



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance

vinegar

SANCO/12896/2014– rev. 1

27 March 2015

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

in view of the approval of vinegar 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 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 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.

EFSA submitted to the Commission the results of its work in the form of a technical report for vinegar on 12 August 2014³.

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

³ 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.

The Commission examined the application, 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 on 29 May 2015.

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) 2015/1108**⁴ 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 178/2002⁵, 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 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. 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.

⁴ OJ L 181, 9.7.2015, p. 75–77.

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.

Considering the EFSA conclusions 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 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 (according to the interim criteria in Regulation (EC) No 1107/2009), 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.

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 the intended use rate, as described in Appendix II, is very low.

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:

- Only uses as basic substance being a fungicide or bactericide are approved.

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.
Preparation to be used	Vinegar to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Fungicide and bactericide

APPENDIX II

VINEGAR

Crop and/or situation (a)	F G I (b)	Target (c)	Product		Application				Application rate per treatment			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)		
Wheat seeds <i>Triticum vulgare</i> Common wheat <i>Triticum aestivum</i> Durum wheat <i>Triticum durum</i> Spelt <i>Triticum spelta</i>	F	fungi like Common bunt: <i>Tilletia caries</i> <i>Tilletia foetida</i>	Liquid for Seed Treatment (LS)	25-50*	Seed treatment just before seeding	Autumn	1	None	25-50* per 100 kg of Seed	Not applicable	24-100**	None: Not applicable Seed treatment	
fungi like Barley leaf stripe <i>Pyrenophora graminea</i>		Autumn to spring											
fungi like <i>Alternaria</i> : <i>Alternaria spp</i>		Seeds are temporary soaked in the dilution then removed				Not applicable							
Market vegetables Gardening like carrot <i>Daucus carota</i> tomato <i>Solanum lycopersicum</i> bell pepper <i>Capsicum spp</i>	F G	<i>Clavibacter Michiganensis</i> <i>Clavibacter Michiganensis</i> subsp. <i>michiganensis</i> <i>Pseudomonas syringae</i> pv. <i>Tomato</i> <i>Xanthomonas</i>	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	
Market vegetables gardening like tomato <i>Solanum lycopersicum</i> bell pepper <i>Capsicum spp</i> Cabbage <i>Brassica oleracea</i>													

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

Crop and/or situation (a)	F G I (b)	Target (c)	Product		Application				Application rate per treatment			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)		
<i>Ailanthus sp Ailanthus altissima</i>		<i>Verticillium spp</i>											
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 <i>Cryptostroma corticale</i>											

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

** 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.

- (*) 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 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
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant,
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (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 between the plant – type of equipment used must be indicated