

APPROVED: 13 September 2016

Outcome of the consultation with Member States and EFSA on the basic substance application for hydrogen peroxide for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tools

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for hydrogen peroxide 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 hydrogen peroxide as a basic substance for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tools. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Keywords: hydrogen peroxide, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00386

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Suggested citation: EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for hydrogen peroxide for use in plant protection as a fungicide and bactericide in seed treatment and for disinfecting cutting tools. EFSA supporting publication 2016:EN-1091. 39 pp.

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Summary

Hydrogen peroxide 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 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 in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in June 2016, EFSA was asked to organise a consultation on the basic substance application for hydrogen peroxide, 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 three months of acceptance of the specific request.

A consultation on the basic substance application for hydrogen peroxide, organised by EFSA, was conducted with Member States via a written procedure in April-June 2016. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for hydrogen peroxide and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Only uses as disinfectant of mechanical cutting tools and seed treatment (lettuce, horticulture flowers) are proposed. Direct treatment of soil or other environmental compartments has not been assessed and should be avoided.

Applicant has clarified that hydrogen peroxide diluted to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted to 1.5% is proposed to be used for seed treatment. Seed treatment (lettuce, horticulture flowers) with hydrogen peroxide at concentrations of 3% or higher should be avoided to prevent adverse effects on germination of plants.

With regards to the impact on human and animal health, a number of potential adverse effects are reported mainly after oral ingestion that would require a dose-response characterisation to perform a proper risk assessment relevant to operators, workers, bystanders and to residential exposure. Therefore the information provided is insufficient to conclude on the non-dietary exposure risk assessment. Regarding skin, eye, respiratory tract irritation and/or corrosivity and repeated inhalation toxicity, low concern would be assumed at concentrations below 5% due to a low irritation potential; however 5%, the highest concentrations proposed to be used for disinfection of mechanical cutting tools, require classification as Eye Irrit. 2, H319: Causes serious eye irritation.

Having regard to the intended uses (seed application, tools disinfection) no residues are expected to be present in plant commodities at harvest.

With respect to the fate and behaviour into the environment, no further data is deemed necessary if the agricultural uses are limited to disinfection of tools and seed treatment. Further data would be needed if direct application to the environment was to be considered in the future.

Regarding the effects on non-target species, in general, the information provided was not sufficient to perform a quantitative risk assessment. However, due to the nature of hydrogen peroxide and considering the low exposure, a low risk was concluded to terrestrial vertebrates, aquatic organisms, bees and organisms involved in the sewage treatment. In the basic substance application it was reported that hydrogen peroxide is toxic to arthropods, though this statement was not supported by a quantitative risk assessment and/or by a scientific justification. The exposure to ground dwelling arthropods and soil macro and microorganisms cannot be completely excluded when the basic substance is applied according to the representative uses (i.e. field seed treatments). However, due to

the nature of the basic substance, a low in-field risk may be concluded for these non-target species. Considering that hydrogen peroxide is not phytotoxic up to a concentration of 15% and that its application is up to a concentration of 5%, a low risk to other non-target organisms (flora and fauna) can be concluded.

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1. Introduction

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

Regulation (EC) No 1107/2009¹ (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.

Hydrogen peroxide is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as a fungicide and bactericide in seed treatment and for disinfecting cutting tools.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for hydrogen peroxide, which was conducted via a written procedure in April – June 2016. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for hydrogen peroxide 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 hydrogen peroxide 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, 2016a, 2016b).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 13 June 2016, EFSA was asked to organise a consultation on the basic substance application for hydrogen peroxide, 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 being prepared by EFSA. The agreed deadline for providing the finalised report is 13 September 2016.

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

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

2. Assessment

The comments received on the basic substance application for hydrogen peroxide and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. ITAB, 2016a. Basic substance application on hydrogen peroxide submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2016. Documentation made available to EFSA by the European Commission.
2. ITAB, 2016b. Basic substance application update on hydrogen peroxide submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2016. Documentation made available to EFSA by the applicant.

