CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance limestone powder (calcium carbonate)

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Czech Republic for the pesticide active substance limestone powder (calcium carbonate) are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of limestone powder in paste form as a repellent in forest plantations and forest tree nurseries (field uses). The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. No concerns are identified.

Keywords: limestone, calcium carbonate, peer review, risk assessment, pesticide, repellent

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Summary

Limestone is an active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), Czech Republic received an application from Agro Radomyšl a.s. on 11 August 2017 for approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 26 July 2019.

An initial evaluation of the dossier on the active substance named limestone was provided by the RMS in the draft assessment report (DAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

Limestone powder and calcium carbonate are considered the same substance in the course of this peer review.

The use of limestone powder (calcium carbonate) according to the representative use as a repellent to prevent browsing damage from red and roe deer and brown hare, applied in paste form manually by gloves or special forestry brush in forest plantations and forest tree nurseries (field uses), as proposed at EU level, results in a sufficient repellent efficacy.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to identity, physical and chemical properties and analytical methods.

In the area of mammalian toxicology, the information available for the active substance did not reveal issues that could not be finalised or critical areas of concern for the representative use as a repellent applied in paste form.

In the area of residues, issues not finalised or areas of concerns were not identified.

Limestone is a naturally occurring sedimentary rock composed largely of the mineral calcite (calcium carbonate: $CaCO_3$). The information available and its evaluation regarding the environmental fate and behaviour of the active substance were considered sufficient to complete the assessments necessary regarding the environmental exposure assessment at the European Union (EU) level for the representative use assessed. Considering the nature of the substance and the use pattern, environmental concentrations (except on the treated trees) are expected to be too low to measure, consequently a definition of the residue in the environment for monitoring is considered unnecessary for limestone powder (calcium carbonate).

In the area of ecotoxicology, low risk to all non-target organisms was concluded based on the low exposure in the environment and relevant food items for non-target organisms.

Limestone powder (calcium carbonate) does not meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States (MS) and the applicant for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant in accordance with Article 12(3).

Limestone is an active substance for which, in accordance with Article 7 of the Regulation, the RMS, Czech Republic (hereinafter referred to as the 'RMS'), received an application from Agro Radomyšl a.s. on 11 August 2017. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 26 July 2019.

The RMS provided its initial evaluation of the dossier on the active substance named limestone in the DAR, which was received by EFSA on 11 September 2020 (Czech Republic, 2020). The peer review was initiated on 14 January 2021 by dispatching the DAR to the MS and the applicant, Agro Radomyšl a.s., for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 27 May 2021. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether the material named limestone in the application can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with MS via a written procedure in March 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of limestone powder (calcium carbonate) as a repellent in forest plantations and forest tree nurseries (field uses) as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the DAR and considered during the peer review, if any, are presented in the conclusion.

[1] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

Furthermore, this conclusion also addresses the requirement for an assessment by EFSA under Article 12 of Regulation (EC) No 396/2005, provided that the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, if any, from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for limestone powder (calcium carbonate) according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2022), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the DAR;
- the reporting table (27 May 2021);
- the evaluation table (25 March 2022);
- the report of the scientific consultation with MS experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (Czech Republic, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the European Union for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Limestone is considered by the International Organization for Standardization not to require a common name. The technical active substance is prepared by converting the stone into a powder. The active substance, named limestone in the application for approval, consists mainly of calcium carbonate (IUPAC) and is considered the same substance as calcium carbonate recently evaluated by EFSA for use in plant protection (EFSA, 2021).

The representative formulated product for the evaluation is 'Neoponit L', a paste (PA) containing 750 g/kg limestone powder.

The representative use evaluated comprises manual applications using gloves or special forestry brush in forest plantations and forest tree nurseries as a repellent to prevent browsing damage from red and roe deer and brown hare. Full details of the Good Agricultural Practice (GAP) can be found in the list of end points in Appendix B.

Information was submitted to conclude that the use of limestone powder (calcium carbonate) according to the representative use proposed at EU level results in a sufficient repellent efficacy against the target organisms, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: European Commission (2000a,b, 2010).

