EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the Food Chain
Pesticides and Biocides

Basic Substance
Milk
SANTE/12816/2019_rev3
19 May 2020

Final Review report for the basic substance cow milk

finalised by the Standing Committee on Plants, Animals, Food and Feed
on 19 May 2020 in view of the approval of milk as basic substance
in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of cow milk made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[2] 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 September 2017 an application from Basic-Eco-Logique, hereafter referred to as the applicant, for the approval of the substance cow milk as basic substance.

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 May 2018. On that occasion the applicant changed the name of the application to the more specific (raw whole) cow milk.

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.

EFSA submitted to the Commission the results of its work in the form of a technical report for cow milk on 22 August 2018[3].

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 by the Standing Committee on 19 May 2020.

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1 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.

2 OJ L 309, 24.11.2009, p. 1.

3 EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for milk for use in plant protection as a fungicide. EFSA supporting publication 2018:EN-1482. 42 pp.

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) 2020/1004**[4] concerning the approval of cow milk as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002[5], in particular with respect to the responsibility of operators, following the approval of cow milk as basic substance, operators 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 cow milk fulfils the criteria of Article 23.

Cow milk 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, 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. The applicant proposed to extend the PHI to 8 days without proving the effectiveness of this measure in order to ensure any residue would have disappeared, hence the risks for consumers cannot be ruled out with this approach. Post-harvest rinsing of the edible crops and further labelling of agricultural commodities treated

4 OJ L 221, 10.7.2020, p. 133.

5 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.

with cow milk were proposed by the applicant. However no insurance as regards the feasibility and effectiveness of such practices could be provided.

Therefore, the potential health concern of the use of cow milk 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 vines and to indoor applications on vegetables until growth stages at which no fruits are present. The application of cow milk on soybean and as disinfecting agent for mechanical cutting tools and glove fingertips are as such not of concern as regards the food allergy issues. As such the conditions of use for the fungicidal and disinfecting functions (e.g. against viruses) are not expected to lead to the presence of residues of concern in food or feed commodities.

Considering the EFSA conclusions on the basic substance application for cow milk, the rate of application and the conditions of use that are described in detail in Appendix I and II, it is concluded that the use of cow milk would in principle not lead to concerns for human health.

Cow milk 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 further restricted as 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 cow milk are given in Appendix I.

The active substance shall have a purity as food grade.

It has been established that for cow milk 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 cow milk

Cow milk must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

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 or a virucide are approved.

Use of cow milk must be in compliance with conditions specified in the Appendixes I and II of this review report.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

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 cow milk in Part C of Annex of the Regulation (EC) No 540/2011[6].

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.

[6] OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I

Identity and biological properties

COW MILK

Common name	Cow Milk
Chemical name (IUPAC)	Not available.
Chemical Name. (CA)	Not available.
CAS No	8049-98-7
EC No	617-095-5
FAO SPECIFICATION	Not available.
Purity	Not applicable
Molecular formula	Not applicable.
Relevant impurities	None
Molecular mass and structural formula	Not applicable.
Mode of Use	Cow milk as specified above to be used in water solution for fungicidal application as listed in Appendix II. Cow milk as specified above to be used undiluted for virucidal application as listed in Appendix II. Plants protected with either of the aforementioned products, which has not been subject to processing standards required by Regulation (EU) No 142/2011, should not be fed to cloven-hoofed animals.
Preparation to be used	Cow milk to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Fungicide and virucide.

APPENDIX II
COW MILK

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)	L a.i./hl min max (L/hl)	Water l/ha min max	Total rate for each application L a.i./ha min max (L/ha) (l) or concentration recommended		
Grapevine *Vitis vinifera*	F	Powdery mildews: *Erysiphe necator*	(SL) Soluble concentrate	100 %	Foliar application Spraying	From 1st shoots (BBCH 07) to inflorescences fully developed; flowers separating (BBCH 57)*	3 to 6	6 to 8 days	10 to 40	100 to 300	10 to 120	n.a.	
Vegetable Gardening pumpkin *Cucurbita pepo*	G	Pumpkins powdery mildew (*Podosphaera xanthii*)	(SL)	100 %	Foliar application Spraying	From leaf development (BBCH01) until flowering (BBCH06) **	3 to 4	7 to 12 days	50	400	200	n.a.	No application in presence of fruits
Flower Gerbera (*Gerbera jamesonii*)	G	Powdery mildew: *Erysiphe cichoracearum*	(SL)	100 %	Foliar application Spraying	Before and during flowering (BBCH 51-69)	3 to 4	7 days	16	500 to 1000	80 to 160	8	
Cucumber *Cucumis Sativus* Zucchini squash *Cucurbita pepo*	G	Powdery mildews: *Sphaerotheca fuliginea*	(SL)	100 %	Foliar application Spraying	From three weeks after sowing (9th leaf unfolded on main stem) to 9 or more primary side shoots visible (BBCH 19-49)***	3 - 4	7 days	5 to 10	1000 to 1500	50 to 150	n.a.	

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)	L a.i./hl min max (L/hl)	Water l/ha min max	Total rate for each application L a.i./ha min max (L/ha) (l) or concentration recommended		
Soybean *Glycine max* (L.) Merr	F	Soybean Powdery mildew *Erysiphe diffusa*	(SL)	100%	Foliar application Spraying	On leaves (BBCH 19 to 49)	3 - 4	7 days	18	1000 to 1500	180 to 270	n.a.	
Glove fingertips and mechanical cutting tools All crops	G, I	Viruses (mechanically transferable) e.g. Tobacco mosaic virus (TMV),Tomato mosaic virus (ToMV),Pepper mild mottle virus (PMMV),Cucumber green mottle mosaic virus (CGMMV)	(SL)	100%	Dipping	On tools	Before/after every plant contact.	Before/after every plant contact.	n.a.	n.a.	n.a.	n.a.	Dipping for 2 seconds. For reasons of efficacy use milk with at least 3,5% protein content. Replace the milk regularly (e.g. after each crop row) to prevent cross-contamination of the plants

* do not apply when any plant is at a later growth stage than BBCH 57

** do not apply when any plant in the greenhouse is at a later growth stage than BBCH 06 and in presence of fruits.

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

(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 sucking 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 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