TECHNICAL REPORT

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# Outcome of the consultation with Member States and EFSA on the basic substance application for approval of whey for the extension of use in plant protection as a fungicide in grapevines and vegetable crops

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 extension of use for 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 whey as a basic substance for an extension of use in plant protection as a fungicide in grapevines and vegetable crops. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.



**Keywords:** whey, basic substance, application, consultation, plant protection, pesticide, fungicide

**Requestor:** European Commission

**Question number:** EFSA-Q-2020-00214

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

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## Summary

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 of an extension of use 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.

On 8 September 2015 EFSA received a first request from the European Commission to organize a consultation on the basic substance application submitted by the applicant Institut Technique de L'Agriculture Biologique (ITAB) for whey, to consult the applicants on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table. A Technical Report containing the finalised reporting table was issued by EFSA on 22 October 2015.

Whey was approved on 2 May 2016 by Commission Implementing Regulation (EU) 2016/560, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use in plant protection as a fungicide on cucumber and zucchini squash crops cultivated indoors in greenhouses.

By a further specific request, received from the European Commission in March 2020 following the application submitted by ITAB for approval of whey as a basic substance for an extension of use in plant protection as a fungicide in grapevines and vegetable crops, EFSA was asked to organise a consultation on the basic substance application, 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 whey as an extension of use, organised by EFSA, was conducted with Member States via a written procedure in December 2019 – February 2020. 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 the extension of use of 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 manufacture 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 manufacture of fresh cheese.

Whey is used as an additive in many processed foods and in animal feed. The initial approval application of whey as basic substance was for uses as a fungicide against powdery mildew in grapevine, cucumber and zucchini squash and against yellow leaf curl virus in tomato. The extension of use concerns foliar application by spraying on grapevines and vegetables, gardening and tomato (*Lycopersicum esculentum*).

The potential health concern from the use of whey, as already identified when assessing the first application (EFSA, 2015), is derived from food allergies to milk proteins and intolerance to lactose from people with low lactase activity.

As for the requested uses in grapevines and tomato, application is intended at growth stages before fruits are present. Residues in fruits could only occur by contamination via treated leaves if whey residues would still be present on leaves when the fruits are formed. However, information to address the time of stability and disintegration of whey in the environment was not provided although bacterial

degradation over time can be reasonably assumed. In view of the use pattern, significant residues of whey cannot be excluded on commodities receiving direct treatment such as vine leaves, regionally marketed to consumers. Unless appropriately labelled, health concerns for vulnerable individuals cannot be readily ruled out in every condition.

The information included in the application was insufficient to conclude any environmental exposure assessment. It is noted that field uses have been applied for and that application to grapevines would include the use of air assisted broadcast spraying. Consequently, the extension of use will result in higher environmental exposure than for the existing basic substance approval, which only approved uses in greenhouses. However, it is of note that the Technical Report issued by EFSA on 22 October 2015 (EFSA, 2015) already considered field uses including the use on grapevines.

Information was available to address the hazard to non-target organisms for whey. High concentrations of 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, a quantitative risk assessment could not be finalised.

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# 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.

Whey is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received a first application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as a fungicide. On 8 September 2015 the European Food Safety Authority (EFSA) was requested by European Commission to organise a consultation on the basic substance application submitted, 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. A Technical Report containing the finalised reporting table was issued by EFSA on 22 October 2015 (EFSA, 2015).

Whey was approved on 2 May 2016 by Commission Implementing Regulation (EU) 2016/560[2], in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use in plant protection as a fungicide on cucumber and zucchini squash.

In June 2016, the European Commission received a further application from ITAB for approval of the basic substance whey for the extension of use in plant protection as a fungicide in grapevines and vegetable crops.

Following a specific mandate received on 10 March 2020, EFSA organised a consultation with Member States on the basic substance application for the extension of use of whey, which was conducted via a written procedure in December 2019 – February 2020. 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 approval of whey for the extension of use as a fungicide in grapevines and vegetable crops, 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 the extension of use of 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 (Institut Technique de l'Agriculture Biologique (ITAB); 2018, 2020).

## 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 10 March 2020, EFSA was asked to organise a

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 Commission Implementing Regulation (EU) 2016/560 of 11 April 2016 approving the basic substance whey in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 96, 12.4.2016, p. 23–25.

consultation on the basic substance application for the extension of use of whey as a fungicide in grapevines and vegetable crops, 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 10 June 2020.

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.

