European Food Safety Authority

EFSA supporting publication 2014:EN-641

**TECHNICAL REPORT**

# Outcome of the consultation with Member States and EFSA on the basic substance applications for vinegar as a fungicide and bactericide in seed treatment and for disinfecting mechanical cutting tools[1]

**European Food Safety Authority**[2]

European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for vinegar are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of vinegar as a basic substance. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.



## KEY WORDS

Vinegar, basic substance, application, consultation, plant protection, pesticide

[1] On request from the European Commission, Question No EFSA-Q-2014-00151 and 2014-00377, approved on 31 July 2014.

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## SUMMARY

Vinegar is an active substance for which in accordance with Article 23(3) of Regulation (EC) No 1107/2009 the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance". Regulation (EC) No 1107/2009 introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013 the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of application received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 21 March 2014. EFSA was asked to organize a commenting on the basic substance application for vinegar as a fungicide and bactericide in seed treatment and for disinfecting mechanical cutting tools, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

A consultation on the basic substance application for vinegar, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in November 2013 – January 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days. (To support their responses the applicant provided an updated application that was dated February 2014).

A second application for the extension of the uses for vinegar was submitted and in May 2014 The European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of new application received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 25 May 2014. EFSA was asked to and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

The current report summarises the outcome of the consultation process organised by the EFSA on the basic substance application for vinegar as a fungicide and bactericide in seed treatment and for disinfecting mechanical cutting tools and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Acetic acid is the IUPAC name for the active substance of the product vinegar. There is no ISO common name for this compound. Acetic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. Acetic acid is not predominantly used for plant protection purposes, however it was approved as a herbicide in pome fruit, stone fruit, paths and roads, ornamental trees and shrubs, turf and lawns.

Acetic acid and vinegar, fulfil the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. European and *Codex Alimentarius* Commission standards exist for vinegar. (CL2000/18-EURO, June 2000), (FAO, 2000)

The intended uses as a basic substance are as a fungicide on wheat and barley seed together with vegetable seeds (carrot, tomato, bell pepper), as a bactericide on vegetable seeds (tomato, bell pepper, cabbage) and as a bactericide and fungicide for disinfecting mechanical cutting tools.

Considering the inhalation toxicity effects of acetic acid in humans, vinegar could be considered as a substance of concern. However, under the proposed conditions of use (seed treatment and disinfection of cutting tools) it is considered unlikely that the relevant effects via inhalation could realistically occur.

Having regard to the uses as seed treatment and disinfecting cutting tools, no residues are expected to be present in food or feed commodities at harvest. Moreover, vinegar fulfils the criteria of a foodstuff under Regulation (EC) No 178/2002.

The acetic acid in vinegar has the potential to contaminate groundwater (due to its very low soil adsorption). Groundwater exposure calculations for acetic acid from the requested uses of vinegar as a seed treatment are not available. The potential for groundwater exposure consequent to the seed treatment uses requested remains open. The legal parametric limit of 0.1µg/L applied for the assessment of groundwater exposure is applicable for acetic acid. For the use of disinfecting mechanical cutting tools used in plant production, the potential for groundwater exposure might be expected to be negligible, provided that the disposal of excess treatment solution is effectively managed.
Information was not provided that might be used for an environmental exposure assessment of the components of vinegar, except for the major component acetic acid.

The available ecotoxicological risk assessments are not considered sufficient to address the risk to birds, wild mammals and carbon mineralisation processes in soil for the representative outdoor uses. The risk to aquatic organisms, honey bees, non-target arthropods, earthworms, soil nitrification processes, non-target terrestrial plants and sewage treatment organisms was indicated as low. A low risk to all groups of non-target organisms was indicated for the representative indoor uses.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as "basic" and used for plant protection purposes.

Vinegar is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance".

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for vinegar as a fungicide and bactericide in seed treatment and for disinfecting mechanical cutting tools, which was conducted via a written procedure in November 2013 – January 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

A second application for the extension of the uses for vinegar was submitted and in May 2014 The European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of new application received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 25 May 2014. EFSA was asked to and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance applications for vinegar as a fungicide and bactericide in seed treatment and for disinfecting mechanical cutting tools and to present EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The application and, where relevant, any update thereof submitted by the applicant for approval of vinegar as a "basic substance" in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2013 and ITAB, 2014).

