TECHNICAL REPORT

APPROVED: 22 October 2015 PUBLISHED: 4 November 2015

# Outcome of the consultation with Member States and EFSA on the basic substance application for sweet whey for use in plant protection as a fungicide on grape vine, tomatoes, cucumber and zucchini squash

## 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 sweet whey 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 sweet whey as a basic substance for use in plant protection as a fungicide on grape vine, tomatoes, cucumber and zucchini squash. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.



**Key words:** sweet whey, basic substance, application, consultation, plant protection, pesticide

**Requestor:** European Commission

**Question number:** EFSA-Q-2015-00514

**Correspondence:** pesticides.peerreview@efsa.europa.eu

**Suggested citation:** EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for sweet whey for use in plant protection as a fungicide on grape vines, tomatoes, cucumbers and zucchini squash. EFSA supporting publication 2015:EN-879. 34 pp.

## Summary

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

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in September 2015, EFSA was asked to organise a consultation on the basic substance application for sweet whey, 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 sweet whey, organised by EFSA, was conducted with Member States via a written procedure in May – July 2015. 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 sweet whey and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Whey is the fluid separated from the curd after coagulation of milk, cream, skimmed milk or buttermilk with milk coagulating enzymes during the manufacturing of cheese, casein or similar products. Acid whey is obtained after the coagulation of milk, cream, skimmed milk or buttermilk, mainly with acids of the type used for the manufacturing of fresh cheese.

Whey is used as an additive in many processed foods and in animal feed.

Whey is intended to be used as a fungicide against powdery mildew in grapevine, cucumber and zucchini squash and against yellow leaf curl virus in tomato. The initial submission was for sweet whey, however following the commenting period the applicant updated its application and sweet whey was changed to whey. This change did not create any additional risk in the identity section that was not identified under the sweet whey application.

The potential health concern of the use of whey is derived from food allergies to milk proteins and intolerance to lactose from people with low lactase activity. A low content of lactose is reported in the application report (around 3-5% in both acid and sweet whey). Published literature indicates that moderate amounts of lactose, such as 10-15 g of lactose in a single dose, and especially when distributed over the day, are expected to be well tolerated by lactose intolerants children and adults. However a concern is identified for sensitive individuals to milk proteins that can act as antigens in humans, especially children and infants and for which no threshold of safety can be established. Clinical reactions referred in public literature include gastro-intestinal (vomiting, abdominal pain, blood in the stools, and diarrhoea), cutaneous (hives and eczema) and respiratory symptoms following food protein intolerance.

The information included in the application was insufficient to conclude on the relevance of residues on treated crops for the health of vulnerable consumers as the concentration of lactose and whey proteins in the preparation alone is not enough. Estimates of consumer exposure to residues of lactose and whey proteins (such as α-lactalbumin, β-lactoglobulin, and lactoferrin) which could remain on crops after treatment with whey are not available. From the pattern of use per se consumer exposure to residues of whey (lactose and milk proteins) and therewith health concerns for vulnerable individuals cannot be readily excluded.

The information included in the application was insufficient to conclude any environmental exposure assessment.

Information was available to address the hazard to non-target organisms for sweet whey. High concentrations of sweet whey were found to produce some adverse effects on aquatic organisms and on sewage treatment. It is considered unlikely that these high concentrations could be reached in the environment as a consequence of the proposed uses. However, due to the data gap identified in the environmental fate section, no quantitative risk assessment could be finalised.

# Table of contents

# 1. Introduction

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

Regulation (EC) No 1107/2009[1] (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.

Sweet whey is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l' Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as a fungicide against powdery mildew in grapevine, cucumber and zucchini squash and against yellow leaf curl virus in tomato.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for sweet whey, which was conducted via a written procedure in May – July 2015. 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 initial submission was for sweet whey, however following the commenting period the applicant updated its application and sweet whey was changed to whey. 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 sweet whey 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 sweet whey as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2015a and 2015b).

## 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 8 September 2015, EFSA was asked to organise a consultation on the basic substance application for sweet whey, 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 8 December 2015.

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 sweet whey 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 C and D, respectively.

## Documentation provided to EFSA

1. ITAB, 2015a. Basic substance application on sweet whey submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2015. Documentation made available to EFSA by the European Commission.