References

European Commission, 2015. 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. SANCO/12896/2014– rev. 1, 27 March 2015.

Abbreviations

a.s.	active substance
CLP	Classification Labelling and Packaging
GAP	good agricultural practice
MRL	maximum residue level
NOAEL	no observed adverse effect level

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for hydrogen peroxide and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		NL: No comments.			Noted
1(2)		DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1a). The rapid degradation and forming of reactive oxygen species present an inherent capacity to cause an adverse effect on humans. Hydrogen peroxide is mutagenic and genotoxic <i>in vitro</i> and is suggested to form hydroxy radicals <i>in vivo</i> , causing lipid peroxidation.		Hydrogen peroxide is a basic para-pharmaceutical product, available in all stores at higher concentration (10-20 %) than uses in this application.	Fulfilment of criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue and no opinion is presented in relation to this. With respect to toxicological properties see Section 5.
1(3)		DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1b). There is no information supporting that hydrogen peroxide is not a neurotoxic agent considering the suggested <i>in vivo</i> lipid peroxidation and other		Contact with sold basic para-pharmaceutical product is avoided in this application by the use of solid tablets of generating agent in order to minimize any contact with low concentration solutions.	See above 1(2)

General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(4)		<p>reported effects of neurologic deficits and hypoxic encephalopathy.</p> <p>DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1).</p> <p>The severity off the acute effects (vomiting, haematemesis, convulsions, coma, shock, respiratory arrest, burns) presents an inherent capacity to cause an adverse effect on humans and this may not be neglected by applying a risk management perspective.</p> <p>Hydrogen is, despite the low in-use dilution, to be used in high quantities for the proposed use. Most likely concentrated products of 30-40% will be used to obtain the dilution.</p>		<p>Hydrogen peroxide in this application is described at 5% maximum not at this 30-40% concentration.</p> <p>Hydrogen peroxide with 10 to 20% concentration is freely available as para-pharmaceutical product.</p>	See above 1(2)
1(5)		<p>EFSA: It is agreed that generically hydrogen peroxide is a widely used chemical that has a huge number of applications (from rockets fuel to pharmaceutical disinfectant). However, here only the uses of the technical hydrogen peroxide similar (in</p>		<p>Applicant agree Point §2.5 amended.</p>	<p>Applicant has clarified that hydrogen peroxide diluted down to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted down to 1.5% is proposed to be used for seed treatment.</p>

General					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		terms of purity and concentration)_ to the one proposed for the agricultural use should be considered (eg, it seems that highly concentrated hydrogen peroxide should be considered out of the scope of this presentation). Nevertheless, further information is still needed to clarify what are the specifications of the hydrogen peroxide that is being proposed for agricultural use.			

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

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.7	NL: The methods under 2.1.7.1 and 2.1.7.2 seems to be interchanged. Please rectify.		Corrected	Addressed
2(2)	2.1.4 Description of the method of manufacture of the	EFSA: It is stated that a stabilizer is used. The stabilizer (or stabilizers) used on the		Tablets are stabilized by sodium salicylate	Applicant has clarified that sodium salicylate is used as stabiliser of hydrogen peroxide.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	substance and of the product.	products intended to be used in agriculture need to be identified.			
2(3)	2.1.5 Description and specification of purity of the active substance and product.	EFSA: the specification or range of the specifications of the technical/s proposed to be used need to be provided (eg technical grade, pharmaceutical grade, concentration, main impurities etc...)	The risks associated to hydrogen peroxide are greatly dependent of its concentration. Therefore, at least the range of these needs to be specified.	Concentrations used are less than 5%.	Applicant has clarified that hydrogen peroxide diluted down to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted down to 1.5% is proposed to be used for seed treatment.

