Basic Substance vinegar SANCO/12896/2014– rev. 3 13 December 2018

Final Review report for the basic substance vinegar

Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 29 May 2015 and amended on 13 December 2018 in view of the approval of vinegar as basic substance in accordance with Regulation (EC)

No 1107/2009¹

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of vinegar 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 24 April 2013 an application from ITAB, hereafter referred to as the applicant, for the approval of the substance vinegar as basic substance. On 17 March 2014 an application from the city of Paris (France) was received to extend the intended uses of the application for the approval of vinegar 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, which was finalised in the new version of February 2014.

In 2016, the Commission also received from Charbonneaux-Brabant SA an application for the extension of use of vinegar as herbicide in non-agricultural areas and for medicinal aromatic and perfume crops. In May 2017, the Commission asked EFSA to organise a consultation on the basic substance application for the extension of use of vinegar as a herbicide.

For both the original request and the request for extension, 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 application to EFSA, who delivered its views on the specific points raised in the commenting phase.

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Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European 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 vinegar on 12 August 2014³ and - for the extension of use as a herbicide - on 4 August 2017⁴.

For both requests, the Commission examined the applications, the comments by Member States and EFSA and the EFSA Technical reports on the substance together with the additional information and comments provided on it by the applicants, before finalising a draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed (afterwards "Standing Committee") for examination. The draft review report was finalised in the meeting of the Standing Committee on 29 May 2015 and amended on 13 December 2018.

The present review report contains the conclusions of the final examinations by the Standing Committee. Given the importance of the EFSA technical report(s), 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) 2015/1108⁵, as amended by Commission Implementing Regulation (EU) 2019/149⁶ concerning the approval of vinegar 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 178/2002⁷, in particular with respect to the responsibility of operators, following the approval of vinegar 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 Reports 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

European Food Safety Authority, 2014; Outcome of the consultation with Member States and EFSA on the basic substance application for vinegar and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2014:EN-641. 37 pp.

EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for vinegar for extension of use in plant a herbicide. EFSA supporting publication 20 17: EN - 1281. protection as doi:10.2903/sp.efsa.20 17 .EN – 1281.

OJ L 181, 9.7.2015, p. 75–77.

OJ L 27, 31.1.2019, p. 20-22.

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.

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. 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 vinegar fulfils the criteria of Article 23.

Vinegar fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA Technical Report from 2014 on the basic substance application for vinegar, 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 vinegar under these conditions would not lead to concerns for human health. Furthermore, no residues are expected as the conditions of use are not expected to lead to the presence of residues in food or feed commodities at harvest.

Vinegar could be regarded as a substance of concern considering the inhalation toxicity in humans of the acetic acid contained in vinegar. However, under the proposed conditions of use, it is considered unlikely that relevant effects via inhalation could realistically occur. Vinegar does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immune-toxic 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. Finally, it is not placed on the market as a plant protection product but available as food.

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 applicant 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 risk for leaching to groundwater and the risk to birds, mammals and carbon mineralisation processes in soils was considered as open by EFSA (2014) for vinegar, however, the risk is considered small or negligible as vinegar is a natural fermentation product which is commonly used as a food. Furthermore most of the intended use rates, as described in Appendix II, are very low.

Considering the EFSA technical report from 2017 on the basic substance application for vinegar for the extension of use as a herbicide for medicinal aromatic and perfume crops, for which the corresponding rates of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of vinegar would not lead to concerns for human health. Under the proposed rate of application for this use (10kg /ha of acetic acid),

relevant effects via inhalation are considered unlikely. The risk for leaching to groundwater and the risk to birds, mammals, aquatic organisms, bees, non-target arthropods and non-target terrestrial plants was considered as open by EFSA for vinegar, however, the risk is considered small or negligible as vinegar is a natural fermentation product which is commonly used as food. Furthermore the intended use rate, as described in Appendix II, is very low.

However, such is not the case for the use applied for in non-agricultural areas. Therefore, the use of vinegar as herbicide on non-agricultural areas is not approved due to the inhalation risks and the eco-toxicological risks.

4. Identity and biological properties

The main properties of vinegar are given in Appendix I.

The active substance shall have a purity as food grade containing a maximum of 10% acetic acid.

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

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

Vinegar 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:

- Uses as basic substance being a fungicide, bactericide are approved;
- Uses as basic substance being a herbicide is approved. To note however that, due to its unspecific phytotoxic effects, fresh vinegar residues may kill the young crop plants.

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

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

The identification of vinegar as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies.

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 vinegar 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

VINEGAR

Common name	Vinegar
Chemical name (IUPAC)	Not applicable.
Chemical Name. (CA)	Vinegar, ext.
CAS No	90132-02-8
CIPAC No and EEC No	290-419-7
FAO SPECIFICATION	Not available.
Purity	Food grade containing a maximum of 10% acetic acid
Molecular formula	Not applicable.
Relevant impurities	Not applicable.
Molecular mass and structural formula	Not applicable.
Mode of Use	Vinegar as specified above to be used in cold water solution for application as seed treatment in various crops or as disinfectant of mechanical cutting tools as listed in Appendix II. Vinegar as specified above to be used in spray applications as a herbicide on medicinal aromatic and perfume crops.
Preparation to be used	Vinegar to be diluted in compliance with rate of application reported in Appendix II. Undiluted for uses as herbicide
Function of plant protection	Fungicide, bactericide and herbicide

