CONCLUSION ON PESTICIDES PEER REVIEW

ADOPTED: 16 June 2020

doi: 10.2903/j.efsa.2020.6182

Peer review of the pesticide risk assessment of the active substance Streptomyces strain K61

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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, Estonia, and co-rapporteur Member State, France, for the pesticide active substance Streptomyces strain K61 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 use of Streptomyces strain K61 as a fungicide on fruiting vegetables, leafy vegetables, bulb vegetables, pulses, ornamentals, aromatic herbs and root crops, onions and seedlings, in permanent greenhouses and walk-in tunnels. 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. Concerns are identified.

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Keywords: Streptomyces strain K61, fungicide, peer review, risk assessment, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00142

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Acknowledgment: EFSA wishes to thank the rapporteur Member State, Estonia, for the preparatory work provided to this scientific output.

Note: This scientific output, approved on 16.6.2020, replaces the earlier version published on the EFSA website on 22 January 2013 (EFSA, 2013).

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Arena M, Auteri D, Brancato A, Bura L, Carrasco Cabrera L, Chaideftou E, Chiusolo A, Crivellente F, De Lentdecker C, Egsmose M, Fait G, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans O, Mangas I, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Santos M, Serafimova R, Sharp R, Stanek A, Sturma J, Szentes C, Terron A, Tiramani M, Vagenende B and Villamar-Bouza L, 2020. Conclusion on peer review of the pesticide risk assessment of the active substance *Streptomyces* strain K61. EFSA Journal 2020;18(7):6182, 23 pp. https://doi.org/10.2903/j.efsa.2020.6182

ISSN: 1831-4732

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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. *Streptomyces* strain K61 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), Estonia, and co-rapporteur Member State (co-RMS), France, received an application from Danstar Ferment AG for the renewal of approval of the active substance *Streptomyces* strain K61.

An initial evaluation of the dossier on *Streptomyces* strain K61 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 *Streptomyces* strain K61 according to the representative uses proposed result in a sufficient fungicidal efficacy for the control of seed-borne and soil-borne fungi in fruiting vegetables, leafy vegetables, bulb vegetables, pulses, ornamentals, aromatic herbs and root crops, onions and seedlings, in permanent greenhouses and walk-in tunnels, in the European Union (EU).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical and technical properties of *Streptomyces* strain K61 or the representative formulation.

In the area of mammalian toxicology, pending further identification of secondary metabolites/toxins produced by *Streptomyces* K61 potentially present after application of the product, further assessment of their toxicological profile needs to be provided (assessment not finalised). No signs of toxicity were observed in the acute toxicity studies conducted by the oral route in rats; however, high toxicity (mortality) upon intratracheal administration in rats was observed. The assessment of infectivity/pathogenicity could not be finalised. No reference values could be set; therefore, a risk assessment could not be performed based on the available data and a conclusion could not be reached on operator and worker exposure with regard to the representative uses of *Streptomyces* K61. This was identified as a critical area of concern; the same applies to residents and bystanders in case of walk-in tunnels.

In the section of residues, consumer exposure to *Streptomyces* K61 and to its secondary metabolites/toxins cannot be excluded. The consumer risk assessment in terms of viable and non-viable residues is not finalised due to data gaps identified in the area of mammalian toxicology with regard to infectivity/pathogenicity of *Streptomyces* K61 and to secondary metabolites/toxins potentially produced by *Streptomyces* K61, respectively. Due to the unfinalised consumer risk assessment for edible crops, the inclusion of *Streptomyces* strain K61 in Annex IV of Regulation (EC) No 396/2005 can currently not be recommended.

In the area of environmental fate and behaviour, the available information regarding the viable *Streptomyces* K61 was considered sufficient to characterise exposure for the representative uses assessed. Secondary metabolites/toxins potentially present after the application in the environment of the product cannot be excluded. In the area of ecotoxicology, the risk assessment for wild mammals, non-target arthropods and soil microorganisms could not be finalised for all representative uses in walk-in tunnels with the exception of the application to leafy vegetables using nutrient film technique (hydroponics) where a low risk was concluded. Furthermore, the risk to non-target organisms from secondary metabolites, which may be formed in the environment after application, could not be finalised for all representative uses except for the use to leafy vegetables using nutrient film technique (hydroponics).
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Background

Commission Implementing Regulation (EU) No 844/2012¹, as amended by Commission Implementing Regulation (EU) No 2018/1659² (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 1107/2009³. 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 1 of the Regulation, the RMS, Estonia, and co-RMS, France, received an application from Danstar Ferment AG for the renewal of approval of the active substance *Streptomyces* strain K61. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on *Streptomyces* strain K61 in the RAR, which was received by EFSA on 15 January 2019 (Estonia, 2018).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Danstar Ferment AG, for consultation and comments on 7 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 8 May 2019. At the same time, the collated comments were 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 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 19 June 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 EFSA should conduct an expert consultation in the areas of human health and residues.

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.

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 May 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 use.

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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.
of *Streptomyces* strain K61 as a fungicide on fruiting vegetables, leafy vegetables, bulb vegetables, pulses, ornamentals, aromatic herbs and root crops, onions and seedlings (permanent greenhouse and walk-in tunnel production systems), 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.

