

## TECHNICAL REPORT

# Outcome of the consultations with Member States and EFSA on the basic substance application and its update on calcium hydroxide for use in plant protection against fungal diseases on pome fruit<sup>1</sup>

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### 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 phases conducted with Member States and EFSA on the basic substance application and on its update for calcium hydroxide 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 calcium hydroxide as a basic substance for use in plant protection against fungal diseases on pome fruit. The current report summarises the outcome of the consultation processes conducted on the original application and its update and presents EFSA's scientific views on the individual comments received.

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### KEY WORDS

calcium hydroxide, basic substance, application, consultation, plant protection, pesticide, fungicide

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## SUMMARY

Calcium hydroxide 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 IFOAM EU Group 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 applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 11 July 2013, EFSA was asked to finalise the Reporting Table for calcium hydroxide, taking into account the information and comments submitted by the applicant following the commenting phase. The outcome of the consultation process and EFSA’s scientific views on the individual comments received are presented in the Technical Report approved on 24 September 2013 (EFSA supporting publication 2013:EN-488).

By a second specific mandate, received from the European Commission on 7 April 2014, EFSA was requested to update the existing Technical Report on calcium hydroxide, taking into account the new information submitted by the applicant in March 2014 and the comments received from Member States on the updated application.

The current report summarises the outcome of the consultation processes conducted on the original basic substance application and its update for calcium hydroxide and presents EFSA’s scientific views on the individual comments received in the format of Reporting Tables, one for each commenting round.

The initial application for calcium hydroxide as a basic substance, received in September 2012, was updated in June 2013 and in March 2014.

Calcium hydroxide is intended to be used in plant protection against *Neonectria galligena* on pome fruit.

The composition of calcium hydroxide depends on the geographical position of the limestone mine, however a „specification” for calcium hydroxide can be proposed based on this submission. It is not possible to conclude on the similarity to the calcium hydroxide used as a food processing aid (E526).

The criteria indicated in Article 23(1)(a) – (d) of Regulation (EC) No 1107/2009 cannot be considered fulfilled for calcium hydroxide. There are no relevant EU evaluations available to show that the substance has no harmful effects on human or animal health, nor an unacceptable effect on the environment. As a consequence, Article 4 of Regulation (EC) No 1107/2009 fully applies.

The available information in the mammalian toxicology section indicates that calcium hydroxide is irritant for the skin, the eye and the respiratory tract and, as such, classified. Based on this, it is not possible to conclude that calcium hydroxide is not a substance of concern as defined in Article 3(4) of Regulation (EC) No 1107/2009. No valid exposure assessments for operators and workers are available, whereas it is available for bystanders. As for the reference values to be applied in the risk assessment, the basis of how the DNEL (derived no-effect level) was derived is unclear (i.e. the underlying data are missing); the TWA (time weighted average) and STEL (short-term exposure limit) limits are mainly derived for industrial and indoor settings, therefore their applicability for comparison with exposure assessments performed in agriculture is limited. In summary, the operator, worker and bystander risk assessment cannot be concluded.

Concerning the residues section, for the intended uses there will be negligible exposure as the uses are during the dormant phase where no fruit is present. Also, calcium hydroxide will be rapidly converted to calcium carbonate which is used in high doses as an antacid.

The available information on the fate and behaviour is considered not sufficient to properly address the exposure assessment of calcium hydroxide as a fungicide in the soil and the aquatic compartments for the proposed uses with spray application and sprinkler application. Negligible levels of environmental exposure are expected for the proposed use with brush application directly on pruning wounds and old cankers on stems, even though information on the application dose (e.g. kg a.s. per number of plants) should be provided. Based on Council Directive 98/83/EC on the quality of drinking water intended for human consumption, calcium hydroxide as an inorganic compound is not considered a pesticide and therefore the parametric drinking water limit of 0.1 µg/L for pesticides, usually used as a decision-making criterion regarding groundwater exposure when a pesticide product is authorised, does not apply.

The available ecotoxicological risk assessments are not considered sufficient to address the risk to aquatic organisms, earthworms and non-target plants for the spray and sprinkler applications. The risk to birds and mammals, honey bees, non-target arthropods and soil microorganisms was considered as low applying a weight of evidence approach. The associated uncertainties are described in Appendix A. It is noted that the season of the applications as proposed by the intended uses was an important element of the weight of evidence approach. As regards the brush application, a low risk to non-target organisms was concluded on the basis of the expected negligible environmental exposure.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009<sup>3</sup> (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.

Calcium hydroxide is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from IFOAM EU Group for approval as a “basic substance”.

The European Commission subsequently organised a consultation with Member States and EFSA on the basic substance application for calcium hydroxide (IFOAM EU Group, 2012), via a written procedure. The comments received were collated by the European Commission 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 information submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table (Appendix A). The outcome of the consultation process and EFSA’s scientific views on the individual comments received were presented in the Technical Report approved on 24 September 2013 (EFSA, 2013).

Following commenting on the finalised Technical Report as required by the European Commission, the applicant submitted in March 2014 additional documentation in order to address the outstanding issues identified in the report and complete the assessment on calcium hydroxide.

In April 2014 the EFSA organised a consultation with Member States on the updated application for calcium hydroxide (IFOAM EU Group, 2014), via a written procedure. 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, were considered by EFSA in column 4 of the Reporting Table (Appendix B).

The current report aims to summarise the outcome of the consultation processes conducted on the original basic substance application and its update for calcium hydroxide and to present EFSA’s scientific views on the individual comments received in the format of Reporting Tables.

The application and its update submitted by the applicant for approval of calcium hydroxide as a “basic substance” in the context of Article 23 of the Regulation, are key supporting documentation, therefore they are considered as background documentation to this report and will also be made publicly available, excluding its appendices (IFOAM EU Group, 2012 and 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 11 July 2013, EFSA was asked to finalise the Reporting Table for calcium hydroxide following the consultation process conducted by the European Commission on the basic substance application, taking into account the information and comments provided by the applicant in June 2013.

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<sup>3</sup> 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.

By a second specific mandate, received from the European Commission on 7 April 2014, EFSA was requested to complete the assessment for calcium hydroxide and update the existing Technical Report (EFSA, 2013), taking into account the information submitted by the applicant in March 2014 with a view to address the outstanding issues identified in the original Technical Report, and the comments received from Member States on the updated application.

To this end, the existing Technical Report on calcium hydroxide (EFSA, 2013) is updated by EFSA with the finalised Reporting Tables. The deadline for providing the updated report is 9 September 2014.

On the basis of the Reporting Tables, 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 original basic substance application for calcium hydroxide (IFOAM EU Group, 2012) and the conclusions drawn by the EFSA are presented in the format of a Reporting Table (Appendix A). A separate Reporting Table (Appendix B) has been prepared on the outcome of the consultation process on the updated application (IFOAM EU Group, 2014) submitted in March 2014.

The comments received are summarised in column 2 of the Reporting Tables. 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 tables.

The finalised Reporting Tables are provided in Appendix A and B of this report.

## DOCUMENTATION PROVIDED TO EFSA

IFOAM EU Group, 2012. Calcium hydroxide. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2012. Submitted by IFOAM EU Group. Documentation made available to EFSA by the European Commission.

IFOAM EU Group, 2013. Calcium hydroxide. Basic substance application update in the form of annexes submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2013. Submitted by IFOAM EU Group. Documentation made available to EFSA by the applicant.

IFOAM EU Group, 2014. Calcium hydroxide. Basic substance application update submitted following commenting on the finalised Technical Report (EFSA supporting publication 2013:EN-488): “Answers to remarks and questions put by EFSA in the Technical Report EN 488”. March 2014. Submitted by IFOAM EU Group. Documentation made available to EFSA by the European Commission.