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 27 May 2014, EFSA was asked to organise a commenting on the basic substance application for vinegar, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table.

To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. The agreed deadline for providing the finalised report is 31 July 2014.

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

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.

## EVALUATION

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

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

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

## DOCUMENTATION PROVIDED TO EFSA

1. ITAB (Institut Technique de l'Agriculture Biologique), 2013. Vinegar. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2013. Submitted by ITAB (Institut Technique de l'Agriculture Biologique). Documentation made available to EFSA by the European Commission.

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

3. Direction des Espaces Verts et de l'Environnement Ville de Paris, 2014 ; Vinegar . Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2014. Submitted by Direction des Espaces Verts et de l'Environnement Ville de Paris. Document

## REFERENCES

EFSA (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

FAO WHO 1987 *Codex Alimentarius* Commission, ALINORM 87/19 APPENDIX II DRAFT EUROPEAN REGIONAL STANDARD FOR VINEGAR p 34-38

FAO WHO 2000 *Codex Alimentarius* Commission, CL 2000/18-EURO, Proposed DRAFT revised REGIONAL STANDARD FOR VINEGAR p 1-5

## APPENDIX

## COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR VINEGAR AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED

### 1. Purpose of the application

| General | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 1(1) | General | DE: Vinegar is irritating to skin and eyes (both Cat 2, H319). It has to be discussed, whether or not criteria set in §23 (d) of the Reg. 1107/2009 are met.<br>(see DE comment 4(1)) | Recipe changed: 10-20% acetic acid vinegar supressed, not representative of major vinegar sales. | See comment 4(1)<br>See also comment 1(2) |
| 1(2) | General | DE: Acetic acid is already approved as an active substance. It is therefore questionable if vinegar – essentially a solution of acetic acid in water – can additionally be approved and if criteria set especially in §23 (d) of the Reg. 1107/2009 are met. It could set a problematic precedence for the concept of an active substance in general. | Vinegar is food product [90132-02-8]<br>Acetic acid [64-19-7] is a synthetic compound derived from oxidation of ethanol. | Article 23 of Reg. 1107/2009[4] says:<br>'d) is not placed on the market as a plant protection product'<br>Acetic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.<br>However, acetic acid, as vinegar, fulfills the criteria of a 'foodstuff' as defined in |

[4] 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 No L 309, 24.11.2009, p. 1-50.

| General | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | | | Article 2 of Regulation (EC) No 178/2002. |
| 1(3) | | DE: Considering that the fungicidal (and bactericidal) activity of the substance vinegar is mainly attributed to the acetic acid which again has currently been regulated as an active substance it seems inconsistent to regulate vinegar as a basic substance. It could also be argued that vinegar basically represents ´dilution´ of naturally synthesised acetic acid. For both, the synthetically and the naturally produced acetic acid the same reasoning is true that it is not predominantly used for plant protection purposes. For the reason of consistency we would rather propose for vinegar a regulation as plant protection product as it also is done for other active substances of plant origin. As for botanical there is still the possibility to waive certain requirement where this is regarded acceptable. It should also be possible to use available data for the active substance acetic acid to perform an appropriate risk assessment for vinegar with acetic acid as its main biologically active component. | No comment, agreement. | Article 23 of Reg. 1107/2009 says:<br>'c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent;'<br><br>Acetic acid is not predominantly used for plant protection purposes, however it was approved as a herbicide in pome fruit, stone fruit, paths and roads, ornamental trees and shrubs, turf and lawns.<br><br>The intended use as a basic substance is as **fungicide/bactericide** on wheat and barley seed together with vegetables seed (carrots, tomatoes …) |
| 1(4) | | DE: For a regulation as basic substance in general a basic risk assessment for non-target organisms should be required which should indicate the risk for the relevant groups of non-target organisms considering the expected exposure conditions. Considering the available evaluation for the | No comment, agreement. | The available ecotoxicological risk assessments are not considered sufficient to address the risk to birds, wild mammals and carbon mineralisation processes in soil for the representative outdoor uses. The risk to aquatic organisms, honey bees, non-target arthropods, earthworms, soil nitrification |

| **General** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | active substance acetic acid it should be possible to deliver a basic risk assessment at least for this main component of vinegar. Considering the intended use rate of vinegar and type of use as seed treatment the environmental risks can generally considered to be rather low. | | processes, non-target terrestrial plants and sewage treatment organisms was indicated as low. A low risk to all groups of non-target organisms was indicated for the representative indoor uses. |
| 1(5) | | ES: No comments | | Addressed. |