In addition, 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 (19 June 2019);
- the evaluation table (8 June 2020);
- the report 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 (Estonia, 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 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 identity of the microorganism and the properties of the formulated product

*Streptomyces* strain K61 is a bacterium deposited at the German Collection of Microorganisms and Cell Cultures (DSMZ) in Braunschweig, Germany, under accession number DSM 7206. *Streptomyces* strain K61 is a naturally occurring strain, initially isolated from Finnish *Sphagnum* peat.

The representative formulated product for the evaluation was ‘Mycostop’, a wettable powder (WP) with a nominal content of $5 \times 10^{11}$ viable spores/kg of *Streptomyces* strain K61 (250 g/kg; minimum $1 \times 10^{11}$ CFU/kg, maximum $2 \times 10^{12}$ CFU/kg). A Food and Agriculture Organization (FAO) specification does not exist for this product.

The representative uses evaluated comprise applications by spray (just to seedlings), drip irrigation, soil drench pre- and post-transplant, by nutrient film technique, by mechanical incorporation of solution and dry seed treatment before sowing and by dipping of rooted cuttings and sets for the biological control of seed-borne and soil-borne fungi, such as *Fusarium*, *Pythium* and *Phytophthora* spp. in fruiting vegetables, leafy vegetables, bulb vegetables, pulses, ornamentals, aromatic herbs and root crops, onions and seedlings, in permanent greenhouses and walk-in tunnels, in the EU. Full details of the GAPs can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of *Streptomyces* strain K61 according to the representative uses proposed, result in a sufficient fungicidal efficacy for the control of seed-borne and soil-borne fungi, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

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 technical grade microbial pest control agent (MPCA) is only a hypothetical stage in the continuous production process of the end-use product (MPCP). As a consequence, the specification is given only for the end-use formulated product ‘Mycostop’ of minimum content of 150 g/kg
Streptomyces strain K61 cell mass and spores and minimum viable spores of $1 \times 10^{11}$ CFU/kg (nominal: 250 g/kg; max. $2 \times 10^{12}$ CFU/kg).

Streptomyces strain K61 can be identified by 16S rDNA sequencing, DNA–DNA hybridisation and by the complete genome map of the strain. The results of the complementary identification studies highlighted the fact that Streptomyces strain K61 is absent from the publicly available databases searched by the applicant and is highly divergent from other Streptomyces species in the databases searched. Based on these results, genomic evidence could not confirm the species identification of the Streptomyces K61 isolate; thus, the species of Streptomyces strain K61 was unknown at the time this conclusion was written. One member state considered that a data gap for further action from the applicant would be appropriate to result in identification of the strain at species level. This represents a disagreement with the way this issue has been approached in this conclusion.

During manufacturing, Streptomyces strain K61 produces an ‘unidentified metabolite compound’ which was however shown to be a non-heptaenic compound, below the detection limit of 50 μg/kg. Streptomyces strain K61 may produce low quantities of toxicologically not relevant indole-3-acetic acid (IAA) and tryptophan.

There is no evidence of direct relationship of Streptomyces strain K61 to known plant, animal or human pathogens. The analyses of contaminating microorganisms in commercially produced batches comply with the requirements of SANCO/12116/2012 rev.0 (European Commission, 2012).

The optimum temperature range for growth of Streptomyces strain K61 was between $+15^\circ$C and $+25^\circ$C. It is inactive in temperatures exceeding $+45^\circ$C and below $+5^\circ$C and at pH below 4 and above 9.

Gene transfers have a central role in the evolutionary history of Streptomyces; therefore, it is theoretically possible that interspecies and intraspecies gene exchange occurs also for Streptomyces K61. However, Streptomyces strain K61 specific data are not available and such information was not found in the published peer-reviewed literature (see also Sections 2 and 4). Streptomyces strain K61 was sensitive to common bacterial antibiotics such as penicillin, kanamycin, ampicillin, tetracycline, streptomycin and rifampicin.

Acceptable methods were available for the determination of the microorganism in the formulation and for the determination of the content of contaminating microorganisms. Viability of Streptomyces strain K61 in ‘Mycostop’ was above the minimum of $1 \times 10^{11}$ CFU/kg for 8 months at a temperature of 22 (±2)°C and for 12 months at +4°C.

A residue definition was not applicable for Streptomyces strain K61; therefore, post-registration monitoring methods are not needed.

2. Mammalian toxicity

Streptomyces K61 was discussed at the Pesticides Peer Review Experts’ Teleconference 25 in March 2020.

General data

No adverse health effects have been observed in the employees exposed during the handling and production of Streptomyces K61 or the representative product ‘Mycostop’. Two instances of allergic reactions have been reported but, in both cases, the appropriate personal protective instructions had been ignored (no respiratory protective equipment). According to the literature review, Streptomyces species are saprophytic soil organisms rarely identified to cause invasive infections in humans rather than mycetoma. They are also known to be associated with farmer’s lung disease (allergic alveolitis) and infections (in immunocompromised individuals only) and, commonly isolated from moisture-damaged buildings, also considered as potent inducers of adverse respiratory health and inflammatory reactions in humans.

Toxicity studies

Toxicity studies were carried out using the formulated product (‘Mycostop’) as its production is a continuous process and the technical grade of MPCA is only a hypothetical stage because the viability of Streptomyces K61 is lost without the formulation components.

The batches tested in toxicity studies were considered compliant with the composition of the end-use formulated product (‘Mycostop’).