## REFERENCES

Anonymous, 2003. Title: Calcium balance in orchards on different soil types, treated with calcium hydroxide against fruit tree canker Source: Request to amend Annex IIB-Pesticides, Annex I.

Bokhorst S.C., Poortvliet L.J. (1962); Title: Scheikunde voor analisten. II systematische anorganische scheikunde; Derde druk; Source: J.B. Wolters, Groningen.

EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for calcium hydroxide and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-488. 41 pp. Available online: [www.efsa.europa.eu/publications](http://www.efsa.europa.eu/publications)

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.1 dated March 2012

Rinsema W.T. (1969); Title: Bemesting en meststoffen; Achtste druk; Source: W.E.J. Tjeenk Willink, Zwolle.

Rooijen, H van, 2006. Title: Evaluation of calcium hydroxide and anti-clotting agents in surface water. Source: Hoogheemraadschap De Stichtse Rijnlanden, Houten (NL). Evaluation based on the criteria in CIW report “Het beoordelen van stoffen en preparaten voor de uitvoering van het emissiebeleid water” (judgement of substances and preparations in the framework of emission management water). Details of the evaluation not available.

Schärer, HJ. A., Häseli, C., Daniel, J., Fuchs, L., Tamm; 2010. Title: Praxisversuche 2010 mit Löschkalk und Hanfextrakt gegen Feuerbrand. Source: Öffentlicher Schlussbericht 2010.

SCOEL (Scientific Committee on Occupational Exposure Limits), 2008. Recommendation from the Scientific Committee on Occupational Exposure Limits for Calcium oxide (CaO) and calcium hydroxide (Ca(OH)<sub>2</sub>). SCOEL/SUM/137. February 2008.

**APPENDIX**

**APPENDIX A - COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE ORIGINAL BASIC SUBSTANCE APPLICATION FOR CALCIUM HYDROXIDE AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED (updated by EFSA following the application update submitted by the applicant in March 2014)**

**1. Purpose of the application**

<b>General</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1a		DE: Referring to current knowledge, an approval for the active substance calcium hydroxide as a basic substance according to Article 23 of Regulation (EC) No 1107/2009 is not supported due to the following reasons: - The conclusion of the evaluation of the documents submitted regarding calcium hydroxide was that a direct or delayed harmful effect on human or animal health according to Art. 23 (2) of Regulation (EC) No 1107/2009 cannot be excluded. - The submitted documents including the literature do not enable a health assessment. The conclusion of a first examination of the documents was that calcium hydroxide can have a harmful impact on health. - Since no reference values were derived from the submitted documentation, no risk assessment is possible for operators, workers and bystanders and consumers. - Exposure for	The applicants decided to restrict the use of calcium hydroxide to - control of fruit tree canker - during leaf drop (late autumn until end of the year) by spray application and sprinkler irrigation - during winter months upon pruning wounds and old canker plots by brush application Risk assessment: - operators, workers and bystanders: see pt 5.13 - consumers: no residue on fruit Drinking water: see pt 7 - honeybees: no bee flight during application period	See EFSA column 4 entries at points 5.13 and 7 below.  Concerning the proposed uses, it is noted that the applicant no longer wishes to support the applications in spring and early summer, and the use on vines. However, no new or updated GAP tables were provided and therefore the current risk assessments reflect the GAP table in the submitted application, which includes the uses on orchards also in spring/summer, and the use on vines.  See also column 3 entries at 3.1(1) and 8.1(2).  <u>EFSA, July - August 2014:</u> In the updated application (March

<b>General</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		honeybees cannot be excluded when calcium hydroxide is applied in the presence of flowering weeds in autumn, but it is expected to be low. However, no data on the acute toxicity to honeybees is available. The fact that calcium hydroxide is used for disinfecting bee hives does not mean that it is not toxic for bees as it is not applied directly to the bees.		2014) a new GAP table was provided supporting sprinkler and spray applications (during leaf drop and from October till end of December), and brush application directly on pruning wounds and old cancers on stems (during winter to March) on pome fruit against <i>Neonectria galligena</i> .
1b		DE : Hydrated lime / calcium dihydroxide (CAS no.: 1305-62-0) is currently being assessed as a biocidal active substance (product type: 2 and 3) according to Directive 98/8/EC. If calcium dihydroxide is included in Annex I of Directive 98/8/EC, it should then be checked to see whether an approval as a basic substance is still possible according to Article 23 of Regulation (EC) No 1107/2009.	- Product type 2 and 3 are fields of use, viz. "private area and public health area disinfectants" and "veterinary hygiene biocidal products".  - To the opinion of the applicants, this is not relevant for an approval as basic substance according to art. 23 of EC 1107/2009. Moreover, Directive 98/8/EC also includes a category type basic substances.	According to Article 23(1) (c) and (d) of Regulation (EC) No 1107/2009: “For the purpose of paragraphs 2 to 6, a basic substance is an active substance which: 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; and d) is not placed on the market as a plant protection product.” According to Directive 98/8/EC <sup>4</sup> calcium dihydroxide is being assessed as a biocidal active substance

<sup>4</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123, 24.4.98, p.1. Replaced by 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 L167, 27.6.2012. p.1.

<b>General</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>(product type: 2 and 3):</p> <p><b>Product-type 2:</b> Private area and public health area disinfectants and other biocidal products<sup>5</sup></p> <p><b>Product-type 3:</b> Veterinary hygiene biocidal products<sup>6</sup></p> <p>The proposed uses under the recent application are on pome fruits (see also point 3.1(1)).</p> <p>The above mentioned details support the opinion of the applicant in column 3.</p>

<sup>5</sup> Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algacides. Usage areas include, *inter alia*, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

<sup>6</sup> Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

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

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2	2.1 Predominant uses, p.6	EFSA: clarification is needed if the calcium hydroxide described in this submission is similar to that used as E526?	<p>- Commission Directive 2009/10/EC of 13 February 2009 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (Text with EEA relevance) describes in pt 7 and 8 that in view of the manufacturing of lime products from available raw materials (calcium carbonate) and the natural high background level - here lead - in the raw material, the purity levels of certain elements should be adjusted to the lowest achievable values.</p> <p>- It can be concluded that calcium hydroxide used as PPP will have about the same chemical composition as calcium hydroxide used as E 526; there is no purification process in the supply as E 526.</p> <p>- In Annex 1 the purity criteria for use of calcium hydroxide in drinking water production are given. Explanation in Annex 2.</p>	<p>From the available data a conclusion cannot be drawn on the similarity of the submitted product with the requirements of the calcium hydroxide as E526.</p> <p>Commission Directive 2009/10/EC of 13 February 2009, amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners<sup>7</sup> describes in recital 7) “On the basis of data provided by the European Lime Association, it appears that the manufacturing of lime products from available raw materials does not permit them to comply with the existing purity criteria set for E526 calcium hydroxide, as regards the level of magnesium and alkali salts. Taking into account that magnesium salts are of no safety concern and the specifications as set out in the Codex</p>

<sup>7</sup> Commission Directive 2009/10/EC of 13 February 2009, amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners. OJ L 44, 14.2.2009, p. 62-78.

