



Basic Substance

whely

SANTE/12354/2015– rev3

25 March 2021¹

**Review report for the basic substance whely finalised in
the Standing Committee on Plants, Animals, Food and Feed at its meeting
on 8 March 2016 and amended on 25 March 2021 in view of the approval of whely as
basic substance in accordance with Regulation (EC) No 1107/2009²**

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of whely made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009³ concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 20 April 2015 an application from ITAB, hereafter referred to as the applicant, for the approval of the substance sweet whely as basic substance as a fungicide on grape vines, tomatoes, cucumbers and zucchini squash.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of September 2015. On that occasion the applicant changed the name of the application to the broader term whely.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ The Standing Committee on Plants, Animals, Food and Feed took note of revision 3 of the review report on 25 March 2021. The review report was amended in order to extend the use of whely as basic substance as a fungicide and virucide in grapevines and vegetable gardening tomato, and for the disinfection of glove tips and mechanical cuttings tools.

² Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European Commission.

³ OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for whey on 28 October 2015⁴.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 8 March 2016.

In June 2016, the Institut Technique de l'Agriculture Biologique (ITAB) submitted an application for an extension of the use of whey as a fungicide and virucide as foliar spray in grapevines (*Vitis vinifera*) and vegetable gardening tomato (*Lycopersicon esculentum*). For this application for extension of use, in accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009, the Commission requested scientific assistance from EFSA for the evaluation of the application and the specific points raised by the Member States and the applicants in the commenting phase. EFSA submitted to the Commission the results of its work in the form of a technical report for the extension of the use of whey as a fungicide in grapevines and vegetable crops on 15 May 2020⁵.

In February 2021, the Dutch authorities requested a further extension of the use of whey for disinfection against viruses of glove tips and mechanical cuttings tools. EFSA was contacted to provide their opinion on this additional use of whey.

The amended Review Report was finalised in the meeting of the Standing Committee on 25 March 2021.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2016/560**⁶ concerning the approval of whey as basic substance under Regulation (EC) No 1107/2009.

The review report has been made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁷, in particular with respect to the responsibility of operators, following the approval of whey as basic substance, operators

⁴ 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.

⁵ EFSA (European Food Safety Authority), 2020. Technical report on the 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. EFSA supporting publication 2020:EN-1868. 39 pp. doi:10.2903/sp.efsa.2020.EN-1868.

⁶ OJ L 96, 12.4.2016, p. 23–25.

are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that whey fulfils the criteria of Article 23.

Whey fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002.

According to Regulation (EU) No 1169/2011 on the provision of food information to consumers, whey, as a product of milk, is listed in Annex II of substances or products causing allergies or intolerances. As noted by EFSA, specific mandatory labelling requests for produce containing such substances apply, should they remain on the crops.

Considering the EFSA Technical Report on the basic substance application for whey, the rate of application and the conditions of use, which are described in detail in Appendixes I and II, it is concluded that the use of whey would in principle not lead to concerns for human health.

The potential health concern of the use of whey regarding food allergy to lactose and milk proteins is considered addressed by limiting the approved use, as described in Appendix II, to outdoor applications in grapevines and to in- and outdoor applications on vegetables until a growth stage at which no fruits are present. These conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities. However, the application of whey in grapevines might raise a problem when the leaves of the grapevines are used for human consumption, even when whey is applied prior to flowering. Therefore, a limitation that the leaves from treated plants cannot be used for consumption is appropriate. The application of whey as disinfecting agent for glove fingertips and mechanical cutting tools are, in general, not expected to lead to the presence of residues of concern in food or feed commodities. However, if treated glove fingertips were employed for touching the surfaces of fruit and vegetables close to or at the time of harvest, there could still be transfer of allergens, even in

⁷ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

small amounts. Therefore, whey should not be employed for treating glove fingertips during or right before harvest of edible commodities.

Whey (as a “dairy product”) may be used as fertiliser or soil conditioner in organic agriculture⁸. Furthermore, milk is approved as basic substance for outdoor spray applications on various crops⁹. Therefore, it is unlikely that the outdoor use of whey for plant protection purposes will lead to a higher exposure of residents or bystanders to milk-proteins via the environment than the already allowed uses.

Whey does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. Identity and biological properties

The main properties of whey are given in Appendix I.

The active substance shall have a purity as food grade.

It has been established that for whey as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

5. Particular conditions to be taken into account in relation to the uses as basic substance of whey

Whey must correspond to the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendices I and II.

⁸ 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.