## 2. Assessment

The comments received on the basic substance application for the extension of use of whey as a fungicide in grapevines and vegetable crops, 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. Institut Technique de l'Agriculture Biologique (ITAB), 2018. Basic substance application on whey submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2018. Documentation made available to EFSA by the European Commission.

2. Institut Technique de l'Agriculture Biologique (ITAB), 2020. Basic substance application update on whey submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2020. Documentation made available to EFSA by the applicant.

## References

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.

## Abbreviations

| | |
|---|---|
| a.s. | active substance |
| BSA | basic substance application |
| CLP | classification, labelling and packaging |
| DE | Germany |
| DK | Denmark |
| ECHA | European Chemicals Agency |
| EFSA | European Food Safety Authority |
| EU | European Union |
| GAP | good agricultural practice |
| MRL | maximum residue level |
| MS | Member State |
| pH | pH value |
| PRIMo | Pesticide Residue Intake Model |
| RMS | rapporteur Member State |

# Appendix A – Collation of comments from Member States and EFSA on the basic substance application for the extension of use of 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** |

No comments

## 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<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 | 2.1.7.2 Analytical methods for the determination of relevant impurities, p.17 | EFSA: clarification is needed if this information is suggesting considering formaldehyde, hydrogen peroxide and hypochlorite as relevant impurities with limits of 0.005%, 0.003% and 0.013%, respectively? | | No EU maximum residue limits are found. Commission Regulation (EU) No 37/2010 of 22 December 2009. | Addressed:<br>No MRL required according to COMMISSION REGULATION (EU) No 37/2010[3] of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. |
| 2(2) | 2.1.7.3 Analytical methods for residues, p.18 | EFSA: it is not clear why this guidance is cited here. | If there are residues to be measured, the compound(s) to be analysed should be defined and a method provided. If not, it should be argued why there are no residues and why a method is not needed. | For each pesticide active substance, MRL in milk is provided in the EU pesticide database. Milk giving whey as sub-product of cheese production should meet the general requirements of theses MRLs, in the food general context outside from this application. All analyses of the 479 approved active | Addressed:<br>The test guideline cited is irrelevant of this submission.<br><br>Whey and therefore initial milk has to be compliant with food regulation. |

[3] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. *OJ L 15, 20.1.2010, p. 1–72.*

| 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** |
| | | | | substance or the 1,425 substances with MRL is out of the scope of this evaluation. Whey and therefore initial Milk has to be compliant with food regulation. | |

| 2.2. Current Former and in case proposed trade names | | | | | |
|---|---|---|---|---|---|
| **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 | | | | | |
|---|---|---|---|---|---|
| **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 | | | | | |
|---|---|---|---|---|---|
| **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

| 2.5. Description of the recipe for the 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** |

No comments

## 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) | 3.2 | DE: Whey can be phytotoxic in higher concentrations. | Please provide a comprehensible explanation that the concentrations stated in the GAP are too low for phytotoxic effects on crop plants. | GAP Table clarified and corrected with maximum concentration fixed at 10%. | Addressed:<br>The maximum concentration was defined. |
| 3(2) | 3.1.1.2 In vegetables | EFSA: According to Bettiol et al. at high concentration (30%) phytotoxicity can be observed. It is not clear 30% refers to what: whey or dry matter? A three times dilution as a possible proposed use would be in this range? | It would be good to clarify that the proposed use concentrations are effective and also not causing phytotoxicity. | GAP Table clarified and corrected with maximum concentration fixed at 10%. | Addressed:<br>The maximum use concentration was included in the GAP table. |

### 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 |
|---|---|---|---|---|---|
| 3(3) | 3.3.1 In greenhouses, p.25 | EFSA: it is not clear what is the relevance for this application the study of Guzmán-Plazola dealing with applications with azoxystrobin, myclobutanil and wettable sulfur | | Used for references<br>Modified in the updated BSA | Addressed:<br>The study of Guzmán-Plazola is not relevant for this submission. |
| 3(4) | 3.3.2 In vineyards, p.25 | EFSA: Pscheidt, 2004 is also showing more ineffectiveness than effectiveness of this substance. | | Non treated incidence 100, Severity 80.6; Water alone incidence 100, Severity 61; Whey Powder incidence 100, Severity 21.8 where is ineffectiveness? | Addressed:<br>Additional data on the study were inserted in column 4. |
| 3(5) | 3.3.2 In vineyards, p.26 | EFSA: Savocchia S.,et al is also an example of ineffectiveness rather to show any use of this substance | | Whey is slightly efficient, nothing comparable to Epoxiconazole but largely less toxic as well (two PBT criteria, toxic for reproduction 1A / 1B, endocrine disrupting properties). These light compounds and substances are not expected to exhibit high level of efficacy. | Addressed. |
| 3(6) | 3.3 Usefulness for plant protection | EFSA: only reaching the GAP table can be identified the whole aim of the extension of use: glasshouse use in vegetable, gardening tomato against *Lycopersicum esculentum* | EFSA: at the beginning of the submission would be good to have a short description of the scope of this extension | Updated | Addressed:<br>The submission was updated, however the updated GAP table is including not only the requested extension but the initial uses, too. |