2.2. Current Former and in case proposed trade names

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

2.3. Manufacturer of the substance/products

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

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)		NL: No comments.			Noted
2(7)		EFSA: At least the concentration of hydrogen peroxide would need to be provided.		Concentration is < 5% in all the application.	Applicant has clarified that hydrogen peroxide diluted down to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted down to 1.5% is proposed to be used for seed treatment.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		NL: No comments.			Noted
2(9)	2.5 Description of the recipe for the product to be used	EFSA: The recipe of the preparation will depend on the concentration in the technical product used, which has not yet been specified. Nevertheless, the text and the table are not coherent. Text states a maximum concentration 1.5 % for seed treatment and the table assumes a final concentration	See also 4(1, 2)	Recipe more detailed.	Applicant has clarified that hydrogen peroxide diluted down to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted down to 1.5% is proposed to be used for seed treatment.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		up to 3 %. The same that for disinfection of mechanical tools, for which the text indicates a maximum of 5 % could be used.			
2(10)	2.5 Description of the recipe for the product to be used. Table	EFSA: Here seed treatment and uses in horticulture are separated. However in the summary of intended uses it seems that all uses (besides the biocide use on tools) are on seeds. Please clarify if also sprayed or soil uses are intended.		Use on tools is not biocide. Bioaggressor targets are from agricultural importance so this application has no issue in Reg. 528/2012 ² . See vinegar approval.	Only uses as disinfectant of agricultural tools and seed treatment are proposed.

² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		NL: No comments.			Noted
3(2)	3.4.1 Summary of intended uses + 3.1 in general	DK: We find that "disinfection of mechanical cutting tools" is a biocidal use.		Use on tools is not biocide. Bioaggressor targets are from agricultural importance so this application has no issue in Reg. 528/2012. See vinegar approval.	Addressed
3(3)	3.1 Field of use	EFSA: Results from Pernezny et al 2000 seem to challenge the application rates proposed. Washing lettuce seed with 5 % hydrogen peroxide may cause a reduction in germination of lettuce up to 28 %. Significant reductions are also reported when 3 % solutions are used.		GAP amended % reduced from 3 to 1.5 %	Applicant has clarified that hydrogen peroxide diluted down to 2.5-5% is proposed to be used for disinfection of mechanical cutting tools and hydrogen peroxide diluted down to 1.5% is proposed to be used for seed treatment. Seed treatment uses at concentrations of 3% or higher should be avoided to prevent adverse effects on germination of plants.

3.2. Effects on harmful organisms or on plants

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

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)	Summary of intended use	NL: Does the intended use for disinfection of cutting tools not fall under a biocidal use? It is noted that hydrogen peroxide is approved as a biocidal active substance.		Use on tools is not biocide. Bioaggressor targets are from agricultural importance so this application has no issue in Reg. 528/2012. See vinegar approval.	Addressed
3(6)		EFSA: Please clarify if also sprayed or soil uses are intended.		No soil treatment uses are claimed.	Only uses as disinfectant of mechanical tools and seed treatment are proposed. No direct soil treatment use is proposed.

4. Classification and labelling of the substance

Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)	Classification and labelling	NL: Minor comment. We prefer to have an overview of the harmonized classification and labelling in the document and not just a reference to ECHA.	EFSA: Please detail the harmonised classification according to Reg. (EC) 1272/2008, considering the relevant concentration(s)	According to REGULATION (EC) no 1272/2008: added to BSA Oxidising Liquid; Category 1; May cause fire or explosion; strong oxidiser Acute toxicity (inhalation); Category 4; Harmful if inhaled Acute toxicity (oral); Category 4; Harmful if swallowed Skin corrosive; Category 1A; Causes severe skin burns and eye damage Chronic aquatic toxicity; Category 3; Harmful to aquatic life with long lasting effects	For the maximum proposed use concentration of 5% (see 1(5)) classification as Eye Irrit. 2; H319: Causes serious eye irritation would be required.
4(2)	Classification and labelling	EFSA: the proposed dilution is up to 5% (to be confirmed, see 2(14)); this concentration would require classification as an eye irritant category 2 (H319) according to Regulation (EC) 1272/2008 ³ .		Concentration is < 5% in all the application.	See 4(1)

