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Peer review of the pesticide risk assessment of the active substance *Pasteuria nishizawae* Pn1

European Food Safety Authority (EFSA),
Maria Arena, Domenica Auteri, Stefania Barmaz, Giulia Bellisai, Alba Brancato, Daniela Brocca,
Laszlo Bura, Harry Byers, Arianna Chiusolo, Daniele Court Marques, Federica Crivellente,
Chloe De Lentdecker, Mark Egsmose, Zoltan Erdos, Gabriella Fait, Lucien Ferreira,
Marina Goumenou, Luna Greco, Alessio Ippolito, Frederique Istace, Samira Jarrah,
Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Jose Oriol Magrans, Paula Medina,
Ileana Miron, Tunde Molnar, Alexandre Nougadere, Laura Padovani, Juan Manuel Parra Morte,
Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Rositsa Serafimova,
Rachel Sharp, Alois Stanek, Franz Streissl, Juergen Sturma, Csaba Szentes, Jose Tarazona,
Andrea Terron, Anne Theobald, Benedicte Vagenende, Alessia Verani and
Laura Villamar-Bouza

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, Denmark, for the pesticide active substance *Pasteuria nishizawae* Pn1 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 *Pasteuria nishizawae* Pn1 as a nematicide on sugar beet. The reliable endpoints, appropriate for use in regulatory risk assessment, are presented.

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Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Pasteuria nishizawae strain Pn1 is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS), Denmark, received an application from Syngenta Crop Protection AG on 27 February 2015 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 3 July 2015.

The RMS provided its initial evaluation of the dossier on *Pasteuria nishizawae* strain Pn1 in the draft assessment report (DAR), which was received by the European Food Safety Authority (EFSA) on 19 December 2016. The peer review was initiated on 10 February 2017 by dispatching the DAR for consultation to the Member States and the applicant, Syngenta Crop Protection AG.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Pasteuria nishizawae* strain Pn1 can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of *Pasteuria nishizawae* strain Pn1 as a nematicide on sugar beet, as proposed by the applicant. Full details of the representative use can be found in Appendix A of this report.

The uses of *Pasteuria nishizawae* strain Pn1 according to the representative uses proposed result in a sufficient efficacy against the sugar beet nematode *Heterodera schachtii*.

There were no data gaps identified in the section identity, physical–chemical and technical properties and analytical methods.

Pasteuria nishizawae Pn1 is considered an obligate parasite; it only germinates and grows inside its host, but not in any other organism, including mammals. There were no data gaps identified in the section mammalian toxicology.

It was not necessary to perform a consumer risk assessment for remaining viable cell colony forming units of the strain, as the latter did not show harmful health effects at higher concentrations and is therefore of no concern. The literature review indicated no production of toxins and/or secondary metabolites. An inclusion of *Pasteuria nishizawae* Pn1 in Annex IV of Regulation (EC) No 396/2005 is therefore recommended.

Potential interference of *Pasteuria nishizawae* Pn1 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC is deemed very unlikely. Being an obligatory parasite with very limited host range, the potential for genetic material exchange between strains or species is considered highly unlikely. The environmental risk is limited by the fact of being an obligatory parasite with very limited host range and therefore no further data on the fate and behaviour into the environment is deemed necessary.

No data gaps were identified in the ecotoxicology section. According to the available information, *Pasteuria* spp. does not produce toxins nor any other secondary metabolites that need further consideration with respect to the environment.

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹ (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 and the applicant(s) 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(s) in accordance with Article 12(3).

Pasteuria nishizawae strain Pn1 is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS Denmark (hereinafter referred to as the 'RMS'), received an application from Syngenta Crop Protection AG on 27 February 2015 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 3 July 2015.

The RMS provided its initial evaluation of the dossier on *Pasteuria nishizawae* strain Pn1 in the DAR, which was received by EFSA on 16 December 2016 (Denmark, 2016). The peer review was initiated on 10 February 2017 by dispatching the DAR for consultation of the Member States and the applicant, Syngenta Crop Protection AG, 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, the RMS on 22 May 2017. 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 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, 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 *Pasteuria nishizawae* strain Pn1 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 Member States via a written procedure in December 2017.

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 *Pasteuria nishizawae* strain Pn1 as a nematicide on sugar beet as proposed by the applicant. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided 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, the Annex IV proposal 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 A.

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.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2017), 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 (22 May 2017);
- the evaluation table (20 December 2017);
- 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 (Denmark, 2017) and the peer review report, both documents are considered as background documents to this conclusion.

It is recommended that this conclusion report 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

Pasteuria nishizawae strain Pn1 is a bacterium deposited at the culture collection of the American Type Culture Collection (ATCC) Safe Deposit, under the accession number SD-5833. *Pasteuria nishizawae* strain Pn1 is a naturally occurring, indigenous wild-type bacterium, originally isolated from an Illinois soybean field.

The representative formulated product for the evaluation was 'A19824C', a flowable concentrate for seed treatment (FS) containing 150 g/kg (minimum 1×10^{14} CFU/kg) *Pasteuria nishizawae* strain Pn1.

