European Food Safety Authority

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TECHNICAL REPORT

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[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for 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. The current report summarises the outcome of the consultation process organised by the European Commission and presents EFSA's scientific views on the individual comments received.

KEY WORDS

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

[1] On request from the European Commission, Question No EFSA-Q-2013-00402, approved on 24 September 2013.

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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 current report therefore summarises the outcome of the consultation process organised by the European Commission on the basic substance application for calcium hydroxide and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The initial application for calcium hydroxide as a basic substance, received in September 2012, was updated in June 2013. Calcium hydroxide is intended to be used against fungal and bacterial diseases on pome fruit and stone fruit and against fungal diseases on vines.

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 table was provided.

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. An exposure assessment for operators and workers for the spraying and the brush uses is missing, 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 majority of uses there will be negligible exposure as the use is during the dormant phase where no fruit is present. For the uses with the 21 day PHI (pre-harvest interval) calcium hydroxide will be rapidly converted to calcium carbonate which is used at high doses as an antacid. Therefore the risk to the consumer will be negligible.

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. 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, does not apply.

The available ecotoxicological risk assessments are not considered sufficient to address the risk to non-target organisms (birds, mammals, aquatic organisms, honey bees, non-target arthropods, earthworms, soil microorganisms and non-target plants).

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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

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, 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.

The current report aims to summarise the outcome of the consultation process organised by the European Commission on the basic substance application for calcium hydroxide and to present EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The application and, where relevant, any update thereof submitted by the applicant for approval of calcium hydroxide as a "basic substance" in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (IFOAM EU Group, 2012).

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.

To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. The deadline for providing the finalised report is 16 October 2013.

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

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

EVALUATION

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

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

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

DOCUMENTATION PROVIDED TO EFSA

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 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.

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 ($Ca(OH)_2$). SCOEL/SUM/137. February 2008.

APPENDIX

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

1. Purpose of the application

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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 honeybees cannot be excluded when	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).

General				
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
		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.		
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[4] calcium dihydroxide is being assessed as a biocidal active substance

[4] 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.

General				
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
				(product type: 2 and 3): ***Product-type 2:*** Private area and public health area disinfectants and other biocidal products[5] ***Product-type 3:*** Veterinary hygiene biocidal products[6] The proposed uses under the recent application are on pome fruits, stone fruits and on vines (see also point 3.1(1)). The above mentioned details support the opinion of the applicant in column 3.

[5] 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 algaecides. 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).

[6] 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?	- 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. - 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. - In Annex 1..the purity criteria for use of calcium hydroxide in drinking water production are given. Explanation in Annex 2.	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. 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[7] 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

[7] 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.

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
				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". 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." In the Annex of the Directive, on p.75, the following is stated:

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
				E526 Calcium hydroxide Purity: "Magnesium and alkali salts - Not more than 2,7 % Lead - Not more than 6 mg/kg" The composition of calcium hydroxide depends on the geographical position of the limestone mine. 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. 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,)

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
				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.

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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	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.	REACH Lime Consortium from IMA-Europe gives the following information: - 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. - The content of Ca is expressed as CaO. In calcium hydroxide, Ca is actually present in the form of this hydroxide. - Calculation of the content of Ca(OH)2 from CaO and Lol - Calculation of the purity of Ca(OH)2 from CaO and CO2 See Annex 3 "Recommended Analytical Methods for Substance Identification and	Addressed: The Ca content of the $Ca(OH)_2$ is expressed as CaO.

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

2.3. Current, former and in case proposed trade names				
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

No comments.

2.4. Manufacturer of the substance/products				
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

No comments.

2.5. Type of preparation				
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	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)2 - A.s. content of powder Münsterkalk: 92% Ca(OH)2 The a.s. content of other powders lies between 85% and 97% Ca(OH)2	Addressed.

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

No comments.

2.7. Function on plant protection				
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

No comments.

3. Uses of the substance and its product

3.1. Field of use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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	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)	The application in viticulture has been cancelled. However, no new GAP table was provided. See also EFSA column 4 entry in point 1a of section General.

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

No comments.

3.3. Summary of intended uses				
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

No comments.

4. Classification and labelling of the substance

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

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.	- In the database of http//echa.europa.eu/web/guest/information-on-chemicals/registered-substances 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 **R**egistration, **E**valuation, **A**uthorization and Restriction on **CH**emical substances. The information from ECHA is also used in the PSDS from Lhoist and Märker Kalk. - Calcium metabolism in humans: in stead of Karlson (Kurzes Lehrbuch der Biochemie) see Annex 4 (from Wikipedia).	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. The studies have been shortly summarised in the application, whereby an independent assessment was not possible. 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. See also point 10(2).
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	- See Annex 1 and 2 for impurities - Chalk CaCO3 is burned (addition of O2 and removal of CO2) > CaO CaO is slaked (addition of H2O) >	Addressed. Despite the high application rates, the presence of impurities is unlikely to represent a toxicological concern.

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
		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)2. 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 *not a substance of concern as defined in Article 3(4) of Regulation 1107/2009*. 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.

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
		considered whether substances which are **only** classified for skin, eye or respiratory tract irritation can also be basic substances?		

5.2. Toxicokinetics and metabolism in humans				
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

No comments.

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

No comments.

5.4. Short –term 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
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.

5.5. Genotoxicity				
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

No comments.

5.6. Long-term 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

No comments.

5.7. Reproductive 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

No comments.

5.8. Neurotoxicity				
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

No comments.

