CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance 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 authorities of the rapporteur Member State Spain and co-rapporteur Member State Hungary for the pesticide active substance calcium carbonate are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of calcium carbonate as a repellent on deciduous and coniferous trees in forestry. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. No concerns were identified.

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

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Calcium carbonate is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Spain, and co-rapporteur Member State (co-RMS), Hungary, received an application from Flügel GmbH for the renewal of approval of the active substance calcium carbonate.

An initial evaluation of the dossier on calcium carbonate was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of calcium carbonate according to the representative uses as a repellent, by applications by painting individual plants and by spraying individual plants with a low-pressure handheld sprayer, on deciduous and coniferous trees in forestry as proposed at Central Europe, result in a sufficient repellent efficacy against game browsing and fraying the antlers.

It should be emphasised that the substance applied for as calcium carbonate is mined limestone and therefore calcium carbonate and limestone are considered the same compound in the course of this peer review.

In the area of physical-chemical properties and analytical methods, the assessment did not reveal any issue not finalised or areas of concern.

In the area of mammalian toxicology, the assessment of the data package revealed no issues that could not be finalised for the representative uses as a repellent neither areas of concerns.

In the area of residues, issues not finalised or areas of concerns were not identified. Calcium carbonate should be considered by risk managers for inclusion in Annex IV of Regulation 396/2005 and the maximum residue level (MRL) review according to article 12 becomes obsolete.

Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). The information available and its evaluation regarding the environmental fate and behaviour of calcium carbonate were considered sufficient to complete the assessments necessary regarding the environmental exposure assessment at the European Union (EU) level for the representative uses assessed. Considering the nature of the substance and the limited usage leading to environmental concentrations which are expected to be too low to measure, a definition of residue in the environment for monitoring is deemed to be unnecessary for calcium carbonate (limestone, $CaCO_3$).

In the area of ecotoxicology, low risk to all non-target organisms was concluded based on the exposure expected to be too low to measure.

Calcium carbonate does not meet the criteria for endocrine disruption for humans and non-target organisms as set out in 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

Commission Implementing Regulation (EU) No 844/2012[1], as amended by Commission Implementing Regulation (EU) No 2018/1659[2], (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS Spain and co-RMS Hungary received an application from Flügel GmbH for the renewal of approval of the active substance calcium carbonate. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Hungary), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on calcium carbonate in the RAR, which was received by EFSA on 23 October 2019 (Spain, 2019).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Flügel GmbH, for consultation and comments on 20 December 2019. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 19 February 2020. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. 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 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 27 April 2020. 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 a joint expert consultation on the endocrine properties in the area of mammalian toxicology/ecotoxicology.

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.

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in 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 252, 19.9.2012, p. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] 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.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in February 2021.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of calcium carbonate as a repellent on deciduous and coniferous trees in forestry (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 RAR and considered during the peer review, if any, are presented in the conclusion. It should be noted that the active substance applied for is composed of mined limestone. Limestone has been permanently included in Annex IV of Regulation (EC) No 396/2005[4] by means of Commission Regulation (EU) 2020/1565[5]. Calcium carbonate as applied for in the current peer review and limestone are considered the same compound. Therefore, calcium carbonate should be considered by risk managers for inclusion in Annex IV of Regulation 396/2005 and the maximum residue level (MRL) review according to article 12 becomes obsolete.

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 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, 2021), 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 RAR;
- the reporting table (27 April 2020);
- the evaluation table (24 February 2021);
- the report(s) of the scientific consultation with Member State 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 RAR, including its revisions (Spain, 2020), 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 (EU) 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

Calcium carbonate (IUPAC) is considered by the International Organization for Standardization not to require a common name. Calcium carbonate as applied for in the current peer review and limestone are considered the same compound.

The representative formulated product for the evaluation was 'FLU17516', a gel for direct application (GD) containing 169 g/kg calcium carbonate and 120 g/kg fish oil.

The representative uses evaluated comprise applications by painting individual plants and by spraying individual plants with a low-pressure handheld sprayer, on deciduous and coniferous trees in forestry as a repellent against game browsing and fraying the antlers in Central Europe (CEU). Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix B.

Data were submitted to conclude that the representative uses of calcium carbonate proposed at CEU level result in a sufficient repellent effect following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[5] Commission Regulation (EU) 2020/1565 of 27 October 2020 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products. OJ L 358, 28.10.2020, p. 3–29.

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011a).

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, 2012).

The minimum purity of calcium carbonate is 950 g/kg. It originates from surface mining from natural sources. There are no relevant impurities in the active substance, specification for SiO_2 relates to the amorphous form only, with crystalline silica below the limit of detection (LOD) of 0.1%. Based on the renewal data, it is proposed to update the reference specification considering that the specification for first approval (min 995 g/kg) was considered provisional and not supported by the renewal data. An FAO specification does not exist for calcium carbonate.

