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Outcome of the consultation with Member States and EFSA on the basic substance application for milk for use in plant protection as fungicide

European Food Safety Authority (EFSA)

Abstract

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

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Keywords: cow milk, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2018-00431

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Summary

Milk 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 Basic-Eco-Logique for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in 23 May 2018, EFSA was asked to organise a consultation on the basic substance application for milk, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for milk, organised by EFSA, was conducted with Member States via a written procedure in January-March 2018. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

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

In food use, the term milk is defined under Codex Alimentarius standards as: 'the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing'.

Cow milk is intended to be used by foliar spray applications after dilution with water against powdery mildew in grapes, vegetables and ornamentals and also as liquid for disinfection of mechanical cutting tools.

As far as the basic substance complies with health safety standards for food milk including microbiological quality (absence of pathogens), no concerns are raised regarding human and animal health, except for the milk allergens. As regards the allergy concerns: Milk and products thereof including lactose are listed in Annex II of Reg. (EU) 1169/2011 as 'Substances or products causing allergies or intolerances', and specific mandatory labelling requests for products containing such substances apply should the applied milk remain on the crops as a residue.

As the residues of milk allergens cannot be ruled out after the proposed treatment of crops with the basic substance milk and the effectiveness of the intended PHI to mitigate consumer exposure to such residues could not be demonstrated, the applicant proposed labelling of treated agricultural produce. EFSA highlights for risk manager consideration that commenting Member States had diverging view on the feasibility and effectiveness of measures mitigating risks to consumer health by labelling of agricultural commodities.

Limited information was provided in relation to the fate and behaviour of milk in the environment. No exposure assessment was presented for milk and its main constituents in the different environmental compartments following the intended uses. It was highlighted that caution should be taken in order to avoid spillage during treatments.

Limited information was provided in the area of ecotoxicology. Due the nature of the substance and the proposed uses, the information is however considered sufficient.

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1. Introduction

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

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Milk is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Basic-Eco-Logique for approval as a 'basic substance' for use in plant protection as elicitor.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for milk, which was conducted via a written procedure in January-March 2018. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for milk 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 milk 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 (Basic-Eco-Logique; 2017, 2018).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 23 May 2018, EFSA was asked to organise a consultation on the basic substance application for milk, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 23 August 2018.

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

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

2. Assessment

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

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

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

Documentation provided to EFSA

1. Basic-Eco-Logique, 2017. Basic substance application on milk submitted in the context of Article 23 of Regulation (EC) No 1107/2009. December 2017. Documentation made available to EFSA by the European Commission.
2. Basic-Eco-Logique, 2018. Basic substance application update on milk submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2018. Documentation made available to EFSA by the applicant.

Abbreviations

a.s.	active substance
CPMA	Cow's milk protein allergy
EC	European Commission
ECHA	European Chemicals Agency
GAP	good agricultural practice
MS	Member State
PEC	predicted environmental concentration

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

1. Purpose of the application

General					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	1 Purpose of the application	DK: There are no reasons described to support the substance as basic.	Please fill out the template: <i>Include here reasons to support the substance as basic, its possible use in plant protection and when possible, information on its traditional use in agriculture e.g. interest for organic agriculture.</i>	Organic Farming citation added.	Addressed: The reason for application was added in the revised submission.
1(2)	Overall	DK: In general please add text. The application should be a stand-alone document. As it is most information is simply given as references without much text explaining what the reference is used for, and in some cases there is not even a relevant summary of the reference.	Please update the application.	Updated in the basic substance application	Addressed: The basic substance application was updated.
1(3)	Uses, p.5	EFSA: it is not clear if the application is for milk in general or milk extracted	730 million tonnes refer to what kind of milk?	Title changed for Cow Milk in the updated basic substance application	Addressed: The basic substance application is for cow milk in