## 4. Classification and labelling of the substance

| Classification and labelling of the 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** |

No comments

## 5. Impact on Human and Animal Health

### 5.1. Toxicokinetics and metabolism 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 |
|---|---|---|---|---|---|
| 5(1) | 5.13 Human health | DK: Please explicitly justify if the extended use in grapes is covered by the currently very sparse argumentation (and no risk assessment). The intended use in grapes is a factor 10 higher than the previously approved use in cucumber, and therefore above the risk envelope. | | Uses in vineyards are limited to BBCH stage 57 before flowering, so the possible impact on table grapes (more concern than wine) is really low. Whey, therefore, then "of concern" lactose is rapidly degraded by all kind of microorganisms. | See 6(1). |
| 5(2) | 5.13 Human health | DK: Please explore if whey as a derivative of milk should address the issue with potential health concern regarding food allergy to lactose and milk proteins. For the proposed basic substance "Cow milk" this potential risk was considers addressed by limiting the approved use until growth stages where no fruit is present. The same is the case here, however, please explicitly write this somewhere relevant. | EFSA: Applicant to clarify whether the product may be found in edible parts of the crops. | Allergy to lactose is overcome by application time, ahead from harvesting, after if milk and whey (application here) are representing too much risk for population, please forbid them from food! Again, you ask more caution (if these considerations are caution) from the same substance in plant protection than from food. The EU produced 172.2 million tonnes of dangerous raw milk in 2018 including 5 million tonnes powder products like whey. | See 5(3). |

| 5.2. Acute toxicity | | | | | |
|---|---|---|---|---|---|
| **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

| 5.3. Short-term toxicity | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | | **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

| 5.4. Genotoxicity | | | | | |
|---|---|---|---|---|---|
| **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

| 5.5. Long-term toxicity | | | | | |
|---|---|---|---|---|---|
| **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

| 5.6. Reproductive toxicity | | | | | |
|---|---|---|---|---|---|
| **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

| 5.7. Neurotoxicity | | | | | |
|---|---|---|---|---|---|
| **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 4**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |

No comments

| 5.8. Toxicity studies on metabolites | | | | | |
|---|---|---|---|---|---|
| **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

| 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** |

No comments

| 5.10. Additional Information related to therapeutic properties or health claims | | | | | |
|---|---|---|---|---|---|
| **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

**5.11. Additional information related to use as food**

| 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 |
|---|---|---|---|---|---|
| 5(3) | | EFSA: Whey is used as food, however concerns already identified when assessing the first application with regard to the known occurrence of cow milk protein allergy and lactose intolerance, if edible parts of the crops are treated, have not been addressed, i.e. 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). A health concern is however identified regarding food allergies or intolerance to milk proteins for which no 'safe' level can be established. | See 5(2) | All components of whey regarding period of treatments are not expected to be present after few days due to rain and consumption by microorganisms. | The potential health concern from the use of whey, as already identified when assessing the first application (EFSA, 2015), is derived from food allergies to milk proteins and intolerance to lactose from people with low lactase activity.<br>Regarding exposure considerations, please see 6(1). |