The representative use evaluated comprises seed treatment application on sugar beet against the plant parasitic cyst nematode *Heterodera schachtii*. Full details of the good agricultural practice (GAP) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of *Pasteuria nishizawae* strain Pn1 according to the representative use proposed at EU level results in a sufficient efficacy against *H. schachtii*, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

Conclusions of the evaluation

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/12116/2012-rev. 0 (European Commission, 2012) and Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012).

The content of *Pasteuria nishizawae* strain Pn1 in the microbial pest control agent is in the range of 1×10^{14} – 1×10^{16} CFU/kg.

Identification of the strain *Pasteuria nishizawae* Pn1 is based on morphological and physiological characteristics and the strain has been characterised by molecular analysis of the 16S rRNA gene sequence. Currently no further methods to distinguish between different strains of *P. nishizawae* are available due to the fact that only two strains have been identified to date.

There is no evidence of direct relationships of *Pasteuria nishizawae* strain Pn1 to known plant, animal or human pathogens. *P. nishizawae* is a host-specific bacterium, infecting and being pathogenic only to cyst nematodes from the genera *Heterodera* and *Globodera*. A main characteristic of this microorganism is its obligatory multiplication in the host. However, in the manufacturing process as described by the applicant, this dependency is not evident. Therefore, a data gap has been identified to clarify under which conditions the vegetative cells are grown in the fermentation tank.

Based on the literature search performed, *Pasteuria nishizawae* strain Pn1 does not produce toxins and/or secondary metabolites.

Since *Pasteuria nishizawae* strain Pn1 cannot be cultured on synthetic solid media, determination of susceptibility to antibiotics is not feasible using current and available microbiological methods. As *Pasteuria nishizawae* strain Pn1 is an obligate parasite of cyst nematodes, infectivity to any other organism, including humans and immunocompromised patients can be excluded.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, biological properties of the technical active agent of the microbial pest control product (MPCA) and technical properties of the representative formulation.

Acceptable methods are available for the determination of the microorganism in the technical material and for the determination of the content of contaminating microorganisms.

No residue definition was applicable for *Pasteuria nishizawae* strain Pn1; therefore, no post-registration monitoring methods are needed.

2. Mammalian toxicity

The applicant submitted a basic set of valid acute toxicity studies to evaluate the risk of the microorganism. From available studies, a conclusion of infectiveness cannot be directly made since it is not possible to germinate recovered spores from tissues. However, in line with the RMS' position, EFSA would agree that the absence of adverse effects from clinical observations, body weight changes and body weight gain, gross necropsy and organ weight endpoints in available studies indicated a lack of concern. Regarding the mode of action, the RMS indicated that the attachment of endospores to the nematode cuticle is the fundamental step in the infection process. This process showed a high degree of host attachment specificity according to literature review. EFSA considered that given the specific obligate parasitism of *Pasteuria nishizawae* Pn1 the lack of clearance and infectiveness investigations in available studies can be acceptable. On this basis, the setting of health-based reference values for the microorganism are not needed.

The literature review indicated no production of secondary metabolites/toxins, and since *Pasteuria nishizawae* strain Pn1 cannot be cultured on synthetic solid media, it is not possible to measure potential production of metabolites/toxins. Also, considering the high degree of host attachment specificity, no further data are considered needed regarding secondary metabolites/toxins.

3. Residues

As a parasite of nematodes, it is not expected to multiply on crops, food or feeding stuffs. Infected nematodes can produce up to 10^6 spores. *P. nishizawae* and in particular its endospores can persist in the environment for several years.

Pasteuria nishizawae Pn1 is intended for sugar beet root seed treatment. The representative use is one application with $1-3 \times 10^{12}$ spores/ha, resulting in around 10^7 spores per seed.

It was not necessary to perform a consumer risk assessment for remaining viable cell colony forming units of the strain, as the latter did not show harmful health effects at higher concentrations and is therefore of no concern. Potential toxins and/or secondary metabolites formation is not to be expected (see also Sections 1 and 2).

An inclusion of *Pasteuria nishizawae* Pn1 in Annex IV of Regulation (EC) No 396/2005² can therefore be recommended (European Commission, 2015).

4. Environmental fate and behaviour

Potential interference of *Pasteuria nishizawae* Pn1 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC³ (see specific Annex VI decision making criteria in Part II Commission Regulation (EU) No 546/2011⁴) is deemed very unlikely due to the practical impossibility that spores of *P. nishizawae* germinate outside of the host nematodes and to the fact that the test methods described in the Directive rely either on highly specific growing media or specific reactions catalysed by the indicator species. In addition, the presence of *Escherichia coli* is tested as part of the final contaminant screening of the product and no effects of interferences in the test due to the presence of *Pasteuria nishizawae* Pn1 have been noted.

² 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.

³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 32–54.

⁴ Commission Regulation (EU) 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.