General

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

2. Identity of the substance/product as available on the market and predominant use
2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2	NL: Generally it seems a lot of template text is still in the document.		Initial Template coloured in blue or removed.	Addressed
2(2)	2.1	NL: Is this application really intended to cover any type of milk, as long as it does not originate from humans, meaning, including goat, sheep or even elephants?		Title changed for Cow Milk in the updated basic substance application	Addressed: The basic substance application is for cow milk in general.
2(3)	2.1.1	NL: The synonyms are translations instead and should not be regarded as synonyms.		Corrected in the updated basic substance application	Addressed
2(4)	2.1.2	NL: Based on information from ECHA, numbers starting with a 6 are list numbers and do not formally classify as an EC number		Corrected in the updated basic substance application	Addressed The application was updated accordingly.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(5)	2.1.2	NL: The typical analysis is probably that of cow's milk. This should be clarified. In addition, is this raw milk, whole milk or does this not matter? Either way, this should be clarified in the document.		Title changed for Cow Milk in the updated basic substance application Should Cow Milk be 'raw whole cow milk' EFSA and Commission may change title anytime.	Addressed: The application is for raw whole cow milk.
2(6)	2.5	NL: Why would you exclude tap water? Can't you use any type of water to dilute milk?		Tap water added in the updated basic substance application	Addressed: The application was updated: tap water can also be used.
2(7)	2	DK: The predominant use and production of milk is very commonly known; please do not unnecessarily elaborate on it. It may be well-meaning, however it reads as a joke in this context e.g. the description " <i>milk is extracted from non-human mammals ...</i> " as well as the figures in 2.1.4 .	Please consider shorten and rephrasing the description to be more suited to the average target reader (a reader who knows what milk is).	Title changed for Cow Milk in the updated basic substance application Should Cow Milk be 'raw whole cow milk' EFSA and Commission may change title anytime.	Addressed: The title was changed to cow milk, however the commented text was not updated.
2(8)	2.1.4	DK: See previous comment; please delete the figures. A simple statement should suffice e.g. "The application is for milk as found commercially in a common grocery store" or something like it.	Please consider changing the "description" to be more suited to the average target reader (a reader who knows what milk is).	Corrected	Addressed: The title was changed to cow milk, however the commented text was not updated.

2.2. Current Former and in case proposed trade names

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

2.3. Manufacturer of the substance/products

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

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(9)	2.4	DE: "or other liquid (AL)" should be deleted since it refers to undiluted liquids and the milk is used diluted with water.		"or other liquid (AL)" removed from formulation codes in updated basic substance application	Addressed

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)	3.1.1.1 In vineyards	DK: Please include some text to shortly describe the function. It is not enough to simply mention a few references and then let the reader look up the facts for themselves. The application should ideally be a stand-alone document.	Please add text.	Abstracts of papers added in the updated basic substance application	Addressed: Abstracts of papers were added to the updated application.
3(2)		ES: A summary should be included for - Bettiol W., Silva H.S.A., Reis R.C. 2008. Effectiveness of whey against zucchini squash and cucumber powdery mildew. Science Horticulturae 117: 82-84.	DOI: 0.1016/j.scienta.2008.03.010	Abstract added in the updated basic substance application	Addressed: A summary of Bettiol W., Silva H.S.A., Reis R.C. 2008 was added to the updated application.

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(3)		<p>ES: Please, authors should be corrected in section 3.1.1.1 and annex I-section 3 for the following article:</p> <p>CRISP P., LORIMER M. and SCOTT E.S. 2006b <i>An evaluation of biological and abiotic controls for grapevine powdery mildew. 2. Vineyard trials. Novel controls for powdery mildew – greenhouse studies. Australian Journal of Grape and Wine Research 12, pp 203-211</i></p>	CRISP P., WICKS T.J., BRUER D. and SCOTT E.S. 2006b	Authors corrected in the updated basic substance application	Addressed: Authors were corrected in the updated application.
3(4)	Field of use, p11	EFSA: is there any information available on the effects on the target plants of the milk decomposition products after application?	Is there any bacterial decomposition on the sprayed leaves, if yes, are there any effects of this on the target plant?	Only phytotoxic aspects were analysed or characterised in trials	Only phytotoxic aspects were analysed or characterised in the trials.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)	3.2.2.	DK: Please include some text to	Please add text.	More references added to	Addressed:

