EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability and Innovation
Pesticides and Biocides

Basic Substance
Chitosan hydrochloride
SANCO/12388/2013– rev. 6
10 July 2025[1]

Final Review report for the basic substance chitosan hydrochloride
finalised in the Standing Committee on the Food Chain and Animal Health
at its meeting on 20 March 2014
in view of the approval of chitosan hydrochloride as basic substance
in accordance with Regulation (EC) No 1107/2009[2],
amended in the Standing Committee on Plants, Animals, Food and Feed at its meetings
on 25 January 2021[3], 5 July 2021[4], 23 March 2023[5] and 10 July 2025[1]

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of chitosan hydrochloride made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[6] concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

1 The Standing Committee on Plants, Animals, Food and Feed endorsed revision 6 of the review report on 10 July 2025. The review report was amended to outline the review of the approval of chitosan hydrochloride in accordance with Art. 23(6) of Regulation (EU) No 1107/2009. The conclusion of the review was that the approval of chitosan hydrochloride as basic substance should be maintened in its current form.

2 Review report established in accordance with Article 13 of Regulation (EU) No 1107/2009. Does not necessarily represent the views of the European Commission.

3 The Standing Committee on Plants, Animals, Food and Feed took note of revision 3 of the review report on 25 January 2021. The review report was amended to include the extension of use on ornamental bulbous plants and beet crops (see chapter 3 and Appendix II).

4 On 5 July 2021, the Standing Committee on Plants, Animals, Food and Feed provided a positive opinion on a correction to the review report for the basic substance chitosan hydrochloride, regarding an error in the CAS (Chemical Abstracts Number of the of the American Chemical Society) number in the Appendix I. This value was amended from 9012-76-4 to 70694-72-3.

5 On 23 March 2023, the Standing Committee on Plants, Animals, Food and Feed provided a positive opinion on a correction to the review report for the basic substance chitosan hydrochloride, regarding an error in the Appendix II (GAP table). The entry “fruits berries and small fruits” was replaced with following entries: “small fruit crops”, “grapevine” and “fruit crops other than small fruit crops and grapevine”.

6 OJ L 309, 24.11.2009, p. 1-50.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 19 December 2011 an application from Chipro, hereafter referred to as the applicant, for the approval of the substance chitosan hydrochloride 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 August 2012.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application by 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 chitosan hydrochloride on 24 May 2013[7].

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 draft review report, which was referred to the Standing Committee on the Food Chain and Animal Health for examination. The review report was finalised in the meeting of the Standing Committee of 20 March 2014.

In October 2019, the Commission received from the company Woodchem B. V. an application for the extension of the use of chitosan hydrochloride to the use on ornamental bulbous plants and beet crops. The Commission consulted EFSA and Member States, following which the Commission did not consider necessary to seek renewed scientific assistance of EFSA due to the nature of the substance and the extension of use applied for. The amended review report was finalised in the meeting of the Standing Committee on 25 January 2021[4].

In March 2022, two Member States requested the Commission to review the approvals of chitosan and chitosan hydrochloride in accordance with Art. 23(6) of Regulation (EU) No 1107/2009. In their view, the current level of information did not allow to conclude that the uses as basic substance do not lead to any risks for human or animals health, nor any unacceptable risk to the environment.

After discussions in the Standing Committee on Plants Animals, Food and Feed, the Commission invited the applicants to submit any relevant information or comments on the eligibility of chitosan and/or chitosan hydrochloride to be approved as a basic substance. The comments received were made available to the Member States and EFSA which were then also invited to comment.

In accordance with Article 23(6) of Regulation (EC) No 1107/2009, the Commission mandated EFSA to provide an opinion regarding the approved use(s) of the substances chitosan and

[7] European Food Safety Authority, 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for chitosan hydrochloride and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-426. 39 pp.

chitosan hydrochloride as basic substances. EFSA published the results of its work as a statement[8] on 3 April 2025 .