<b>2.1. Predominant Use</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA), it is appropriate to adjust the levels of magnesium and alkali salts for E526 calcium hydroxide to the lowest achievable values, which remain lower or equal to the levels set by JECFA”.</p> <p>8) “In addition, it is necessary to take into account the specifications as set out in the Codex Alimentarius drafted by JECFA with regard to the level of lead for E526 calcium hydroxide. However, due to the natural high background of lead contained in the raw material (calcium carbonate) extracted in some Member States, and from which those additives are derived, it appears difficult to align the level of lead contained in those food additives with the upper limit of lead set by JECFA. Therefore the current level of lead should be reduced to the lowest achievable threshold.”</p> <p>In the Annex of the Directive, on p.75, the following is stated:</p>

<b>2.1. Predominant Use</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>E526 Calcium hydroxide Purity: “Magnesium and alkali salts - Not more than 2,7 % Lead - Not more than 6 mg/kg”</p> <p>The composition of calcium hydroxide depends on the geographical position of the limestone mine.</p> <p>Taking into account the Certificate for the product ‘Akdolit SL 24HR’ reported in the updated application received in June 2013, the values for magnesium and alkali salts and lead are met. However, to assure that all sources used for the production of calcium hydroxide comply with these values, the magnesium and alkali salt content and the lead content should be maximised to the values as given in Commission Directive 2009/10/EC.</p> <p>It should be noted that in the specifications given in section 2.2.5 of the original application (Proposal for approbation of basic substances in the context of Regulation (EC) No 1107/2009, September 2012, p.7-8.)</p>

<b>2.1. Predominant Use</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>no information is available on the Ba, F and As content of the submitted product, and as a consequence, a comparison with the values prescribed in the above Directive cannot be made.</p> <p><u>EFSA, July - August 2014:</u> In the updated submission (March 2014) a certificate of analysis was submitted containing also the As and Ba content of the sample CL 90Q Super 60.</p>

<b>2.2. Identity and Physical and chemical properties of the substance and product to be used</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3	2.2.5 Description and specification of purity of the a.s. and product, p.7-8	EFSA: clarification is needed on the way the composition of the products is expressed, as it is not clear from where the figures for CaO are coming.	<p>REACH Lime Consortium from IMA-Europe gives the following information:</p> <ul style="list-style-type: none"> <li>- The composition of calcium hydroxide is expressed as oxide equivalents of the elements present in it, even though these elements are analytically determined as elements and not as oxides.</li> <li>- The content of Ca is expressed as CaO. In calcium hydroxide, Ca is actually present in</li> </ul>	<p>Addressed: The Ca content of the Ca(OH)<sub>2</sub> is expressed as CaO.</p>

<b>2.2. Identity and Physical and chemical properties of the substance and product to be used</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			<p>the form of this hydroxide.</p> <ul style="list-style-type: none"> <li>- Calculation of the content of Ca(OH)<sub>2</sub> from CaO and Lol</li> <li>- Calculation of the purity of Ca(OH)<sub>2</sub> from CaO and CO<sub>2</sub></li> </ul> <p>See Annex 3 "Recommended Analytical Methods for Substance Identification and Purity"</p>	
4	2.2.5 Description and specification of purity of the a.s. and product, p.7-8	EFSA: it would be helpful to include the content of the DIN standards concerning these products, as it is not possible to access them and have information on the composition of the products.	See pt. 3 "Description of analytical methods and test-procedures" in above mentioned Annex 3. Recommended Analytical Methods for Substance Identification and Purity.	Addressed: The principles of the analytical methods are presented in the updated application received in June 2013.
5	2.2.7 Methods of analysis, p.8	EFSA: the methods of analysis should be part of the submission, the standards DIN EN459-2 and DIN EN 12518 are not freely accessible.	See pt. 3 "Description of analytical methods and test-procedures" in above mentioned Annex 3. Recommended Analytical Methods for Substance Identification and Purity.	<p>The principles of the analytical methods are presented in the updated application received in June 2013, however the methods themselves are still missing from the submission.</p> <p><u>EFSA, July - August 2014:</u> In the updated submission (March 2014) the English translation of DIN EN 12485:2010-08 (Chemicals used for treatment of water intended for human consumption – Calcium carbonate, high-calcium lime, half-burnt dolomite, magnesium oxide and calcium magnesium carbonate –Test</p>

<b>2.2. Identity and Physical and chemical properties of the substance and product to be used</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application (methods) was submitted.

<b>2.3. Current, former and in case proposed trade names</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

<b>2.4. Manufacturer of the substance/products</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

<b>2.5. Type of preparation</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6	2.5 Type of preparation, p. 9	EFSA: at least the nominal content of the a.s. in the proposed products, or the nominal a.s. range should be given.	- A.s. content of lime water Lhoist: 24% Ca(OH) <sub>2</sub> - A.s. content of powder Münsterkalk: 92% Ca(OH) <sub>2</sub> The a.s. content of other powders lies between 85% and 97% Ca(OH) <sub>2</sub>	Addressed.  <u>EFSA, July - August 2014:</u> In the updated submission (March 2014) it was proposed to use a 36 % solution in water of Marmorweisskalkhydrat CL90-S(33,1%.Ca(OH) <sub>2</sub> ), without additives, instead of the powder product Münsterkalk.

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

<b>2.7. Function on plant protection</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.				

### 3. Uses of the substance and its product

<b>3.1. Field of use</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1	Section 3.3, Summary of intended uses	EFSA: Clarification is needed as to what is meant by 'ES 15 - ES 80' for the application timing/ growth stage for the proposed use to vines (row number 7). In particular it would need to be clarified if 'ES' is the same as a BBCH growth stage.	The application in viticulture has been cancelled, see No 1 (a)	<p>The application in viticulture has been cancelled.</p> <p>However, no new GAP table was provided.</p> <p>See also EFSA column 4 entry in point 1a of section General.</p> <p><u>EFSA, July - August 2014:</u></p> <p>In the updated application (March 2014) a new GAP table was provided supporting sprinkler and spray applications (during leaf drop and from October till end of December), and brush application directly on pruning wounds and old cancers on stems (during winter to March) on pome fruit against <i>Neonectria galligena</i>.</p>

<b>3.2. Effects on harmful organisms or on plants</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

<b>3.3. Summary of intended uses</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

#### 4. Classification and labelling of the substance

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

## 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 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1		EFSA: for the assessment of calcium hydroxide health effects only limited toxicological data summaries are available, therefore no independent assessment is possible. It is noted that several documents are in German and it is not possible to assess them.	<p>- In the database of <a href="http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances">http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances</a> the toxicological information is presented. This central database, run by ECHA (European Chemicals Agency), registers the information on chemicals in the framework of REACH, the European Community Regulation on chemicals and their safe use (EC 1907/2006). REACH deals with the Registration, Evaluation, Authorization and Restriction on Chemical substances. The information from ECHA is also used in the PSDS from Lhoist and Märker Kalk.</p> <p>- Calcium metabolism in humans: in stead of Karlson (Kurzes Lehrbuch der Biochemie) see Annex 4 (from Wikipedia).</p>	<p>The ECHA database mentioned in column 3 does not represent an assessment, but the submission of information by companies for registration purposes. Therefore there are no relevant EU evaluations available to show that the substance has no harmful effects on human or animal health.</p> <p>The studies have been shortly summarised in the application, whereby an independent assessment was not possible.</p> <p>Considering the skin and eye irritating effects, and also the effects on the respiratory tract, it cannot be concluded that calcium hydroxide is not a substance of concern as defined in Article 3(4) of Regulation (EC) No 1107/2009.</p> <p>See also point 10(2).</p>
2		EFSA: the identity of calcium hydroxide used in agriculture has to be defined to further check its toxicological relevance in the frame of the definition of what a basic substance is. In particular, it is mentioned	<p>- See Annex 1 and 2 for impurities</p> <p>- Chalk <math>\text{CaCO}_3</math> is burned (addition of <math>\text{O}_2</math> and removal of <math>\text{CO}_2</math>) &gt; <math>\text{CaO}</math></p> <p><math>\text{CaO}</math> is slaked (addition of <math>\text{H}_2\text{O}</math>) &gt;</p>	<p>Addressed.</p> <p>Despite the high application rates, the presence of impurities is unlikely to represent a toxicological concern.</p>

<b>5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		that no relevant impurities are present. However, as the application rates are huge, any impurities might represent a concern due to the high levels it could reach in the environment.	Ca(OH) <sub>2</sub> . So, impurities are not added or removed. - In pt 7 No (2) the calcium balance of orchard soils has been analysed. See Annex 5. Conclusion: the application rates of calcium hydroxide in crop protection are comparable with or lower than the application rates in liming practice. Accumulation of impurities as a consequence of PPP-application does not occur. - In surface water calcium hydroxide will be diluted. Moreover, after application with spray-drift reducing techniques the precipitate on surface water is more than 95% less than the precipitate on orchard soil, see pt 7 No (3) and Annex 6.	
3	Classification for eye, skin and respiratory tract irritation	NL: The draft guidance document on basic substances states that a basic substance is <i>not a substance of concern as defined in Article 3(4) of Regulation 1107/2009</i> . According to this definition, a substance classified for skin, eye and/or respiratory tract irritation cannot be a basic substance. However, regarding skin, eye and/or respiratory tract irritation, indicating on the label/MSDS which PPE are needed is sufficient. Based on this, it can be		See EFSA column 4 entry in 5.1(1) above.