2. ITAB, 2015b. Basic substance application update on whey submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2015. Documentation made available to EFSA by the applicant.

## Abbreviations

| | |
|---|---|
| a.s. | active substance |
| BOD | biological oxygen demand |
| CAS | chemical abstracts service |
| CMPA | cows milk protein allergy |
| DAR | draft assessment report |
| GAP | good agricultural practice |
| ECHA | European Chemicals Agency |
| EU | European Union |
| PNEC | predicted no-effect concentration |
| SC | suspension concentrate |
| TC | technical concentrate |

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

## 1. Purpose of the application

| General | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 1(1) | General comment applicable to the entire document | UK: Overall, we are of the view that sweet whey meets the criteria of Art 23 for a basic substance and the related SANCO guidance (10363/2012 rev 9). It is a foodstuff (fluid milk obtained from the process of making cheese) and it is widely used in agriculture as a fertiliser. It is not classified. At the level to be used as a PPP, exposure is almost negligible compared to its use as a fertiliser. There is no concern from its use as PPP.<br>However, we would like to comment on the template and the way the data are presented. For most headings, references are given and described, with no overall conclusion about the relevance of such data or the | UK: The application should be updated to address this comment, but we do realise that this point might be something for future basic substance applications. | Question is raised about the evaluation process.<br>Procedure was amended in order to request Conclusion at each chapter.<br>As applicant, having a Dossier in hands, this is to our point of view disturbing since an evaluation process should occur independently. An applicant would always produce "positive" conclusions.<br>In fact, if all conclusions are drawn by applicant, evaluation is "automatically" done.<br>Status of the substance should be a good indication, but even for common substance like whey, with CAS number, definition is not accepted by all party.<br>The intrinsic understanding of a "basic substance" is probably | This is a general comment to be considered for future applications. |

| General | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | conclusion to be drawn from such data. This is essential. | | the most difficult problem and no definition is up to now commonly accepted by applicants, MS and Commission. | |
| 1(2) | General comment applicable to the entire document | EFSA: the submission contains a compilation of information, data concerning different types of whey and in many cases just the reference, without a summary of the referenced paper. | From this compilation of data it is not always clear that the intention is to define sweet whey as a basic substance or whey of any type and any provenience. It is also unclear that sweet whey as a liquid or as a powder or both are intended to be defined as basic substance. In any of the cases an unequivocal definition would be welcome. | Dossier was changed to Whey with unequivocal CAS number ECHA inclusion and accepted definition. | Addressed:<br><br>See comment 2(1) |

## 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 | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 2(1) | 2.1.2. and 2.1.2.1 Sweet whey | EFSA: clarification is needed if sweet whey is only that obtained from cheddar and mozzarella, or also other type | For unequivocal definition a kind of specification should be given or a clear reference to one or more existing standards. | Reference CODEX changed to 192 1995 | Addressed:<br>For unequivocal definition reference was made to the General Standard for Food |

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

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
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| | | of cheese | Reference was made to CODEX standard for whey powders (CODEX STAN 289-1995). Does this mean that the basic substance should meet the requirements of this standard? This would be an acceptable proposal, as there are data for composition and reference content of the components, but also requirements for contaminants and microbiological criteria.<br>If this standard is to be followed, some information would be needed how these quality criteria are met and controlled before use. | | Additives (CODEX STAN 192-1995) defining whey as:<br>01.8.1 Liquid whey and whey products, excluding whey cheeses:<br>Whey is the fluid separated from the curd after coagulation of milk, cream, skimmed milk or buttermilk with milk coagulating enzymes during the manufacturing of cheese, casein or similar products. Acid whey is obtained after the coagulation of milk, cream, skimmed milk or buttermilk, mainly with acids of the type used for the manufacturing of fresh cheese.<br>01.8.2 Dried whey and whey products, excluding whey cheeses:<br>Whey powders are prepared by spray- or roller-drying whey or acid whey from which the major portion of the milk fat has been removed.<br>According to this standard both types of whey should meet the requirements of Standard for Whey Powders (CODEX STAN |