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

| 2.1. Predominant Use | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(1) | 2.2.1 Common name, p.5 | EFSA: there is no ISO common name for this 'substance' | Corrected | Vinegar is not an ISO common name .<br>A correction was not made in the application update. |
| 2(2) | 2.2.1 Common name, p.6 | EFSA disagrees to call vinegar as active substance. The a.s. is acetic acid. | Corrected | Corrected, the active substance of vinegar is acetic acid. |
| 2(3) | 2.2.2 IUPAC name, p.6 | EFSA: vinegar is not an IUPAC name. The IUPAC name of the a.s. is acetic acid. | Corrected | Corrected, The IUPAC name of the a.s. is acetic acid. |
| 2(4) | | ES: No comments | | Addressed. |

| 2.2. Identity and Physical and chemical properties of the substance and product to be used | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(5) | 2 Identity | DE: See DE comment at 1(3) | | See comment at 1(3) |
| 2(6) | 2.2.1 Common name of the substance and product and their synonyms/plant nomenclature | ES: The synonym in Spanish should be included. | Corrected | Addressed. The synonym in Spanish was included. |

| 2.3. Current Former and in case proposed trade names | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(7) | | ES: No comments | | Addressed. |

| 2.4. Manufacturer of the substance/products | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(8) | | ES: No comments | | Addressed. |

| 2.5. Type of preparation | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(9) | | ES: No comments | | Addressed. |

| 2.6. Description of the recipe for the product to be used | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(10) | | ES: No comments | | Addressed. |

| 2.7. Function on plant protection | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 2(11) | | ES: No comments | | Addressed. |

## 3. Uses of the substance and its product

| 3.1. Field of use | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 3(1) | 3.1 Field of use, p.9 | EFSA: according to section 2.6 the concentration of the acetic acid in the preparation is 50 g/l, it is not clear how this concentration is influencing the germination ability of seeds? | According to section 2.6 recipe claim:<br>Conc. of acetic acid (main a. s.) is 25-50g/L<br>No phytotoxicity is found at this concentration<br>Above 2L vinegar/qt of seeds some phytotoxicity can be found. | Addressed:<br>No phytotoxicity was found at concentrations of 25-50 g/L. |
| 3(2) | 3.3.1 GAP table, p.13 | EFSA: it is not clear from where the numbers 50-80 g/kg and 25-40 g/kg come from. | According to section 2.6 recipe claim:<br>Conc. of acetic acid (main a. s.) is 25-50g/L | Addressed:<br>Concentration of acetic acid is 25-50 g/L.<br>Disagree with the terminology main a.s., as this would implicate that the other acids at levels below 0.5 g/l are also considered a.s. |
| 3(3) | | ES: No comments | | Addressed. |

| 3.2. Effects on harmful organisms or on plants | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 3(4) | 3.2 Effects on harmful organisms, Tobias 2011, p.10 | EFSA: expressing the concentration as % vinegar is ambiguous, the concentration of acetic acid is not unequivocally defined in this way. | Corrected in GAP Table<br>Conc. of acetic acid (main a. s.) is 25-50g/L | Addressed:<br>The concentration of acetic acid is 25-50 g/L. |
| 3(5) | 3.2 Effects on harmful organisms, Saidi 2001, p.11 | EFSA: clarification is needed on the a.s. concentration when 30-50 ml/kg of vinegar is used. | Corrected in GAP Table<br>Conc. of acetic acid (main a. s.) is 25-50g/L | Addressed:<br>The concentration of acetic acid is 25-50g/L. |
| 3(6) | General comment | ES: It might be useful to include the next | Indeed, included in BSA vinegar section | Addressed: |

| 3.2. Effects on harmful organisms or on plants | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | reference with a summary of its information:<br>Sholberg, PL; Gaudet, DA; Puchalski, B; Randall, P (2006) Control of common bunt (Tilletia tritici and T-laevis) of wheat (Triticum aestivum cv. 'Laura') by fumigation with acetic acid vapour. Canadian Journal of Plant Science, 86(3), 839-843. | 3.2 although fumigation is not in the GAP Table of BSA vinegar. | Reference was included, however fumigation is not a proposed use in the GAP Table. |