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

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

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)		<p>DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1).</p> <p>The severity off the acute effects (vomiting, haematemesis, convulsions, coma, shock, respiratory arrest, burns) presents an inherent capacity to cause an adverse effect on humans and this may not be neglected by applying a risk management perspective.</p> <p>Hydrogen is, despite the low in-use dilution, to be used in</p>		<p>We focalized this application on low concentration of hydrogen peroxide using tablets to dissolve in water without physical contact with hands</p> <p>Concentration is < 5% in all the application.</p> <p>Hydrogen peroxide in this application is described at 5% maximum not at this 30-40% concentration.</p>	<p>See 5(10)</p> <p>See also 1(2)</p>

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		high quantities for the proposed use. Most likely concentrated products of 30-40% will be used to obtain the dilution.			
5(3)	5.2, Acute toxicity, p. 18-20	EFSA: there are concerns for skin, eye, respiratory tract irritation and/or corrosivity and repeated inhalation toxicity for workers, depending on concentration used. There are a number of reported human incidents by oral ingestion of H ₂ O ₂ water solutions, but few reports have given data on the dose.	EFSA: a dose-response characterisation is needed for the adverse effects reported. See also 5(10)		See 5(10)

5.3. Short-term toxicity

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

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		<p>DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1a).</p> <p>The rapid degradation and forming of reactive oxygen species present an inherent capacity to cause an adverse effect on humans.</p> <p>Hydrogen peroxide is mutagenic and genotoxic <i>in vitro</i> and is suggested to form hydroxy radicals <i>in vivo</i>, causing lipid peroxidation.</p>		<p>Concentration is < 5% in all the application.</p> <p>Hydrogen peroxide in this application is described at 5% maximum not at this 30-40% concentration.</p>	See 5(10)

5.5. Long-term toxicity

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

5.6. Reproductive toxicity

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

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)		<p>DK: We strongly disagree that hydrogen peroxide fulfils the criteria laid down in Article 23 (1b).</p> <p>There is no information supporting that hydrogen peroxide is not a neurotoxic agent considering the suggested <i>in vivo</i> lipid peroxidation and other reported effects of neurologic deficits and hypoxic encephalopathy.</p>		Recipe is intended to suppress any high concentration of hydrogen peroxide with tablet directly solubilized into water with concentration < 5%.	See 5(10)

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)		No comments			Noted

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)	5 Impact on human and animal health	EFSA: a number of adverse effects are reported for which NOAELs should be set to perform a proper risk assessment.	EFSA: a dose-response characterisation is needed for the adverse effects reported. See also 5(3)	The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that local irritation and, in extreme and uncommon cases, corrosion of the skin, eye, gingivae or the teeth are the critical adverse effects caused by exposure to H ₂ O ₂ . Most of the effects reported are transient or are considered mild. However, even rather dilute solution of H ₂ O ₂ (3%) may cause danger, if swallowed in large enough volume accidentally. Effects of splashes of strong solutions to the eye (> 5%) and skin (> 35%) represent scenarios that may be relevant in terms of consumer	Considering the toxicological profile of the substance, with a number of potential adverse effects reported (mainly after oral ingestion), a dose-response characterisation would be needed to perform a proper risk assessment. Regarding skin, eye, respiratory tract irritation and/or corrosivity and repeated inhalation toxicity (mainly relevant to worker exposure), low concern would be expected at concentrations below 5% due to a low irritation potential; 5% concentrations proposed to be used for disinfection of mechanical cutting tools still required classification as Eye

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				exposure. In ref HERA 2005	Irrit. 2 (see 4(1)). See also 5(2, 3, 5, 8, 14)