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		shortly describe the mode of action. It is not enough to simply mention a few references and then let the reader look up the facts for themselves. The application should ideally be a stand-alone document.		Mode of Action i.e. Chen et al. 2003 Cervato et al., 1999	Additional references were presented in the revised submission.
3(6)	3.2.1	ES: A summary should be included for - Gangneux Jean-Pierre, Lavarde Dominique, Bretagne Stéphane, Guiguen Claude, Gandemer Virginie. 2002 Transient aspergillus antigenaemia: think of milk. THE LANCET, Vol 359, p 1251.	DOI:10.1016/S01406736(02)08238-7	Reference removed	Addressed: The reference was removed from the updated application
3(7)	3.2.2	ES: A summary should be included for - Cerkauskas Raymond F. and Ferguson Gillian 2014 Management of powdery mildew (<i>Podosphaera xanthii</i>) on greenhouse cucumber in Ontario. Can. J. Plant Pathol. Vol. 36, No. 1, pp22-37.	DOI:10.1080/07060661.2013.878754	Abstract added in the updated basic substance application	Addressed: The abstract was added to the updated application
3(8)	3.2.2	ES: A summary should be included for - Mete Emin, Çatal Ferhat, Tayman Cüneyt, URAS Nurdan, Akça Halise, ulukanligil,	http://journals.tubitak.gov.tr/medikal/issues/sag-09-39-1/sag-39-1-11-0809-2.pdf	Abstract added in the updated basic substance application	Addressed: The abstract was added to the updated application

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Mustafa, Özkaragöz Fatih 2009 Comparison of Human Milk, Cow's Milk and Infant Formulas for Their Antifungal Effects against Environmental Fungi. Turk J Med Sci. 39 (1): pp67-72.			
3(9)	3.3.1, p.14	EFSA: it is not clear from the abstract of Guzman-Plazola what is the significance of this study to the application of milk as basic substance		Reference removed	Addressed: The reference was removed from the updated application.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(10)	3.4	NL: The summary of intended uses (GAP) needs clarification, the different columns related to the dose rate appear to conflict: For the use in grapevine, in the column for L ai/hl min max L/ha a concentration of 10 to 40 L per 100 liter water		GAP Corrected in the updated basic substance application	Addressed: The GAP table was updated in the revised application.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		(hl) is given; the next column (water l/h min max) implies that the spray volume to be used is 300 L - 1000 L(3-10 hl). This means that the amount in L a.i./ha should be 30-400 Liters per hectare, not 3.			
3(11)		NL: milk is also in use for prevention of plant-to-plant virus transmission, where plants, cutting tools and/or hands are rinsed before handling of the plants. This may be an important use for some sectors.		New GAP added ref added in NL folder, more references may be provided by NL MS	Addressed: New line was added to the GAP table.
3(12)	3.3.2 In vineyards	DK: Please include a little more text to give the context of the statement "Milk at 10% is effective" e.g. how does this compare to the proposed uses. Otherwise it is too esoteric.		Results and table added and translated	Addressed: The application was updated with additional information.
3(13)	3.3.3.	DK: Please note that use in cereals is not applied for (as seen on the GAP in 3.4).	Please re-name this section to 'In soybeans', and exclude the reference for cereals –or justify why the reference is relevant here.	GAP Corrected in the updated basic substance application	Addressed: The GAP table was corrected.
3(14)	3.3.1 Usefulness in the Framework of	ES: A summary should be included for - Bettiol W.,	DOI: 10.1016/j.scienta.2008.03.010	Abstract added in the updated basic substance	Addressed: A summary of Bettiol W.,