| 2.1. Identity and Physical and chemical properties of the substance and product to be used | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | | | 289-1995). |
| 2(2) | 2.1.4 Method of manufacture | EFSA: it should be clearly clarified what is meant by sweet whey | For clarity and unequivocal definition it should be stated what is intended by sweet whey as basic substance, as the submission contains information about sweet whey, acid whey and whey in general. If all of them can be used, the title should be changed, if just the sweet one, a clear specification should be set to be able to differentiate the two (for example the lactose, lactic acid content, pH…). | Acknowledgment: Title and Dossier changed for Whey | Addressed:<br>The submission is intended for both sweet whey and acidic whey. |
| 2(3) | 2.1.7.1 Methods of analysis for the determination of the a.s as manufactured, p.16 | EFSA: It is true, that sweet whey cannot be determined as an active substance, but we think it is not proper to say that this is not relevant. For identification and quality control some basic parameters should be measured to be able to judge the identity and the quality of the product. It should be possible to check whether the product is meeting the referenced food standards. | | All EU specifications were added. | Addressed:<br>The methods were referenced in the updated submission. |
| 2(4) | 2.1.7.1 Analytical | EFSA: if this is not relevant, why it | | Reference to Analytical method | Addressed: |

| 2.1. Identity and Physical and chemical properties of the substance and product to be used | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | methods for the determination of relevant impurities, p.16 | is mentioned in several cases that it should meet the limits of impurities described in the "Food Chemicals Codex" | | proposed. | A reference to the published methods has been included in the updated submission. |
| 2(5) | 2.1.7.1 Analytical methods for the determination of residues, p.16 | EFSA: it is not clear why residue methods for plants are not mentioned, only those for animal matrices? Is there any residue definition proposed for monitoring sweet whey in plant and animal commodities? | Before discussing the residue methods, first one should be able to decide what compound of the sweet whey can be considered as residue to be monitored.<br>Probably some explanation would be helpful why the lactose content can or cannot be a problem for the residue intake of the people with lactose intolerance | Residues are identical to the possible milk residues: pesticides, antibiotics (chloramphenicol), chemicals, phytosanitary products, anti-inflammatory products, PCB, heavy metals, mycotoxins, germs, somatic cells… | Data gap:<br>The proposed use is on grapevine, tomatoes, cucumber and zucchini squash, however no residue definition is proposed and no residue analytical method was submitted for food of plant origin. |

| 2.2. Current Former and in case proposed trade names | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |

No comments

| 2.3. Manufacturer of the substance/products | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |

No comments.

| 2.4. Type of preparation | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 2(6) | 2.4 Type of preparation | EFSA: by stating that this is a SC formulation, it should be clarified if there is a TC, too? | For clarity and unequivocal definition it should be stated what is intended by sweet whey as basic substance | Modification was done :TC Technical material | Addressed:<br>Whey is considered the basic substance and not as a formulation produced by a TC. |

| 2.5. Description of the recipe for the product to be used | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 2(7) | 2.5 Description of the recipe for the product to be used | EFSA: according to this paragraph, the basic substance is a liquid, while in other places (ex. 3.1.1.1) the possibility of using whey powder is also indicated. Clarification is needed whether both forms are considered under this application or just one? | For clarity and unequivocal definition it should be stated what is intended by sweet whey as basic substance | Whey is by definition a liquid obtain after cheese production.<br>Recipe is just a dilution with water.<br>Solid dry "whey protein" was sometimes used in referred experimental papers, but compare to "liquid whey" | Addressed:<br>Defining whey as a liquid obtained after cheese production is in slight contradiction with the reference to CODEX STAN 192-1995, which includes also dried whey. |

| 2.5. Description of the recipe for the product to be used | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | | quantities, amount need to be 37.5 times much higher! | |

| 3. Uses of the substance and its product | | | | | |
|---|---|---|---|---|---|
| **3.1. Field of use** | | | | | |
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**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 | EFSA: it is stated that the product is safe and can be easily stored. Are there any data showing these properties? What is the minimum storage period? | When such basic and fundamental properties are stated, it is necessary to have some supporting data, information. For example at least a study supporting the minimum storage period, or an indication that should be used immediately. A short term storage stability test would be sufficient with the analysis of basic parameters before and after storage including the possible contaminants, impurities. Also to reflect on the possible formation of galactose or lactic acid during the storage. If these parameters do not have any influence on the efficacy, this should be somehow proven. | Applicant agrees up to the fact that understanding of effective "active substance" will be demonstrated.<br>Lactoferin is envisaged as the active substance.<br>Difference of efficacy between liquid whey and solid whey powder may due to protein denaturation during drying process.<br>Added in 3.4 GAP Table<br>**** Whey should be used rapidly after collection, not stored in metal vessel.** | Addressed:<br>It should be clearly mentioned that whey should be used rapidly after collection, not stored in metal vessels. |