The product ‘Mycostop’ was found to be sensitising in a Magnusson & Kligman maximisation test. As the available methods for testing dermal sensitisation are not suitable for testing microorganisms and there are no validated test methods for sensitisation by inhalation, the following warning phrase is
proposed: ‘Contains Streptomyces K61. Microorganisms may have the potential to provoke sensitising reactions’.

Regarding acute toxicity, low acute toxicity was observed upon oral administration of ‘Mycostop’ to rats. However, high toxicity potential of the test substance was observed by inhalation: mortality was observed upon intratracheal administration, although the cause of high rate mortality remains unclear (i.e. if due to the microorganism itself or to the high viscosity of the test fluid) (data gap). Mortality was also observed upon intraperitoneal administration with high-dose microorganism and autoclaved microorganism, suggesting a toxic response rather than an infective process. Based on the available data on oral and intratracheal administration and the deficiencies of these studies (no information at all or limited reporting of enumeration and clearance in tissues, organs and body fluids), the assessment of infectivity and pathogenicity of Streptomyces K61 could not be finalised (data gap). It was also noted that clearance of the microorganism had not been investigated/reported in many studies (data gap).

‘Mycostop’ was found to be negative in a bacterial mutation assay (supplementary study).

No adverse effects were observed in a 28-day oral toxicity study in rat (NOEL = 1,000 mg/kg body weight (bw) per day); however, the study was considered supplementary and suitable for the assessment of toxicity only, since an estimation of the microorganism clearance and investigation for pathogenicity and infectiveness end points were missing (data gap).

**Secondary metabolites/toxins**

Pending further identification of secondary metabolites/toxins, potentially produced by Streptomyces K61 after application and the levels produced (see Section 4.2), further assessment of their toxicological profile needs to be provided (data gap and issue not finalised).

Satisfactory information was not provided on the potential transfer of genetic material from Streptomyces K61 to other organisms (data gap). This represents an issue not finalised since some species of Streptomyces are human or animal pathogens (see also Sections 1 and 4).

**Reference values and non-dietary exposure**

Considering the data gaps regarding the potential infectivity/pathogenicity in humans, the potential adverse effects after inhalatory administration and the not excluded potential for the formation of secondary metabolites/toxins after application, no reference values can be set; therefore, the risk assessment for the representative uses of Streptomyces K61 for operators and workers cannot be concluded. The same applies to residents and bystanders in case of walk-in tunnels (critical area of concern).

**3. Residues**

Streptomyces K61 was discussed at the Pesticides Peer Review Experts’ Teleconference 25 in March 2020.

Information on colonisation and persistence of Streptomyces ssp. on plants was available from public literature reports, while most reports were not relevant to the strain K61 or were not properly addressing the agricultural use pattern, and were thus only indicative for the potential behaviour of Streptomyces strain K61 upon application to crops (see Evaluation table, data requirement 7.1; EFSA, 2020). Based on this information and in view of a PHI of zero days requested for the representative uses, the presence of viable residues on plant commodities cannot be excluded. Therefore, consumer exposure to Streptomyces strain K61 and potential metabolites/toxins cannot be excluded.

Since the assessment of infectivity and pathogenicity of Streptomyces strain K61 was not finalised (see Section 2), a consumer risk assessment with regard to viable residues on edible crops was not possible.

The consumer risk assessment could also not be finalised with regard to non-viable residues until the outstanding issues on potential production of toxins/secondary metabolites by Streptomyces strain K61 after application are sufficiently addressed (data gap) and it is confirmed by the toxicological assessment that a quantitative consumer risk assessment is not necessary for the edible uses, or further information on occurrence levels of potential metabolites/toxins on crops under use conditions is available to enable a quantitative consumer risk assessment.

Due to the unfinalised consumer risk assessment for edible crops, the inclusion of Streptomyces strain K61 in Annex IV of Regulation (EC) No 396/2005 can currently not be recommended.
4. Environmental fate and behaviour

Generic information has been provided in the RAR (Estonia, 2020) in relation to potential interference of Streptomyces strain K61 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC4 (see specific Annex VI decision-making criteria in Part II Commission Regulation (EU) No 546/20115). As the organisms that have to be controlled in drinking water are pathogenic bacteria, it is unlikely that the filamentous Streptomyces strain K61 will give false-positive results with the specific microbiological methods used for drinking water monitoring. Streptomyces strain K61 is a ‘wild type’ and there are no marker genes in the strains which would permit analysis of a frequency of genetic exchange. As the genetic diversity and drift in the wild-type population have not been ascertained, it would not be possible to distinguish any genetic drift from that in the wild population based on the information provided. Satisfactory information on the potential transfer of genetic material to/from Streptomyces strain K61 after application was not available (data gap). Antibiotic producing Streptomyces represent a natural reservoir of antibiotic resistance genes. The extent to which these could be transferred to Streptomyces strain K61 following application could not be assessed with the available information. See also Section 2 where a data gap was identified as the lack of information on strain K61 represents an issue not finalised, because some species of Streptomyces are human or animal pathogens.