| 3.3. Summary of intended uses | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 3(7) | | DE: Acetic acid is already approved as an active substance in the EU. vinegar is essentially a solution of acetic acid in water. | Vinegar is a food product with more than 12 chemically different molecules (included in §2).<br>Aguiar A. de Alencar Nascimento R.A. Ferretti L.P. Gonçalves A.R. 2005 Determination of Organic Acids and Ethanol in Commercial Vinegars *Braz. J. Food Technol*., 5º SIPAL<br>And later publications cited | See comment in 1(2) |
| 3(8) | | ES: No comments | | Addressed. |

## 4. Classification and labelling of the substance

| Classification and labelling of the substance | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 4(1) | 2 p. 5 and 4, p. 15 | DE: The concentration of acetic acid in vinegar is claimed to be up to 20 % according to the report p. 5. According to annex VI of Reg. EC 1272/2008 a mixture containing more than ten and less than 25 % of acetic acid would have to be classified as Eye irrit. Cat 2 (H319) and skin irrit cat 2 (H319). | Recipe changed: 10-20% acetic acid vinegar supressed, not representative of major vinegar sales. | Classification and labelling of mixture is outside of EFSA's remit |

## 5. Impact on Human and Animal Health

| 5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 5(1) | General comment | EFSA: the application indicates the DAR of acetic acid (2008) to address all toxicological endpoints. EFSA prepared a conclusion on acetic acid in 2013 (EFSA Journal 2013;11(1):3060 [57 pp.]. doi:10.2903/j.efsa.2013.3060)<br>no data gaps or concerns were highlighted for the mammalian toxicology, apart for the potential of skin corrosion (but only for concentration >90%). It was concluded that no reference values need to be set for consumer exposure, however the critical effects of acetic acid for operators/workers/bystanders are related to its irritating properties by inhalation, triggering by neurobehavioral signs and changes in red blood cells at 15 mg/m³ in a valid human volunteer study. Based on a NOAEC of 10 mg/m³, and with the application of an uncertainty factor of 10 for intra-species variability, the Acceptable Operator Exposure Concentration (AOEC) is 1 mg/m³.<br><br>Considering the inhalation toxicity effects of acetic acid in humans, vinegar could be considered as a substance of concern. However, under the proposed conditions of use (seed treatment) it is considered unlikely that the relevant effects via | Indeed, included in BSA vinegar §5.1 | Vinegar is considered as foodstuff as defined in Article 2 of Regulation (EC) No 178/2002, and acetic acid was approved as a herbicide in pome fruit, stone fruit, paths and roads, ornamental trees and shrubs, turf and lawns (see 1(2) and 1(3)).<br>Considering the inhalation toxicity effects of acetic acid in humans (neurobehavioral signs and changes in red blood cells at 15 mg/m³, an Acceptable Operator Exposure Concentration (AOEC) of 1 mg/m³ was established), vinegar could be considered as a substance of concern. However, under the proposed conditions of use (seed treatment and disinfection of cutting tools) it is considered unlikely that the relevant effects via inhalation could realistically occur. |

| 5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | inhalation could realistically occur. It is noted that the key component of vinegar (acetic acid) is approved as a plant protection product. | | |

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

No comments.

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

No comments.

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

No comments.

| 5.5. Genotoxicity | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |

No comments.

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

No comments.

| 5.7. Reproductive toxicity | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |

No comments.

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

No comments.

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

No comments.

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

No comments.

| 5.12. Additional information related to use as food | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 5(2) | | DE: Acetic acid is approved as active substance. It has to be discussed, whether or not criteria set in §23 (d) of the Reg. 1107/2009 are met. | Vinegar is food product [90132-02-8]<br>Acetic acid [64-19-7] is a synthetic compound derived from oxidation of ethanol. | See 5(1) |

| 5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |

No comments.