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(11)		No comments			Noted

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)	2, identity of the substance/product as available on the market and predominant use, EU status, p. 6	EFSA: hydrogen peroxide is approved for use as biocidal product for several product-types (1, 2, 3, 4, 5, 6), however the following specific conditions are established for all product-types: "for professional users, safe operational procedures and appropriate		Hydrogen peroxide is commercially available to any people in stores under liquid form 10%. We describe recipe with tablets in order to minimize or to avoid any physical contact.	Predominant uses of hydrogen peroxide as biocidal products do not support the use of the derogation from Art. 4 foreseen in Art. 23(2) as the biocide assessment concluded that the following specific conditions are established for all product-types: "for professional users,

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means"</p> <p>Therefore the risk assessment under biocide Regulation does not support the use of the derogation from Art. 4 foreseen in Art. 23(2).</p>			<p>safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means'.</p>

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(13)		<p>EFSA: as mentioned above, NOAELs should be set for the adverse effects observed in humans and animals and a proper risk assessment should be performed for operators, workers, bystanders and residents.</p>		<p>The limit of 6% for tooth whitening products refers to the limit given in the Terms of Reference in relation to the Opinion SCCP/0844/04. In Ref SCCP 2007</p>	<p>The SCCP opinion of 2007 states that the 'use of oral hygiene and tooth whitening products containing up to 0.1% hydrogen peroxide does not pose a risk to the health of the consumer'.</p> <p>Regarding tooth whitening products containing > 0.1%</p>

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					<p>and ≤ 6% hydrogen peroxide, 'based on the available data, the SCCP is not in a position to define a level of hydrogen peroxide and a frequency of application that would result in exposure which would be considered safe for the consumer'.</p> <p>Thus this opinion does not support the use of the derogation from Art. 4 foreseen in Art. 23(2) for a safety assessment of hydrogen peroxide and a proper exposure risk assessment should be performed for operators, workers, bystanders and residents.</p>

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application																				
5(14)		DE: It is not agreed to approve hydrogen peroxide as basic substance. According to Article 23 of Regulation (EC) No 1107/2009 a basic substance is an active substance of no concern. However, the CLP classification of hydrogen peroxide is Ox. Liq. 1, H271; Acute Tox. 4, H302; Skin Corr. 1A, H314 and Acute Tox. 4, H332. Therefore, the conditions of Article 23(a) are not fulfilled for hydrogen peroxide.		<p>Applicant agrees hydrogen peroxide is a basic chemical with some concern but freely available in all M.S. as para-pharmaceutical concentrations higher (10-20%) than this application (5%). No spray is intended. But</p> <table border="1" data-bbox="1267 699 1697 842"> <thead> <tr> <th colspan="2">Specific Concentration Limits</th> </tr> </thead> <tbody> <tr> <td>C ≥ 70 %</td> <td>Ox. Liq. 1, H271 - May cause fire or explosion; strong oxidiser</td> </tr> <tr> <td>50 % ≤ C < 70 %</td> <td>Ox. Liq. 2, H272 - May intensify fire; oxidiser</td> </tr> <tr> <td>C ≥ 70 %</td> <td>Skin Corr. 1A, H314 - Causes severe skin burns and eye damage.</td> </tr> <tr> <td>50 % ≤ C < 70 %</td> <td>Skin Corr. 1B, H314 - Causes severe skin burns and eye damage.</td> </tr> <tr> <td>35 % ≤ C < 50 %</td> <td>Skin Irrit. 2, H315 - Causes skin irritation</td> </tr> <tr> <td>8 % ≤ C < 50 %</td> <td>Eye Dam. 1, H318 - Causes serious eye damage</td> </tr> <tr> <td>5 % ≤ C < 8 %</td> <td>Eye Irrit. 2, H319 - Causes serious eye irritation</td> </tr> <tr> <td>C ≥ 35 %</td> <td>STOT SE 3, H335 - May cause respiratory irritation</td> </tr> <tr> <td>C ≥ 25 %</td> <td>Chronic Aqu. 3, H412 - Harmful to aquatic life with long lasting effects</td> </tr> </tbody> </table> <p>Included in the Basic Substance Application</p>	Specific Concentration Limits		C ≥ 70 %	Ox. Liq. 1, H271 - May cause fire or explosion; strong oxidiser	50 % ≤ C < 70 %	Ox. Liq. 2, H272 - May intensify fire; oxidiser	C ≥ 70 %	Skin Corr. 1A, H314 - Causes severe skin burns and eye damage.	50 % ≤ C < 70 %	Skin Corr. 1B, H314 - Causes severe skin burns and eye damage.	35 % ≤ C < 50 %	Skin Irrit. 2, H315 - Causes skin irritation	8 % ≤ C < 50 %	Eye Dam. 1, H318 - Causes serious eye damage	5 % ≤ C < 8 %	Eye Irrit. 2, H319 - Causes serious eye irritation	C ≥ 35 %	STOT SE 3, H335 - May cause respiratory irritation	C ≥ 25 %	Chronic Aqu. 3, H412 - Harmful to aquatic life with long lasting effects	See 5(10)
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6. Residues

