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Peer review of the pesticide risk assessment of the active substance *Beauveria bassiana* strain 203

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the Netherlands for the pesticide active substance *Beauveria bassiana* strain 203 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 uses of *Beauveria bassiana* strain 203 as an insecticide on *Phoenix canariensis* (field use, indoor and greenhouse applications) and *Phoenix dactylifera* (field use) in southern Europe. The reliable endpoints, 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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Summary

Beauveria bassiana strain 203 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, the rapporteur Member State (RMS), the Netherlands, received an application from GlenBiotech on 10 March 2017 for approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 20 July 2017.

An initial evaluation of the dossier on *Beauveria bassiana* strain 203 was provided by the RMS in the draft assessment report (DAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The uses of *Beauveria bassiana* strain 203 according to the representative uses as an insecticide on *Phoenix canariensis* (field use, indoor and greenhouse applications) and *Phoenix dactylifera* (field use), as proposed at southern Europe (SEU) level result in a sufficient insecticidal efficacy against the target red palm weevil larvae and adults.

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

In the area of mammalian toxicology, considering that the (non-dietary) exposure to secondary metabolites (present in the product and secreted after application) has not been determined (data gap), and that their potential toxicity has not been fully characterised and since genotoxic potential of beauvericin could not be excluded (data gap) the risk assessment for operators, workers, bystanders and residents cannot be concluded (issue not finalised).

In the area of residues, without data addressing the transfer of beauvericin and of viable residues on date fruits during treatments, the possible colonisation and secondary metabolite production by *Beauveria bassiana* strain 203 on date fruits after application, and further toxicological data, a higher tier consumer risk assessment cannot be conducted for the representative use in cultivated date palms. Available tentative assessments cannot rule out a concern for consumers.

Satisfactory information was not provided to demonstrate that under the conditions of use, any toxins/secondary metabolites produced by *Beauveria bassiana* strain 203 will not occur in the environmental compartments in concentrations considerably higher than under natural conditions. Consequently, further data on the persistence, transformation and mobility of these compounds may be needed in order to assess the potential for groundwater contamination and soil and surface water exposure.

Satisfactory information was not provided for the risk assessment to address the potential toxicity, infectivity and pathogenicity to birds, to aquatic organisms, to earthworms and the potential adverse effects to soil microorganisms leading to an assessment not finalised.

Likewise, satisfactory information was not provided for the hazard characterisation and risk assessment to non-target terrestrial organisms, to fish and to algae from toxins/secondary metabolites such as beauvericin and to aquatic organisms from toxins/secondary metabolites (other than beauvericin) leading to an assessment not finalised.

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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).

Beauveria bassiana strain 203 is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, the Netherlands (hereinafter referred to as the 'RMS'), received an application from GlenBiotech on 10 March 2017 for approval of the active substance *Beauveria bassiana* strain 203. 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 20 July 2017.

The RMS provided its initial evaluation of the dossier on *Beauveria bassiana* strain 203 in the DAR, which was received by EFSA on 5 June 2019 (The Netherlands, 2019). The peer review was initiated on 17 July 2019 by dispatching the DAR for consultation of the Member States and the applicant, GlenBiotech, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 19 November 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 area of effects on human health.

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 where this took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Beauveria bassiana* strain 203 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 August-September 2020.

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 uses of *Beauveria bassiana* strain 203 as an insecticide on *Phoenix canariensis* (field use, indoor and greenhouse applications) and *Phoenix dactylifera* (field use) as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the DAR and considered during the peer review are presented in the conclusion.

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, 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 DAR;
- the reporting table (25 November 2019);
- the evaluation table (28 September 2020);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its revisions (The Netherlands, 2020) 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 (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Beauveria bassiana strain 203 is a fungus deposited at the Centraal Bureau voor Schimmelcultures (Fungal Biodiversity Centre, Institute of the Royal Netherlands Academy of Arts and Sciences, Utrecht, Netherlands) with accession number CBS 121097. *Beauveria bassiana* strain 203 is a naturally occurring strain, wild-type and non-modified strain of *Beauveria bassiana*, originally isolated from infected red palm weevil (*Rhynchophorus ferrugineus*) cadavers collected from the wild in South-East Spain.

The representative formulated product for the evaluation was 'Phoemyc+', a macrogranule (GG) containing 2.4×10^{12} colony forming unit (CFU)/kg (minimum content 2×10^{11} CFU/kg, maximum 4.5×10^{12} CFU/kg) *Beauveria bassiana* strain 203. An FAO specification does not exist for this product.