4.1. Fate and behaviour in the environment of the microorganism

In relation to its persistence and multiplication in soil, satisfactory strain-specific measurements with Streptomyces strain K61 in five different soil incubations from a study performed at a recognised testing facility were presented in the RAR. The study indicated that viable cells of Streptomyces strain K61 decline after application when strain K61 is applied alone. However, the population decline was more rapid when Streptomyces strain K61 was introduced to the soils in combination with the fungal species Fusarium sp. Under these conditions, Streptomyces strain K61 was not competitive. In published scientific studies on the population dynamics of different species of Streptomyces, a decline of the organism after application was observed. Worst-case initial PEC soil calculations for use in the environmental risk assessment show that the concentration from application of Streptomyces strain K61 is below the natural background concentrations of Streptomyces species in fertile soil and peat soil and would not significantly increase actinomycete amounts in the soil ecosystem. This information was considered sufficient to conclude on the expected low multiplication ability in soil for strain K61 for the representative uses.

In respect to the persistence and multiplication in surface water of Streptomyces K61, unpublished experimental reports indicated that viable cells of the strain survived for 4–14 days in non-sterile tap water. In these experiments, where nutrient levels would be lower than in natural water systems, Streptomyces strain K61 was not competitive. In another unpublished experimental report, a slight decline in viable cells in lake water was seen over 3 days (when the study was terminated). Worst-case initial PEC surface water calculations for use in the environmental risk assessment were presented in the RAR using an emission of 0.1% from permanent greenhouses. These emission values do not cover more open protected cropping systems (walk-in tunnels) where the standard FOCUS procedure for open field should be applied (spray on soil or growing substrate (seedlings of vegetables, aromatic herbs and root crops)). Therefore, EFSA calculated PEC surface water using 2.7% spray drift (see Appendix A). For the use as a dry seed treatment (vegetables, pulses, herbs’ seed and onion sets) in walk-in tunnels, dust drift cannot be excluded when seed drilling machinery is used. For the uses as a dry seed treatment, considering the seeds are planted in permanent greenhouse while the structure is closed, exposure to surface water can be considered negligible. For the other intended uses where Streptomyces K61 will be applied by dip of cuttings/soak of bulbs, drip irrigation, hydroponic nutrient solution, mechanical incorporation of solution or soil drench, exposure to surface water can be considered low. The information on the persistence/multiplication/germination of Streptomyces K61 in natural surface water from the unpublished report of the experiment of 3 days with Streptomyces K61 was considered insufficient to demonstrate that Streptomyces K61 is likely to decline in surface water.

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4 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.
5 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.
Therefore, a data gap (see Section 7) was identified for spray application to seedlings in walk-in tunnels that might not be closed at the time of spraying and dry seed treatment in walk-in tunnels that might not be closed at the time of planting the seed, when planted using machinery.

Information was not provided on the fate and behaviour of *Streptomyces* K61 in air. Dispersal of spores of *Streptomyces* K61 via aerosols to air for the intended uses when applied by dip of cuttings/soak of bulbs, drip irrigation, hydroponic nutrient solution, mechanical incorporation of solution or soil drench emission through air can be considered low. For the intended uses by spray and seed treatment emission through air cannot be excluded. However, the exposure route via air can be considered covered by the available PECs for soil and surface water as described in the paragraphs above related to persistence in soil and surface water.

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

In published scientific papers, several secondary metabolites, such as antibiotics and toxins, have been reported to be produced by *Streptomyces* spp. During manufacture, *Streptomyces* strain K61 produces an 'unidentified metabolite compound' which was however shown to be a non-heptaenic compound. The amount produced was low (below the detection limit of 50 μg/kg) (see Section 1).

It is not known to what extent *Streptomyces* strain K61 might produce any other metabolites following its application to soil or other growing substrate according to the intended uses. Adequate information to address the potential for *Streptomyces* strain K61 to produce secondary metabolites/toxins and their levels was not available. Consequently, it is not clear if any metabolites might fulfil the criteria according to Part B section 7 (iv) of Commission Regulation (EU) 283/20136 namely:

- the relevant metabolite is stable outside the microorganism;
- a toxic effect of the relevant metabolite is independent of the presence of the microorganism;
- the relevant metabolite is expected to occur in the environment in concentrations considerably higher than under natural conditions.

Therefore, data on the potential for *Streptomyces* strain K61 to produce metabolites in relation to these criteria are necessary to assess if the further data requirements and the corresponding risk assessment according to Commission Regulation (EU) No 283/2013, part A, section 7 (standard data requirements and assessment mandatory for chemical plant protection active substances) are triggered. Consequently, this resulted in a data gap (see Section 7) and issue that could not be finalised (see Section 9).

5. Ecotoxicology

The applicant confirmed that the representative uses in protected cropping systems are intended for use in permanent greenhouses and walk-in tunnels.7 Accordingly, the risk assessment for non-target organisms for these representative uses accounted for exposure from use in permanent greenhouses and walk-in tunnels.

As discussed in Section 4.2, the identification and exposure assessment for secondary metabolites in the environment could not be finalised. Consequently, the risk to non-target organisms from such metabolites cannot be assessed and a data gap (see Section 7) is identified resulting in an issue not finalised (see Section 9). This data gap is relevant for all non-target organisms where exposure is expected and summarised as follows:

- For the representative uses as dry seed treatment and spray in walk-in tunnels: birds, mammals, aquatic organisms, bees, non-target arthropods, soil organisms.
- For the representative uses as soil drench, drip irrigation, incorporation, dipping of root cuttings, quick dipping of sets until wet in walk-in tunnels: birds, mammals, bees, non-target arthropods, soil organisms.

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6 Commission Regulation (EU) 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.

7 Please refer to the applicant response in column 3 of 9(3) and 9(4) of the Reporting Table (EFSA, 2020).
• For representative uses as a spray in permanent greenhouses: aquatic organisms and, in the case that secondary metabolites, once identified, are persistent in soil, then a further assessment of the risk to aquatic organisms and soil organisms is needed.