APPENDIX II

VINEGAR

			Product			Applica	tion		Applica	ation rate per t			
Crop and/or situation (a)	F G I (b)	Target (c)	Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season**	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)	PHI (days) (m)	Remarks (*)
Wheat seeds Triticum vulgare Common wheat Triticum aestivum Durum wheat Triticum durum Spelt Triticum spelta		fungi like Common bunt: Tilletia caries Tilletia foetida	Liquid	25- 50*	Seed treatment just before seeding	Autumn		None	25-50* per 100 kg of Seed	Not applicable	24-100* [‡]	None:	
Barley seeds Hordeum vulgare	F	fungi like Barley leaf stripe Pyrenophora graminea	for Seed Treatment (LS)				1					Not applicable Seed treatment	
Market vegetables Gardening like carrot Daucus carota tomato Solanum lycopersicum bell pepper Capsicum spp		fungi like Alternaria: Alternaria spp				Autumn to spring			Seeds are temporary soaked in the dilution then removed	Not applicable	Seeds are temporary soaked in the preparation then removed		
Market vegetables gardening like tomato Solanum lycopersicum bell pepper Capsicum spp Cabbage Brassica oleracea	F G	Clavibacter Michiganensis Clavibacter Michiganensis subsp. michiganensis Pseudomonas syringae pv. Tomato Xanthomonas	Liquid for Seed Treatment (LS)	25- 50*	Seed treatment just before seeding	Autumn to spring	1	None	Seeds are temporary soaked in the dilution then removed	Not applicable	Seeds are temporary soaked in the dilution then removed	None: Not applicable Seed treatment	

Cron and/or			Product			Applica	tion		Applic	ation rate per t	reatment			
Crop and/or situation (a)	F G I (b)	Target (c)	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)	PHI (days) (m)	Remarks (*)	
		campestris pv. Vesicatoria Botrytis aclada												
White and red chestnut Aesculus L. Sycamore spp (option) Acer spp		Bacteria Pseudomonas syringae pv aesculi	Liquid for disinfection of mechanical cutting tools			None			400	None: Not applicable	None: Not applicable		Waiting period 30 seconds after washing	
Hawthorns (Rosaceae) Crataegus spp. Amelanchir, Aronia, Chaenomeles, Cotoneaster, Cydonia, Malus,Photinia, Potentilla, Prunus, Pyracantha, Prunus, Pyrus, Rosa, Sorbus and Spiraea	F	Fire blight Erwinia amylovora	(LS)		Tools application before		per day					- None:		
Many ornamental plants including Acer, Cotoneaster, Euonymus, Forsythia, Magnolia, Philadelphus, Populus, Prunus, Pyrus, Rosa, Rubus, Syringa and Vaccinium		F	F	/canker Pseudomonas syringae pv. syringae		4**	sawing or cutting		to each time	1 tree				Not applicable
Plane sp, Platanus, Prunus sp, Chestnut sp, Aesculus L. Sophora spp, Linden sp Tilia		rot fungi, especially phellins Phellinus, Tinder polypore and ruffled Fomes fomentarius					before use							
Elm (elm other than Lutèce) <i>Ulmus</i> spp Maple sp, <i>Acer</i> sp.		vascular fungi Ophiostoma spp wilt disease												

	F		Product		Application				Applica	ntion rate per t			
Crop and/or situation (a)	G I (b)	Target (c)	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)	PHI (days) (m)	Remarks (*)
Ailanthe sp <i>Ailanthus</i> altissima		Verticillium spp		ì									
Maple sp, <i>Acer</i> sp.; Sycamore, <i>Acer</i> spp; Chestnut sp, <i>Aesculus</i> L.; Beech sp, <i>Fagus</i> spp.		Sooty-Bark disease Cryptostroma corticale											

^{*} expressed as acetic acid. 1/1 dilution of vinegar/water L/L

- (*) For uses where the column "Remarks. As above or other conditions (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, to take into account
- For crops, the EU and Codex classification (both) should be taken into account; where relevant, the use situation should be described (j) (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 sucking insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e) GCPF Codes GIFAP Technical Monograph N° 2, 1989
- All abbreviations used must be explained
- Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- 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
- (m) PHI minimum pre-harvest interval between the plant type of equipment used must be indicated

^{**} expressed as acetic acid. 50 mL/1 L dilution of vinegar/water for vinegar at 8% acetic acid

[#] Considering 0.9 to 2 qt of seeds per ha.

Uses as a herbicide

Crop and/or	Member	Example product	F		Prod	luct**		Applic	cation		Applicatio	n rate pe	r treatment	Total rate	PHI	
situation (a)	State for use	name as available on the market	G I (b)	Target (c)	Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season**	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) (1)	kg a.i./ha min max (kg/ha) (l)	(days) (m)	Remarks (**)
Medicinal aromatic and perfume crops	All MS	Vinegar	F G	Weeds	Any other liquid (AL)	100*	Spray	Pre crop emergence	1	-	10	100	10	10	> 120	phytotoxic to plant, may kill the young plants

* Of main active substance acetic acid.

** Treatments must be delayed 24-48 hours or more after rain

- to take into account
- For crops, the EU and Codex classification (both) should be taken (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule
- (e) GCPF Codes GIFAP Technical Monograph N° 2, 1989
- All abbreviations used must be explained
- Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- For uses where the column "Remarks. As above or other conditions (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant,
 - (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- into account; where relevant, the use situation should be described (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
 - (m) PHI minimum pre-harvest interval between the plant type of equipment used must be indicated