The representative uses evaluated comprise direct applications into palm crown by dosing cup on *Phoenix canariensis* (field use, indoor, greenhouse and walk-in tunnel applications) and *Phoenix dactylifera* (field use), against red palm weevil (*Rhynchophorus ferrugineus*) larvae and adults in Southern Europe. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of *Beauveria bassiana* strain 203 according to the representative uses proposed at southern Europe (SEU) level result in a sufficient insecticidal efficacy against red palm weevil, following the guidance document SANCO/10054/2013 - rev. 3 (European Commission, 2013).

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

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).

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 formulated product 'Phoemyc+' of minimum content of 2×10^{11} CFU/kg (max. content: 4.5×10^{12} CFU/kg).

A single locus sequence typing system can be used to identify *Beauveria bassiana* strain 203. By sequence typing of a single intergenic region, the Bloc region, strain 203 was distinguishable from *Beauveria bassiana* strains GHA and ATCC 74040 and the majority of wild strains.

Beauveria bassiana strains are able to synthesise metabolites with very different chemical and biological properties, like low molecular weight compounds, non-peptide pigments, cyclodepsipeptides, high molecular weight proteins. Potential effects on humans or the environment also differ between metabolites. Some of these metabolites are key determinants in pathogenicity for *Beauveria bassiana* towards their host insects. Effects of metabolites on target hosts depend on both the *Beauveria* strains that differ in the production of metabolites and the target insects that differ in susceptibility towards metabolites. Most *Beauveria* strains were only assessed for a single type of secondary metabolites, and no specific information on the capacity to produce different groups of metabolites with potential impact on humans or the environment is available for any strain, including *Beauveria bassiana* strain 203 (data gap). *Beauveria bassiana* strain 203 produces beauvericin.

There is no evidence of direct relationships of *Beauveria bassiana* strain 203 to known plant, animal or human pathogens.

The analysis of contaminating microorganisms in commercially produced batches complies with the requirements of SANCO/12116/2012 rev.0 (European Commission, 2012).

Beauveria bassiana strain 203 was capable of growing at 25°C and at 32°C, however, it did not grow at 37°C and 40°C. After 14 days at 37–40°C, the fungus did not grow when it was exposed to 25°C. The fungus did not grow at 4°C but it was able to grow when it was moved to 25°C after 14 days of 4°C exposure.

Beauveria bassiana strain 203 was sensitive to at least six different antimycotic compounds (amphotericin B, caspofungin, itraconazole, ketoconazole, posaconazole and voriconazole).

A data gap was identified for the determination of shelf life of the formulation (including data on beauvericin content).

Acceptable methods are available for the determination of the microorganism and beauvericin content in the formulation and for the determination of the content of contaminating microorganisms.

No residue definition was applicable for *Beauveria bassiana* strain 203, therefore no post-registration monitoring methods are needed.

2. Mammalian toxicity

The toxicological profile of *Beauveria bassiana* strain 203 was discussed at the Pesticides Peer Review Meeting Teleconference 17 (June 2020).

General data

No adverse reactions in individuals as a result of contact with *Beauveria bassiana* strain 203 during its development, manufacture, preparation or field application have been reported. *Beauveria bassiana* without strain identification was isolated in few cases from people suffering from eye infection, suggesting a possible affinity of *Beauveria bassiana* to ocular tissues once the cornea had been penetrated and disseminated infections in people under immunosuppression. *Beauveria bassiana* is not recommended for the Qualified Presumption of Safety list (EFSA BIOHAZ Panel, 2020).

Toxicity studies

Based on information from the literature, *Beauveria bassiana* strains show allergic potential and sensitising properties via both dermal and inhalatory contacts. There are no sensitisation toxicological studies available since standard methods for testing dermal sensitisation are not suitable for testing microorganism and until a test is ready, as all microorganisms *Beauveria bassiana* strain 203 should be regarded as a potential sensitiser and the following warning phrase is proposed: 'Contains *Beauveria bassiana* strain 203. Micro-organisms may have the potential to provoke sensitising reactions'.

No signs of toxicity, pathogenicity or infectivity have been detected upon single oral, intratracheal and intravenous studies conducted with the microorganism. It is noted that the negative Ames test was not conducted with the microorganism but with an extract potentially containing metabolites produced by *Beauveria bassiana* and therefore no conclusion can be made on the genotoxicity of the individual metabolites on the basis of this study, but only on the extract as a whole. No more studies were considered necessary for the representative use under consideration.