• For the representative uses as dry seed treatment, soil drench, drip irrigation, incorporation, dipping of root cuttings, quick dipping of sets until wet in permanent greenhouses: only in the case that secondary metabolites, once identified, are persistent in soil, then an assessment of the risk to aquatic organisms and soil organisms is needed.

• Nutrient film technique to leafy vegetables in hydroponics in walk-in tunnels and permanent greenhouses: not relevant for any non-target organism.

Two studies on different bird species investigating the toxicity, infectivity and pathogenicity of Streptomyces strain K61 to birds were available and did not indicate any adverse effects. Consequently, a low risk to birds was concluded for all representative uses. As concluded in Section 2, insufficient information is available to finalise the assessment of infectivity and pathogenicity in mammals. Consequently, the assessment for wild mammals could not be finalised (relevant for all representative uses in walk-in tunnels except for the application to leafy vegetables in hydroponic nutrient solutions where exposure to mammals is not anticipated and a low risk can be concluded). Furthermore, a concern over the potential for infectivity and pathogenicity via inhalation was noted (see Section 2). Consequently, a further data gap was concluded to further consider the risk of infectivity and pathogenicity to wild mammals via inhalation for the representative uses as spray in walk-in tunnels. For the other representative uses in walk-in tunnels, low exposure to mammals via inhalation is anticipated. Owing to the lack of exposure, a low risk to mammals for all representative uses in permanent greenhouses is concluded.

Adequate studies were available with aquatic organisms showing no infectivity and pathogenicity to aquatic organisms from Streptomyces strain K61. A high margin of safety was observed when comparing the end points with expected spore concentrations in the environment after entry into surface water from the intended uses in permanent greenhouses and walk-in tunnels. Surface water exposure estimations were not available for the representative dry seed treatment uses in walk-in tunnels where dust drift cannot be excluded. Nevertheless, based on the lack of infectivity and pathogenicity in the available studies, a low risk to aquatic organisms was concluded for all representative uses.

No reliable data were available for honeybees. With the exception of the representative uses in walk-in tunnels via spray and mechanically sown seed treatments, negligible exposure to honeybees is anticipated, and therefore, a low risk is concluded. For the representative uses applied as sprays and mechanically sown seed treatments in walk-in tunnels, exposure via residues on flowering plants in the field margin cannot be excluded; therefore, a data gap to address the risk to bees for these representative uses was concluded. No information was available to assess the effects on pollinators which may be introduced to greenhouses.

No data were provided to assess the risk of Streptomyces strain K61 to non-target arthropods. Exposure to non-target arthropods is anticipated for all representative uses in walk-in tunnels except for the application to leafy vegetables in hydroponic nutrient solutions; therefore, a data gap and an assessment not finalised were identified to further address the potential for toxicity, infectivity and pathogenicity to non-target arthropods. For the representative uses to leafy vegetables in hydroponic nutrient solutions and for all uses in permanent greenhouses, exposure to non-target arthropods is considered to be negligible and a low risk is concluded.

Adequate data were available and indicated that Streptomyces strain K61 is unlikely to be toxic, infectious or pathogenic to earthworms, and therefore, a low risk is concluded for all representative uses. No specific data were available demonstrating the effects of Streptomyces strain K61 on soil microorganism communities; therefore, a data gap was concluded for the intended uses in walk-in tunnels, except for the application to hydroponic nutrient solutions, resulting in an issue that could not be finalised. For the application to leafy vegetables in hydroponic nutrient solutions, no exposure to the soil is anticipated, and therefore, a low risk was concluded.
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                                                                                      |
|----------------------------------------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| *Streptomyces* strain K61                               | Decreases to background levels within a few months                                            | Low risk to earthworms. Data gap for soil microorganisms (for the representative uses in walk-in tunnels except for the application to leafy vegetables in hydroponic nutrient solutions) |
| Toxins/secondary metabolites of *Streptomyces* strain K61 | Open, pending on the identification and quantification of secondary metabolites of *Streptomyces* strain K61 for all intended uses | Open(a),(b)                                                                                        |

(a): For all representative uses, except using nutrient film technique to leafy vegetables in hydroponics, in walk-in tunnels.
(b): For all representative uses, except using nutrient film technique to leafy vegetables in hydroponics, in permanent greenhouses: only in the case that secondary metabolites, once identified, are persistent in soil.

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 |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------|-------------------------|
| Toxins/secondary metabolites of *Streptomyces* strain K61 | Open, pending on the identification and quantification of secondary metabolites of *Streptomyces* strain K61 | Open                                                   | Open                | Open                    |

(a): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

| Compound (name and/or code)                              | Ecotoxicology                                                                                      |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| *Streptomyces* strain K61                               | Low risk for all representative uses                                                              |
| Toxins/secondary metabolites of *Streptomyces* strain K61| Open(a),(b)                                                                                        |

(a): For the representative uses in walk-in tunnels only when applied as a dry seed treatment and spray.
(b): For all representative uses, except using nutrient film technique to leafy vegetables in hydroponics, in permanent greenhouses.