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	Plant Protection	Silva H.S.A., Reis R.C. 2008. Effectiveness of whey against zucchini squash and cucumber powdery mildew. Science Horticulturae 117: 82-84.		application	Silva H.S.A., Reis R.C. 2008 was added to the updated application.
3(15)	3.3.1 Usefulness in the Framework of Plant Protection	ES: A summary should be included for - Smither-Kopperl, M.L., Datnoff, L.E., Cantliffe, D.J., 2005. Evaluation of fungicides and prophylactic treatments for control of powdery mildew on Beit Alpha cucumber, 2004. Fungicide & Nematicide Report Tests 60, V008. Pest Management Network	http://dx.doi.org/10.1094/FN60 .	Abstract added in the updated basic substance application	Addressed: A summary of Smither-Kopperl, M.L., Datnoff, L.E., Cantliffe, D.J., 2005 was added to the updated application.
3(16)	3.4.	ES: No information about the effect of milk on downy mildews and more specifically on <i>Bremia lactucae</i> have been described in this dossier, therefore we consider that the use lettuce* <i>Bremia lactucae</i> is not justified and it should be removed from	Justification if information was provided, otherwise this use should be removed.	GAP line removed	Addressed: The line of the GAP table concerning the use on lettuce (<i>Bremia lactucae</i>) was removed

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		intended uses.			
3(17)	3.4.	ES: According to data on application rate per treatment (L a.i./hl and Water L/ha) and being considered as a valid data, the proposed rates would be higher than those showed on the table for grapevine and soybean. In grapevine, Application rate per treatment L/a.i/ha should be 30 to 400 instead of 3 to 40 and then total rate (L a.i./ha): 90 to 2400 instead of 9 to 240. In soybean, Application rate per treatment L/a.i/ha should be 180 to 270 instead of 180 and then total rate (L a.i./ha): 540 to 1080 instead 540 to 720.	It is proposed in the column 2. The original application should be checked.	GAP Corrected in the updated basic substance application	Addressed: The GAP table was corrected in the updated application.
3(18)	GAP table, and type of preparation, p.9 and 16	EFSA: The preparation is claimed to be a SL while in the GAP is a SC		Corrected in GAP	Addressed: The GAP table was corrected.
3(19)	GAP table, and type of	EFSA: The concentration of the formulation is probably the		Density added in §2 100% corrected,	Addressed.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	preparation, p.9 and 16	density of the milk. The 'concentration' of milk in a product called milk is 100%.		although i) g/kg or g/L.	

4. Classification and labelling of the substance

Classification and labelling of the substance

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

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

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

5.2. Acute toxicity

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

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments

5.4. Genotoxicity

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

5.5. Long-term toxicity

Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 1 Reference to Application Template	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments

5.6. Reproductive toxicity

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

5.7. Neurotoxicity

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

5.8. Toxicity studies on metabolites

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

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.9.2 Carroccio 2000	NL: In the study it is recommended that food producers using milk and milk-derived products be required to specify, along with the nutritional information, the content of lactose in their products. However, this is about dairy products produced by large manufacturers as lactose intolerance-friendly products and not about crops or processed food after contamination due to the use of milk as plant protection product.		No comment from applicant Ref was cited as known adverse effects, not to request labelling of plant protection substance.	Noted
5(2)	5.9.2 Silanikove 2015	NL: This article proposes to label food that may contain lactose. However, this article is about the dairy industry.		No comment from applicant Ref was cited as known adverse effects, not to request labelling of plant	Noted