<b>5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		considered whether substances which are <b>only</b> classified for skin, eye or respiratory tract irritation can also be basic substances?		

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

No comments.

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

No comments.

<b>5.4. Short –term toxicity</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA’s scientific views on the specific points raised in the commenting phase conducted on the application
4	Eye irritation / skin irritation	NL: The information on eye irritation reported under skin irritation should be moved to the paragraph on eye irritation.	See 5.13	Noted.

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

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

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

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

No comments.

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

No comments.

<b>5.10. Medical data adverse effects reported in humans</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

<b>5.11. Additional information related to therapeutic properties or health claims</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> 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 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

**5.13. 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 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	AOEL regarding powder exposure	NL: From a toxicological point of view inhalation exposure appears to be the most relevant route. A statement / assessment should be included in the document showing that powder exposure does not exceed the 8 h TWA of 1 mg/m <sup>3</sup> or the 15 min STEL of 4 mg/m <sup>3</sup> during mixing/loading and application.	<p>INHALATION EXPOSURE POWDER, OPERATOR (AND WORKER)</p> <p>* In the Appendix of Lhoist PSDS, page 16-95, many exposure scenario's are given. The methodology for exposure assessment is described on pg 14-15, see Annex 7A: "By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measures (RMMs) the substance can be handled safely".</p> <p>* In all relevant scenario's (outdoor handling of high dusty powders), using respiratory protective equipment, the inhalation exposure estimate is below the repeated DNEL of 1 mg/m<sup>3</sup>. See e.g. 9.9 and 9.10. The operator has to check the relevant exposure scenario's, given in the Appendix or available via the supplier, in order to choose the suitable filter mask.</p>	<p>No reference values have been proposed: according to the applicant, a reference value derived from the no-effect level (DNEL) can be used in the risk assessment, being a worst case. However, the basis of how the DNEL was derived is unclear (i.e. the underlying data are missing):</p> <p>SCOEL recommendation (SCOEL/SUM/137 February 2008):</p> <p>Occupational Exposure Limit (OEL), 8 h TWA: 1 mg/m<sup>3</sup> respirable dust of calcium hydroxide</p> <p>Short-term exposure limit (STEL), 15 min: 4 mg/m<sup>3</sup> respirable dust of calcium hydroxide</p> <p>The TWA and STEL limits are mainly derived for industrial and indoor settings, therefore their applicability for comparison with</p>

**5.13. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			<p><b>INHALATION EXPOSURE BYSTANDER</b> Bystanders are persons walking, cycling or running on the paths outside the orchard. These bystanders are exposed to the drift of spray/irrigation liquid. In annex 7B the risk assessment inhalation exposure bystander is given. It is concluded that the exposure to calcium hydroxide in the droplets is far less than the acute DNEL and repeated DNEL of 4 and 1 mg respirable dust/m<sup>3</sup>.</p> <p><b>DERMAL AND EYE EXPOSURE BYSTANDER</b> A DNEL for dermal exposure and exposure to the eye is not available, see PSDS from Lhoist and Märker Kalk. Therefore, in Annex 7c a different approach has been followed. It is concluded that the dermal exposure is at least 50.000 times less than the application rates in the toxicological experiments reviewed in ECHA database. It is concluded that the eye exposure is at least 8.000 times less than the lowest application rate in the toxicological experiments.</p>	<p>exposure assessments performed in agriculture is limited.</p> <p>An exposure assessment for operators and workers for the specific scenarios “spraying” and for the “brush” uses is missing, whereas it is available for bystanders.</p> <p>In summary, based on the available data the operator, worker and bystander risk assessment cannot be concluded.</p> <p><u>EFSA, July - August 2014:</u> The new GAP table does not specify which product should be considered for the exposure assessment and the application rates for the brush application. It is unclear why the operator exposure assessment has been performed with EUROPOEM I, which is not validated for this purpose. In addition, some parts of the calculations provided are not clear (e.g. DNEL calculation: the concept of mg droplets).</p>

<b>5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>Re-entry: in Annex 4 (of application update of March 2014) no exposure assessment is reported.</p> <p>Bystander inhalation exposure: some parts of the calculations provided are not clear (e.g. DNEL calculation: the concept of mg droplets); the data on drift reducing techniques are very interesting, but insufficient details are reported to assess them (e.g. with regard to the application of the data in the scenario under discussion).</p> <p>Eye exposure: the assessment is not routinely done, therefore it is unclear for the reader how calculations have been performed (e.g. based on which parameters, and why they were selected).</p> <p>In summary, as in the previous assessment, no reference values can be established and no operator, worker and bystander risk assessment can be performed.</p> <p>In the product safety data sheet several DNEL are reported; however</p>

<b>5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				the basis of how the DNELs (derived no-effect levels) were derived is still unclear (i.e. the underlying data are missing) as it was in the previous assessment.

<b>5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		EFSA: No comment.		

## 6. Residues

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

## 7. Fate and Behaviour in the environment

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1	Fate and behaviour in the environment, general	EFSA: It is noted that the references relied on (refer to Annex I of the Application template dated September 2012) are not available to EFSA and therefore it is not possible to evaluate them.	<p>- Evaluation by Hoogheemraadschap De Stichtse Rijnlanden (Annex 8): see pt 7 No (3) surface water and pt 8.2 aquatic organisms</p> <p>- Environmental yardstick CLM (Annex 9): see pt 8.2 aquatic organisms and pt 8.4 earthworms/ soil macro-organisms.</p> <p>- Additional information concerning the quick reaction between Ca(OH)<sub>2</sub> and CO<sub>2</sub>: calcium hydroxide is used as CO<sub>2</sub> absorbant in closed circuit breathing apparatus (PSDS from Lhoist.</p>	<p>All the references relied on and included in Annex I of the original application dated September 2012 are now available, except for Rooijen, H. van (2006). It is noted that the following references:</p> <ul style="list-style-type: none"> <li>- Bokhorst S.C., Poortvliet L.J. (1962); Title: Scheikunde voor analisten. II systematische anorganische scheikunde; Source: J.B. Wolters, Groningen</li> <li>- Rinsema W.T. (1969); Title: Bemesting en meststoffen; Source: W.E.J. Tjeenk Willink, Zwolle</li> </ul> <p>are in German language only.</p> <p><u>EFSA, July - August 2014:</u></p> <p>Further information has been provided by the applicant in the document: "Answers to remarks and questions put by EFSA in the Technical Report EN 488".</p> <ul style="list-style-type: none"> <li>• As regards the reference Rooijen, H. van (2006) see EFSA comment under point 7(3).</li> <li>• The translations provided for some sentences included in the</li> </ul>