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	Paragraph 6	NL: It could be added that no residues are expected, and therefore, no MRLs are required.		Expected residues are water and oxygen.	No residues expected and therefore the setting of MRL is not requested.

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(2)	6; Residues	EFSA: Having regard to the intended uses (seed application, tools disinfection) no residues are expected to be present in plants at harvest.		Expected residues are water and oxygen.	No residues expected and therefore the setting of MRL is not requested.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7.1 Fate and behaviour in the environment	NL: Reference has been made towards HERA 2005. Please provide a comparison between the uses in products assessed in HERA 2005 compared to the current Basic substance applications (risk envelope approach) in order to ensure that proposed uses are covered indeed. Also, more information could be provided regarding the exposure routes of the uses accounted for in the basic substance application.		The EU risk assessment for hydrogen peroxide (in ref European Union, 2003) found that local irritation and, in extreme and uncommon cases, corrosion of the skin, eye, gingivae or the teeth are the critical adverse effects caused by exposure to H ₂ O ₂ . Most of the effects reported are transient or are considered mild. However, even rather dilute solution of H ₂ O ₂ (3%) may cause danger, if swallowed in large enough volume accidentally. Effects of splashes of strong	No further data is required for the agricultural uses limited to seed treatment. Further data would be needed if direct application to soils is also considered as part of the intended uses.

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		The Assessment report regarding hydrogen peroxide as a biocide (<i>Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products</i>) might be of use as well.		solutions to the eye (> 5%) and skin (> 35%) represent scenarios that may be relevant in terms of consumer exposure.	
7(2)		EFSA: No comments as long the agricultural uses are limited to seed treatment. Further data would be needed if direct application to soils is also considered as part of the intended uses.		No comment.	See 7(1)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(3)	7.2 Estimation of short and long-term exposure of relevant env. media	NL: Just referring to the HERA 2005 risk assessment is a bit unsatisfactory. Please provide a short overview regarding relevant fate and behaviour exposure routes covered in the HERA 2005		When exposed to sunlight or metallic impurities, Hydrogen Peroxide rapidly decomposes to Oxygen gas: $2 \text{H}_2\text{O}_2(\text{aq}) \rightarrow 2 \text{H}_2\text{O}(\text{l}) + \text{O}_2(\text{g})$	See 7(1)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment, endpoints and conclusions.		H ₂ O ₂ is used for soil remediation, ref added in Basic Substance Application	
7(4)	7.2 Estimation of short and long-term exposure of relevant env. media	NL: typo: tolls disinfection --> tools disinfection		Corrected	Noted