⁹ https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=1255.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being a fungicide and virucide are approved.
- The whey solution can only be applied on plants in the growth stages before flowering.
- The leaves from plants treated with the whey solution cannot be used for human consumption.
- The whey solution cannot be employed for treating glove fingertips during or right before harvest of edible commodities.
- Plants treated with the whey solution, which have not been subject to processing standards required by Regulation (EU) No 142/2011, cannot be fed to cloven-hoofed animals.

The identification of whey as food ingredient implies that Regulation (EC) No 178/2002 on food safety applies.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for whey in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

WHEY

Common name	Whey
Chemical name (IUPAC)	Not available.
Chemical Name. (CA)	Not available.
CAS No	92129-90-3
CIPAC No and EEC No	Not available.
FAO SPECIFICATION	Not available.
Purity	CODEX STAN 289-1995
Molecular formula	Not applicable.
Relevant impurities	None
Molecular mass and structural formula	Not applicable.
Mode of Use	<p>Whey, as specified above, is to be used in a water solution for applications as listed in Appendix II.</p> <p>The whey solution can only be applied in the growth stages before flowering.</p> <p>The leaves from plants treated with the whey solution cannot be used for human consumption.</p> <p>The whey solution cannot be employed for treating glove fingertips during or right before harvest of edible commodities.</p> <p>Plants treated with the whey solution, which have not been subject to processing standards required by Regulation (EU) No 142/2011, cannot be fed to cloven-hoofed animals.</p>
Preparation to be used	Whey to be diluted in compliance with the rate of application reported in Appendix II.
Function of plant protection	Fungicide and virucide.

APPENDIX II
WHEY

Crop and/ or situation (a)	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days)	Remarks
			Type (d- f)	Conc. of a.i. g/L (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l) or concentration recommended		
Cucumber <i>Cucumis</i> <i>Sativus</i> Zucchini squash <i>Cucurbita</i> <i>pepo</i>	G	Powdery mildews: <i>Podosphaera</i> <i>fusca</i> <i>Podosphaera</i> <i>xanthii</i> <i>Golovinomyces/</i> <i>Erysiphe</i> <i>cichoracearum</i> and <i>orontii</i> <i>Sphaerotheca</i> <i>fuliginea</i> <i>Leveillula</i> <i>cucurbitacearum</i>	TC Tec hnic al mat eria l	60-80 g/L	Foliar spray*	From three weeks after sowing (9th leaf unfolded on main stem) to 9 or more primary side shoots visible (BBCH 19- 49)**	3 - 5	7 days	0.6 L to 3 L (0.036 to 0.24 kg a.s.)	1000 to 1500	6 to 30 L (0.36 to 2.4 kg a.s.)	n.a.	Whey should be used rapidly after collection, not stored in metal vessel.
Grapevine <i>Vitis</i> <i>vinifera</i>	F	Powdery mildews: <i>Erysiphe</i> <i>necator</i>					From 1st shoots to cluster tightening Spring (BBCH 10- 57) **	7 to 10 days	6 L to 30 L (0.36 to 2.4 kg a.i.)	100 to 300 \$			
Vegetable Gardening Tomato <i>Lycopersicu</i> <i>m</i> <i>esculentum</i>	F/G	Tomato (Sinaloa) yellow leaf curl virus <i>Begomovirus</i>					First inflorescenc e visible Summer (BBCH 10- 51) **	3 to 4 days	0.6 L to 3 L (0.036 to 0.24 kg a.i.)	1000 to 1500			

Crop and/or situation (a)	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days)	Remarks
			Type (d-f)	Conc. of a.i. g/L (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l) or concentration recommended		
Glove fingertips and mechanical cutting tools All crops	G, I	Viruses (mechanically transferable) e.g. <i>Tobacco mosaic virus</i> (TMV), <i>Tomato mosaic virus</i> (ToMV), <i>Pepper mild mottle virus</i> (PMMV), <i>Cucumber green mottle mosaic virus</i> (CGMMV), <i>Tomato brown rugose fruit viruses</i> (ToBRFV)	(SL)	50 g/L	Dipping	On tools and glove fingertips	Before/after every plant contact. £	Before/after every plant contact. £	n.a.	n.a.	n.a.	n.a.	Dipping for 5 seconds for gloves and 5 minutes for mechanical cutting tools. For reasons of efficacy use whey protein powder with at least 80% protein content. Replace the whey solution regularly (e.g. after each crop row) to prevent cross-contamination of the plants

* spray when there is sun (preferably morning)

** do not apply when any plant is at a later growth stage than BBCH 49.

\$ with a maximum of 10% concentration (30L in 300 L)

£ do not apply on treating fingertips right before or during harvest of edible commodities.

<p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. pests as biting and sucking insects, soil born insects, foliar fungi, weeds or plant elicitor</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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