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		NL wonders whether labelling of crops should be a standard practice. It seems more an unacceptable approach (see also residues).		protection substance.	
5(3)	5.9.3 Conclusion	NL: Both cutaneous and oral exposure could induce allergic reactions to milk protein. Therefore we are on the opinion that allergic reactions to milk cannot be excluded by consuming crops due to the use of milk as plant protection product. As for allergic substances there is no limit to control the allergic reactions.		Applicant agrees but crop products should be washed or peeled if possible to avoid pesticide contaminations (natural substance, organic or chemicals)	Addressed. As far as the basic substance complies with health safety standards for food milk including microbiological quality (absence of pathogens), no concerns are raised regarding human and animal health, except allergy concerns. Milk and products thereof (including lactose) are listed in Annex II of Reg. (EU) 1169/2011 ² as 'Substances or products causing allergies or intolerances', and specific mandatory labelling requests for products containing such substances apply should the applied milk remain on the

² Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					crops as a residue. See also comments 5(5), 5(6) and 5(7).
5(4)	5.9.3 Conclusion	NL: Applicant has stated 'CMPA is totally linked to immune responses, since it is the defense to a protein not recognized by the body'. This is incorrect.	NL: Please adapt to 'CMPA is totally linked to immune responses, since it is the defense to a non-self-protein or an allergic substance'.	Corrected in the updated basic substance application	Addressed.
5(5)	5.9.3 Conclusion	NL: It is stated that 'professional nutritionists need to analyse and adapt to the nutrient intake, optimizing the availability of macro and micronutrients necessary for the maintenance and good health'. NL wonders whether this should be a standard practice to exclude milk protein allergy or lactose intolerance due to contamination of crops or processed food by using milk as plant protection product.		No comment from applicant. Milk is used on field. If some chemicals are subject to labelling (like for postharvest treatments), milk uses may or should be advertised.	See comment 5(3).

5.10. Additional Information related to therapeutic properties or health claims

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

5.11. Additional information related to use as food

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

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

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

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)		EFSA: as far as the basic substance complies with health safety standards for		Applicant agrees except allergy concerns.	See comment 5(3).

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		food milk including microbiological quality (absence of pathogens), no concerns are raised regarding human and animal health.			
5(7)		EFSA: It is noted that milk and products thereof (including lactose) are listed in Annex II of Reg. (EU) 1169/2011 as 'Substances or products causing allergies or intolerances', and specific mandatory labelling requests for produce containing such substances apply should the applied milk remain on the crops as a residue. See Section 6. Residues		Applicant agrees, many references provided in current basic substance application.	See comment 5(3).

6. Residues

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	6. Residues	<p>NL: If understood correctly, it is described that labelling of the treated crops would be required because of possible contamination with lactose and/or milk proteins. However, labelling of crops is not standard practice, and is considered an unacceptable approach.</p> <p>Has it been tested whether after a PHI of at least 3 days still lactose and/or milk proteins are present at the treated crops?</p>	<p>The applicant is requested to justify the length of the proposed PHI or any other mitigation measure to avoid as much as possible consumer exposure to allergens and demonstrate the effectiveness of such mitigation measures by further evidence.</p>	<p>All GAP lines were associated with highest PHI of 8 days. Crop labelling is common: see post-harvest information on bananas for instance.</p>	<p>The applicant has proposed a PHI of 8 days and considers crop labelling a workable approach. The effectiveness of the proposed PHI to mitigate consumer exposure to food allergens has not been demonstrated though.</p> <p>See also comment 6(3)</p>
6(2)	Summary of intended uses/ Point 6. Residues	<p>ES: A PHI is established for each crop; please specify the criterion used to set these PHI values. Are these waiting periods based on studies on the behaviour of the residue levels?</p> <p>According to the Working Document on the procedure for application of basic substances to be approved in compliance with Article 23</p>		<p>All GAP lines were associated with highest PHI of 8 days. No residue analyses were done as determination or with limit of detection (LOD). More time and money may be need to such results. No funding was allowed and applicant is not selling milk or intends to sell it either in case of approval.</p>	Refer to comment 6(3)