A data gap was identified for the effect of low temperature on stability of the representative formulation and shelf-life storage study at ambient temperature.

Acceptable analytical methods are available for the determination of the active substance content of the formulation.

The need for methods of analysis for monitoring this compound in food of plant and animal origin and in the environment has been waived due to the nature of the compound. A method for body fluids and tissues is not available, however the need for such method can also be waived due to the nature of the compound.

2. Mammalian toxicity

Calcium carbonate was discussed at the Pesticides Peer Review Teleconference 32 in November 2020 and assessed based on the following guidance documents: European Commission (2012), EFSA PPR Panel, (2012).

With regard to the updated technical specification (see section 1), it has not been demonstrated to be covered by the batches used in the toxicological studies. However, considering the toxicity profile of the active substance and the absence of toxicologically relevant impurities (crystalline silica being below the LOD in the technical specification, see section 1), no concern is raised. Similarly, the lack of analytical methods in support of the toxicological studies was not identified as a concern.

Calcium carbonate was moderately **absorbed** (20–40%) in rats and humans, as reported in the Scientific Opinion re-evaluating the safety of calcium carbonate as food additive (E 170) (EFSA, 2011c). Based on the physico-chemical properties of the substance, the information on the available ADME studies and considering its use as a food additive, comparative *in vitro* metabolism data was not considered necessary.

Calcium carbonate is considered of low **acute toxicity** by the oral, dermal and inhalation routes, based on the use as food additive, literature data, history of safe uses, and support by summary information from REACH registration dossiers (Spain, 2020). Furthermore, the compound was neither skin irritant, eye irritant nor skin sensitiser. For the **short-term** toxicity, data from published studies (rats and mice) and from REACH registration dossiers were taken into account (no original study reports). 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 the 90-day rat study. For the short-term toxicity by inhalation, considering that local effects were observed in the lower airways at the high dose, the experts agreed that the short-term toxicity of calcium carbonate by inhalation might need to be further addressed relevant for other uses)[6] in view of possible derivation of an acceptable operator exposure concentration (AOEC) (independently of the

[6] See Experts' consultation 2.2 from Peer Review TC32 (EFSA, 2021).

representative uses and of the representative formulation, if it cannot be justified that exposure by inhalation is not expected; see also below).

Calcium carbonate is unlikely to be **genotoxic**, and no concern was identified by the experts for the **long-term toxicity** and carcinogenicity of the compound.[7] 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 developmental rat 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 high dose tested (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 low toxicity profile of the active substance and the representative uses of the product, no **toxicological reference values** (acceptable daily intake (ADI, acute reference dose (ARfD), acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL) values) were considered necessary for calcium carbonate. The **dermal absorption** value for the representative formulation FLU17516 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 uses and representative formulation (gel for direct application), exposure by inhalation is not expected to be significant; however, some experts agreed that, on a precautionary basis, the use of respiratory protective equipment for operators and workers may be considered at Member State (MS) level for national authorisations.

3. Residues

Standard studies according to EU/OECD guidance documents and EU data requirements have not been submitted to address the residue behaviour of calcium carbonate from the proposed use. Due to the nature of the active substance and the proposed uses, such studies are not required.

The proposed uses of calcium carbonate on deciduous and coniferous forestry trees 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 has been permanently included in Annex IV of Regulation (EC) No 396/2005 by means of Commission Regulation (EU) 2020/1565. The inclusion in Annex IV followed the statement of EFSA for substances that do not require a review of existing MRLs (EFSA, 2019). In particular, it was proposed to retain limestone in Annex IV of Regulation (EC) No 396/2005 based on the outcome of the peer review (EFSA, 2011b). Consequently, the review of MRLs under Art 12 of Regulation (EC) No 396/2005 for limestone became obsolete. Calcium carbonate and limestone are considered the same compound in the course of this peer review. Based on the outcome of the peer review for calcium carbonate that consumer risk assessment is not considered required, calcium carbonate should be considered by risk managers for inclusion in Annex IV of Regulation 396/2005 and the MRL review according to article 12 becomes obsolete.

4. Environmental fate and behaviour

Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). In some regions it is the water bearing rock material of groundwater aquifers.

After application (by brush coating or hand-held trigger spraying) the formulation dries and forms a protective coating. The dried formulation is not water soluble. The spray application is performed with a low-pressure hand-held sprayer with a cone nozzle leading to the formation of large droplets. Therefore, it is very likely that the environmental concentrations of the product due to spray drift are too low to measure.

