ must be applied to prevent such contamination of the extract and subsequently potentially of the harvested produce (see also chapter 5).

Chapter 8: Effects on non-target organisms

- *Due to potential insecticidal activity of *Urtica* spp. and considering the available information, it was not possible to exclude a high risk to soil dwelling arthropods.*

Urtica spp. are ubiquitous weeds that die off at the end of the growing season, leaving the plant's remains on the soil. There are no reports of detrimental effects on the environment of such remains and substances leeching from such remains. Therefore, it is unlikely that a mulch or a diluted steeping of *Urtica* spp. would have an unacceptable risk to soil dwelling arthropods and it is concluded that this risk is negligible.

4. Identity and biological properties

The main properties of *Urtica* spp. are given in Appendix I.

It has been established that for *Urtica* spp. as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

⁶ European Medicines Agency, Assessment report on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix, 24 September 2012, EMA/HMPC/461156/2008.

⁷ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs - OJ L 139, 30.4.2004, p. 1.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Urtica* spp.

Urtica spp. must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being an insecticide, fungicide and acaricide are approved.

Use of *Urtica* spp. must be in compliance with conditions specified in the Appendixes I and II of this review report.

The producer of the *Urtica* spp. fermented extract shall maintain good hygienic and environmental conditions and maintain quality control (e.g. use of sterilized container and tools, use of clean and washed *Urtica* leaves, use of potable water, container should be closed with a tight lid and stored inside, pH testing, testing for the presence of harmful microorganisms such as *E. coli* and *Salmonella* etc.) to prevent microbial contamination of the fermented *Urtica* spp. extract. The producer shall take all necessary measures in accordance with Regulation (EC) No 852/2004 to prevent contamination of the harvested produce with pathogenic microorganisms.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for *Urtica* spp. in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

URTICA SPP.

Common name	<i>Urtica</i> spp., nettle, nettle aqueous extract, nettle leaf/herb
Chemical name (IUPAC)	Not applicable
Chemical Name. (CA)	Not applicable
CAS No	84012-40-8 (<i>Urtica dioica</i> extract) 90131-83-2 (<i>Urtica urens</i> extract)
CIPAC No and EEC No	Not applicable
FAO SPECIFICATION	Not available
Purity	European Pharmacopeia
Molecular formula	Not relevant, the substance is a complex mixture
Relevant impurities	Not applicable
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	<p>For spray applications:</p> <ol style="list-style-type: none"> 1. Steep fresh (75 gr/L) or dry (15 gr/L) nettle leaves (choose young shoots not gone to seeds; clean and washed) in potable water. The fermentation can be facilitated if nettle is previously chopped. 2. Stir the mix daily. 3. Let macerate 3 to 4 days at 20°C (unless otherwise indicated in Appendix II). 4. Filter maceration and dilute the filtrate in 5 times its volume of potable water in a closed and identified container. <p>Make sure that the pH is around 6 to 6.5 to assure of a good fabrication.</p> <p>The producer of the <i>Urtica</i> spp. fermented extract shall maintain good hygienic and environmental conditions and maintain quality control (e.g. use of sterilized container and tools, use of clean and washed <i>Urtica</i> leaves, use of potable water, container should be closed with a tight lid and stored inside, pH testing, testing for the presence of harmful organisms such as <i>E. coli</i> and <i>Salmonella</i> etc.) to prevent contamination of the fermented <i>Urtica</i> spp. extract with pathogenic microorganisms.</p> <p>The grower shall take all necessary measures in accordance with Regulation (EC) No 852/2004 to prevent contamination of the harvested produce with pathogenic microorganisms.</p> <p>For mulch applications:</p> <p>Mix dry plant material (aerial part) with mulch at 83g per kg of mulch.</p>
Function of plant protection	Insecticide, fungicide, acaricide.