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: No comments			Noted
8(2)	8.1. Effects on terrestrial vertebrates	EFSA: For the representative uses of hydrogen peroxide, a low risk to terrestrial vertebrates can be concluded due to low exposure		No comment Applicant agrees	Considering the nature of hydrogen peroxide and its intended uses, a low risk to terrestrial vertebrates can be concluded.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)		NL: No comments			Noted
8(4)	8.2. Effects on aquatic organisms	EFSA: Brief abstracts were provided without reporting detailed data or a critical evaluation of these data in order to consider the potential effects on aquatic organisms from the representative uses of hydrogen peroxide. It should be ensured that the risk assessment covers the representative uses of hydrogen peroxide.	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk for aquatic organisms.	No spray uses intended.	No additional information and insufficient data to perform a quantitative risk assessment for aquatic organisms were provided. However, due to the nature of the basic substance and its intended uses it may be reasonable to conclude a low risk to aquatic organisms.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)		NL: No comments			Noted
8(6)	8.3.1. Effects on bees	EFSA: typo error: my → may		Corrected	Addressed The typo error was corrected
8(7)	8.3.1. Effects on bees	EFSA: For the representative uses of hydrogen peroxide, a low risk to bees can be concluded due to low exposure		No comment	Due to the representative uses of hydrogen peroxide and to its nature, it is reasonable to conclude a low

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					risk to bees
8(8)	8.3.2 Effects on other arthropods	EFSA: The statement "hydrogen peroxide is toxic to arthropods" should be supported by a clear justification.	A risk assessment and/or a scientific justification should be given in order to address the risk to non-target arthropods from the representative uses of hydrogen peroxide.	According to ECHA "Data waiving: study scientifically unjustified"	No additional information and insufficient data to perform a quantitative risk assessment for arthropods were provided. The exposure to ground dwelling arthropods cannot be completely excluded when the basic substance is applied according to the representative uses (i.e. seed treatments in field). However, due to the nature of the basic substance, a low in-field risk may be concluded for ground dwelling arthropods.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)		NL: No comments			Noted
8(10)	8.4 Effects on earthworms and other soil macroorganisms	EFSA: More data are needed in order to assess the potential risk for soil macroorganisms. It should be ensured that the risk assessment covers the	A risk assessment and/or a scientific justification should be given in order to address the risk to soil macroorganisms from the representative uses of hydrogen peroxide.	Expected residues are water and oxygen.	No additional information and insufficient data to perform a quantitative risk assessment for soil macroorganisms were provided. The exposure of soil macroorganisms cannot

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		representative uses of hydrogen peroxide.			be completely excluded when the basic substance is applied according to the representative uses (i.e. seed treatments in field). However, due to the nature of the basic substance, a low in-field risk may be concluded for soil macroorganisms.

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)		NL: No comments			Noted
8(12)	8.5 Effects on soil micro-organisms	EFSA: The conclusions reported for soil microorganisms are related to sewage treatment plant organisms. Data are not provided for soil microorganisms	More information should be provided in order to assess the risk to soil microorganisms related to the intended uses of hydrogen peroxide.	According to ECHA "Data waiving: study scientifically unjustified"	No additional information and insufficient data to perform a quantitative risk assessment for soil microorganisms were provided. The exposure of soil microorganisms cannot be completely excluded when the basic substance is applied according to the representative uses (i.e. seed treatments in field). However, due to the nature of the basic