| 5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 5(3) | 5.14 (exposure assessment) | DE: No information is given under this point but the reference to the DAR on acetic acid. The intended uses considered in the DAR (spraying) are different from the intended use of vinegar in this evaluation report (dipping of seed). However, as long as no systemic AOEL exists for acetic acid no further calculations are considered necessary. | RMS for acetic acid did not ask for systemic AOEL for this synthetic chemical product sprayed in fields at high concentration with adjuvants.<br>Is this gap in the DAR crucial?<br><br>Quantities and concentration are largely less in BSA vinegar and usages are of less concern, no spray, as seed treatment. | An exposure assessment for operator exposed to seed dipping in vinegar and for the disinfection of cutting tools was not provided. Data gap.<br>See also 5(1) |

## 6. Residues

| **Residues** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 6(1) | | ES: No comments | | Addressed |

## 7. Fate and Behaviour in the environment

| Fate and Behaviour in the environment | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 7(1) | 7.0 Fate and behaviour in the environment, application dated August 2013. | EFSA: Reference is made to the draft assessment report (DAR) on acetic acid. The use assessed in this report was for spray application as a herbicide. The exposure assessment for spray use in the field is not applicable to application as a seed treatment before planting. An exposure assessment that relates to the use being requested should have been presented. Considering the data gaps in the EFSA conclusion (EFSA Journal 2013;11(1):3060)), the following issues (identified under comments 7(2) to 7(4)) will be open based on read across from the herbicide uses already assessed in respect of the approval of acetic acid: | Indeed, quantities and concentration are less in vinegar BSA and usages are of less concern, no spray, as seed treatment. | See column 4 entries against comments 7(2) to 7(4) below. |
| 7(2) | 7.0 Fate and behaviour in the environment, application dated August 2013. | EFSA: Information on volatilisation and re-deposition of acetic acid (the major component of vinegar) in the short range would be needed to complete surface water exposure assessment, consequent to use as a seed treatment. | RMS for acetic acid did not ask for information on volatilisation for this synthetic chemical product sprayed in fields at high concentration with adjuvants. Is this gap in the DAR crucial?<br>Quantities and concentration are largely less in vinegar BSA and usages are of less concern, no spray, as seed treatment. | EFSA calculated FOCUS Step 2 PEC surface water (Version 2.1 of Step 1-2 Calculator). These are presented below:<br>Application rate: 80 g acetic acid / ha (application update dated Feb 2014).<br>Soil DT50 1.23 days, water DT50 0.55 days, sediment DT50 12.3 days, Koc 0mL/g. (EFSA, 2013;11(1):3060) Crop winter cereals, 5% runoff/drainage (North Europe Oct to Feb), no spray drift, no crop interception. The resulting maximum PECsw is 1.4µg/L. It is considered that the assumption of 5% loss to surface water in the calculation will cover the volatilised and |

| Fate and Behaviour in the environment | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | | | re-deposited acetic acid that might occur via the air. |
| 7(3) | 7.0 Fate and behaviour in the environment, application dated August 2013. | EFSA: The acetic acid in vinegar has the potential for long-range atmospheric transport. Although using the estimates of sales volumes provided by the notifier, the contribution to exposure in remote areas from the use of acetic acid as a herbicide was indicated to be insignificant when compared to other anthropogenic emission sources. An estimate of the quantity that might be used as a seed treatment has not been made available, so a comparison to other anthropogenic emission sources is not possible from this use requested as a basic substance. | No comment | A comparison of the contribution that use of vinegar as a seed treatment might make to the quantity of acetic acid that reaches remote areas via atmospheric transport, compared to other anthropogenic emission sources of acetic acid is not available, though the contribution might be expected to be limited. |
| 7(4) | 7.0 Fate and behaviour in the environment, application dated August 2013. | EFSA: The acetic acid in vinegar has the potential to contaminate groundwater (due to its very low soil adsorption). Groundwater exposure calculations from the requested uses of vinegar as a seed treatment are not available. Though the seed treatment uses would be covered (lower application rates) by the herbicide use assessments in the acetic acid DAR, a groundwater contamination problem was indicated from the herbicide uses. | Due to seed treatment, vinegar, or its mains a.s. acetic acid, is not at the seeds sewing time in the liquid form, contrary to approved acetic acid uses. | The acetic acid in vinegar has the potential to contaminate groundwater (due to its very low soil adsorption). Groundwater exposure calculations from the requested uses of vinegar as a seed treatment and as a disinfectant of cutting tools are not available.<br><br>For the higher application rate uses assessed when acetic acid is used as a herbicide a groundwater contamination problem was indicated.<br><br>(Note whether acetic acid is applied as a liquid or a solid does not change its low soil adsorption potential. Soil water may |