Secondary metabolites/toxins

Beauveria bassiana strain 203 is able to synthesise beauvericin and could be able to synthesise several other metabolites (see Section 1) that should be identified and if relevant human exposure is observed, further investigations of their toxicological properties will have to be provided (data gap).

As regards of beauvericin a genotoxic potential cannot be excluded based on positive *in vitro* chromosomal aberrations and micronucleus test and equivocal *in vivo* data that should be further investigated (data gap). The RMS proposed the use of the Cramer Class III value of 0.0025 µg/kg body weight (BW) per day applicable to beauvericin (as indicated by EFSA CONTAM Panel, 2014), all of the experts agreed. However, after the experts' meeting, EFSA re-considered the Threshold of Toxicological Concern (TTC) approach for beauvericin and concluded it is not applicable, since the TTC approach as proposed in the EFSA PPR Guidance on the Residue Definition for risk assessment has not been endorsed by risk managers and currently is not applicable for pesticides metabolites. In addition, the EFSA CONTAM Panel demonstrated the exposure estimates were exceeding the TTC.^{2,3}

Reference values and exposure

For the representative uses on ornamental palm trees and cultivated date palms, since the non-dietary exposure to secondary metabolites (in the product and after application) has not been determined, and their potential toxicity has not been fully characterised and the genotoxic potential of beauvericin could not be excluded the risk assessment for operators, workers, residents and bystanders cannot be concluded (issue not finalised). In the absence of a quantitative risk assessment, the use of personal protective equipment (PPE) and respiratory protective equipment (RPE) for the operators and workers might be considered to reduce the non-dietary exposure (dermal and inhalation).

3. Residues

Extensive information was provided on the potential of the species *Beauveria bassiana* to grow endophytically after inoculation of plant surfaces, which could lead to the accumulation of secondary metabolites in plant tissue. Strain-specific data for *Beauveria bassiana* strain 203 was not among the information submitted.

The microorganism itself is not infective and not pathogenic (see section 2). The assessment of consumer exposure to viable residues of *Beauveria bassiana* strain 203 is therefore not necessary.

However, due to the possible endophytic lifestyle of *Beauveria bassiana* strain 203, the microorganism could grow and produce non-viable residues (metabolites) in plant matrices. Several metabolites with different chemical and biological properties can be produced by the species *Beauveria bassiana* (see section 1). While strain-specific information on metabolite production is limited, specifically in the context of an endophytic lifestyle, the capability of *Beauveria bassiana* strain 203 to produce beauvericin has already been proven (see Section 1).

Data to address whether *Beauveria bassiana* strain 203 applied on the palm crown will colonise date fruits as an endophyte and produce the secondary metabolite beauvericin *in situ* were not submitted. It is noted that for beauvericin a genotoxic potential cannot be excluded (see Section 2). Moreover, consumer dietary exposure to levels of the emerging mycotoxin beauvericin in different food items arising from fungal contamination already indicated a potential health risk for humans in previous assessments (EFSA CONTAM Panel, 2014).

For the representative uses in palm trees, estimates of expected beauvericin concentrations on date fruits that may arise from the maximum beauvericin content in the formulation (see Section 1) and the resulting acute and chronic dietary intakes could not rule out safety concerns for consumers.⁴ These estimates do not consider any additional possible *in situ* formation of beauvericin by the microorganism or any dietary exposure to beauvericin from other sources. Without data addressing the transfer of beauvericin and of viable residues on date fruits during treatments, the possible colonisation and secondary metabolite production by *Beauveria bassiana* strain 203 on date fruits after application (data gap), and further toxicological data on beauvericin and other likely metabolites (see Section 2), a

² The EFSA CONTAM Panel concluded that there were insufficient data to establish a tolerable daily intake (TDI) or/and an acute reference dose (ARfD) for *Beauvericin*. The fact that the exposure estimates exceed this value indicates the need for additional compound-specific toxicity data for beauvericin to assess its potential health risks for humans.

³ Refers to Experts' consultation 6.1 of the Pesticides Peer Review Meeting Teleconference 17 (June 2020).

⁴ Refer to Evaluation table *Beauveria bassiana* strain 203, Section 7, Open point 7.1.

higher tier consumer risk assessment cannot be conducted. Based on tentative assessments, a consumer safety concern cannot be excluded for the representative use in cultivated date palms.