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>references Bokhorst S.C., Poortvliet L.J. (1962) and Rinsema W.T. (1969) do not provide further information (additional to the qualitative assessment reported in the Application template dated September 2012) on the environmental fate of calcium hydroxide in the environment.</p>
2	7. A Soil	<p>EFSA: due to the natural occurrence of calcium and carbonate in the environment, conducting specific environmental fate studies is not required. However, taking into consideration the high application rate of calcium hydroxide added as a fungicide to the same environment, further details on the potential impact on the natural background concentrations of calcium carbonate in soil should be provided.</p>	<p>In Annex 5. the calcium balance of orchard soils has been analysed. Conclusion: the application rates of calcium hydroxide in crop protection are comparable with or lower than the application rates in liming practice.</p>	<p>The calcium balance in orchards presented in Annex 5 (Anonymous, 2003) is based on some assumptions (i.e. natural loss from soils, loss from rainfall and loss by scab and mildew control by sulphur), which are uncertain and would require further explanations in order to fully address the potential impact of calcium hydroxide added as a fungicide on the natural background concentrations of calcium carbonate in soil.</p> <p><u>EFSA, July - August 2014:</u> Further information on the calcium balance in orchards presented in Annex 5 (of the application update in June 2013) has been provided by the applicant in the document: "Answers</p>

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>to remarks and questions put by EFSA in the Technical Report EN 488". The references which were the basis for inputs of the estimated calcium balance of orchard soils were provided. The applicant concluded that the application rates of calcium hydroxide in crop protection are comparable with or lower than the application rates in liming practice. However, it is EFSA's opinion that this analysis does not address the potential impact of calcium hydroxide added as a fungicide on the natural background concentrations of calcium in soil. In fact, it is not clear how the ABC units/ha for the supply and the losses of calcium were calculated in Annex 12 (of the application update of March 2014). It seems that more explanations are provided in the text but as long as it is in Dutch, it is not possible for EFSA to get this information and validate the numbers in the table on p. 5. The data derived from Annex 13 (scab and mildew control by sulphur) are derived from a paper, which does not seem to be publicly available and seems to be not peer reviewed. The text is in Dutch and can not be validated by EFSA to</p>

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>support the quantitative assessment of the impact on the amount of calcium derived from the use of calcium hydroxide with respect to the natural background concentration levels of calcium in EU agricultural soils. Therefore a data gap is identified. This is in line with the evaluation of other inorganic compounds that have been requested to be approved as active substances for use in PPP with high application rates (e.g. calcium ions in soil for lime sulfur and potassium ions for potassium hydrogen carbonate).</p> <p>EFSA note: taking into consideration an application rate of 350 kg a.s./ha (total annual loading) to a soil depth of 5 cm and a bulk density of 1.5 g/cm<sup>3</sup> (with no crop interception), an initial PECsoil value of 466 mg/kg is derived. This is valid for the intended uses with spray application and sprinkler application. Negligible levels of environmental exposure to soil are expected for the intended use with the brush application directly on pruning wounds and old cancers on stems, even though information on</p>

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				the application dose (e.g. kg a.s. per number of plants) should be provided.
3	7.B Surface water	<p>EFSA: In line with the other inorganic compounds that have been requested to be approved as a PPP, an assessment of the impact of the amount of calcium hydroxide and its degradation/transformation products in the aquatic environment arising from the use of calcium hydroxide as a fungicide with respect to the natural background concentration levels in natural surface water systems in the EU should be provided. Additionally, as details on the report on the effects of calcium hydroxide in surface water (Rooijen van, 2006) are not available, the results of the study can not be considered acceptable to support the approval of calcium hydroxide as a basic substance.</p>	<p>In Annex 6. transformations of calcium hydroxide in surface water are described. It is concluded that the precipitate of calcium hydroxide on surface water after PPP application will have negligible effects upon pH and chemical composition.</p>	<p>The aquatic exposure to calcium hydroxide as a PPP, as presented in Annex 6, cannot be considered addressed due to the following reasons:</p> <ul style="list-style-type: none"> <li>- The maximum total annual application for the intended uses applied for is 350 kg/ha</li> <li>- A justification for using a value of 2.5 % for spray drift should be provided (note that at Step 1 for pome/stone fruit, early applications the value considered for spray drift is 29.2 %)</li> <li>- The standard FOCUS ditch is 30 cm depth</li> <li>- The estimated calcium concentrations as a result of the addition of calcium hydroxide as a PPP are compared to natural background concentration levels in natural surface water in the Hoogheemraadschap region and in Belgium only.</li> </ul> <p>It should also be noted that the</p>

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>reference Rooijen H. van (2006) is still missing.</p> <p><u>EFSA, July – August 2014:</u> Further information has been provided by the applicant in the document: “Answers to remarks and questions put by EFSA in the Technical Report EN 488”.</p> <p>Because the reference Rooijen H. van (2006) is not available, the information on the behaviour and effects of calcium hydroxide in surface water provided in the Application template can not be accepted.</p> <p>The use of the eco-toxicological model SLOOTBOX is not agreed at the EU level for the approval of active substances for use in PPP. This model is based on some assumptions which are valid for the Dutch national authorisation. For the intended uses with spray application and sprinkler application, a quantitative estimation of PEC<sub>sw</sub> for Ca ions following the use of calcium hydroxide as a fungicide should be performed based on the standard FOCUS (2001) ditch dimensions, a spray drift value</p>

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>according to the FOCUS drift calculator and the default % for runoff/drainage at FOCUS (2001) Step 1-2. This is in line with the evaluation of other inorganic compounds that have been requested to be approved as active substances for use in a PPP with high application rates (e.g. calcium ions in soil for lime sulfur and potassium ions for potassium hydrogen carbonate). Negligible levels of environmental exposure to surface water bodies are expected for the intended use with brush application directly on pruning wounds and old cancers on stems, even though information on the application dose (e.g. kg a.s. per number of plants) should be provided.</p>
4	7. Ground water	<p>EFSA: It should be clarified that, based on Council Directive 98/83/EC on the quality of drinking water intended for human consumption, calcium hydroxide as an inorganic compound is not considered a pesticide and therefore the parametric drinking water limit of 0.1 µg/L for pesticides, usually used as a decision</p>	<p>Based on Council Directive 98/83/EC, calcium hydroxide as an inorganic compound is not considered a pesticide and therefore the parametric drinking water limit of 0,1 microgram/L for pesticides, usually used as a decision making criterion regarding groundwater exposure, does not apply.</p>	<p>The information regarding the fact that, based on Council Directive 98/83/EC on the quality of drinking water intended for human consumption<sup>8</sup>, calcium hydroxide as an inorganic compound is not considered a pesticide and therefore the parametric drinking water limit of</p>

<sup>8</sup> Council Directive 98/83/EC of 3 November 1998 on the quality of drinking water intended for human consumption. OJ L 330, 5.12.98, p.32-54.

No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		making criteria regarding groundwater exposure, does not apply.	Calcium hydroxide is very quickly transformed and calcium is naturally present in soils. Moreover, calcium hydroxide is used in the production process for drinking water (Annex 1 and 2). The purpose is regulation of hardness and pH correction.	0.1 µg/L for pesticides, usually used as a decision-making criterion regarding groundwater exposure, does not apply, should be reported in the application.  <u>EFSA, July - August 2014:</u> No comments.