Pasteuria spp. reproduce asexually by binary fission. Genetic variability is produced mainly by mutations, however, other mechanisms as intraspecific recombination and integration of extracellular DNA into the bacterial genome has been observed for *Pasteuria ramosa* and *Pasteuria penetrans*. No recombination events have been described between *Pasteuria* strains or species. *Pasteuria nishizawae* Pn1 may be able to transfer genetic information to another population via recombination events (as already described for *P. penetrans*), but, being an obligatory parasite with very limited host range, the genetic material exchange between strains or species is highly unlikely.

4.1. Fate and behaviour in the environment of the microorganism

Published studies have investigated the **persistence and multiplication in soil** of *Pasteuria* spp. mainly with *P. penetrans*. These studies demonstrated that *Pasteuria* spores could survive in soil for several seasons. Bacteria multiplication depends on the presence of the specific host. It has been found that environmental conditions (soil texture, pH, irrigation and temperature) can influence the attachment of the spore to the juvenile nematode larvae. *Pasteuria nishizawae* Pn1 can therefore be expected to persist in soil in concentrations considerably higher than the natural background levels for long periods of time, taking into account repeated applications over the years. However, the environmental risk is limited by the fact of being an obligatory parasite with very limited host range (see Sections 1 and 5 for further information). Predicted environmental concentrations (PEC) in soil have been calculated based on the initial loadings as result of the representative use as seed treatment for sugar beet.

With respect to the **persistence and multiplication in water**, the literature search indicated that there are no reports where *Pasteuria* spp. were detected in the aquatic environment. However, no specific investigations with *Pasteuria nishizawae* Pn1 are available. Worst-case initial PEC surface water have been calculated considering the route of exposure by deposition of dust drift at the time of planting treated sugar beet seeds.

The literature search indicated that there are no reports of findings of *Pasteuria* spp. in **air**. Being an obligatory parasite with very limited host range among plant nematodes, it is expected that its natural habitat will be restricted to that of its host (i.e. soil) and its presence in or transport to air is very limited. In regard to the method of application (seed treatment), transport of dust may occur during seeding at low levels but further information is not regarded necessary based on the limited host range and lack of pathogenicity to humans and non-target organisms (see Section 5).

Regarding **mobility**, the studies described above in relation to persistence and multiplication in soil with *P. penetrans* indicated that spores of *Pasteuria* spp. have the potential to leach to deeper soil layers to various extend (up to 50 cm depth) depending on the soil texture and irrigation regime. Also, they can be mobilised when attached to the cuticle of infected nematodes or by organisms insensitive to their infection. In these investigations, it is claimed that the majority of the endospores are found in the 0–30 cm depth soil layer.

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

Based on the information in the literature, *Pasteuria* spp. does not produce toxins nor any other secondary metabolites.

5. Ecotoxicology

Pasteuria species including *P. nishizawae*, are obligate parasites. They only germinate and grow inside their host, but not in any other organism. No data that *P. nishizawae* acts pathogenically in **birds** and **mammals** were reported.

For **aquatic organisms**, no studies on fish or aquatic plants were performed because *P. nishizawae* was considered to be highly host specific. Data on invertebrates and algae indicated that *P. nishizawae* spores have no adverse effect on those organisms. Overall, considering the host specificity and the likely low exposure of the aquatic environment, no adverse effects are expected to occur on aquatic organisms.

The submitted data showed no adverse effects on **bees**. For **non-target arthropods**, **earthworm** and **soil macro- and microorganisms**, no data were retrieved reporting adverse effects. No adverse effects are expected also in **terrestrial non-target plants**.

6. 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
<i>Pasteuria nishizawae</i> Pn1	Spores expected to exhibit high or very high persistence	Low risk

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
–	–	–	–	–

(a): At least one FOCUS scenario or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
<i>Pasteuria nishizawae</i> Pn1	Low risk

Table 4: Air

Compound (name and/or code)	Toxicology
<i>Pasteuria nishizawae</i> Pn1	No mortality, no adverse effects, no pathogenicity following intratracheal administration of 1.6×10^8 spores of <i>Pasteuria nishizawae</i> Pn1 per rat

7. 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 the Regulation concerning information on potentially harmful effects).

- A data gap has been identified for further information on the manufacturing process to clarify under which conditions the vegetative cells are grown in the fermentation tank (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Section 1).

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

No particular conditions are proposed for the representative uses evaluated.

9. Concerns

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 the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011⁵ 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 the Regulation.

No issues that could not be finalised have been identified for the representative use evaluated.

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 the Regulation 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 the 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 the Regulation.

No critical areas of concern have been identified for the representative use evaluated.

9.3. 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 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

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.

Table 5: Overview of concerns

Representative use	Sugar beet	
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	
	Parametric value of 10 µg/L breached	
	Assessment not finalised	

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Abbreviations

ATCC	American Type Culture Collection (ATCC)
CFU	colony forming units
EEC	European Economic Community
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FS	flowable concentrate for seed treatment
GAP	good agricultural practice
MPCA	active agent of the microbial pest control product
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in groundwater

PEC_{sed} predicted environmental concentration in sediment
PEC_{soil} predicted environmental concentration in soil
PEC_{sw} predicted environmental concentration in surface water
RMS rapporteur Member State

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.2018.5159>

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
—	—	—