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					substance, a low in-field risk may be concluded for soil microorganisms.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)		NL: No comments			Noted
8(14)	8.6 Effects on other non-target organisms (flora and fauna)	EFSA: For the representative uses of hydrogen peroxide, a low risk to other non-target organisms (flora and fauna) can be concluded due to low exposure. It is noted that hydrogen peroxide is not phytotoxic up to a concentration of 15%.		Applicant agrees hydrogen peroxide is a basic chemical with some concern but freely available in all M.S. as para-pharmaceutical concentrations higher (10-20%) than this application (5%). No spray is intended.	Considering that hydrogen peroxide is not phytotoxic up to a concentration of 15% and that its application is up to a concentration of 5%, a low risk to other non-target organisms (flora and fauna) can be concluded.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)		NL: No comments			Noted
8(16)	8.7 Effects on biological methods of sewage treatment	EFSA: More data are needed in order to assess the potential effects on biological methods of sewage treatment. It should be ensured that the assessment covers the representative uses of hydrogen peroxide.	A scientific justification should be given in order to address the effects on biological methods of sewage treatment from the representative uses of hydrogen peroxide.	Rapidly decomposed in water. ECHA ref added	No additional information and insufficient data to perform a quantitative risk assessment on the effects on biological methods of sewage treatment were provided. However, due to the nature of the basic substance and its intended uses, a low risk may be concluded for organisms involved in the sewage treatment from the representative uses.
8(17)	8.7 Effects on biological methods of sewage treatment	EFSA: It is reported that 'risk reduction measures already being applied are considered sufficient', please clarify which risk reduction measures are referred to.		Uses of tablets instead of liquid is a risk reduction measure.	Addressed The applicant reported that the use of tablets instead of liquid is considered a risk reduction measure

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		NL: No comments.			Noted

10. Other comments**Other comments**

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

Appendix B – Identity and biological properties

Common name (ISO)	not applicable
Chemical name (IUPAC)	hydrogen peroxide
Chemical name (CA)	hydrogen peroxide
Common names	not applicable
CAS No	7722-84-1
CIPAC No and EEC No	not applicable
FAO specification	not applicable
Minimum purity	solution in water (1.5 % and 2.5 – 5 %)-
Relevant impurities	none identified
Molecular mass and structural formula	34.01 [g/mol] □; H ₂ O ₂
Mode of Use	for seed treatment dilute to 1.5 %
Preparation to be used	solution in water (1.5 % and 2.5 – 5 %)-
Function of plant protection	Fungicide, bactericide

Appendix C – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			Total rate		PHI (days) (m)	Remarks (*, **)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Vegetables <i>Solanaceae</i> spp like Tomato <i>Lycopersicum</i> <i>Esulentum</i> bell pepper <i>Capsicum</i> spp	FR Not relevant	Oxypur	G	Soil bacteria <i>Ralstonia Solanacerum</i> <i>Botrytis cinerea</i>	Liquid for Disinfection of mechanical cutting tools Concerned Tools Small Miscellaneous equipment: Cuttings scissor with injection (LS) ***	15 to 30	Tools application before cutting *	None	continuous during use	Not relevant	n.a.	n.a.	n.a.	n.a.	n.a.	Waiting period 30 seconds after washing

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			Total rate		PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Lettuce <i>Lactuca sativa</i>	FR Not relevant	Oxyapur	F G	Bacterial leaf spot pathogen <i>Xanthomonas Campestris</i> pv. <i>vitians</i>	Liquid for Seed Treatment (LS) ***	10 to 15	Seed application before seedling g*	Not relevant	1	None	Not relevant	Seeds are temporary deep in the preparation then removed	Not relevant	Seeds are temporary deep in the preparation then removed	n.a.	5 to 15 min Seed treatment
Horticulture flowers Like common zinnia <i>Zinnia elegans</i>				Fungi, especially pathogenic <i>Alternaria zinnia</i> <i>Alternaria alternata</i> <i>Fusarium</i> Spp.		25 to 50										

* Of active Hydrogen peroxide solution

** Treatment, just before sowing.

*** Preparation is describe in the recipe §2.5.

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor

(d): e.g. 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, between the plant – type of equipment used must be indicated

(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)

(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

- (k): Indicate the minimum and maximum number of application possible under practical conditions of use
- (l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m): PHI - minimum pre-harvest interval