Table 4: Air

| Compound (name and/or code)                              | Toxicology                                                                                      |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| *Streptomyces* K61                                      | Toxicity of concern by inhalation (intratracheal administration); acute rat LC50 \( \geq 10^8 \) CFU/kg bw |

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 Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Further data to investigate the cause of mortality after intratracheal administration (relevant for all representative uses evaluated; see Section 2).
An assessment of infectivity and pathogenicity of *Streptomyces* K61 via both oral and inhalation exposure should be provided (relevant for all representative uses evaluated; see Section 2).

Identification of secondary metabolites/toxins potentially present after the application of the product and their levels (relevant for all representative uses evaluated; see Sections 2, 3, 4.2 and 5).

Pending the outcome of the data gap to identify secondary metabolites/toxins potentially present after the application of the product and their levels, assessment of their toxicological profile needs to be provided (relevant for all representative uses evaluated; see Sections 2 and 3).

Potential transfer of genetic material between *Streptomyces* K61 and other organisms (relevant for all representative uses evaluated; see Sections 1, 2 and 4).

Information on the clearance of *Streptomyces* K61 (relevant for all representative uses evaluated; see Section 2).

Adequate information to address the uniform principles criterion of the strain not being expected to persist and multiply in surface water in concentrations considerably higher than the natural background levels, provided that repeated applications over the years was not available (relevant for the spray uses in walk-in tunnels and dry seed treatment in walk-in tunnels that might not be closed at the time of planting the seed, when planted using machinery; see Section 4).

Pending the outcome of the data gap to identify secondary metabolites/toxins potentially present after the application of the product and their levels, an assessment of their risk to non-target organisms may be needed (relevant for all representative uses except for the uses to leafy vegetables via nutrient film technique (hydroponics); see Sections 4.2 and 5).

Pending the outcome of the data gap for an assessment of infectivity and pathogenicity via oral exposure in mammals, the risk to wild mammals should be further considered (relevant for all representative uses in walk-in tunnels, except for the uses via nutrient film technique to leafy vegetables in hydroponics; see Section 5).

Pending the outcome of the data gap for an assessment of infectivity and pathogenicity via inhalation in mammals, the risk to wild mammals should be further considered (relevant only for the representative uses via spray to seedlings in walk-in tunnels; see Section 5).

Further data are necessary to address the potential for infectivity and pathogenicity to honeybees (relevant for the representative uses via spray application to seedlings and dry seed treatment (and applied with a mechanical driller) in walk-in tunnels; see Section 5).

Further data are necessary to address the toxicity, infectivity and pathogenicity of *Streptomyces* strain K61 to non-target arthropods (relevant for all representative uses, except for the uses via nutrient film technique to leafy vegetables in hydroponics, in walk-in tunnels; see Section 5).

Further data are necessary to address the effect of *Streptomyces* strain K61 to soil microorganism communities (relevant for all representative uses, except for the uses via nutrient film technique to leafy vegetables in hydroponics, in walk-in tunnels; see Section 5).

### 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.

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8 For the representative uses in walk-in tunnels as dry seed treatment and spray in walk-in tunnels, a risk assessment for secondary metabolites might be needed for birds, mammals, aquatic organisms, bees, non-target arthropods, soil organisms. Whereas for the representative uses in walk-in tunnels as soil drench, drip irrigation, incorporation, dipping of root cuttings, quick dipping of sets until wet in walk-in tunnels, a risk assessment for secondary metabolites might be needed for birds, mammals, bees, non-target arthropods, soil organisms.

9 For representative uses as a spray in permanent greenhouses, a risk assessment for secondary metabolites to aquatic organisms might be needed as the application technique will lead to exposure to surface water. Furthermore, in the case that secondary metabolites, once identified, are persistent in soil then a risk assessment to both soil organisms and aquatic organisms would be needed.
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 Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011 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.

1) The potential for secondary metabolites/toxins to be produced in the environment by Streptomyces K61 after application could not be finalised. Should they be formed further assessment of their toxicological profile/hazard, their levels in relevant matrices to assess against the criteria outlined in the bullets indicated in Section 4.2 and, if triggered, possibility for exposure of groundwater would be outstanding (see Sections 2 and 4.2).

2) Based on the available data on both oral and intratracheal administration and the deficiencies of these studies (no information at all or limited reporting of enumeration and clearance in tissues, organs and body fluids), the assessment of infectivity and pathogenicity of Streptomyces K61 could not be finalised (see Section 2).

3) The assessment of potential transfer of genetic material from Streptomyces K61 to other organisms could not be finalised (see Sections 1, 2 and 4).

4) The consumer risk assessment cannot be finalised in view of the outstanding issues on infectivity and pathogenicity of viable residues of Streptomyces strain K61 as well as potential non-viable residues (toxins/secondary metabolites) if formed after application and confirmation from the toxicological assessment that a quantitative consumer risk assessment is not necessary for the edible uses (see Section 3).

5) The risk assessment for infectivity and pathogenicity to wild mammals, non-target arthropods and soil microorganisms could not be finalised (relevant for all representative uses in walk-in tunnels, except for the uses using nutrient film technique (hydroponics) to leafy vegetables) (see Section 5).

6) The risk to non-target organisms from secondary metabolites, which may be formed in the environment after application, could not be finalised (relevant for all representative uses in walk-in tunnels and permanent greenhouses except for the uses using nutrient film technique (hydroponics) (see Section 5).

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

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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.