5.9. Toxicity studies on metabolites				
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

No comments.

5.10. Medical data adverse effects reported in humans				
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

No comments.

5.11. Additional information related to therapeutic properties or health claims				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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

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/m3 or the 15 min STEL of 4 mg/m3 during mixing/loading and application.	INHALATION EXPOSURE POWDER, OPERATOR (AND WORKER) * 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". * 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/m3. 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.	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): SCOEL recommendation (SCOEL/SUM/137 February 2008): Occupational Exposure Limit (OEL), 8 h TWA: 1 mg/m³ respirable dust of calcium hydroxide Short-term exposure limit (STEL), 15 min: 4 mg/m³ respirable dust of calcium hydroxide The TWA and STEL limits are mainly derived for industrial and indoor settings, therefore their applicability for comparison with

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
			INHALATION EXPOSURE BYSTANDER 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/m3. DERMAL AND EYE EXPOSURE BYSTANDER 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.	exposure assessments performed in agriculture is limited. 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. In summary, based on the available data the operator, worker and bystander risk assessment cannot be concluded.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.	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

No comments.

7. Fate and Behaviour in the environment

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	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.	- Evaluation by Hoogheemraadschap De Stichtse Rijnlanden (Annex 8): see pt 7 No (3) surface water and pt 8.2 aquatic organisms - Environmental yardstick CLM (Annex 9): see pt 8.2 aquatic organisms and pt 8.4 earthworms/ soil macro-organisms. - Additional information concerning the quick reaction between Ca(OH)2 and CO2: calcium hydroxide is used as CO2 absorbant in closed circuit breathing apparatus (PSDS from Lhoist.	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: - Bokhorst S.C., Poortvliet L.J. (1962); Title: Scheikunde voor analisten. II systematische anorganische scheikunde; Source: J.B. Wolters, Groningen - Rinsema W.T. (1969); Title: Bemesting en meststoffen; Source: W.E.J. Tjeenk Willink, Zwolle are in German language only.
2	7. A Soil	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.	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.	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.

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	7.B Surface water	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.	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.	The aquatic exposure to calcium hydroxide as a PPP, as presented in Annex 6, cannot be considered addressed due to the following reasons: - The maximum total annual application for the representative uses applied for is 350 kg/ha - 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 %) - The standard FOCUS ditch is 30 cm depth - 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. It should also be noted that the reference Rooijen H. van (2006) is still missing.
4	7. Ground water	EFSA: It should be clarified that, based on	Based on Council Directive 98/83/EC,	The information regarding the fact

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
		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 criteria regarding groundwater exposure, does not apply.	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. 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.	that, based on Council Directive 98/83/EC on the quality of drinking water intended for human consumption[8], 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, does not apply, should be reported in the application.

[8] 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.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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	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.	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. Please refer to the specific points below relating to each area of the ecotoxicology assessment. 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.
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	- The applicants cancelled the proposed uses in spring and early summer. - Not-hibernating mammals and birds will be frightened away from the orchard by the	It is considered that the information available is not sufficient to address the acute and long-term risk to birds and mammals.

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
		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.	noise of spraying/irrigation equipment and operators/workers. Young birds or mammals are not present during application time.	- 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. - 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 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. - An acute risk assessment for birds and mammals is also

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
				required. - It is noted that toxicity data are available for mammals, a quantified risk assessment could therefore be performed.

8.2. Effects on aquatic organisms				
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.	- Evaluation by Hoogheemraadschap (Annex 8). * 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. * 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	Please refer to point 3 of section 7 regarding the approach taken in the surface water exposure assessment. 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.

8.2. Effects on aquatic organisms				
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
			zone of 3 meter alongside surface water. - Environmental yardstick CLM Same conclusion. See Annex 9 for details. - In Annex 8 several drift reducing techniques for sprinkler irrigation and spray application are described.	

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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.	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. It may be possible to conclude a low risk to honey bees for the proposed uses of calcium hydroxide during the winter months.

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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	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.	- 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). - Moreover, the winter moth (*Operophtera brumata*) is active during winter. But this insect is a plague and not a non-target arthropod in the sense of the application. - Explanation of life cycle diagrams in A. van Frankenhuyzen/ H. Stigter * earwig (Forficula auricularia): 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 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. 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 the use on orchards also in spring/summer and the use on vines.

8.4. Effects on earthworms and other soil macro-organisms				
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.	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. Please also refer to point 2 of section 7 regarding the soil exposure assessment.

8.5. Effects on soil micro-organisms				
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	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 soil microorganisms.	As clarified in Pt 7 No (2), the application rates of calcium hydroxide in crop protection are comparable with or lower than the application rates in liming practice, so in accordance with good agricultural practice.	Please refer to point 2 of section 7 regarding the soil exposure assessment. The available information is not considered sufficient to address the risk to soil microorganisms from the proposed uses of calcium hydroxide.

8.6. Effects on other non target organisms (flora and fauna)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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 considered sufficient to address the risk to non-target plants.

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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

Other comments				
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

No comments.

10. Other comments

Other comments				
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	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.

ABBREVIATIONS

µg	microgram
a.s.	active substance
cm	centimetre
DIN	Deutsches Institut für Normung (the German Institute for Standardization)
DNEL	derived no effect level
ECHA	European Chemical 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
h	hour
ha	hectare
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
L	litre
mg	milligram
MSDS	material safety data sheet
OC	operational conditions
OEL	occupational exposure limit
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
TWA	time weighted average
WHO	World Health Organisation