### 3.1. Field of use

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 3(2) | 3.1 Field of use | EFSA: the references presented are not always convincing of the effectiveness of sweet whey in the intended applications and examples are also given using milk and not whey | Examples:<br>Cromwell thesis states "Overall, milk did not provide management of disease and caused premature leaf yellowing and defoliation of the apple trees."<br>"Milk as an antifugal" we do not think that such "blog" information can be a proper support of a scientific submission | This dossier is about Whey. Milk would be another "Dossier" already envisaged by some M.S.<br><br>This is1 over more than 30 references, and even a blog information is an information: whey is used, this dossier has the goal to allowed it as basic substance | Addressed:<br>EFSA doesn't think that information whose quality cannot be controlled should be taken into account. |

### 3.2. Effects on harmful organisms or on plants

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

## 4. Classification and labelling of the substance

| Classification and labelling of the substance | | | | | |
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| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 4(1) | | DE: According to the BSA Template sweet whey has been described as corrosive. However, no data has been presented. | DE: The applicant should provide appropriate information on the corrosive properties of whey. | Reference added:<br>HERSCHDORFER, S. M. *Quality control in the food industry*. London: Academic Press, v. 2, 1972. | Addressed:<br>A reference was added to the updated submission. |

## 5. Impact on Human and Animal Health

### 5.9. Medical Data: adverse effects reported in humans

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
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| 5(1) | | NL: There is a known occurrence of cow milk protein allergy and lactose intolerance. It is stated that use should be avoided by those who are intolerant. While this is an option for the operator this is not the case for residents (or consumers). This problem is not addressed in the assessment. | EFSA: This comment should be addressed, together with clarifications regarding the identity of sweet whey under consideration (see comments in chapter 2). On p. 12 it is mentioned that dried whey contains levels of lactose (76.9%) that should be avoided by individuals who are lactose intolerant, while on p. 29, it is mentioned that moderate amounts of lactose, and especially when distributed over the day across meals, are well tolerated by children and adults who have demonstrated to be lactose intolerant in a typical traditional lactose intolerance test. The amount of lactose in sweet whey has therefore to be clarified. | This dossier is about Whey under the liquid form containing lactose at 4.2 to 5.475 % later diluted by 3 to 50.<br><br>Final concentration of lactose in the preparation is then 0.084 to 1.825% (0.1 to 18.25 g/L). | Partly addressed:<br>In the application report, it is suggested that 10-15 g of lactose, corresponding to approx. 250-300 mL of cow's milk can be consumed without any symptoms of lactose intolerance. This value is supported by other published literature such as "The outcome of the National Institutes of Health Consensus Development Conference: Lactose Intolerance and Health" (Suchy *et al.* 2010).<br>A health concern is however identified regarding food allergies or intolerance to milk proteins for which no 'safe' level can be established.<br><br>See also residue section. |