The proposed specification for limestone powder (calcium carbonate) is based on batch data from industrial plant production. The proposed minimum purity of the technical material is 974 g/kg expressed as calcium carbonate. The technical material contains silica (SiO_2), however no information was provided as to whether SiO_2 is present in its crystalline form. If present, this can lead to a

toxicological concern. As discussed further in Section 2, the lack of information on this is not relevant for the representative formulation (paste); however, this might be an issue for different types of formulations and/or equivalence check of technical materials done by MS. The material used in the (eco)toxicological assessment does not support the proposed specification (see Sections 2 and 5). FAO specifications are not available for calcium carbonate, limestone and limestone powder.

The main data regarding the identity of limestone powder (calcium carbonate) and its physical and chemical properties are given in Appendix B.

Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulation. A data gap for validation data for the methods for determination of some of the impurities in the technical material was identified (see Section 10).

Methods for the analysis of residues in food and feed of plant origin, animal products, body fluids and tissues and environmental compartments are not required as residue definitions were not set.

2. Mammalian toxicity

Limestone powder (calcium carbonate) was discussed at the Pesticides Peer Review Experts' Teleconference 70 in January 2022 and assessed based on the following guidance documents: European Commission (2003, 2012), EFSA PPR Panel (2012), EFSA (2014) and ECHA (2017). Furthermore, calcium carbonate was also discussed earlier, at the Pesticides Peer Review Experts' Teleconference 32 in November 2020, in the context of another application (EFSA, 2021).

Silica is present in the technical material. The presence of significant amounts of crystalline silica with particle size below 10 μm has not been excluded (see Section 1). Should this fraction below 10 μm be present as crystalline silica at or above 0.1% w/w of the total silica, this would raise a toxicological concern. With regard to the technical specification, it has not been demonstrated to be covered by the material used in the toxicological studies. However, further information is not needed on these points considering the representative formulation (paste) and the intended application method (see also Section 1).

The toxicological risk assessment of limestone powder is mainly based on studies from the open literature, the REACH registration dossier of calcium carbonate,[2] the Scientific Opinion re-evaluating the safety of calcium carbonate (E 170) of the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel, 2011).

Absorption of calcium from dietary calcium carbonate accounts for 20–40% in rats and humans (EFSA ANS Panel, 2011). After intestinal absorption, calcium and carbonate/bicarbonate ions enter the blood stream and distribute into the body. The majority of absorbed calcium is stored in the skeleton. Excess calcium is excreted with water via kidneys (and also via faeces and sweat) and excess carbonate is excreted as carbon dioxide via respiration. A comparative *in vitro* metabolism study was not considered necessary given (i) that calcium carbonate is essential to all life forms, (ii) its long history of safe use as a food additive and as a gastric antiacid and (iii) the available toxicokinetic (**ADME**) information not suggesting any significant metabolic difference between humans and other species.

Calcium carbonate has low **acute toxicity** by the oral, dermal and inhalation routes, based on the use as food additive, literature data, history of safe uses, and supported by summary information from REACH registration dossiers. Furthermore, the compound is neither a skin or eye irritant, nor a skin sensitiser.

Concerning **short-term** oral toxicity, no target organs and no signs of systemic toxicity were observed, with a relevant oral short-term no observed adverse effect level (NOAEL) of 1,000 mg/kg body weight (bw) per day from a 90-day rat study. Concerning short-term inhalation toxicity, in a 90-day inhalation toxicity study with a nanoform of calcium carbonate, treatment-related local effects were identified in the lower airways, i.e. increased lung weight accompanied by slight increases in bronchoalveolar lavage-derived inflammation and cytotoxicity biomarkers (partly reversible within 4 weeks), with a no observed adverse effect concentration (NOAEC) of 0.212 mg/L (= 212 mg/m^3).

Limestone powder (calcium carbonate) is unlikely to be **mutagenic** or **clastogenic**. Aneugenic potential was not investigated but this is not considered needed considering the nature and use of the substance.

Despite the absence of studies, there is no concern for the **long-term** effects and **carcinogenicity** of the compound since both calcium and carbonate are natural constituents of the

[2] https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/16050/10 [Accessed: March 2022].

body and normal metabolites of humans, animals and plants, and have a long history of safe use as a source of calcium supplementation for humans.

Regarding the **reproductive toxicity**, no adverse effects were observed on reproductive parameters in a combined repeated dose toxicity study with the reproductive and developmental toxicity screening test in rats.