The Commission amended the draft review report under consideration that EFSA indicated in its statement that no toxicological concerns were identified for chitosan hydrochloride, and that the estimated levels of chitosan hydrochloride in the environment following application in accordance with its approved uses as basic substance would be within the same range, or below, the expected natural background exposure levels in soil and freshwaters, and that therefore those levels would not create any risk for non-target organisms. The Committee concluded that it is appropriate to maintain the approval of chitosan hydrochloride as basic substance in its current form and endorsed the amended review report in its meeting of 10 July 2025.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report on the first application, 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) No 563/2014[9] corrected by Commission Implementing Regulation (EU) 2021/1446[10]** concerning the approval of chitosan hydrochloride 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[11], in particular with respect to the responsibility of operators, following the approval of *Chitosan hydrochloride* 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 has made 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

8 Statement concerning the review of the approval of the basic substances chitosan and chitosan hydrochloride when used in plant protection. EFSA Panel on Plant Protection Products and their Residues (PPR); EFSA Journal 2025;23:e9318; https://doi.org/10.2903/j.efsa.2025.9318

9 OJ L 156, 24.05.2014, p. 5–7.

10 OJ L 313, 6.9.2021, p. 9-12.

11 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.

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, and the comments and further additional information provided by the applicant to address the open points identified in the Technical report from EFSA, is that there are clear indications that it may be expected that chitosan hydrochloride fulfils the criteria of Article 23.

There are a number of chitosan derivatives which differ with regard to their chemical and physical properties but are made up of glucosamine monomers. Chitosan derivatives are used in medicine, food and cosmetics.

Glucosamine is one of the most abundant mono-saccharides in nature. It is part of the structure of chitin, which composes the exoskeleton of crustaceans and other arthropods, as well as the cell walls of several fungi.

Chitin is a long chain polymer of N-acetyl- glucosamine and is abundantly occurring in nature. Fungal chitin has several forms and is also related to the species of edible fungi.

The form chitin-glucan from *Aspergillus niger* was authorised as novel food ingredient by the Commission Decision 2011/76/EU authorising the placing on the market of a chitin-glucan ingredient under Regulation (EC) No 258/97 of the EU Parliament and Council[12]. The decision was based on the EFSA scientific opinion of the Panel on Dietetic Products, Nutrition and allergies[13] which reports safe use under the proposed conditions of use and levels of intake (maximum dose of 5 g per day).

Specifications reported in the Commission Decision 2011/76/EU refers to chitin-glucan composed of two polysaccharides: chitin composed of repeating units of N-acetyl –D-glucosamine (CAS No 1398-61-4) and beta (1,3) glucan composed of repeating units of Dglucose (CAS No 9041-22-9). Moreover, in chapter 8.5 of the EFSA scientific opinion "the polysaccharides related to chitin-glucan and on which toxicological data are available are chitin (of crustacean origin), chitosan (derived from chitin of crustacean origin), beta-glucan (of vegetable and fungal origin) and oligomers of chitosan. No safety concern arises from these data."

In addition, the form glucosamine-hydrochloride has been subject to a scientific opinion of the EFSA Panel on Dietetic Products, Nutrition and allergies of the safety of glucosamine hydrochloride from *Aspergillus niger* as food ingredient in the context of Regulation (EC) No 258/97 on novel food. The Panel therein concluded on the safety of the product as food ingredient for adult consumers at the proposed intake of 750 mg of glucosamine per day[14]. As reported in that EFSA scientific opinion: "The toxicity of glucosamine has been studied in a

12 OJ L 29, 3.2.2011, p.34-35.
13 EFSA Journal (2010) 8(7):1687.
14 EFSA Journal (2009) 1099:1-19.

number of animal species. Glucosamine has a very low acute oral toxicity. The Panel considers that glucosamine has also a low chronic toxicity"[15].