APPENDIX II

List of uses supported by available data *URTICA SPP.*

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	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*, **)	
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max				g a.i./ha min max (g/ha) (l)
Fruit trees Apple tree <i>Malusdomestica</i> , Plum tree <i>Prunusdomestica</i> , Peach tree <i>Prunuspersica</i> , redcurrant <i>Ribesrubrum</i> , Walnut tree <i>Juglans sp.</i> , Cherry tree <i>Prunus sp.</i>	Proposed by France All member states	Nettle extract	F	peach-potato aphid <i>Myzuspersicae</i> , <i>Macrosiphum rosae</i> , woolly apple aphid <i>Eriosoma Lanigerum</i> , Currant aphid <i>Cryptomyzusribis</i> , Walnut aphid <i>Callaphisjuglandis</i> , Black cherry aphid <i>Myzuscerasi</i>	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	4500 to 67500 g/ha	7 days	Preventive treatment is inefficient 24h of maceration at 20°C is enough
Bean, for example french bean <i>Phaseolus vulgaris</i>				Black bean aphid <i>Aphis fabae</i>				Spring Summer until BBCH89 (fully ripe)				300 to 500 l/ha	4500 to 7500 g/ha	4500 to 37500 g/ha		
Potato <i>Solanumtuberosum</i>			F	Peach-potato aphid <i>Myzuspersicae</i>				Spring Summer until BBCH49 (end of tuber formation)				300 to 500 l/ha	4500 to 10000 g/ha	4500 to 50000 g/ha		

Uses against acarids

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*, **)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max	Water l/ha min max	g a.i./ha min max (l)			
Bean, for example french bean <i>Phaseolus vulgaris</i>	Proposed by France All member states	Nettle extract	F	two-spotted spider mite <i>Tetranychusurticae</i>	Dispersible Concentrate (DC)	Up to 75 /L (fresh nettle) Or 15 g/L (dry matter)	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	7	24h of maceration at 20°C is enough
Grapevine <i>Vitisvinifera</i>				two-spotted spider mite <i>Tetranychusurticae</i> Red spider mite <i>Tetranychustelarius</i>				Filtration	Spring Summer until BBCH89 stage			1 to 6 (three before flowering, three after flowering)	300 to 600 l/ha	4500 to 9000 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	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max	Water l/ha min max	g a.i./ha min max (l)			
Brassicaceae (mustard family <i>Brassica sp</i> , <i>Sinapis sp</i> , radish <i>Raphanussativus</i>)	Proposed by France All member states	Nettle extract	F	<i>Alternariasp</i>	Dispersible Concentrate (DC)	Up to 75 /L (fresh nettle) Or 15 g/L (dry matter)	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	7	-
Cucurbitacea (cucumber <i>Cucumissativus</i>)				Powdery mildew <i>Erysiphe polygoni</i> , <i>Alternaria alternata f. sp. cucurbitae</i>			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 <i>Malus domestica</i> , Plum trees <i>Prunus domestica</i> , Peach trees <i>Prunus persica</i> , Sweet cherry tree <i>Prunus avium</i>)				Leaf spot <i>Alternaria alternata</i> , Brown Rot Blossom Blight <i>Monilinia laxa</i> , <i>Botrytis cinerea</i> , black bread mold <i>Rhizopus stolonifer</i>			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 <i>Vitis vinifera</i>	Proposed by France	Nettle extract	F	Mildew <i>Plasmopara viticola</i>	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	7	

Potato <i>Solanumtuberosu</i> <i>m</i>	All member states		Potato blight <i>Phytophthorainfestans</i>	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	
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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.

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| <p>* For uses where the column „Remarks. As above or other conditions to take into account</p> <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor</p> <p>(d) e.g. wettablepowder (WP), emulsifiableconcentrate (EC), granule (GR) etc..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p> | <p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
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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 <i>Cucumis sativus</i>	France (MS) Not relevant	<i>Nettle (i.e. aerial parts of stinging nettle)</i>	G/F	Powdery mildews <i>Podosphaera xanthii</i> Root fungi like common root rot seedling blight <i>Pythium</i> spp.	Dry (D) ***	83	Included in mulch	Not relevant	1	-	-	-	15	15	Not relevant	Dry Plant aerial parts
Tomato <i>Lycopersicon esculentum</i>			F	Early blight <i>Alternaria solani</i> Septoria blight <i>Septoria lycopersici</i>												
Ornamental trees uses of which <i>Prunus</i> spp. Roses <i>Rosa</i> spp.			F/G	Ornamental Cryptogamic diseases Rose Black spot <i>Marsonia</i> spp. Rose rust <i>Phragmidium mucronatum</i> Leaf curl diseases, Monilioses, Oidium and Mildew												
<p>*** The product is mixed/included in mulch</p> <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p>								<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>								