11 For representative uses as a spray in permanent greenhouses the assessment to aquatic organisms could not be finalised as the application technique will lead to exposure to surface water. Furthermore, in the case that secondary metabolites, once identified, are persistent in soil, then a risk assessment to both soil organisms and aquatic organisms would be needed. This is relevant for all uses in permanent greenhouses except for the use to leafy vegetables using nutrient film technique (hydroponics).
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.

7) High toxicity (mortality) following intratracheal administration of the viable microorganism in test animals. Since no reference values could be set and a risk assessment could not be performed on the basis of the available data, a conclusion could not be reached on the operator and worker exposure with regard to the representative uses of *Streptomyces* K61; the same applies to residents and bystanders in the case of walk-in tunnels (see Section 2).

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

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

| Representative use                  | Fruiting vegetables Permanent greenhouse | Leafy vegetables, aromatic herbs and aromatic root crops Permanent greenhouse | Leafy vegetables, Aromatic herbs and aromatic root crops Permanent greenhouse | Nutrient film technique | Root vegetables and tubers Permanent greenhouse | Cabbages Permanent greenhouse | Pulses Permanent greenhouse | Bulb and corm crops Permanent greenhouse | Ornamentals: Pot plants, cut flowers and cuttings Permanent greenhouse | Onion family (onion and garlic sets) Permanent greenhouse | Seedlings of e.g. fruiting vegetables, leaf vegetables, aromatic herbs and root crops, indoor grown onions Permanent greenhouse |
|-------------------------------------|----------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------|------------------------------------------------|-----------------------------|-----------------------------------|-----------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|
| 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 use

| Permanent greenhouse |
|----------------------|
| Fruiting vegetables  |
| Leafy vegetables, aromatic herbs and aromatic root crops |
| Leafy vegetables, aromatic herbs and aromatic root crops |
| Root vegetables and tubers |
| Cabbages |
| Pulses |
| Bulb and corm crops |
| Ornamentals: Pot plants, cut flowers and cuttings |
| Onion family (onion and garlic sets) |
| Seedlings of e.g. fruiting vegetables, leaf vegetables, aromatic herbs and root crops, indoor grown onions |

Permanent greenhouse

| Risk to aquatic organisms | Permanent greenhouse |
|---------------------------|----------------------|
| Risk identified           | X6(c) |
| Assessment not finalised  | X6(c) |

Groundwater exposure to active substance

| Permanent greenhouse |
|----------------------|
| Legal parametric value breached |
| Assessment not finalised |

Groundwater exposure to metabolites

| Permanent greenhouse |
|----------------------|
| 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 2–6 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.

(c): For representative uses as a spray in permanent greenhouses a risk assessment for secondary metabolites to aquatic organisms might be needed as the application technique will lead to exposure to surface water. Furthermore, in the case that secondary metabolites, once identified, are persistent in soil, a risk assessment to both soil organisms and aquatic organisms would be needed; this is relevant for all uses and application techniques in permanent greenhouses except for the use to leafy vegetables using nutrient film technique (hydroponics).
| Representative use | Fruiting vegetables | Leafy vegetables, Aromatic herbs and aromatic root crops | Leafy vegetables, Aromatic herbs and aromatic root crops | Root vegetables and tubers | Cabbages | Pulses | Bulb and corm crops | Ornaments: pot plants, cut flowers and cuttings | Onion family (onion and garlic sets) | Seedlings of e.g. fruiting vegetables, leaf vegetables, aromatic herbs and root crops, indoor grown onions |
|---------------------|--------------------|--------------------------------------------------------|--------------------------------------------------------|---------------------------|----------|--------|---------------------|--------------------------------|-----------------------------|-------------------------------------------------------|
| Walk-in tunnel      |                    | Walk-in tunnel                                         | Nutrient film technique                                | Walk-in tunnel            | Walk-in tunnel | Walk-in tunnel | Walk-in tunnel | Walk-in tunnel | Walk-in tunnel                      | Walk-in tunnel |

**Operator risk**
- Risk identified
- Assessment not finalised

Risk identified: X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7

**Worker risk**
- Risk identified
- Assessment not finalised

Risk identified: X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7

**Resident/bystander risk**
- Risk identified
- Assessment not finalised

Risk identified: X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7 X1,2,7

**Consumer risk**
- Risk identified
- Assessment not finalised

Risk identified: X4 X4 X4 X4 X4 X4 X4 X4 X4

**Risk to wild non-target terrestrial vertebrates**
- Risk identified
- Assessment not finalised

Risk identified: X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6

**Risk to wild non-target terrestrial organisms other than vertebrates**
- Risk identified
- Assessment not finalised

Risk identified: X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6 X5,6

**Risk to aquatic organisms**
- Risk identified
- Assessment not finalised

Risk identified: X6(c) X6(c) X6(c) X6(c) X6(c) X6(c) X6(c) X6(c) X6(c)
### Representative use

| Representative use                        | Fruiting vegetables | Leafy vegetables, Aromatic herbs and aromatic root crops | Leafy vegetables, Aromatic herbs and aromatic root crops | Root vegetables and tubers | Cabbages | Pulses | Bulb and corn crops | Ornamentals: pot plants, cut flowers and cuttings | Onion family (onion and garlic sets) | Seedlings of e.g. fruiting vegetables, leafy vegetables, aromatic herbs and aromatic root crops | Indoor grown onions | Indoor grown onions |
|------------------------------------------|---------------------|--------------------------------------------------------|--------------------------------------------------------|----------------------------|----------|--------|-------------------|-----------------------------------------|----------------------------------|------------------------------------------------------------|-------------------|-------------------|
| Walk-in tunnel                           | Walk-in tunnel      | Walk-in tunnel                                         | Nutrient film technique                               | Walk-in tunnel             | Walk-in tunnel          | Walk-in tunnel          | Walk-in tunnel                     | Walk-in tunnel                     | Walk-in tunnel                                      | Walk-in tunnel | Walk-in tunnel |