The form chitosan has been subject to an EFSA opinion on the substantiation of health claims[16] related to chitosan effecting maintenance of normal blood LDL-cholesterol concentrations with positive results, leading to the inclusion of chitosan into the Commission Regulation (EC) 432/2012 establishing a list of permitted health claims made on foodstuffs[17], where the recommended use is 3 g of chitosan as daily intake for adult.

The food grade specifications refer to Chitosan as a polymer composed of ß-(1-4) linked D-glucosamine and N-acetyl-D-glucosamine.

The characterisation of chitosan in that opinion was "Chitosan is a linear cationic polysaccharide composed of randomly distributed ß-(1-4)-linked D-glucosamine and Nacetyl-D-glucosamine produced commercially by the de-acetylation of chitin, which is a component of the exoskeleton of crustaceans and the cell walls of fungi. The degree of deacetylation can be measured by established methods, and ranges from 60-100 % in commercial preparations. The molecular weight of chitosan in commercial preparations ranges from 3,800 to 20,000 Da. Chitosan is insoluble in water.

The Panel considers that the food constituent, chitosan, which is the subject of the health claims, is sufficiently characterised."

Chitosan hydrochloride which is subject to the current application as basic substance, is produced by the de-acetylation of chitin (crustaceans cells) and salinization using hydrochloric acid to result in the form of hydrochloride in order to enhance its solubility in water . The molecular weight in this form ranges from 47.000 to 65.000 Da [18].

Considering the EFSA conclusions on the basic substance application for chitosan hydrochloride, the opinions of the EFSA Panel on Dietetic Products, Nutrition and allergies on chitosan and derivatives, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of chitosan hydrochloride would not lead to concerns for human health. Furthermore, no residues are expected as the conditions of use would not significantly increase the background level due to the natural occurrence of the substance.

Chitosan hydrochloride is not a substance of concern and does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immune-toxic 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.

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15 EFSA Journal (2009) 1099:1-19.

16 EFSA Journal (2011); 9(6):2214

17 OJ, L 136, 25.5.2012, p.1.

18 Outcome of the consultation with member States and EFSA on the basic substance application for *Chitosan Hydrochloride* and the conclusions drawn by EFSA on the specific points raised. 2013:EN-NNNN.39 pp.

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.

These conclusions were reached within the framework of the uses which were supported by the applicant having submitted the first application and mentioned in the list of uses supported by available data included in 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.

The intended uses on ornamental bulbous plants and beet crops in the application for extension of use submitted in October 2019 (and further updated in June 2020) by the applicant Woodchem B. V. can be considered comparable to the already approved uses and are thus acceptable. Therefore, they are included in Appendix II to this review 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 chitosan hydrochloride are given in Appendix I.

Chitosan Hydrochloride of animal origin must be in compliance with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011.

Specifications laid down in the European Pharmacopeia must be complied with.

It has been established that for chitosan hydrochloride as notified by the applicant, the following manufacturing impurities are considered, on the basis of information currently available, of toxicological or environmental concern:

Heavy metals: Maximum level of 40 ppm.

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

Chitosan hydrochloride 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 elicitor of the crop's self-defence mechanisms are approved.

Use of chitosan hydrochloride must be in compliance with conditions specified in the Appendixes I and II of this review report and the maximum application rate of chitosan hydrochloride for a single treatment is: 800 gr/ha.

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

The identification of Chitosan as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies and consequently this includes the respect to any maximum permissible levels of chemical and biological contaminants legally set for this type of product.