## 8. Effects on non-target species

<b>8.1. Effects on terrestrial vertebrates</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1	Section 8, General	EFSA: It is noted that the references relied on (refer to Annex I of the Application template dated September 2012) are not available to EFSA and therefore it is not possible to evaluate them.	Missing references: see additions below.	<p>Most of the data referred to in the reference list have been submitted. However, some of the information is not available in English. Moreover, the underlying ecotoxicological data, referred to in a number of the submitted papers, are not available.</p> <p>Please refer to the specific points below relating to each area of the ecotoxicology assessment.</p> <p>Currently there are no relevant EU evaluations available to show that the substance has no unacceptable effect on the environment. As a consequence, Article 4 of Regulation (EC) No 1107/2009 fully applies and the following comments relate to the data and risk assessment provided by the applicant to address Article 4 of Regulation (EC) No 1107/2009.</p> <p><u>EFSA, July – August 2014:</u> Please refer to the specific points below relating to each area of the</p>

<b>8.1. Effects on terrestrial vertebrates</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				ecotoxicology assessment. The underlying ecotoxicological data are still not available.
2	Section 8.1, Risk assessment for terrestrial vertebrates	EFSA: A consideration of the risk to some species of terrestrial vertebrates has been included in the assessment. However, the risk assessment is based on the fact that at the time of application some species will be hibernating. It is noted that the proposed use of calcium hydroxide includes applications made in July and therefore the argumentation provided is not consistent with the proposed uses. In addition, a risk assessment is considered necessary for birds and mammals that may not be hibernating and could potentially be exposed.	<ul style="list-style-type: none"> <li>- The applicants cancelled the proposed uses in spring and early summer.</li> <li>- Not-hibernating mammals and birds will be frightened away from the orchard by the noise of spraying/irrigation equipment and operators/workers. Young birds or mammals are not present during application time.</li> </ul>	<p>It is considered that the information available is not sufficient to address the acute and long-term risk to birds and mammals.</p> <ul style="list-style-type: none"> <li>- The argumentation that birds and mammals will be scared away during application is not accepted as exposure to residues on food items can still occur following the application. Furthermore, some mammals may not retreat large distances during application.</li> <li>- It is acknowledged that some species will not be breeding in the winter months. However, for this argumentation to be used to address the long-term risk to birds and mammals it would be necessary to clearly demonstrate that exposure during the breeding season of key focal species present in orchards will not occur. Moreover, no new GAP table has been submitted to change the intended uses of calcium hydroxide, therefore, the current</li> </ul>

<b>8.1. Effects on terrestrial vertebrates</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>risk assessment reflects the GAP table in the submitted application which includes the use on orchards also in spring/summer and the use on vines.</p> <ul style="list-style-type: none"> <li>- An acute risk assessment for birds and mammals is also required.</li> </ul> <p>It is noted that toxicity data are available for mammals, a quantified risk assessment could therefore be performed.</p> <p><u>EFSA, July – August 2014:</u></p> <p>No quantified risk assessment was available in the updated application (March 2014). EFSA notes that for the acute dietary risk to mammals, TER values of &gt; 0.3 to &gt; 7.7 could be calculated using the first tier step of pertinent EFSA guidance document (EFSA, 2009) and considering an oral LD<sub>50</sub> of &gt; 2000 mg/kg bw and a single application of 50 kg/ha. However, the documentation in the updated application (March 2014) included some argumentation suggesting that food for birds and mammals is practically not available</p>

**8.1. Effects on terrestrial vertebrates**

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>during the wintertime and/or they are hidden for hibernating (e.g. insects). These argumentations were however not supported by data. EFSA notes that the majority of non-migrating birds and mammals in Europe are actively foraging for food also during the wintertime and, in general, considerable food is still available in agricultural landscapes in late autumn. Therefore the exposure of the food items during and after the application is a relevant scenario. Considering the high application rate (up to 7 x 50 kg/ha), the theoretical exposure of birds and mammals is very high for the spray and sprinkler application. Additionally, the toxicity profile of calcium hydroxide to birds was not characterised (although considering the data on mammals it has likely low toxicity). On the other hand, the attractiveness of pome fruit orchards to birds and mammals during the winter/late autumn is considered as relatively low. The available food what the orchards may offer this time is rather limited. Also, the likely exposure of food items, such as arthropods, larvae of</p>

**8.1. Effects on terrestrial vertebrates**

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>arthropods or worms is also considered to be limited (considering the season). Therefore, on the basis of weight of evidence considerations, the risk to birds and mammals might be considered as low. However, it has to be noted that this conclusion includes some uncertainty considering both the exposure and the hazard characterisation.</p> <p>As regards the brush application, although the application rate was not indicated, a low exposure, and therefore a low risk to birds and mammals can be predicted (assuming that the application rate is not extremely high).</p> <p>Also, a low long-term risk to birds and mammals can be predicted considering the fate and behaviour of calcium hydroxide in the environment and considering the fact that the last application is envisaged in December or March (March is for the brush application where the exposure was assumed to be low).</p>

<b>8.2. Effects on aquatic organisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3	Section 8.2, Risk to aquatic organisms	EFSA: It is proposed that the risk to aquatic organisms is low on the basis of the expected exposure is not expected to exceed an 'ecological standard' (or environmental yard stick). However, as noted in comments from EFSA in the fate and behaviour section a number of concerns with the exposure assessment have been highlighted. Therefore, pending on the outcome of the exposure assessment, a risk assessment (comparing exposure and effects) is required.	<p>- Evaluation by Hoogheemraadschap (Annex 8).</p> <p>* Contrary to the references in the application template, calcium hydroxide as a PPP was not evaluated according to the criteria in the CIW report but according to the ecotoxicological model SLOOTBOX. See Annex 9 for details.</p> <p>* It is concluded that calcium hydroxide does not have negative side-effects on aquatic organisms if applied with drift-reducing techniques. This condition is quite normal in countries with much surface water such as The Netherlands. Basic condition for all Dutch fruit growers, both conventional and organic, is a crop-free zone of 3 meter alongside surface water.</p> <p>- Environmental yardstick CLM Same conclusion. See Annex 9 for details.</p> <p>- In Annex 8 several drift reducing techniques for sprinkler irrigation and spray application are described.</p>	<p>Please refer to point 3 of section 7 regarding the approach taken in the surface water exposure assessment.</p> <p>The available information is not considered suitable to perform a risk assessment for aquatic organisms. The underlying ecotoxicological data have not been submitted and therefore the endpoints cannot be verified.</p> <p><u>EFSA, July – August 2014:</u> The link to the ECHA database is not referring to a complete assessment of data for calcium hydroxide, but only to the information submitted by the companies for their registration. Therefore the available ecotoxicological data do not allow defining the ecotoxicological profile of calcium hydroxide. It is noted that according to the provided safety data sheet, calcium hydroxide does not seem to be particularly toxic to aquatic organisms. These data, however could not be validated. No reliable exposure estimation was available for the spray and the</p>

<b>8.2. Effects on aquatic organisms</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>sprinkler applications for surface water (see point 3 of section 7). Therefore, and due to the uncertainty in the ecotoxicological profile, the risk could not be assessed for these uses.</p> <p>The exposure of surface water bodies was expected to be negligible for the intended use with brush application directly on pruning wounds and old cancers on stems. Therefore the risk is considered to be low for this use.</p>

<b>8.3. Effects on bees and other arthropods species</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4	Section 8.3, Risk to bees	EFSA: The proposed use to pome and stone fruit includes spray applications from March to July. Therefore, there is potential exposure to bees. Further information is needed to demonstrate a low risk to bees.	No bee flight during application period in late autumn and winter.	<p>No new GAP table has been submitted, therefore the current risk assessment reflects the GAP table in the submitted application which includes the use on orchards also in spring/summer and the use on vines. Exposure to honey bees cannot be excluded and a risk assessment is required.</p> <p>It may be possible to conclude a low</p>

<b>8.3. Effects on bees and other arthropods species</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>risk to honey bees for the proposed uses of calcium hydroxide during the winter months.</p> <p><u>EFSA, July – August 2014:</u> Some exposure to bees in autumn in the presence of flowering weeds may occur, but it is expected to be rather low. Overall, a low exposure, therefore a low risk to honey bees is concluded for the intended uses (assuming that the application rate for the brush application is not extremely high).</p>
5	Section 8.3, Risk to non-target arthropods	EFSA: No risk assessment has been provided for non-target arthropods as some of the representative uses are made in the winter. However, some non-target arthropods could potentially be exposed (even during the winter months). Some information has been summarised in the application; however, this data is not available to EFSA and therefore cannot be fully evaluated.	<p>- During late autumn and winter most non-target arthropods are hidden behind the bark and in the layer of litter/fallen leaves. Only spiders may be dwelling on the trees. However, Schärer (2010) observed no differences between calcium hydroxide treated and untreated trees (see application template, par. 8.3.B Other diseases).</p> <p>- Moreover, the winter moth (<i>Operophtera brumata</i>) is active during winter. But this insect is a plague and not a non-target arthropod in the sense of the application.</p> <p>- Explanation of life cycle diagrams in A.</p>	<p>The study of Schärer et al (2010) is not available in English and therefore could not be used in the risk assessment. With the information currently available, the risk assessment for non-target arthropods cannot be completed.</p> <p>It should also be noted that no new GAP table has been submitted, therefore the current risk assessment reflects the GAP table in the submitted application which includes</p>