## 6. Residues

| Residues | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 6(1) | | NL: See also the comment for the toxicological section. Please address whether residues of sweet whey might be of concern for consumers with milk protein allergies or lactose intolerance. | EFSA: This comment should be addressed (see also EFSA comment below), together with clarifications regarding the identity of sweet whey under consideration (see comments in chapter 2). The amount of lactose in sweet whey has therefore to be clarified. | Final concentration of lactose in the preparation is then 0.084 to 1.825% (0.1 to 18.25 g/L).<br>Degradation of lactose, a disaccharide that consists of beta-D-galactose and beta-D-glucose molecules bonded through a beta-1-4 glycosidic linkage. | See comment 6(1) |
| 6(2) | | EFSA: 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. Therefore, risks for consumers cannot be ruled out per se. With regard to potential residues of Sweet whey on grapes, tomatoes and cucurbit vegetables | EFSA: It should be demonstrated in greater detail how following the application of Sweet whey to grapes, tomatoes and cucurbit vegetables a high level of health protection for consumers consuming treated produce can be achieved in line with the requirements of current food safety legislation. | Final concentration of lactose in the preparation is then 0.084 to 1.825% (0.1 to 18.25 g/L). | Health issues for consumers consuming treated produce, in particular with regard to allergens, have not been addressed. From the pattern of use consumer exposure to residues of whey / milk proteins cannot be excluded, and therefore a potential consumer health risk cannot be excluded.<br><br>According to the applicant's response only the aspect of possible lactose intolerance has been considered. Yet, an estimation of consumer exposure to residues of lactose from crops treated with whey is not available. It is difficult |

| Residues | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | previously treated with Sweet whey according to the intend use patterns information is insufficient to come to an appropriate conclusion in terms of a consumer risk assessment. | | | to conclude from the final concentration of lactose in the preparation on the relevance of residues on treated crops for consumer exposure and the health of vulnerable consumers.<br>Moreover, proteins in whey specified as α-lactalbumin, β-lactoglobulin, and lactoferrin were described as pertinent compounds in the product. Cow milk protein allergy (CMPA) (different from lactose intolerance) is an adverse immune reaction that may cause a life-threatening response in vulnerable people, mainly children.<br>An estimation of consumer exposure to residues of lactalbumin, β-lactoglobulin, and lactoferrin from whey on treated crops is not available, and therefore it is not possible to conclude on the relevance of potential residues on crops for the health of vulnerable consumers. From the pattern of use consumer exposure to residues of whey (lactose and milk proteins) cannot be excluded. |

## 7. Fate and Behaviour in the environment

### 7.1 Fate and Behaviour in the environment

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 7(1) | 7.1 page 34 | EFSA: Information / evidence of use of sweet whey in European agriculture as fertiliser has not been provided. What is presented relates to New Zealand and North America. The N American evidence is only a scientific article / experiment investigating the potential to use sweet whey. It is not evidence of actual commercial use. | Applicant should contact European Member State agricultural extension services and obtain what recommendations (if any) they have for using sweet whey as a fertiliser (amounts applied per ha, quality requirements etc.). In addition the applicant should explain the EU regulations that enable sweet whey to be used as a fertiliser (i.e. 1. organic farming regulation 2. referring to text that excludes sweet whey from the scope of the fertiliser regulation (2003/2003)). | References added 1991-2015<br>+<br>Commission Regulation (EC) No 889/2008[2] of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control Annex I par A: dairy products | Data gap<br>The applicant has not stated that as a mixture of primarily organic compounds, sweet whey in particular and whey more generally are not covered by Regulation (EC) No 2003/2003[3] relating to fertilisers, though EFSA understands this to be the case. Therefore any use of Whey as a fertiliser would be covered by national provisions. The applicant has not provided any evidence that a national administration allows / makes recommendations for the use of whey as a fertiliser or allows / has assessed the acceptability of disposing of whey by spreading on agricultural land.<br>So no information was presented regarding an existing EU assessment that would cover environmental exposure and or risk consequent to spreading sweet whey in a diffuse way in the environment. Reference was only made to Commission Regulation (EC) No 889/2008. Any environmental assessment done by a European Member State national administration in the context of use as a fertiliser in organic farming has not been provided. The Egtop/2/2011 report |

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. OJ L 250, 18.9.2008, p. 1-250.

[3] Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers. OJ L 304, 24.11.2003, p. 1-194.