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 chitosan hydrochloride 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 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

CHITOSAN HYDROCHLORIDE

Common name (ISO)	Not relevant
Chemical name (IUPAC)	Not relevant
Chemical Name. (CA)	Not relevant
Common names	Chitosan hydrochloride Hydrochloride of linear polysaccharide composed of randomly distributed 1-4 linked D glucosamine and N-acetyl-D-glucosamine produced by de-acetylation of chitin.
CAS No	70694-72-3
CIPAC No and EEC No	Not relevant
FAO SPECIFICATION	Not relevant
Minimum purity	European Pharmacopeia Chitosan hydrochloride being a product of animal origin must be in compliance with the requirements of Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011.
Molecular formula	Not relevant
Relevant impurities	Max content of heavy metals: 40 ppm
Molecular mass and structural formula	Not relevant
Mode of Use	Chitosan hydrochloride as specified above to be used in water solution for application on various crops or for seed treatment.
Preparation to be used	Chitosan hydrochloride to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Elicitor, having a fungicide and bactericide effect via the stimulation of natural defence mechanisms.

APPENDIX II

CHITOSAN HYDROCHLORIDE

Crop and/ or situation (a)	**F G or I** (b)	**Pests or group of pests controlled** (c)	**Formulation**		**Application of chitosan hydrochloride**				**Application rate of chitosan hydrochloride**			**PHI** (days) (m)	**Remarks***
			Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	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)		
Small fruit crops (3SMFC)	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - development of fruit (BBCH 10-79)	4-8	2 weeks	50 - 200	200 - 400	100-800	0	
Grapevine Vitis vinifera (VITVI)	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	BBCH 10 to BBCH 79	4-8	2 weeks	50 - 100	200 - 600	100-600	0	
Fruit crops (3FRUC) Other than small fruit crops and grapevine	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	BBCH 10 to BBCH 79	4-8	2 weeks	50 - 100	200 - 400	100-400	0	Specific application rates are defined for small fruit crops and grapevine as set out in rows 1 and 2 of this table
Vegetable crops (3VEGC)	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - development of fruit (BBCH 10-79)	4-8	2 weeks	50 - 100	200 - 400	100-400	0	
Cereal crops (3CERC)	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - development of fruit (BBCH 10-79)	4 - 8	2 weeks	50 - 100	200 - 400	100-400	0	

Crop and/ or situation (a)	**F G or I** (b)	**Pests or group of pests controlled** (c)	**Formulation**		**Application of chitosan hydrochloride**				**Application rate of chitosan hydrochloride**			**PHI** (days) (m)	**Remarks***
			Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	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)		
Spice crops (3SPIC)	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - development of fruit (BBCH 10-79)	4 - 8	2 weeks	50 - 100	200 - 400	100-400	0	
Crops grown for animal consumption	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - development of fruit (BBCH 10-79)	4 - 8	2 weeks	50 - 100	200 - 400	100-400	0	
Cereal crops (3CERC) Seed treatment	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low volume spraying	Before sowing	1	Not applicable	50 - 100	Not applicable	Not applicable	0	
Potato (SOLTU) Seed treatment	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low volume spraying/ dipping	Before sowing	1	Not applicable	50 - 100	Not applicable	Not applicable	0	
Sugar beet (BEAVA) Seed treatment	FG	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low volume spraying/ dipping	Before sowing	1	Not applicable	50 - 200	Not applicable	Not applicable	0	
Ornamental herbaceous plants - bulbous plants	F,G, I	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Bulb treatment – Dipping/drenching	Germination (BBCH 00-01)	1	Not applicable	50-100	200-800	100-800	n.a.	

Crop and/ or situation (a)	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application of chitosan hydrochloride				Application rate of chitosan hydrochloride			PHI (days) (m)	Remarks*
			Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	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)		
Bulb treatment													
Ornamental herbaceous plants - bulbous plants	F, G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - Senescence (BBCH 10-92)	1 - 8	5-7 days	50-200	200-400	100-800	0	
Arable crops - Beet crops (3BEEC)	F	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	Leaf development - Senescence (BBCH 10-92)	1 – 8	5-7 days	50-200	200-400	100-800	0	

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

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure), EPPO codes are provided in brackets where relevant (https://gd.eppo.int)

(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 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