Because of the method of application and the natural presence of calcium carbonate in soils, aquatic sediments and it being a groundwater aquifer material, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

[7] See Experts' consultation 2.4 from Peer Review TC32 (EFSA, 2021).

5. Ecotoxicology

Toxicity data with the active substance were not available for any group of non-target organisms (data gap for aquatic organisms). Acute toxicity data with the representative formulation were available for honeybees. Acute toxicity data with fish, aquatic invertebrates and algae[8] and chronic toxicity data with earthworms were available with a formulation different than the representative one. According to Regulation 283/2013[9], acute toxicity data with active substances should always be submitted for fish, aquatic invertebrates and algae and therefore a data gap was identified. As reported in section 3 and 4, exposure to calcium carbonate following the representative uses is expected to be too low to be measured. Therefore, based on this, low risk was concluded for all non-target organisms.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of 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 since the substance is used as food and feed additive, pharmaceutical and cosmetic substance. It has no toxic mode of action as it is used as repellent and it has a very low solubility in water. Moreover, no exposure is anticipated to non-target organisms.

Considering the above, it can be concluded that calcium carbonate does not to 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	Not triggered
Considering the nature of the substance, it being a constituent of many soils and the limited exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for calcium carbonate (limestone)	

[8] All the available studies have deficiencies as the test item was not analytically verified. By considering the nature of the substance, i.e. ubiquitous in nature and of very low solubility, they have been considered supportive and the endpoint set at the solubility level.

[9] 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.

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 and the limited exposure from the representative uses a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for calcium carbonate (limestone)	Due to calcium carbonate being inorganic and its function as a repellent, the parametric drinking water limit (0.1 µg/L) 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.

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 sediments and the limited exposure from the representative uses a definition of residue in the environment for risk assessment triggering assessment of effects data is deemed to be unnecessary for calcium carbonate (limestone)	Not triggered

Table 4: Air

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

LC_{50}: lethal concentration, median.

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 uses 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[10] 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:

- **None**

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.

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:

- **None**

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.)

[10] 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.

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		Deciduous and coniferous trees in forestry By painting individual plants and by spraying individual plants with a low-pressure handheld sprayer
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	

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–7 for further information.

(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:

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011a–c) (relevant for all representative uses evaluated).
- Further information on the effect of low temperature on stability of the representative formulation and shelf-life storage study at ambient temperature (relevant for all representative uses evaluated; see Section 1).
- Further information on the toxicity of calcium carbonate on aquatic organisms, i.e. acute toxicity data (relevant for all representative uses evaluated; see Section 5).

References

ECHA and EFSA (European Chemicals Agency and European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311,135 pp. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN

EFSA (European Food Safety Authority), 2011a. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. https://doi.org/10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority), 2011b. Conclusion on the peer review of the pesticide risk assessment of the active substance limestone. EFSA Journal 2011;9(7):2299, 32 pp. https://doi.org/10.2903/j.efsa.2011.2299

EFSA (European Food Safety Authority), 2011c. Scientific Opinion on re-evaluation of calcium carbonate (E 170) as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). EFSA Journal 2011;9(7):2318, 73 pp. https://doi.org/10.2903/j.efsa.2011.2318

EFSA (European Food Safety Authority), 2019. Statement on the pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(12):5954, 12 pp. https://doi.org/10.2903/j.efsa.2019.5911

EFSA (European Food Safety Authority), 2021. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance calcium carbonate. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on dermal absorption. EFSA Journal 2012;10(4):2665, 30 pp. https://doi.org/10.2903/j.efsa.2012.2665

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

European Commission, 2014. Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012. SANCO/2012/11251-rev. 4, 12 December 2014.

Spain, 2019. Renewal Assessment Report (RAR) on the active substance calcium carbonate prepared by the rapporteur Member State Spain, in the framework of Commission Implementing Regulation (EU) No 844/2012, October 2019. Available online: www.efsa.europa.eu

Spain, 2020. Revised Renewal Assessment Report (RAR) on calcium carbonate prepared by the rapporteur Member State Spain in the framework of Commission Implementing Regulation (EU) No 844/2012, December 2020. Available online: www.efsa.europa.eu

Abbreviations

ADI	acceptable daily intake
AAOEL	acute acceptable operator exposure level
AOEC	acceptable operator exposure concentration
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
DAR	draft assessment report
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
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

LC_{50}	lethal concentration, median
LOD	limit of detection
MRL	maximum residue level
MS	Member State
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RMM	risk mitigation measure
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
ToxCAST	(US EPA) Toxicity Forecaster
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for 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)	Calcium carbonate is not considered to be carcinogenic, mutagenic or toxic for reproduction.
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine disrupting properties		Calcium carbonate is not considered to meet the criteria for endocrine disruption for human health 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**	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**	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**	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.2021.6500