<b>8.3. Effects on bees and other arthropods species</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			van Frankenhuyzen/ H. Stigter * earwig ( <i>Forficula auricularia</i> ): imago in rest-phase in the soil * Braconidae (wasp parasites): pupa in cocoon of moths in the soil * ladybird: in rest-phase * pupa in soil	the use on orchards also in spring/summer and the use on vines.  <u>EFSA, July – August 2014:</u> No new data or risk assessments were submitted. However, a summary of the study by Schärer et al (2010) in English was made available. The results of this study indicated no large effect on the arthropod community that was involved. However, this study cannot be considered as representative of the intended uses as it was conducted with lower application rates, different season of the year (this has pros and cons) and during the night in order to avoid exposure of some non-target organisms, such as bees. Therefore the usefulness of this study in the risk assessment is limited.  Some exposure of communities of non-target arthropods in late autumn may occur, but it is expected to be rather low, in general. Although the populations of some species that are more active in late autumn than others maybe relatively high. Pending on the

<b>8.3. Effects on bees and other arthropods species</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>sensitivity of those species, large effects on their populations cannot be excluded. On the other hand, considering the fate and behaviour of calcium hydroxide in the environment, this effect might not be considered as long lasting, therefore a re-colonisation from neighbouring areas within a reasonable time (i.e. in next spring) can be assumed.</p> <p>Overall, taking into account all of these considerations above, a low risk to non-target arthropods was concluded for the intended uses (assuming that the application rate for the brush application is not extremely high). However, it has to be noted that this conclusion includes some uncertainty considering both the exposure and the hazard characterisation.</p>

<b>8.4. Effects on earthworms and other soil macroorganisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6	Section 8.4, Risk to earthworms	EFSA: Please refer to EFSA fate and behaviour comment regarding the exposure assessment for soil. Pending the outcome of this comment further information may be required to address the risk to earthworms.	Environmental yardstick CLM: see Annex 9 for details concerning the conclusion that the application of calcium hydroxide does not exceed the ecological standard for soil life.	<p>The 'environmental yardstick' is not an EU recognised approach for an ecotoxicological risk assessment. Moreover, the underlying toxicity data for earthworms, referred to in the 'environmental yardstick' assessment, have not been submitted. As such, further information is considered necessary to address the risk to earthworms from the proposed uses of calcium hydroxide.</p> <p>Please also refer to point 2 of section 7 regarding the soil exposure assessment.</p> <p><u>EFSA, July – August 2014:</u> The link to the ECHA database is not referring to a complete assessment of data for calcium hydroxide. Therefore the available ecotoxicological data do not allow defining the ecotoxicological profile of calcium hydroxide. For information; if the endpoint of LC<sub>10</sub> or NOEC of 2000 mg/kg was considered in a risk assessment, the resulting acute TER was (&gt;) 4.3 (considering PECsoil of</p>

<b>8.4. Effects on earthworms and other soil macroorganisms</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>466 mg/kg).</p> <p>However as described in point 2 of section 7, no reliable impact assessment to soil of the use of calcium hydroxide was available for the spray and the sprinkler applications. Therefore, and due to the uncertainty in the ecotoxicological profile, the risk could not be assessed for these uses. However see also point 7 below.</p> <p>The exposure of soil was expected to be negligible for the intended use with the brush application directly on pruning wounds and old cancers on stems. Therefore the risk was considered to be low for this use.</p>

<b>8.5. Effects on soil microorganisms</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7	Section 8.4, Risk to soil microorganisms	EFSA: Please refer to EFSA fate and behaviour comment regarding the exposure	As clarified in Pt 7 No (2), the application rates of calcium hydroxide in crop	Please refer to point 2 of section 7 regarding the soil exposure

<b>8.5. Effects on soil microorganisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment for soil. Pending the outcome of this comment further information may be required to address the risk to soil microorganisms.	protection are comparable with or lower than the application rates in liming practice, so in accordance with good agricultural practice.	assessment.  The available information is not considered sufficient to address the risk to soil microorganisms from the proposed uses of calcium hydroxide.  <u>EFSA, July – August 2014:</u> The link to the ECHA database is not referring to a complete assessment of data for calcium hydroxide. Therefore the available ecotoxicological data do not allow defining the ecotoxicological profile of calcium hydroxide. It is noted that according to the provided safety data sheet, calcium hydroxide does not seem to be toxic to aquatic organisms. These data, however, could not be validated. In the updated information (March 2014) a calculation was available explaining that after the application of calcium hydroxide, the change of the soil pH is not expected to be more than 0.1 unit. Some elements of these calculations are not agreed or could not be validated, however the results, in general, were considered as

<b>8.5. Effects on soil microorganisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				reliable. However, see also point 2 in section 7. Considering the information above, the fact that the applications are envisaged in wintertime and that soil microorganisms, in general, are considered to have a high recovery potential, the risk to soil microorganisms is considered to be low (weight of evidence approach).

<b>8.6. Effects on other non target organisms (flora and fauna)</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8	Section 8.5, Risk to non-target plants	EFSA: It is stated that the authors of the assessment do not know of any adverse effects to plants. However, to support this assessment it is considered that further information (e.g. a scientific publication) is required.	The application against fruit tree canker is out of the growing season.	Even outside of the main growing season, exposure to some species of non-target plants can occur. Moreover, no new GAP table has been submitted, therefore the current risk assessment reflects the GAP table in the submitted application which includes the use on orchards also in spring/summer and the use on vines. The available information is not

<b>8.6. Effects on other non target organisms (flora and fauna)</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>considered sufficient to address the risk to non-target plants.</p> <p><u>EFSA, July – August 2014:</u> No further information was provided, except a reference to a seedling emergence test which however was not considered relevant. Therefore no further assessments could be performed.</p> <p>The exposure of non-target plants was expected to be negligible for the intended use with brush application. Therefore the risk was considered to be low for this use (provided that the application rate is not extremely high).</p> <p>It is noted that the mentioned GLP study on seedling emergence would have been useful information.</p>

<b>8.7. Effects on biological methods of sewage treatment</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

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

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

No comments.

## 10. Other comments

<b>Other comments</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1	2.1 Predominant uses, p.6	EFSA: calcium hydroxide as a food processing aid with the E-number E526 can be considered foodstuff as defined in Art. 2 of Regulation 178/2002, being 'intentionally incorporated into the food during its manufacture, preparation or treatment'.		See point 2.1(2).
2	Overall conclusion with respect of eligibility of the substance as basic substance, p.20	EFSA: based on the available data it was not possible to conclude whether calcium hydroxide is or isn't a 'substance of concern' according to the provisions of Art.3 of Regulation 1107/2009. Ca hydroxide is classified as H315, H318, H335 but it was not possible to conclude on the concentration to be considered. It is not clear that the notified 85 to 97% calcium hydroxide or any other dilution should be considered as basic substance.	The fungicidal activity of calcium hydroxide is based on the very high pH of the spray- and irrigation-liquid. In all applications a suspension in water with a pH of more than 12 is used.	Concentrated material as well as its simple dilutions are intended for use according to sections 2.2.5 and 3.3 of the original application (Proposal for approbation of basic substances in the context of Regulation (EC) No 1107/2009, Calcium hydroxide, September 2012). Based on the available toxicological data it is not possible to conclude that calcium hydroxide is not a substance of concern as defined in Article 3(4) of Regulation (EC) No 1107/2009.
3		EFSA agrees that the provisions of Art. 23.1. (b) – (d) of Regulation (EC) No 1107/2009 are fulfilled.		See point 5.1(1). The criteria indicated in Article 23(1)(a) – (d) of Regulation (EC) No 1107/2009 cannot be considered fulfilled for calcium hydroxide.