**7.1 Fate and Behaviour in the environment**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | | | on fertilisers soil conditioners that are used in organic production that EFSA could locate (http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/final_report_egtop_on_fertilizers_en.pdf) does not include an environmental exposure / risk assessment for whey. EFSA's reading of Regulation (EC) No 889/2008 is that via this regulation whey is allowed as an animal feed in organic production but there is no indication that it has been listed as being allowed to be used as a fertiliser.<br>In conclusion, an appropriate environmental exposure or risk assessment relevant for the proposed uses was not available. |
| 7(2) | 7.1 page 34 | EFSA: No information is presented on an existing EU assessment that would cover environmental exposure and or risk consequent to spreading sweet whey in a diffuse way in the environment. | Applicant should explain the EU regulations or national legislation that enables sweet whey to be used as a fertiliser (i.e. EU organic farming regulation, National rules on organic farming, referring to text that excludes sweet whey from the scope of the EU fertiliser regulation (2003/2003), national rules / legislation on fertilisers). They should then explain how this plant protection use would lead to | Commission Regulation (EC) No 889/2008<br>of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control Annex I par A: dairy products | See comment 7(1). |

| 7.1 Fate and Behaviour in the environment | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | lower environmental exposure. | | |

| 7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water) | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 7(3) | 7.2 Page 35 | EFSA: No information is presented on levels of soil, surface water or groundwater exposure resulting from the proposed use. | Applicant should explain the EU regulations or national legislation that enables sweet whey to be used as a fertiliser (i.e. EU organic farming regulation, National rules on organic farming, referring to text that excludes sweet whey from the scope of the EU fertiliser regulation (2003/2003), national rules / legislation on fertilisers). They should then explain how this plant protection use would lead to lower environmental exposure. Alternatively regulated allowed disposal practice of sweet whey by spreading on agricultural | Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control Annex I par A: dairy products | See comment 7(1). |

| 7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water) | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | land in an EU member state could be described along with reference to the authority that assessed that such disposal was acceptable. | | |

## 8. Effects on non-target species

### 8.1. Effects on terrestrial vertebrates

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

No comments.

### 8.2. Effects on aquatic organisms

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

No comments.

### 8.3. Effects on aquatic organisms

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(1) | | EFSA: The available study (Karadima et al., 2010) demonstrates that cheese whey effluent can have an adverse effect on aquatic organisms, in some case also lowering the overall ecological quality of water bodies. Based on the ecotoxicological | It could be sufficient to estimate a very worst case exposure (e.g. concentration of whey that would result if the entire applied amount would reach a typical water body i.e. focus water bodies). This exposure could be then compared with the ecotoxicological endpoint | Karadima presents evidence of concern for direct massive reject of Cheese whey effluents consisting in the main degradation factor in river. Effluent concentration was 20 times higher than the predicted no risk concentration<br>Our product is at least diluted | Data gap<br>Despite some hazard data were available on sweet whey, and despite the indications provided by EFSA in column 3, the applicant failed to provide a quantitative estimation of the environmental exposure. Therefore, the environmental |

**8.3. Effects on aquatic organisms**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | information presented in the submitted paper (Karadima et al., 2010), the applicant should demonstrate that the amount used for fungicidal treatment on crops cannot reach toxic concentrations in the edge-of-field water bodies. | presented in the Karadima et al. study to address the risk to aquatic organisms. | by 3 to 50, at rate of 6 to 30 L/ha, so we believe to be under PEC/PNEC of concern. | risk assessment cannot be finalised using the available information.<br><br>Risk managers might want to consider that even if the entire amount of the worst-case application from a field of 1 ha (10 kg) would simultaneously reach the water body considered at lower tier in FOCUS (surface 1/10 of field = 0.1 ha; depth 30 cm), the resulting dilution would be 0.003% w/w. The PNEC available in Karadima et al. (2010) was 0.0065% with respect to the pure effluent. The amount of the a.s. (w/w) in the pure effluent is unknown, but one can assume that this would be rather concentrated. |

### 8.4. Effects on earthworms and other soil macroorganisms

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

No comments.

### 8.5. Effects on soil microorganisms

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

No comments.

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

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

No comments.