In a rat **developmental toxicity** study, a developmental NOAEL of 1,250 mg/kg bw per day was identified on the basis of increased incidence of external and skeletal foetal findings at the higher dose tested of 1,526.5 mg/kg bw per day (maternal NOAEL). Calcium carbonate is not considered to be teratogenic. In the absence of indications of potential **neurotoxic effects** in the available studies and considering the history of safe use and the chemical structure of the substance, it has been agreed that calcium carbonate has no potential for neurotoxicity.

Based on the representative use of the product (as a paste), and the low toxicity profile of the active substance, **toxicological reference values** (acceptable daily intake (ADI), acute reference dose (ARfD), acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL) values are considered not needed for limestone powder (calcium carbonate)).

The dermal absorption value for the representative formulation is 25% (default value). In the absence of toxicological reference values, **non-dietary exposure** estimates are not necessary. It is noted that for the representative use and representative formulation (paste), exposure by inhalation is not expected to be significant. For other potential uses triggering inhalation exposure, e.g. spray, should they be considered for national authorisations, an acceptable operator exposure concentration (AOEC) could be based on the NOAEC of 0.212 mg/L (=212 mg/m^3) identified for treatment-related changes in the lower airways (increased lung weight accompanied by slight increases in bronchoalveolar lavage-derived inflammation and cytotoxicity biomarkers) in a 90-day inhalation toxicity study with a nanoform of calcium carbonate. It should however be noted that, concerning inhalation exposure, particular attention should be given to the possible presence of toxicologically relevant crystalline silica in the technical material (see Section 1).

EFSA notes that the representative formulation 'Neoponit L' contains styrene polymer, a co-formulant of potential concern in the case styrene monomers were released from the polymer. Styrene is classified as Skin Irrit. 2, Eye Irrit. 2, Acute tox 4, STOT RE1 and Repr. 2 according to Regulation (EC) No 1272/2008[3]. Additionally, EFSA has recently re-assessed styrene safety for use as a food contact material (EFSA CEP Panel, 2020) and concluded that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. For the representative use and the representative formulation (paste), exposure by inhalation and/or ingestion is not expected (see Section 3). For other potential uses triggering inhalation exposure, e.g. spray, consideration should be given by MS to the possible presence of styrene in the product.

3. Residues

Standard studies according to EU/OECD guidance documents and EU data requirements have not been submitted to address the residue behaviour of limestone powder (calcium carbonate) from the proposed use. Due to the nature of the active substance and the proposed use, such studies are not required. The proposed use of limestone powder (calcium carbonate) as repellent which is applied to the shoots with brushes or manually (forest plantations, forest tree nurseries) will not result in exposure via food and feed to humans and livestock. Hence, a consumer risk assessment and the underlying data are not required.

Limestone powder and calcium carbonate are considered the same substance in the course of this peer review and hence the conclusions from the calcium carbonate output (EFSA, 2021) regarding the inclusion for Annex IV of Regulation (EC) No 396/2005 are applicable to limestone / limestone powder.

With regard to the five assessment criteria according to Commission guidance SANCO/11188/2013 rev. 2 (European Commission, 2015) for potential inclusion of substances in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V), three criteria were considered to be met for limestone powder (calcium carbonate) for the following reasons:

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

- Toxicological reference values are not required for limestone powder (calcium carbonate) (criterion III) (see Section 2).
- The application for the proposed use is unlikely to result in consumer exposure (criterion V). Therefore, the natural exposure from use as food item and food ingredient is higher than the one linked to the use as plant protection product (criterion IV).
- The other two criteria (criteria I and II) are not fulfilled.

It is noted that the representative plant protection product contains a co-formulant of potential concern. However, regarding the assessment of potential residues resulting from the co-formulant in the representative plant protection product (see Section 2), consumer exposure is not expected for the representative use as a repellent which is applied to the shoots with a brush or manually (in forest plantations or forest tree nurseries).

4. Environmental fate and behaviour

Limestone is a naturally occurring sedimentary rock composed largely of the mineral calcite (calcium carbonate: $CaCO_3$). In some regions it is the water bearing rock material of groundwater aquifers. The active substance is limestone powder (calcium carbonate). After application (by brush or glove) the formulation dries and forms a protective coating. The dried formulation is not water soluble. Because of the method of application environmental concentrations, except on the treated trees, are expected to be too low to measure. Considering the natural presence of calcium carbonate in soils and aquatic sediments and limestone being a groundwater aquifer material, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

