EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Basic Substance
Sodium chloride
SANTE/10383/2017– rev.1
20 July 2017

Review report for the basic substance sodium chloride
Finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 20 July 2017
in view of the approval of sodium chloride 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 sodium chloride 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 7 June 2016 an application from Agriculture and Horticulture Development board and from Institut Technique de l'Agriculture Biologique (ITAB), hereafter referred to as the applicant, for the approval of the substance salt as basic substance. In addition, the Commission received on 21 July 2016 an application from Institut Technique de l'Agriculture Biologique (ITAB) for the approval of the substance sea salt as basic substance. Since both applications concern food-grade sodium chloride, the applications were merged.

The application and attached information were distributed to the Member States and the 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 November 2016.

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] Report established in accordance with Art. 13 of Regulation (EC) No 1107/2009; does not necessarily represent the views of the European Commission.
[2] 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 sodium chloride on 20 January 2017[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 in the meeting of the Standing Committee of 20 July 2017.

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) 2017/1529[4]** concerning the approval of sodium chloride 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 sodium chloride 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.

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3 EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for (sea) salt (sodium chloride) for use in plant protection as fungicide and insecticide. EFSA supporting publication 2017:EN-1172. 56 pp.

4 OJ L 232, 8.9.2017, p. 1.

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.

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 sodium chloride fulfils the criteria of Article 23.

Sodium chloride fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA conclusions on the basic substance application for sodium chloride, 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 sodium chloride would not lead to concerns for human health. Furthermore, the conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

Sodium chloride does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation (EC) No 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection as a granule or 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.

The following points were considered as open by EFSA (2017) for sodium chloride, followed by the reason why the risk is considered negligible:

- *The information in the application has not addressed the potential for negative impacts on soil fertility / soil structure / crop safety from all the uses requested or on plant germination in compost derived from mushroom production that is subsequently used as growing media or spread on agricultural / horticultural land.*

  According to the intended use as fungicide on vines, the maximum amount of sodium chloride applied per year is 6 kg/ha. The predicted initial environmental concentrations in soil due to this application are estimated to be 4 mg/kg[6]. This represents only a fraction of the naturally occurring levels in agricultural soil, which are reported to be in the range of 0,15-25 g/kg with a median of 5 g/kg[7]. For chloride a median of 108 mg/kg is reported for

[6] Initial PECsoil calculated using SFO degradation kinetics, one application of 6 kg/ha, 50% crop interception.

[7] Bowen (1979), Environmental chemistry of the elements. Academic press, London.

UK soils[8]. However, potential adverse effects of applying sodium chloride on the soil depend highly on local conditions, such as soil and ground water salinity, mineral content of irrigation water and potential for mineral leaching. It is therefore appropriate to include a recommendation that farmers take stock of these conditions before applying sodium chloride for plant protection purposes to ascertain that use of sodium chloride would not have an unacceptable impact on soil fertility and structure.

With regard to the spreading of sodium chloride treated growth substrate on horticultural land, the amount applied (0,03 g/kg substrate) is negligible compared to the total amount of mineral salts naturally present in the soil.

- *The potential effects on the soil organisms following the exposure to (sea) salt still need to be addressed for all uses. For the use on grapevine the information available in the application is considered as not sufficient to address the risk for non-target organisms with the exception of biological methods of sewage treatment.*

  - For the intended use in vines:

    Sodium chloride is an essential nutrient for birds and mammals. LD50 values for birds and mammals range in the order of grams per kg body weight[9]. The amount and frequency of application would not lead to exposure of such levels. Therefore, the risk to birds and mammals is considered to be low.

    Considering the low predicted environmental concentrations in soil estimated for the use of sodium chloride for plant protection purposes (4 mg/kg), compared to the naturally present background levels of total mineral salts and compared to the NOEC for the rainworm *Eisenia foetida* (3507 mg/kg soil)[8] and the predatory soil mite *Hypoaspis aculeifer* (LC50 9766 mg/kg)[8] the risk to soil organisms, earthworms and soil micro-organisms can be considered acceptable.

    The worst case estimated environmental concentration in surface water resulting from the intended use is 2,1 mg/L[10], which is lower than the mean level of sodium and chloride reported by OECD (2002[11]) in a considerable number of rivers (28 resp. 41 mg/L). As noted in OECD (2002) aquatic organisms have adapted to a certain level of salts in their habitat. The EC50 and NOEC values for *Daphnia magna* for sodium chloride are reported as 874 and 314 mg/L respectively[8]. The LC50 for fish is reported as 5840 mg/L and the NOEC as 252 mg/L (long-term)[8]. Therefore, the risk to aquatic organisms is considered as low.