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

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

## 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) | | EFSA: The relevance of the information presented in the section of residues (i.e. a list of regulations and regulatory decisions) with regard to the requirement to address potential residues and consumer exposure is not clear. It should be demonstrated in greater detail why the applicant believes that 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. | EFSA: It is suggested that the applicant presents an argumentation, explaining whether or not residues of whey are expected to result on commodities for human consumption (gapes, wine leaves, tomato, cucurbits) and whether in turn a potential health concerns for consumers regarding food allergy and food intolerance to components of whey can or cannot be excluded from the intended use of whey in those commodities. The applicant should consider the intended use pattern requested under 3.4 of the application from and specifically the crop growth stage of last application in their argumentation. | All components of whey regarded as residues due to the period of treatments are not expected to be present after few days due to rain and consumption by microorganisms.<br>EU funded millions of Euros for testing whey as food preservatives through the last years (program ENREMILK with € 5 335 615 EU). Later in Oct. 2018, bovine milk basic whey protein was again considered as novel food.<br>Please be consistent! | The applicant should note that the referred to novel food 'bovine milk basic whey protein isolate' is obtained from skimmed bovine milk through a series of purification steps and is not identical to 'Whey' requested in the remit of this application as PPP, neither is the intended use pattern and exposure scenario comparable.<br>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 are not available. EFSA takes note of the applicant's opinion that residues are not expected although any evidence or substantiated argumentation in support of this claim was not provided.<br>For the extension of uses, whey is intended to be used in |

| 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** |
| | | | | | grapevine and in vegetable production with a total application rate up to 12 kg/ha.<br>In turn, the amount of milk proteins and lactose applied to crops cannot be considered negligible.<br>As for the requested use in grapevines, application is intended at BBCH 10-57 and in tomato at BBCH 10-51, i.e. before fruits are usually present. Residues in fruits may only be expected from contamination via treated leaves if whey residues would still be present on the leaves at the time the fruits are formed. Information is not available to address the longevity/decline of whey when applied into the environment, however, degradation by bacterial activity in the course of time can be reasonably expected.<br>Yet, significant residues of whey cannot be excluded on commodities such as vine leaves that could also be |

| 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** |
| | | | | | marketed to consumers for consumption. |

## 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 37 | 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. 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 | 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 regulatory framework(s) that enable sweet whey to be used as a fertiliser (i.e. 1. organic farming regulation 2. referring to the | 6 more publications of the "non existence" fertilizer use at general regulation of whey are added in the BSA.<br>Future Organic Regulation 2018/848 will not change Annex I (Fertilisers, soil conditioners and nutrients) of the Reg. 889/2008 allowances, unless later voluntary removal by any party (note that applicant is permanent member of EGTOP).<br>Regulation 2019/1009 does not ban whey. | Data gap<br>The applicant has not provided any evidence that an EU 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. Note: assessments for fertiliser products based on sweet whey (in our context only non-fermented products would be relevant) which might be circulated around the single market will be needed shortly according to the provisions of the Regulation (EU) No 2019/1009[4].<br>Information was not 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[5]. Any environmental assessment done by a European Member State national administration in the context of use as a fertiliser in organic farming |

[4] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003. *OJ L 170, 25.6.2019, p. 1–114.*

[5] 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. 1–84.*

**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 |
|---|---|---|---|---|---|
| | | has not been provided. The Egtop/2/2011 report 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>An appropriate environmental exposure or risk assessment relevant for the proposed uses does not seem to be available. | relevant provisions of the fertiliser Regulation 2019/1009). | | has not been provided. The Egtop/2/2011 report 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 or silage additive in organic production but there is no indication that it has been listed positively 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 in the application. |
| 7(2) | 7.1 page 37 | 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 regulatory framework or national legislation that enables sweet whey to be used as a fertiliser (i.e. EU organic farming regulation, national rules on organic farming, national | Leaching to rivers has to be avoided, as any pesticide application. | See data gap at comment 7(1).<br>Note: a pesticide product authorisation requires an exposure assessment covering the potential for surface water body exposure and risk to aquatic organisms for every pest / disease recommendation. The applicant has to provide this assessment and when relevant exposure mitigation measures tailored to the product and use situation, that need to be followed by the user. The application for the use of whey as a basic substance did not contain such an |

| 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** |
| | | | rules / legislation on fertilisers). They should then explain how this plant protection use would lead to lower environmental exposure. | | assessment. Note information is needed to assess the exposure and risk to a range of wildlife, not just aquatic organisms. In addition, the potential for the contamination of groundwater also needs an assessment. The application for the use of whey as a basic substance did not provide an exposure assessment that might be used to address these issues. |

| 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 38 | EFSA: No information is presented on levels of soil, surface water or groundwater exposure resulting from the proposed use. | Applicant should explain the EU regulatory framework or national legislation that enables sweet whey to be used as a fertiliser (i.e. EU organic farming regulation, national rules on organic farming, national rules / legislation on fertilisers). They should then | Future Organic Regulation 2018/848 will not change Annex I (Fertilisers, soil conditioners and nutrients) of the Reg. 889/2008 allowances, unless later voluntary removal by any party (note that applicant is permanent member of EGTOP). | See data gap at comment 7(1) and column 5 entry at comment 7(2). |

| 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** |
| | | | explain how this plant protection use would lead to lower environmental exposure. Alternatively, regulated allowed disposal practice of sweet whey by spreading on agricultural land in an EU member state could be described along with reference to the authority that assessed that such disposal was acceptable. | Regulation 2019/1009 does not ban whey. | |