**APPENDIX B - COLLATION OF COMMENTS FROM MEMBER STATES ON THE UPDATED APPLICATION SUBMITTED BY THE APPLICANT IN MARCH 2014 ON CALCIUM HYDROXIDE AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED**

**4. Classification and labelling of the substance**

<b>Classification and labelling of the substance</b>				
No.	<u>Column 1</u> Reference to Application Template	<u>Column 2</u> Comments from Member States / EFSA	<u>Column 3</u> Follow up response from applicant	<u>Column 4</u> EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1		<p>DE: The proposal to include calcium hydroxide in the list of basic substances is not supported.</p> <p>§ 23 of Reg (EC) No 1107/2009 allows to approve a substances as a basic substance only if it is “(a) not a substance of concern” with ‘substance of concern’ being defined as “...substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No 1272/2008...”. Ca(OH)<sub>2</sub> is considered to meet the criteria to be classified for its corrosive potential. Hence it cannot be approved as a basic substance.</p>	<p>Applicants information is that the criteria for basic substance, mentioned in Reg (EC)No 1107/2009, do not include the corrosive potential. Thus, it is not really transparent for the applicants why this is discussed in the context of approvment as basic substance.</p> <p>However, applicants understand that MS DE is concerned of eventual risks deriving from the use of calcium hydroxide in plant protection due to a corrosive potential. The applicants point to the fact that neither in the Application Template nor in the follow-up papers a corrosive risk has been mentioned. However, considering the wide spread use of calcium hydroxide as fertilizer (liming material) in agriculture an additional risks due to the proposed use in plant protection does not exist.</p>	<p>According to the safety data sheet provided for ‘milk of lime’ (mixture of calcium dihydroxide and water) the product is classified as Skin irrit. 2, H315; STOT SE 3, H335; Eye Dam. 1, H318; the link to the ECHA database is not referring to a complete assessment of calcium hydroxide, but only to the information submitted by the companies for their registration. Therefore the available toxicological data do not allow defining the complete toxicological profile of calcium hydroxide. However, its classification indicates that calcium hydroxide cannot be considered a basic substance.</p> <p>The Regulation lays down specific criteria to identify an active substance as eligible as basic:</p> <p>(a) is not a substance of concern as defined in Article 3(4) of Regulation 1107/2009; and</p> <p>(b) does not have an inherent capacity</p>

<b>Classification and labelling of the substance</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				<p>to cause endocrine disrupting, neurotoxic or immunotoxic effects; and</p> <p>(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; and</p> <p>(d) is not placed on the market as a plant protection product.</p> <p>With regard to (a), “ ‘substance of concern’ means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect”.</p> <p>Such substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No 1272/2008.</p> <p>This is not changing the conclusion of the previous assessment.</p>

## 5. Impact on Human and Animal Health

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1		<p>DE: The proposal to include calcium hydroxide in the list of basic substances is not supported.</p> <p>§ 23 of Reg (EC) No 1107/2009 allows to approve a substances as a basic substance only if it is “(a) not a substance of concern” with ‘substance of concern’ being defined as “...substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No 1272/2008...”. Ca(OH)<sub>2</sub> is considered to meet the criteria to be classified for its corrosive potential. Hence it cannot be approved as a basic substance.</p>	<p>Applicants information is that the criteria for basic substance, mentioned in Reg (EC)No 1107/2009, do not include the corrosive potential. Thus, it is not really transparent for the applicants why this is discussed in the context of approvment as basic substance.</p> <p>However, applicants understand that MS DE is concerned of eventual risks deriving from the use of calcium hydroxide in plant protection due to a corrosive potential. The applicants point to the fact that neither in the Application Template nor in the follow-up papers a corrosive risk has been mentioned. However, considering the wide spread use of calcium hydroxide as fertilizer (liming material) in agriculture an additional risks due to the proposed use in plant protection does not exist.</p>	<p>See column 4 entry at point 4(1) above.</p>

## 8. Effects on non-target species

<b>8.1. Effects on terrestrial vertebrates</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1	Risk assessment for terrestrial vertebrates	DE: Agreement to both EFSA's scientific views concerning Section 8, General, and Section 8.1, Risk assessment for terrestrial vertebrates.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 2 in section 8.1 in Appendix A.
<b>8.2. Effects on aquatic organisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2	Risk to aquatic organisms	DE: Agreement to EFSA's scientific views concerning Section 8.2, Risk to aquatic organisms.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 3 in section 8.2 in Appendix A.
<b>8.3. Effects on bees and other arthropods species</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3	Risk to non-target arthropods	DE: Agreement to EFSA's scientific views concerning Section 8.3, Risk to non-target arthropods.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488	See point 5 in section 8.3 in Appendix A.

<b>8.3. Effects on bees and other arthropods species</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			(Revision III, 14 February 2014)"	
4	Effects on bees	DE: Exposure for honey bees can not be excluded when calcium hydroxide is applied in the presence of flowering weeds in autumn, but it is expected to be low. However, no data on the acute toxicity to honey bees is available. The fact that calcium hydroxide is used for disinfection of bee hives does not adduce evidence that it is not toxic for bees since it is not applied directly onto the bees.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 4 in section 8.3 in Appendix A.

<b>8.4. Effects on earthworms and other soil macroorganisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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	Risk to earthworms	DE: Agreement to EFSA's scientific views concerning Section 8.4, Risk to earthworms.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 6 in section 8.4 in Appendix A.

<b>8.5. Effects on soil microorganisms</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6	Risk to soil micro-organisms	DE: Agreement to EFSA's scientific views concerning Section 8.5, Risk to soil micro-organisms.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 7 in section 8.5 in Appendix A.

<b>8.6. Effects on other non-target organisms (flora and fauna)</b>				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7	Risk to non-target plants	DE: Agreement to EFSA's scientific views concerning Section 8.6, Risk to non-target plants.	We commented this already in the document "ANSWERS TO REMARKS AND QUESTIONS PUT BY EFSA IN THE TECHNICAL REPORT EN 488 (Revision III, 14 February 2014)"	See point 8 in section 8.6 in Appendix A.

## ABBREVIATIONS

µg	microgram
ABC	acid binding capacity
a.s.	active substance
cm	centimetre
DIN	Deutsches Institut für Normung (the German Institute for Standardization)
DNEL	derived no effect level
ECHA	European Chemicals Agency
ES	exposure scenario
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FOCUS	FORum for Co-ordination of pesticide fate models and their USE
GAP	good agricultural practice
GLP	good laboratory practice
h	hour
ha	hectare
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
L	litre
LC <sub>10</sub>	lethal concentration for 10 % of the organisms
LD <sub>50</sub>	lethal dose, median; dosis letalis media
mg	milligram
MSDS	material safety data sheet
NOEC	no observed effect concentration
OC	operational conditions
OEL	occupational exposure limit
PEC <sub>sw</sub>	predicted environmental concentration in surface water
PEC <sub>soil</sub>	predicted environmental concentration in soil
PHI	pre-harvest interval
PPE	personal protective equipment
PSDS	product safety data sheet
PPP	plant protection product
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	risk management measures
SCOEL	Scientific Committee on Occupational Exposure Limits
STEL	short-term exposure limit
TER	toxicity exposure ratio
TWA	time weighted average
WHO	World Health Organization