    For arthropods it is generally reported that sodium is an essential nutrient[12]. Plant-feeding insects often need to harvest it specifically because the plants they feed on are very low in sodium[13]. Honeybees are reported to collect brackish or even seawater and prefer sodium chloride solutions over deionised water, indicating their need of sodium

8 Rawlins et al. (2012). The advanced soil geochemical atlas of England and Wales. British Geological Survey, Keyworth.
9 ECHA sodium chloride registration dossier.
10 PEC surface water calculation using Steps in FOCUS, step 1 (1 application of 6kg/ha).
11 OECD SIDS (2002): Sodium carbonate; OECD SIDS (2002) Calcium chloride.
12 Cohen (2015) Insect Diets: Science and Technology, Second Edition.
13 Xiao et al (2010) Effects of dietary sodium on performance, flight and compensation strategies in the cotton bollworm, Helicoverpa armigera (Hübner); Frontiers in Zoology 2010 7:11 DOI: 10.1186/1742-9994-7-11.

chloride as a nutrient[14]. They respond preferentially to a sodium chloride solution of 1,5% and accept water with sodium chloride concentrations higher than 2%[15]. Therefore risk to honeybees is assumed to be low. For other non-target arthropods data on standard test species is not available, but since LD50 values for arthropods generally range in the grams per kg range (e.g. silkworm larvae, LD50 8900 mg/L[8]) an unacceptable residual effect of the intended use is not expected, allowing rapid natural regeneration from surrounding fields. Therefore, the risk to non-target arthropods is assumed to be low.

- For the intended use in mushrooms:

  Soil organisms are not exposed to sodium chloride during the growth stage of the crop. The exposure of soil organisms from the spread of the discarded growth medium on horticultural land can be expected to be negligible compared to the total amount of minerals naturally present in the soil (see above). Therefore, the risk to soil organisms is concluded to be low.

4. Identity and biological properties

The main properties of sodium chloride are given in Appendix I.

The sodium chloride used shall be of food grade quality.

It has been established that for sodium chloride of food grade quality 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 sodium chloride

Sodium chloride 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 and insecticide are approved.
- The use of sodium chloride shall not exceed 6 kg/ha per year.

The user is advised to take into account the salinity of the soil in his decision to apply sodium chloride, to ensure the application will not have a negative impact on soil fertility or soil structure.

[14] Bonoan et al. (2017): Seasonality of salt foraging in honey bees (*Apis mellifera*); Ecological Entomology (2017), 42, 195–201 DOI: 10.1111/een.12375.

[15] Lau & Nieh (2016): Salt preferences of honey bee water foragers; Journal of Experimental Biology (2016) 219, 790-796 doi:10.1242/jeb.132019.

Use of sodium chloride 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 sodium chloride 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

SODIUM CHLORIDE

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Sodium chloride
Chemical name (CA)	Sodium chloride
Common names	Salt, sea salt
CAS No	7647-14-5
CIPAC No and EEC No	231-598-3(EINECS/ELINCS)
FAO specification	Not available
Minimum purity	970 g/kg, food grade
Relevant impurities	none
Molecular mass and structural formula	Na^+Cl^- (58.44 g/mol)
Mode of Use	Foliar spraying / Hand application
Preparation to be used	Water soluble powder (SP) The user is advised to take into account the salinity of the soil in his decision to apply sodium chloride, to ensure the application will not have a negative impact on soil fertility or soil structure. Granule (GR)
Function of plant protection	Fungicide, insecticide

APPENDIX II

List of uses supported by available data SODIUM CHLORIDE

Fungicide use

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	g a.i./ha min max (g/ha) (l)		
Grapevine *Vitis vinifera*	All MS	Not relevant	F	Fungi diseases Powdery mildews: *Erysiphe necator*	SP Water soluble powder *	>970	Foliar application spraying	From 1st shoots (BCH10) to cluster tightening (BBCH57) Spring to summer	1 to 2	-	600 to 2000	200	1200 to 4000	1200 to 6000 (n)	30	(n) (o) (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)
(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
(n): In case of 2 applications: one at 20 g/L + one at only10 g/L. Maximum total rate of salt shall not exceed 6 kg / ha per year.
(o): Careful application should be controlled in terms of spray and target should be only the foliage. Low volumes are recommended in order to avoid spill. It is recommended not to spray every year, only in emergency cases.
(p): Maximum total rate of sodium chloride shall not exceed 6 kg / ha per year

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	g a.i./ha min max (g/ha) (l)		
Mushrooms like *Agaricus bisporus*	All MS	Not relevant	G	Fungal diseases like cobweb disease *Cladobotryum* strains (i.e. *Mycophilum*); Dry Bubble Disease *Lecanicillium (Verticillium) fungicola* Wet bubble disease *Mycogone perniciosa*	GR Granule	>970	Hand Trowel Cup Scoop	On finding the pathogen. No earlier than 16 days into grow cycle.	1	-	0.03g/kg of substrate	- Dry	80 to 100	80 to 100	-	Salt is used as a spot treatment to cover incidents of disease. On a well-managed farm, disease will be spotted early with specialist teams identifying and spot treating. This avoids harvesters accidently spreading disease thorough contamination of Personal protective equipment (ppe) and transfer to other areas. This in turn will keep on site disease levels low and avoid the use of large volumes of salt.

Insecticide use

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	g a.i./ha min max (g/ha) (l)		
Grapevine *Vitis vinifera*	All MS	Not relevant	F	European grapevine moth: *Lobesia botrana*	SP Water soluble powder *	>970	Foliar application spraying	1st late April to May (BCH 55-57) 2nd July (BBCH 75-77) 3rd September (BBCH 83-91)	1 to 3	Depending on egg stage	600	200	1200	1200 to 3600	30	(n)

(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
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(m): PHI - minimum pre-harvest interval
(n): Careful application should be controlled in terms of spray and target should be only the foliage. Low volumes are recommended in order to avoid spill. It is recommended not to spray every year, only in emergency cases.