| **Fate and Behaviour in the environment** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | | | dissolve the acetic acid present on seeds at the time of planting). |
| 7(5) | | ES: No comments | | Addressed. |
| 7(6) | 7.0 Fate and behaviour in the environment, application dated February 2014. | | | Information was not provided that might be used for an environmental exposure assessment of the components of vinegar citric acid, tartaric acid, malic acid, malonic acid, succinic acid, lactic acid, propionic acid, glycerol and ethanol, identified by the applicant as being present in food grade vinegar. |

## 8. Effects on non-target species

| 8.1. Effects on terrestrial vertebrates | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(1) | Section 8, Effects on non-target species, general. | EFSA: In relation to the ecotoxicological risk assessment being compliant with paragraph 2 of Article 23 of Regulation (EC) 1107/2009 the following comments are noted:<br>i) Even if it is agreed that vinegar is a 'foodstuff' and therefore is considered to be a basic substance, in accordance with paragraph 2 of Article 23 of Regulation (EC) 1107/2009, it is still necessary to refer to a relevant evaluation which demonstrates that the substance has no unacceptable effect on the environment.<br>ii) The applicant has referred to the Draft Assessment Report (DAR) for acetic acid (2008). It would be more appropriate to refer to the EFSA conclusion for acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]. doi:10.2903/j.efsa.2013.3060SA Journal).<br>iii) Whilst some information can be gained from reference to the previous EU assessment of acetic acid, it is noted that the proposed uses are different (foliar spray) to that currently under consideration (seed treatment), and therefore the previous assessment is not completely relevant.<br>iv) Moreover, the EFSA conclusion for acetic acid identified several data gaps in the risk assessment. | Corrected, reference to EFSA Journal 2013;11(1):3060 added.<br>No comment. Considering seed treatment instead of spay technique question is reasonable.<br>Corresponding input is done as much as possible in new version of BSA vinegar section 8 | Given that the previous assessment for acetic acid which the applicant has referred to does not address the risk to all non-target organisms from the representative use of vinegar, further consideration of the risk is needed, see specific comments below. |

| 8.1. Effects on terrestrial vertebrates | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | Therefore, the assessment that the applicant has referred to does **not** demonstrate that the a.s. does not have an unacceptable effect on the environment.<br>Therefore derogation from Article 4 of the Regulation is not considered appropriate and a risk assessment for non-target organisms is required. | Corresponding input is done as much as possible in new version of BSA vinegar section 8 | |
| 8(2) | Section 8.1, Effects on terrestrial vertebrates | EFSA: Please refer to comment 8(1), it is considered that a risk assessment is needed. | Corresponding input is done as much as possible in new version of BSA vinegar section 8 | The information provided is not considered sufficient to address the risk to birds and wild mammals from the representative outdoor use of vinegar.<br><br>For the representative use to vegetable seeds sown in the glasshouse and for the disinfection of cutting tools a low risk to birds and mammals can be concluded given that exposure is unlikely.<br><br>For the representative field uses, exposure to granivorous birds and mammals cannot be excluded and therefore a risk assessment is required. The applicant has referred to the previous EU assessment for acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) where some data are available. However, no actual risk assessment (taking account of the level of exposure and the toxicity) has been presented. |
| 8(3) | | ES: No comments | | Noted. |

| **8.2. Effects on aquatic organisms** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(4) | Section 8.2, Effects on aquatic organisms | EFSA: Please refer to comment 8(1), it is considered that a risk assessment is needed. | Answered :<br>Babcock C. Holmes Farley R. 2012 Vinegar Dosing Methodology for the Marine Aquarium, Tank of the month vol 10 (6) http://reefkeeping.com/joomla/index.php/current-issue/article/116-vinegar-dosing-methodology-for-the-marine-aquarium | A low risk to aquatic organisms from the representative uses of vinegar is concluded.<br><br>Taking the lowest aquatic endpoints (18.9 mg/L aquatic invertebrates (acute) and 5.8 mg/L algae (chronic) (EFSA, 2013;11(1):3060)) and the exposure concentration of 0.0014mg/L (column 4 entry at comment 7(2)), the resulting TERs were 13500 (acute) and 4143 (chronic), which are above the relevant uniform principles triggers, thus indicating low risk.<br><br>Note, reference to a recommendation that vinegar can be used in marine aquariums is not considered to address the risk to aquatic organisms from the representative use of vinegar.<br>The applicant has also referred to some additional aquatic toxicity values in the updated basic substance application for vinegar. However, these toxicity values appear to be derived from material safety data sheets (MSDS) and therefore are not primary data. The toxicity values can therefore not be relied upon for risk assessment. |
| 8(5) | | ES: No comments | | Noted. |