5. Ecotoxicology

Valid toxicity data with the active substance or representative formulation were not available for any group of non-target organisms. Therefore, an assessment of the compliance of material tested with the specification was not required. The representative use of limestone powder (calcium carbonate) envisages localised application (by brush or gloves) in forest plantations/forest tree nurseries to prevent browsing damage. Upon application, the formulation dries and forms a protective coating. As reported in Sections 3 and 4, given the type of application and the properties of the active substance, the representative use is expected to result in exposure levels which are too low to measure in the environment. Additionally, it is anticipated that the exposure through food items relevant for non-target organisms would be low, considering the type of application and the properties of the active substance. Therefore, low risk was concluded for **all non-target organisms**. However, according to Regulation (EU) No 283/2013[4], acute toxicity data with active substances should always be submitted for fish, aquatic invertebrates and algae. Therefore, a data gap was identified for these data regarding these aquatic organisms (see Section 10).

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of limestone powder (calcium carbonate) for humans and non-target organisms according to the ECHA/EFSA guidance (2018), although no (eco)toxicological data are available to assess the endocrine disrupting properties, this does not appear scientifically necessary for the following reasons:

- It is a commonly occurring mineral of low solubility, though calcium and carbonate ions form in acidic aqueous media (including rainwater) due to the formation of the more soluble calcium bicarbonate;
- It is used as a repellent and therefore it has no toxic mode of action;
- Calcium carbonate is used as a food and feed additive; pharmaceutical and cosmetic substance.
- For the proposed use no exposure is anticipated to humans and non-target organisms, see Sections 3, 4 and 5.

[4] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. OJ L 93, 3.4.2013, p. 1–84.

Based on the available information, it can be concluded that limestone powder (calcium carbonate) does not meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
Not applicable Considering the nature of the substance, it being a constituent of many soils and the limited environmental exposure from the representative use, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for limestone powder (calcium carbonate)	Not triggered

Table 2: Groundwater[a]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
Not applicable Considering the nature of the substance, it being a groundwater aquifer material and the limited environmental exposure from the representative use, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for limestone powder (calcium carbonate)	Due to limestone (calcium carbonate) being inorganic and its function as a repellent, the parametric drinking water limit (0.1 µg/L) for pesticides and their relevant metabolites as defined by the drinking water directive 98/83/EEC[c] is not applicable according to the regulatory framework	Yes	Not triggered	No	Not triggered

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or a relevant lysimeter.
(c): Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, p. 32–54.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable Considering the nature of the substance, it being a constituent of many soils and the limited environmental exposure from the representative use, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for limestone powder (calcium carbonate)	Not triggered

Table 4: Air

Compound (name and/or code)	Toxicology
Not applicable Considering the nature of the substance, it being a constituent of many soils and the limited environmental exposure from the representative use, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for limestone powder (calcium carbonate)	Rat LC_{50} inhalation > 3 mg/L per 4 h (nose only) (no classification required)

LC_{50}: lethal concentration, 50%.

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of MS and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level).

No particular conditions are proposed for the representative use evaluated.

9. Concerns and related data gaps

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[5] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

Issues or assessments that could not be finalised were not identified.

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

[5] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concern were not identified.

9.3. Overview of the concerns identified for each representative use considered (Table 5)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		Forest plantations Forest tree nurseries Manual applications by gloves or special forestry brush
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Resident/bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	
	Parametric value of 10 µg/L[(b)] breached	
	Assessment not finalised	

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for

some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections.

- Description and validation data for the methods used for determination of some of the impurities (metals, some inorganic elements and SiO_2) in the technical material (relevant for the representative use evaluated; see Section 1).
- Further information is needed on the toxicity of limestone powder (calcium carbonate) on aquatic organisms, i.e. acute toxicity data (relevant for the representative use evaluated; see Section 5).

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEC	acceptable operator exposure concentration
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
DAR	draft assessment report
DAT	days after treatment
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
MS	Member State
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
RMM	risk mitigation measure
SMILES	simplified molecular-input line-entry system
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for limestone powder (calcium carbonate) according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[(a)]
CMR	**Carcinogenicity (C)**	Limestone powder (calcium carbonate) is not considered to be mutagenic, carcinogenic, or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation (EC) 1107/2009
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine disrupting properties		Limestone powder (calcium carbonate) does not meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Limestone powder (calcium carbonate) is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Limestone powder (calcium carbonate) is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	Limestone powder (calcium carbonate) is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

Appendix B – List of end points for the active substance and the representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7315