## 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 |
|---|---|---|---|---|---|
| 8(1) | 8.4.1 | DE: The literature provided is considered inadequate and only refers to a feeding study. Nevertheless, there are no concerns about the basic substance whey for honey bees, if the representative product is used as recommended. A risk caused by direct contact (including sticking of the wings) or oral uptake (including entry into the hive by pollen or nectar) is regarded as unlikely.<br>DK: Please add to the text that the intended uses are before flowering only, therefore negligible exposure is expected in this case (non-systemic substance). | | BBCH stages are described and are before flowering.<br>Text added in the updated BSA. | Addressed.<br>The applicant updated the GAP to indicate that the use is pre-flowering. Furthermore, the risks to bees from the representative uses is low. |
| 8(2) | | EFSA: We agree with MS that negligible exposure is expected. | | BBCH stages are described and are before flowering.<br>Text added in the updated BSA. | Data gap<br>Information in the application indicates that high concentrations of whey were found to produce some adverse effects on aquatic |

### 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 |
|---|---|---|---|---|---|
| | | | | | 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, a quantitative risk assessment could not be finalised. |

### 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 bees and other arthropods species | | | | | |
|---|---|---|---|---|---|
| **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

| 8.4. 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** |

No comments

## 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) | | DE: From the toxicological point of view we agree with "*the extension of use after approval of whey as a basic substance according to Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and Council.*" Whey is not considered a substance of concern. Whey (CAS No. 92129-90-3) is not classified, and according to the majority of notifications provided by companies to ECHA in CLP notifications no hazards have been classified. Furthermore, whey is a foodstuff according to Regulation (EC) No 178/2002. According to the submitted application the pH of whey can strongly vary and the acidity may be adjusted by the addition of safe and suitable pH-adjusting ingredients. Therefore, it is proposed that the approval | | Whey is a foodstuff, produced and use by hundred million tonnes per year in Europe used, USED, **USED**, although not registrated as fertilizer, since nobody wants to pay for its registration in this regulation. It is also intended to be used as plant protection means **legally** by the way of this application, in order to avoid illegal uses, to calibrate legal uses, to avoid non described uses, as our constant goal since the first BSA *Equisetum arvense*.<br>Of course, we are aware that some people are intolerant to lactose and some have severe effects when absorbed, but legal pesticides do the same legally, including self-murder.<br>Proposed extension due to time of treatments is largely les dangerous than already authorized uses on cucumber in fact! | See 5(3) |

| 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** |
| | | considers the pH of the product to prevent adverse effects on human and animal health. Furthermore, the approval should also consider possible intolerances or allergies caused by ingredients as lactose. | | | |

## 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 – 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 (max. 10%) |
| **Function of plant protection** | fungicide |

# Appendix C – List of extension 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 | | | PHI (days) (m) | Remarks (*,**) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc of a.i. g/L (i) | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | L a.i./hl min max (g/hl) | Water l/ha min max | kg a.i./ha min max (kg/ha) (l) | | |
| Grapevine *Vitis vinifera* | FR France All Member States | | F | Powdery mildews: *Erysiphe necator* | TC Technical material | 1040 g/L £ | foliar application spraying * | From 1st shoots to cluster tightening<br>Spring (BBCH 10-57) ** | 3 to 5 | 7 to 10 days | 6 L to 30 L<br>(0.36 to 2.4 kg a.i.) | 100 to 300$ | 6 to 30 L | | ** |
| Vegetable Gardening Tomato *Lycopersicum esculentum* | | | F/G | Tomato (Sinaloa) yellow leaf curl virus *Begomovirus* | | a.i. 60 to 80 g/L | | First inflorescence visible<br>Summer (BBCH 10-51) ** | | 3 to 4 days | 0.6 L to 3 L<br>(0.036 to 0.24 kg a.i.) | 1000 to 1500 | (0.36 to 2.4 kg a.i.) | | |

* spray when there is sun (preferably morning) and not during flowering
£ Density = 1.04
** Whey should be used rapidly after collection, not stored in metal vessel.
$ with a maximum of 10% concentration (30L in 300 L)

(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