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>of Reg. (EC) No 1107/2009, (SANCO/10363/2012 rev.9), information on the residue behaviour of the substance should not be provided for foodstuffs, a simple comparison with possible background range of exposure could be sufficient.</p> <p>Nevertheless, we agree that due to increasing number of allergic people to milk and milk products, residues of milk like lactose and milk proteins, historically not of concern, may be now of concern. In our opinion, <u>labelling of such possibilities of milk, lactose and milk proteins contamination is necessary</u>. Furthermore, other mitigation measures as: <u>Crop products should be rinsed before consumption</u> should be also taken into account in the labelling of the crop products.</p>		<p>Basic substances have such definition in whereas 18 of EC regulation 1107/2009.</p>	
6(3)		<p>EFSA: Milk and products thereof (including lactose) are listed in Annex II of Reg. (EU)</p>		<p>Demonstration of PHI efficiency would require time and money.</p>	<p>Residues of milk allergens on fruit and vegetables cannot be reasonably expected by</p>

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>1169/2011 as 'Substances or products causing allergies or intolerances', and specific mandatory labelling requests for produce containing such substances apply should they remain on the crops. Therefore, risks for consumers cannot be ruled out per se even if the role of milk in human nutrition is extensively explained in the application. EFSA take note of the proposed PHI to 'avoid presence of milk allergic components'.</p> <p>Can it be demonstrated that the proposed PHI is effective to exclude allergy-causing residual milk components are left on the crops after the waiting period following a treatment, i.e. are any measurements such as immunoassays available?</p> <p>Alternatively, is the proposed washing step part of the GAP / the product label and can its effectiveness be demonstrated?</p>		<p>No funding was allowed and applicant is not selling milk or intends to sell it either in case of approval.</p> <p>Washing step or peeling may be sufficient but is quite usual.</p>	<p>consumers. The applicant clarified that the effectiveness of the proposed PHI in order to ensure any residue would have disappeared was not experimentally verified. Applicant hence proposes labelling of treated agricultural produce since it cannot be ruled out that after treatment of crops with milk for plant protection purposes (despite a waiting period), residues of food allergens will be present on the commodities.</p> <p>EFSA highlights for risk manager consideration that commenting parties had diverging view on feasibility and effectiveness of consumer risk mitigation by labelling of agricultural commodities (see comments 6(1) and 6(2)).</p>

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7.1	NL: Chemical properties of many of the (main) constituents of Milk are known and an indication of their terrestrial, aquatic and atmospheric fate should be described.	Please elaborate on the fate related chemical properties of the major constituents of Milk, proteins, sugars and fats.	More references added in updated basic substance application	Limited information on the biological oxygen demand of milk was added.
7(2)	7.1	DK: A little more argumentation is required as to why not milk is not expected to have a negative impact on the environment, and then why caution should be taken of spillage during treatment?	Please add text.	More references added in updated basic substance application	Limited information was added on the fate and behaviour of milk in the environment. No clear conclusion was made regarding why caution should be taken in avoiding spillage during treatment.
7(3)		ES: Spain would like to note that no estimation of potential levels of milk in the different environmental compartment was conducted by the applicant. The applicant explains that milk is an organic material with degradation and consumption by microorganisms. However, details such as the time of		More references added in updated basic substance application but only few bibliographic references are available.	Limited information on the degradation of milk in the different environmental compartments was provided.

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>degradation in different compartments are not described.</p> <p>Please, could include further details on the fate and behaviour of milk in the environment?</p>			
7(4)		EFSA concurs with the comments of the Netherlands, Denmark and Spain above		More references added in updated basic substance application	See comments 7(1), 7(2) and 7(3).

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(5)	7.2	<p>NL: No information is included regarding the predicted environmental concentrations following the intended uses of milk and its major constituents. No conclusions have been drawn regarding the effect on the environment by the use of milk.</p>	<p>Please provide predicted environmental concentrations for the (main) constituents of Milk following the intended use. Predicted environmental concentrations should be compared to the natural background concentrations of the major constituents of Milk, and it should be demonstrated that the use of Milk will not have an unacceptable effect on the</p>		<p>Predicted environmental concentrations for milk and its main constituents following the intended uses were not provided. It was pointed out that caution should be taken in order to avoid spillage during treatments.</p>

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			environment.		
7(6)		EFSA concurs with the comment of the Netherlands above			See comment 7(5).