| 8.3. Effects on bees and other arthropods species | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(6) | Section 8.3, Effects on bees and other arthropods | EFSA: Please refer to comment 8(1), it is considered that a risk assessment is needed. | As seed treatment, contact with bees should not occur, and vinegar is not a systemic insecticide.<br>Furthermore, corresponding input is done as much as possible in new version of BSA vinegar section 8 | A low risk to bees and non-target arthropods from the representative uses of vinegar is concluded.<br><br>The applicant proposed that honey bees should not be exposed for the representative use of vinegar as a seed treatment. It should be noted that exposure cannot be totally excluded for the representative field uses, as during the drilling (sowing) of the seed, dust particles may occur and drift on to adjacent vegetation. The applicant referred to a publication which showed that acetic acid can have repellent effects to honey bees. However, a comparison of the exposure and the tested concentrations has not been provided. The EFSA Conclusion for Acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) provides toxicity data for a formulated product containing acetic acid. The acute oral and contact $LD_{50}$ values were greater than the highest does tested in the study. Ideally a risk assessment accounting for the likely exposure and the toxicity of vinegar should be available. However, given the low toxicity further consideration of the risk to honey bees from the representative use of vinegar is not considered necessary.<br><br>No information has been provided to address the risk to ground-dwelling non-target arthropods. The EFSA Conclusion |

| 8.3. Effects on bees and other arthropods species | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | | | for Acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) provides toxicity data for the ground-dwelling non-target arthropods, *Aleochara bilineata* and *Poecilus cupreus*.<br><br>At the rates tested in the available studies, there was <50% effect on mortality and sublethal parameters indicating a low risk to ground-dwelling arthropods. The application rate used was equivalent to 1000 L product/ha which can be estimated to be 102 kg acetic acid/ha. This is greater than the application rate proposed for vinegar as a seed treatment to vegetables (80 g a.s./ha) and therefore, a low risk to non-target arthropods from the representative use of vinegar is concluded. |
| 8(7) | | ES: No comments | | Noted. |

| 8.4. Effects on earthworms and other soil macroorganisms | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(8) | Section 8.4, Effects on earthworms and other soil macro-organisms | EFSA: Please refer to comment 8(1), it is considered that a risk assessment is needed. | Corresponding input is done as much as possible in new version of BSA vinegar section 8 | A low risk to earthworms is indicated.<br><br>The applicant has referred to the EFSA Conclusion for Acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) which concluded |

| 8.4. Effects on earthworms and other soil macroorganisms | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | | | a low risk to earthworms. The exposure to soil from the representative use of vinegar is less than that for the use assessed for acetic acid. A low risk to earthworms can therefore be concluded for the representative use of vinegar. |
| 8(9) | | ES: No comments | | |

| **8.5. Effects on soil microorganisms** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(10) | Section 8.5, Effects on soil micro-organisms | EFSA: Please refer to comment 8(1), it is considered that a risk assessment is needed. | Corresponding input is done as much as possible in new version of BSA vinegar section 8 | Information is needed to address the risk to carbon mineralisation processes in soil.<br><br>The applicant has referred to the EFSA Conclusion for Acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) which concluded a low risk to soil nitrogen transformation processes. The exposure to soil from the representative use of vinegar is less than that for the use assessed for acetic acid. A low risk to soil nitrogen transformation processes can therefore be concluded for the representative use of vinegar.<br>The EFSA Conclusion for Acetic acid (EFSA Journal 2013;11(1):3060 [57 pp.]) concluded a data gap for information to address carbon mineralisation in soil. No additional information has been presented in the basic substance application for vinegar and therefore the data gap is still valid for the representative outdoor uses.<br>With regard to the representative glasshouse use of vinegar, given the short $DT_{50}$ in soil (acetic acid = 1.23 days) exposure to soil outside of the glasshouse is not anticipated. Therefore, a low risk to soil microorganisms from the representative glasshouse use is concluded. |
| 8(11) | | ES: No comments | | Noted. |

| **8.6. Effects on other non-target organisms (flora and fauna)** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(12) | | ES: No comments | | Noted. |

| **8.7. Effects on biological methods of sewage treatment** | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 8(13) | | ES: No comments | | Noted. |