### Groundwater exposure to active substance

| Groundwater exposure to active substance | Legal parametric value breached |
|------------------------------------------|---------------------------------|
|                                          | Assessment not finalised        |

### Groundwater exposure to metabolites

| Groundwater exposure to metabolites      | Legal parametric value breached | Parameter value of 10 μg/L breached | Assessment not finalised |
|------------------------------------------|---------------------------------|------------------------------------|--------------------------|
| (a)                                      |                                 | (b)                                | X¹                        |

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 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.

(c): The assessment to aquatic organisms from secondary metabolites could not be finalised only for the uses as a spray application to seedlings and for the dry soil treatment to fruiting vegetables, leafy vegetables, aromatic herbs and aromatic root crops, root vegetables, root tubers, cabbages, pulses, onion family (onion and garlic sets). The other application techniques to these representative uses are not expected to lead to exposure to the surface water from secondary metabolites.
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Abbreviations

1/n slope of Freundlich isotherm
\( \lambda \) wavelength
\( e \) decadic molar extinction coefficient
AAOEL acute acceptable operator exposure level
a.s. active substance
ADE actual dermal exposure
ADI acceptable daily intake
AF assessment factor
AAOEL acute acceptable operator exposure level
AP alkaline phosphatase
AR applied radioactivity
AR androgen receptor
AV avoidance factor
BCF bioconcentration factor
BUN blood urea nitrogen
bw body weight
CAS Chemical Abstracts Service
CFU colony-forming units
CHO Chinese hamster ovary cells
CI confidence interval
CIPAC Collaborative International Pesticides Analytical Council Limited
C&L classification and labelling
CL confidence limits
DAR draft assessment report
DAT days after treatment
DDD daily dietary dose
DM dry matter
DT\(_{50}\) period required for 50% dissipation (define method of estimation)
DT\(_{90}\) period required for 90% dissipation (define method of estimation)
EEC European Economic Community
EINECS European Inventory of Existing Commercial Chemical Substances
ELINCS European List of New Chemical Substances
EMDI estimated maximum daily intake
ER\(_{50}\) emergence rate/effective rate, median
ErC\(_{50}\) effective concentration (growth rate)
ERO ecological recovery option
ETO ecological threshold option
| Abbreviation | Definition                                                                 |
|--------------|----------------------------------------------------------------------------|
| ETR          | exposure toxicity ratio                                                    |
| FAO          | Food and Agriculture Organization of the United Nations                     |
| FID          | flame ionisation detector                                                  |
| FIR          | food intake rate                                                           |
| FOB          | functional observation battery                                             |
| FOCUS        | Forum for the Co-ordination of Pesticide Fate Models and their Use         |
| GAP          | Good Agricultural Practice                                                 |
| GC           | gas chromatography                                                         |
| GCCPF        | Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products GIFAP) |
| CFU          | colony forming unit                                                        |
| GGT          | gamma glutamyl transferase                                                  |
| GM           | geometric mean                                                             |
| GS           | growth stage                                                               |
| GSH          | glutathione                                                                |
| Hb           | haemoglobin                                                                |
| HQ           | hazard quotient                                                            |
| HR           | hazard rate                                                                |
| IEDI         | international estimated daily intake                                        |
| IESTI        | international estimated short-term intake                                  |
| ISO          | International Organization for Standardization                            |
| IUPAC        | International Union of Pure and Applied Chemistry                          |
| iv           | intravenous                                                                |
| JMPR         | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LC           | liquid chromatography                                                      |
| LC50         | lethal concentration, median                                               |
| LC-MS        | liquid chromatography–mass spectrometry                                    |
| LC-MS-MS     | liquid chromatography with tandem mass spectrometry                        |
| M/L          | mixing and loading                                                         |
| mm           | millimetre (also used for mean measured concentrations)                    |
| MS           | mass spectrometry                                                          |
| NOEL         | no observed effect level                                                   |
| Pa           | pascal                                                                     |
| PD           | proportion of different food types                                         |
| PEC          | predicted environmental concentration                                      |
| PHI          | preharvest interval                                                        |
| RAR          | Renewal Assessment Report                                                  |
| SC           | suspension concentrate                                                     |
| SMILES       | simplified molecular-input line-entry system                               |
| w/v          | weight per unit volume                                                     |
| w/w          | weight per unit weight                                                     |
| WHO          | World Health Organization                                                  |
| WP           | wettable powder                                                            |
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.2020.6182
## Appendix B – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChlKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-------------------------------------------------|----------------------------------|
| indole-3-acetic acid (IAA)    | (1H-indol-3-yl)acetic acid O=C(O)Cc1c[NH]c2cccc21 SEOVTRFCIGRIMH-UHFFFAOYSA-N | ![Structural formula](image) |
| tryptophan                    | L-tryptophan O=C(O)[C@@H][N]Cc1c[NH]c2cccc21 QIVBCDIIAJPQS-VIFPVBQESA-N | ![Structural formula](image) |

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>(c)</sup> ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).