8. Effects on non-target species
8.1. General consideration

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1	NL: There is a reference to PAN (Pesticide action Network Europe) which is no academic institute or an institute that is controlled in any official way.	Find another source or explain way PAN is used (like lack of official data for instance).	PAN ref removed. No more data found except phytotoxicity.	Addressed
8(2)	8.1	NL: An overall explanation why milk is not relevant would be appreciated.		More data added	Addressed
8(3)		DE: Numeration of chapter 8 in the application is not consistent with commenting table		Corrected in updated basic substance application	Addressed
8(4)	General	DE: Citations of Non-		PAN ref removed.	See comment 8(1)

8.1. General consideration

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	consideration:	governmental Organisations' opinion in official document is not appropriate; please delete			
8(5)	8. Effects on non-target organisms	EFSA: in accordance with the guidance on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (SANCO/10363/2012 rev.9 21 March 2014) an assessment of the effects of milk on non-target organisms should be provided.			The updated application has reported more information. Due to the nature of the substance, the available information is considered sufficient.

8.2. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)		NL: See second remark in 8.1			See comment 8(2)
8(7)		ES: ES would like to note that no ecotoxicological information was provided by the applicant.		Food stuffs are controlled for any contaminant.	Addressed

8.2. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>A statement indicating '<i>Milk is not toxic for environment, if not contaminated by chemical pesticides</i>' is included by applicant. Please could you explain if an analytical verification of pesticides and/or other chemicals such as antibiotics are checked before the application of milk as plant protection product?</p>			
8(8)		<p>ES: Applicant explains '<i>Although Milk is not expected to have negative impact environment at low concentration, caution should be taken of spillage during treatments</i>'. Please, could provide further details on which this assumption was based on?</p>		<p>Large amounts of milk (> 500 Litter) may be toxic for environment, as explained in chapter 8. Quantities claimed in GAP are largely below.</p>	<p>Addressed</p>

8.3. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)		NL: An explanation why the avoidance of contamination of open waters is stated is missing, and the reference thereby is not logical by itself and not really academic.	Like the general statement we asked for an explanation why contamination is a problem. (Milk being a polluting substance because bacteria will feed on it, blossom, and use up oxygen that would otherwise be used by fish and other animals in the water).	Demand in oxygen for milk degradation is may.	Noted See comment 7(1), 8(8) and 8(10)
8(10)	8.3 aquatic organisms	DK: Please elaborate on this issue. It is simply stated that usage should be carefully preceded to avoid river and surface water contamination. However references are given without any summary, justification or use in a weight-of-evidence approach etc.. The risk assessment should be made with the proposed uses in mind; the GAP (3.4) is for up to 6 applications on a weekly interval.	Add a qualitative risk assessment for aquatic organisms.	Milk damage to aquatic organisms is only described in large quantities of raw and undiluted milk spilling due to transportation accident. Quantities in GAP may involve a maximum of 300 L per hectare and dilution may be and is usually proceed carefully at farm level not at field level.	Addressed

8.4. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)		NL: See second remark in 8.1			See comment 8(2)
8(12)	8.4.1-2	DE: 'Not relevant' is no appropriate comment or proof	DE: Provide literature or reasoned opinion	General pesticide information suggests that spray should be avoided during bee's activity. This statement is valuable for any substance spray including basic substances.	Addressed
8(13)	8.4.1	DK: Please add that as the intended uses are not for flowering crops, and due to the inherent properties of the substance etc., the exposure to bees in this case is expected to be negligible.		Although all crops are flowering, Milk and general fungicide treatments are usually sprayed early in the morning.	Addressed