## 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<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 9(1) | 9. Overall conclusion, p.18 | EFSA disagrees with the fulfilment of the criterion described in Article 23 (1) of Regulation (EC) No. 1107/2009 under point (d): 'is not placed on the market as a plant protection product'.<br>The a.s. of vinegar is acetic acid, which is one of the fourth stage substances covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007.<br>Acetic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 790/2013.<br>As a consequence acetic acid is placed on the market as a herbicide. According to the DAR of acetic acid and the EFSA Conclusion (EFSA Journal 2013;11(1):3060), the representative formulations are very similar to the substance vinegar proposed as a basic substance. | Vinegar is food product CAS [90132-02-8]<br>Acetic acid [64-19-7] is a synthetic compound derived from oxidation of ethanol.<br>Vinegar is a food product with more than 12 chemically different molecules (included in §2).<br>Aguiar A. de Alencar Nascimento R.A. Ferretti L.P. Gonçalves A.R. 2005 Determination of Organic Acids and Ethanol in Commercial Vinegars *Braz. J. Food Technol*., 5º SIPAL<br>As matter of fact, this application is done for Organic Farming sector, which does not allow herbicide uses. | EFSA disagrees with the fulfilment of the criterion described in Article 23 (1) of Regulation (EC) No. 1107/2009 under point (d): 'is not placed on the market as a plant protection product'.<br>Acetic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 790/2013. |

| Overall conclusions with respect of eligibility of the substance to be approved as basic substance | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| | | It should be mentioned however that the approval refers to the use as herbicide, while the proposed use as a basic substance is as fungicide and bactericide.<br>The fact that the supporting information for vinegar as a basic substance is the public version of the acetic acid DAR would also suggest that vinegar is not an active substance. | BSA vinegar for vinegar as Basic Substance does not describe and does not allow any further formulation, with any adjuvant or co-formulator product, as DAR acetic acid does. | |
| 9(2) | 9. Overall conclusion, p.18 | EFSA: based on the fact that the supporting information is the public DAR of the acetic acid, the data gaps identified in the EFSA conclusion should be considered also for this proposal. | Corresponding input is done as much as possible in new version of BSA vinegar section 8 | Entries in column 4 of this table above identify several risk assessments that remain open. |
| 9(3) | 9. Overall conclusion, p.18 | EFSA agrees that vinegar as described in 'FAO WHO 2000 Codex Alimentarius Commission, CL 2000/18-EURO, Proposed DRAFT revised REGIONAL STANDARD FOR VINEGAR p 1-5' and 'Draft european regional standard for vinegar' in ALINORM 87/19 APPENDIX II, p. 34-38, as proposed in this submission fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and can be considered as a basic substance. | No comment | EFSA agrees that vinegar as described in 'FAO WHO 2000 Codex Alimentarius Commission, CL 2000/18-EURO, Proposed DRAFT revised REGIONAL STANDARD FOR VINEGAR p 1-5' and 'Draft european regional standard for vinegar' in ALINORM 87/19 APPENDIX II, p. 34-38, as proposed in this submission fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and can be considered as a basic substance |
| 9(4) | | ES: No comments | | |

## 10. Other comments

| Other comments | | | | |
|---|---|---|---|---|
| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
| 10(1) | | ES: No comments | | |

**ABBREVIATIONS**

| | |
|---|---|
| µg | microgram |
| µm | micrometer (micron) |
| a.s. | active substance |
| DG SANCO | European Commission Directorate General Health and Consumers |
| EU | European Union |
| g | gram |
| kg | kilogram |
| L | litre |
| $LC_{50}$ | lethal concentration, median |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| mg | milligram |
| mL | millilitre |
| mm | millimetre |
| 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 |
| PPP | plant protection product |