### 8.7. Effects on biological methods of sewage treatment

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(2) | | NL: from the environmental fate part it is clear that whey has a | | Whey discharges in rivers are much higher in concentration | Data gap<br>We agree with NL that this |

| 8.7. Effects on biological methods of sewage treatment | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | high BOD which effects the waste water treatment. In the ecotox part a publication on anaerobic waste water treatment is cited. Though for the uses as PPP applied for the exposure to WWT plants is less relevant, this issue could have been addressed in a bit more detail. | | and quantities than possible deviance from these diluted whey treatments. | issue should have been better addressed in the assessment.<br>We are of the opinion that concentrations of whey in the environment due to these treatments are unlikely to pose high risk for WWT plants, however no exposure estimations are available and therefore no quantitative risk assessment can be finalised. |

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

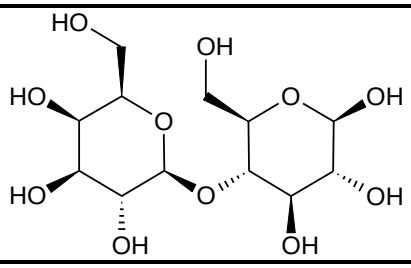
| Overall conclusions with respect of eligibility of the substance to be approved as basic substance | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 9(1) | | NL: sweet whey can be considered a basic substance in line with art 23 | | May be, but EFSA exhibited dangerousness of possible lactose residues.<br>However, whey powder is already sold in Germany as: mOlnasa Sprühmolkenpulver-natursauer by JHA (Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 2. Juli 2015), although we believe this powder from requires up to 40 time more product than liquid form. | Addressed:<br>See also comment 1(1) |

## 10. Other comments

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

No comments.

## Appendix B – Used compound code

| Code/trivial name* | Chemical name/SMILES notation** | Structural formula** |
|---|---|---|
| **lactose** | 4-*O*-β-D-galactopyranosyl-β-D-glucopyranose<br><br>O[C@H]2[C@H](O[C@@H]1O[C@H](CO)[C@H](O)[C@H](O)[C@H]1O)[C@@H](CO)O[C@@H](O)[C@@H]2O |  |

* The compound name in bold is the name used in the report.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

## Appendix C – Identity and biological properties

| | |
|---|---|
| **Common name (ISO)** | none |
| **Chemical name (IUPAC)** | none |
| **Chemical name (CA)** | none |
| **Common names** | Whey, sweet whey |
| **CAS No** | 92129-90-3 (whey) |
| **CIPAC No and EEC No** | none |
| **FAO specification** | none |
| **Minimum purity** | CODEX STAN 289-1995 |
| **Relevant impurities** | none |
| **Molecular mass and structural formula** | Not applicable |
| **Mode of Use** | spray |
| **Preparation to be used** | diluted whey |
| **Function of plant protection** | fungicide |

## Appendix D – 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.s. g/L (i) | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | L a.s./hl min max (kg/hl) | Water l/ha min max | kg a.s./ha min max (kg/ha) (l) | kg a.s./ha min max (kg/ha) (l) | | |
| Grapevine *Vitis vinifera* | France All Member States | | F | Powdery mildews: *Erysiphe necator* | TC Technical material | 1040 g/L* a.s. 60 to 80 g/L | foliar application spraying ** | From 1st shoots to cluster tightening Spring (BBCH 10-57) | 3 to 5 | 7 to 10 days | 6 L to 30 L (0.36 to 2.4 kg a.s.) | 100 to 300 | 6 to 30 L (0.36 to 2.4 kg a.s.) | 36 to 150 L (1 to 10 kg a.s.) | | *** |
| Vegetable Gardening Tomato *Lycopersicum esculentum* | | | | Tomato (Sinaloa) yellow leaf curl virus *Begomovirus* | | | | First inflorescence visible Summer (BBCH 10-51) | | 3 to 4 days | 0.6 L to 3 L (0.036 to 0.24 kg a.s.) | 1000 to 1500 | | | | |
| Cucumber *Cucumis Sativus* Zucchini squash *Cucurbita pepo* | | | G | Powdery mildews: *Podosphaera fusca* *Podosphaera xanthii* *Golovinomyces/ Erysiphe cichoracearum* and *orontii* *Sphaerotheca fuliginea* *Leveillula cucurbitacearum* | | | | From three weeks after sowing (9th leaf Unfolded on main stem) to 9 or more primary side shoots visible (BBCH 19-49) | | 7 days | | | | | | |

*** Density = 1.04**
**** spray when there is sun (preferably morning)**
***** Whey should be used rapidly after collection, not stored in metal vessel.**

* For uses where the column „Remarks. As above or other conditions to take into account

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

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

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

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..

(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

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

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

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval