CONCLUSION ON PESTICIDES PEER REVIEW

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# Peer review of the pesticide risk assessment of the active substance blood meal

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## Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Austria and co-rapporteur Member State Lithuania for the pesticide active substance blood meal and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 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 blood meal as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants and as a vole repellent on deciduous and coniferous trees in forestry (field uses). 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 are identified.



**Keywords:** blood meal, peer review, risk assessment, pesticide, game repellent, vole 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. Blood meal 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), Austria, and co-rapporteur Member State (co-RMS), Lithuania, received an application from Plantskydd AB for the renewal of approval of the active substance blood meal. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on blood meal 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 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 blood meal according to the representative uses as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants, as proposed at European Union (EU) level, result in a sufficient repellent efficacy against the target games. The proposed uses as a vole repellent were not supported by efficacy data.

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.

No data gaps or critical areas of concern were identified in the mammalian toxicology section.

Considering the uses of blood meal according to the representative uses as a game repellent on orchard trees, the consumer dietary risk to blood meal residues is considered as very unlikely. Blood meal meets the criteria for inclusion in Annex IV of Regulation (EC) No 396/2005.

The fate and behaviour in the environment of blood meal residues are expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary, with the exception of when application is made by less targeted spray application methods such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying. In this situation, further information would be needed to refine the environmental exposure assessment to aquatic systems.

In the area of ecotoxicology, the available data for aquatic organisms were not sufficient to demonstrate a low risk from the uses with less targeted spray application methods such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying. No critical areas of concern were identified.

Blood meal 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). 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, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, Austria, and co-RMS, Lithuania, received an application from Plantskydd AB for the renewal of approval of the active substance blood meal. In addition, the applicant submitted an application for inclusion of the substance into Annex IV of Regulation (EC) No 396/2005[4]. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Lithuania), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on blood meal in the RAR, which was received by EFSA on 18 February 2019 (Austria, 2019a). The RAR included a proposal to include the substance into Annex IV of Regulation (EC) No 396/2005. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 19 August 2019, EFSA invited the Member States to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Plantskydd AB, for consultation and comments on 25 March 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 28 May 2019. 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 5 July 2019. 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 there was no need to conduct an expert consultation.

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

[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.

[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.

were identified as unresolved at the end of the comment evaluation phase and which required further consideration 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 written consultation on the assessment of additional information, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 maximum residue level (MRL) review of Regulation (EC) No 396/2005, took place with Member States via a written procedure in December 2019–January 2020.

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 blood meal as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants, and as a vole 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. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2020), 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 (5 July 2019);
- the evaluation tables (16 December 2019);
- 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 (Austria, 2019b), 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 report and its background documents would not be accepted to support any registration outside the 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

The active substance blood meal is formed from dried red cells of porcine blood of food grade quality, collected in authorised slaughterhouses, heat treated to destroy microorganism contamination. This substance is considered by the International Organization for Standardization not to require a common name.

The representative formulated product for the evaluation was 'Certosan', a wettable powder (WP) containing 998 g/kg blood meal.

The representative uses evaluated are as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants by coating with brush, spraying or dipping individual plants, entire plants, and as a vole repellent on deciduous and coniferous trees in forestry (field uses), by application on the plants via brush, spray or dipping of individual plants at plantation. Full details of the representative uses can be found in the list of end points in Appendix A.

The uses of blood meal according to the representative uses as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants, as proposed at EU level, result in a sufficient repellent efficacy against the target games. It should be noted that the use as a vole repellent was not supported by efficacy data.

## 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, 2000, 2010.

The active substance is 100% blood meal with a minimum haemoglobin content of 80%. The blood conforms with the specific requirements for processed animal protein set out in Commission Regulation (EU) No 142/2011[5] and with the public health and animal health rules for animal by-products and derived products not intended for human consumption laid down in Regulation (EC) No 1069/2009[6]. Regulation (EC) No 853/2004[7] laying down specific hygiene rules for food of animal origin and Council Directive 97/78/EC[8] laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries also apply. It is proposed to update the reference specification from the first approval with the correct expression of the minimum haemoglobin content.

The batch data and the analytical method proposed for quantification of the active substance in the plant protection product are based on the determination of the iron content, considering the relationship between the iron content and the corresponding haemoglobin content.[9] Internationally agreed methods are used for the control of the human pathogenic germs content of the formulation.

The main data regarding the identity of blood meal and its physical and chemical properties are given in Appendix A.

It should be noted that swirling is necessary to wet the product, requiring proper label instructions.

As residue definition is proposed only for water, the need for methods of analysis for monitoring can be waived, with the exception of a method for water. An inductively coupled plasma optical emission spectroscopy (ICP-OES) method exists for the determination of the residues in water expressed as iron content with a limit of quantification (LOQ) of 1.0 μg/L. The reference method for measuring haemoglobin by the International Committee for Standardization in Haematology (ICSH) is the haemoglobincyanide (HiCN) test.

## 2. Mammalian toxicity

Blood meal does not have a toxic mode of action and does not in itself present a toxicological concern. Since the manufacturing process ensures a food grade quality of the active substance, all toxicological data requirements are waived. Furthermore, blood is a major constituent of the human body and in general of all vertebrates, and it may be present in food items such as meat consumed as part of normal diet. Toxicological reference values are not required and a quantitative risk assessment for operators, workers and bystanders is not considered necessary. This conclusion is in line with the one reached during the previous peer review (EFSA, 2011).

## 3. Residues

For the representative uses on forestry and ornamental plants, no exposure of food and feed items is expected, and a consumer dietary risk assessment is therefore not required for these uses.

For the representative use in orchards consisting of coating with brush, spraying or dipping the plants, residues of blood meal may be present on the fruits and a consumer exposure to blood meal residues cannot be excluded. The use in orchards strictly requires the use of blood meal of food grade quality in accordance with the current EU legislation for animal by-products.

Based on this consideration, toxicological reference values are not required for blood meal and a consumer dietary risk to blood meal residues is considered as very unlikely. Therefore, blood meal meets the criteria for inclusion in Annex IV of Regulation (EC) No 396/2005.

Based on these considerations, the data requirement to determine the residues of blood meal in pollen and bee products can be considered as addressed.

As regards to the submitted European authorised uses in different crop groups, some of these uses were characterised by two instead of one foliar spray application and were therefore not covered by

[5] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive. *OJ L 54, 26.2.2011, p. 1–254.*

[6] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). OJ L 300, 14.11.2009, p. 1–33.

[7] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. *OJ L 139, 30.4.2004, p. 55–205.*

[8] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries. *OJ L 24, 30.1.1998, p. 9–30.*

[9] For further details please refer to the Evaluation Table, data requirement point 1.2 (EFSA, 2020)

the representative use in orchards. However, provided that blood meal is of food grade quality, the criteria for the inclusion of this active substance in the Annex IV of Regulation (EC) No 396/2005 are met and MRLs are not required for the authorised uses.

## 4. Environmental fate and behaviour

No studies to investigate the fate and behaviour in the environmental compartments of blood meal were submitted as blood meal residues are expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The degradation of organic N-combinations starts with mineralisation followed by nitrification. The application rate (ca. 20 kg/ha) is not expected to produce exposures to the terrestrial environment to this kind of material at levels above those that may occur by natural causes (e.g. arising from the death of mammals). The influence of an application of blood meal of ca. 20 kg/ha compared to the natural N-content in soils in 0–20 cm depth is considered to be negligible. Therefore, further data or considerations of the fate and behaviour in the environment of this active substance in soil are deemed to be unnecessary for the representative uses with application by coating with brush and spraying or dipping individual plants. However, in the situation where less targeted spray methods of application are employed (such as, e.g. tractor-mounted hydraulic sprayers or air-assisted broadcast spraying), that do not preclude surface water exposure, an aquatic exposure assessment is needed.[10] Predicted environmental concentrations (PECs) in surface water and sediment were carried out using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator) considering worst-case assumptions (i.e. no degradation in both the soil and water/sediment compartments, no crop interception). Based on the available aquatic risk assessment (refer to Section 5), information on the degradation of the active substance in water/sediment is needed to refine the assessment for the representative uses with spray application on the entire plant when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed (data gap). For the more direct application methods to the plants/trees (by brush, hand-held spraying directed to the tree base or trunk or dipping of individual plants at planting), the potential for the exposure of aquatic systems can be considered negligible.

The applicant did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. However, based on the conclusion in Section 3 that a consumer dietary risk to blood meal residues is considered as very unlikely, this lack of information is considered not an issue of concern and no further data need to be provided.

## 5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002), EFSA PPR Panel (2013) and ECHA/EFSA (2018).

The risk to **birds** and **wild mammals** was assessed considering that (i) the active substance is a game/vole repellent without any toxic mode of action (see Section 2), and (ii) it is a part of human diet and there are no indications that it is of human or animal concern (see Section 3). On this basis, a low risk to birds and wild mammals was concluded.

For **aquatic organisms**, standard toxicity data with the representative formulation were available with fish, aquatic invertebrates (daphnia) and algae. A quantitative tier 1 risk assessment for aquatic organisms indicated low risk for algae at FOCUS Step 2 but not for fish and aquatic invertebrates. Therefore, the risk to fish and aquatic invertebrates would need to be further addressed for the representative uses with spray application on the entire plant when less targeted spraying techniques such as, e.g. tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed (data gap). For the more direct application methods to the plants/trees (i.e. by brush, hand-held spraying directed to the tree base or trunk or dipping of individual plants at planting), negligible environmental exposure is expected (see Section 4), and consequently, the risk to aquatic organisms from these uses is considered to be low.

Acute toxicity data were available for honey **bees** with the representative formulation indicating that the substance is not acutely toxic to bees. On the basis of the available information and considering the representative uses, a low risk to bees, via contact and oral exposure, was concluded.

The risk to honey bees via consumption of contaminated water was assessed as low.

[10] See also Reporting Table comment 4(4) (EFSA, 2020).

No toxicity data were available for bumblebees or solitary bees.

In accordance with European Commission (2002), two toxicity tests were available with the representative formulation and the **non-target arthropod** species *Pardosa* ssp. and *Poecilus cupreus* indicating no adverse effects at application rates equal to the maximum application rate of the representative uses. Thus, the risk to non-target arthropods was considered to be low.

No toxicity data with blood meal and **earthworms** and other **soil macroorganisms**, **soil microorganisms** and **non-target terrestrial plants** or quantitative risk assessments were submitted nor required due to the expected negligible environmental exposure in soil (see Section 4).

No exposure for **sewage treatment plants** would be expected for all representative uses; therefore, no data were necessary.

## 6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of blood meal 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 manufacturing process ensures a food grade quality of the active substance; red blood cells only are used in the final product while plasma fraction is disregarded; blood is a major constituent of the human body and in general of all vertebrates, and it may be present in food items such as meat consumed as part of normal diet or provided as part of the basal diet when breeding fish. Furthermore, blood meal has a non-toxic mode of action and is non-toxic by itself. Therefore, it is justified to waive the assessment of endocrine-disrupting properties of this substance for both humans and non-target organisms.

Considering the above, it can be concluded that blood meal 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[11].

## 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) | Persistence | Ecotoxicology |
|---|---|---|
| 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 by other disciplines is deemed to be unnecessary for blood meal | Not applicable | Low risk to soil organisms |

**Table 2:** Groundwater

| Compound (name and/or code) | Mobility in soil | > 0.1 µg/L at 1 m depth for the representative uses[(a)] | Pesticidal activity | Toxicological 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 by other disciplines is deemed to be unnecessary for blood meal | Not applicable | Not applicable | Not applicable | Not applicable |

(a): FOCUS scenarios or relevant lysimeter.

[11] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. *OJ L 101*, **20.4.2018, p. 33–36**.

**Table 3:** Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| Generally, not applicable, considering the nature of the substance and the limited exposure from the representative uses. The degradation of blood meal follows the normal route of organic N-combinations in nature<br>However, for the exception where application is made by less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying to entire plants, blood meal requires further consideration by ecotoxicology | A low risk to aquatic organisms was not demonstrated at FOCUS Step 2 for the representative uses with spray application on the entire plant when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed |

**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 by other disciplines is deemed to be unnecessary for blood meal | Not applicable |

# 8. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Information to refine the risk to fish and aquatic invertebrates when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed was not available (relevant for the representative uses employing these application techniques; see Sections 4 and 5).

# 9. Particular conditions proposed to be taken into account to manage the risk(s) identified

No particular conditions are proposed for the representative uses evaluated.

# 10. Concerns

## 10.1. 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 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[12] 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.

None.

## 10.2. 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

[12] 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.

(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.

No critical areas of concern have been identified.

## 10.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 9, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

**Table 5:** Overview of concerns

| Representative uses | | Deciduous and coniferous trees in forestry | Trees in orchards | Ornamental plants | Deciduous and coniferous trees in forestry (Agriculture and garden) | | |
|---|---|---|---|---|---|---|---|
| | | Game repellent | | | | | Vole repellent |
| | | Central EU, North EU | | | North EU | | |
| | | Coating with brush, spraying or dipping individual plants, entire plants | | | Coating with brush or dipping individual plants; entire plants | | Spraying individual plants; entire plants |
| **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 | | | | | | |

| Representative uses | | Deciduous and coniferous trees in forestry | Trees in orchards | Ornamental plants | Deciduous and coniferous trees in forestry (Agriculture and garden) | | |
|---|---|---|---|---|---|---|---|
| | | Game repellent | | | | | Vole repellent |
| | | Central EU, North EU | | | North EU | | |
| | | Coating with brush, spraying or dipping individual plants, entire plants | | | Coating with brush or dipping individual plants; entire plants | | Spraying individual plants; entire plants |
| **Risk to aquatic organisms** | Risk identified | X* | X* | X* | | | X* |
| | 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 low risk to fish and aquatic invertebrates was not demonstrated with the available information for uses when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed.
(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.

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## Abbreviations

| | |
|---|---|
| ADI | acceptable daily intake |
| ECHA | European Chemicals Agency |
| EEC | European Economic Community |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| GAP | Good Agricultural Practice |
| ICP-OES | inductively coupled plasma optical emission spectroscopy |
| ISO | International Organization for Standardization |
| LOQ | limit of quantification |
| mm | millimetre (also used for mean measured concentrations) |
| MRL | maximum residue level |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| RAR | Renewal Assessment Report |
| WHO | World Health Organization |

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

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6006