8.5. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)		NL: See second remark in 8.1			See comment 8(2)
8(15)	8.5	DE: 'Not relevant' is no appropriate comment or proof	DE: Provide literature or reasoned opinion	More ref added in the updated basic substance application Milk is compatible with	Addressed

8.5. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				earthworms	
8(16)	8.5 earthworms	DK: Please justify why it is not relevant to assess the potential risk for earthworms in this case (weekly applications of milky water throughout the whole of spring).	Please consider adding a qualitative risk assessment for earthworms and other soil organisms based on the applied for GAP (6 applications).	Basic substance application Updated	Addressed

8.6. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(17)		NL: See second remark in 8.1			See comment 8(2)
8(18)	8.6	DE: 'Not relevant' is no appropriate comment or proof	DE: Provide literature or reasoned opinion	More ref added in updated basic substance application	Addressed

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(19)		NL: See second remark in 8.1		Basic substance application	See comment 8(2)

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

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

8.8. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(20)		NL: See second remark in 8.1		Basic substance application Updated	See comment 8(2)

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

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

10. Other comments

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

Appendix B – Identity and biological properties

Common name (ISO)	Cow milk (not ISO)
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Not applicable
Common names	milk
CAS No	8049-98-7
EC /List no.	617-095-5
FAO specification	none
Minimum purity	Not applicable
Relevant impurities	none
Molecular mass and structural formula	Not applicable
Mode of Use	spray
Preparation to be used	SL (soluble concentrate)
Function of plant protection	fungicide

Appendix C – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m) *	Remarks
					Type (d-f)	Conc of a.i. (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	L a.i./hl min max (L/hl)	Water l/ha min max	L a.i./ha min max (L/ha) (l)			
Grapevine <i>Vitis vinifera</i>	All Member States	-	F	Powdery mildews: <i>Erysiphe necator</i>	(SL) Soluble concentrate	100 %	foliar application spraying	From 1 st shoots to cluster tightening Spring (BBCH 10 to 57)	3 to 6	6 to 8 days	10 to 40	100 to 300	10 to 120	30 to 720	8	Crop products should be rinsed before consumption
Vegetable Gardening pumpkins <i>Cucurbita pepo</i> <i>cv.Howden</i>	All Member States		FG	pumpkins powdery mildew <i>Podosphaera xanthii</i>	(SL) Soluble concentrate	100 %	foliar application spraying	between 21 and 28 d after 50% emergence (BBCH 09 + ~25 days)	3 to 4	7 to 12 days	50	400	200	600 to 800	8	
Flower like Gerbera <i>Gerbera jamesonii</i>	All Member States		FG	powdery mildew <i>Erysiphe cichoracearum</i>	(SL) Soluble concentrate	100 %	foliar application spraying	Before and during flowering (BBCH	3 to 4	7 days	16	500 to 1000	80 to 160	240 to 640	8	

Outcome of the consultation on the basic substance application for milk

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate (l)	PHI (days) (m)*	Remarks
					Type (d-f)	Conc of a.i. (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	L a.i./hl min max (L/hl)	Water l/ha min max	L a.i./ha min max (L/ha) (l)			
Cucumber <i>Cucumis Sativus</i> Zucchini squash <i>Cucurbita pepo</i>	All Member States		F G	Powdery mildews: <i>Sphaerotheca fuliginea</i>	(SL) Soluble concentrate	100 %	foliar application spraying	51-69	3 to 4	7 days	5 to 10	1000 to 1500	50 to 150	150 to 600	8	
								From three weeks after sowing (9th leaf Unfolded on main stem) to 9 or more primary side shoots visible (BBCH 19 to 49)								
Soybean <i>Glycine max</i> (L.) Merr	All Member States		F	Soybean Powdery mildew <i>Erysiphe diffusa</i>	(SL) Soluble concentrate	100 %	foliar application spraying	On leaves (BBCH 19 to 49)	3 to 4	7 days	18	1000 to 1500	180 to 270	540 to 1080	8	