A consumer risk assessment is not considered relevant for uses in ornamental palms.

4. Environmental fate and behaviour

Information has been provided in relation to potential interference of *Beauveria bassiana* strain 203 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC11 (see specific Annex VI decision making criteria in Directive 2005/25/EC12). As these methods require pathogenic bacteria to be identified and confirmed as absent, it is unlikely that filamentous fungi or their conidia would interfere with methodologies used for such determinations.

Being a mitotic asexual fungus (no sexual recombination or meiosis having been observed in its life cycle), *Beauveria bassiana* would not be expected to have the potential for transfer of genetic material to other organisms.

The majority of the information available in the dossier of *Beauveria bassiana* strain 203 was extrapolated from published review or articles gathering relevant information on different strains of *Beauveria bassiana*. In particular, information available from the draft assessment report of *Beauveria bassiana* strain GHA was considered. This was considered acceptable by the peer review.

4.1. Fate and behaviour in the environment of the microorganism

Strain specific data on *Beauveria bassiana* strain 203 to address the **persistence and multiplication in soil** were not provided. The information provided was generally related to *Beauveria bassiana* species from the open literature. *Beauveria bassiana* exists naturally at a background level of ca. 830 CFU/g soil, which is based on the 95th percentile of the geometric mean of six field studies. Several investigations showed that *Beauveria bassiana* populations decreased gradually in time due to many factors: frequency of application, pest densities, ecological fitness of inoculum and agricultural practices (e.g. ploughing). After inoculation, the population of *Beauveria bassiana* gradually declines until reaching the background level 0.5–1.5 years after treatment. In general, MPCA persisting in the environment may be present in an inactive state and activated under very specific conditions. Germination of *Beauveria bassiana* conidia and subsequent multiplication only occurs in the presence of a host. Predicted environmental concentration (PEC) in soil calculations are presented in Appendix A for *Beauveria bassiana* strain 203. For the representative uses in field and in walk-in tunnels it was assumed that soil exposure to *Beauveria bassiana* strain 203 was mainly caused by spillage. For the uses in greenhouses (permanent) and indoor the soil exposure was not considered relevant as 'Phoemyc+' is applied directly to the crowns of young palm trees, and then spillages are considered unlikely.

Studies on persistence and multiplication in **water** of *Beauveria bassiana* strain 203 were not available. Literature information in the dossier indicates that conidia of *Beauveria bassiana* in water are unlikely to proliferate and will probably be rapidly degraded by bacteria and protozoa in natural non-sterile water bodies. Maximum initial PEC surface water values following applications of 'Phoemyc+' are presented in Appendix A. Exposure to surface water is considered negligible for the uses in field and walk-in tunnels. For the uses in permanent structures, as 'Phoemyc+' is applied to the crowns of young palm trees which are subsequently irrigated from above, PEC surface water were calculated using a standard (FOCUS, 2001) ditch scenario assuming 0.1% emission from greenhouses to surface water. For the indoor uses exposure of surface water is not expected.

Specific studies on the *Beauveria bassiana* strain 203 were not conducted to evaluate its persistence and mobility in **air**. Its degradation in the air has been related in the literature to exposure to ultraviolet (UV) irradiation and different technologies are even developed to protect the fungus from this kind of exposure to UV. Overall, taking all the observations into consideration, it has been concluded that *Beauveria bassiana* is expected to be degraded rapidly in the air and no accumulation is expected.

With respect to the **mobility** of the microorganism, different studies showed that conidia of *Beauveria bassiana* are not very mobile in soil and generally remain on the soil surface. The movement of conidia vertically through the soil profile was correlated with high infiltration rate in soil. Furthermore, the horizontal movement is possible via insects and heavy rainfall. However, no groundwater assessment is necessary since *Beauveria bassiana* is neither pathogenic nor toxic to

humans. The presence of conidia in air outside of greenhouses or in water is low and survival of the fungus in these environments is limited.

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

Strain specific information on secondary metabolites/toxins production in the environment following applications of 'Phoemyc+' is not available. Only if, under the conditions of use, relevant secondary metabolites/toxins are produced by the microorganism, the data requirement and the corresponding risk assessment as outlined in Part B point 7 of Commission Regulation (EU) No 544/2011⁵ need to be fulfilled. Accepting that exposure is negligible, the first and the third condition below would not be met:

- 1) the relevant metabolite is stable outside the microorganism
- 2) a toxic effect of the relevant metabolite is independent of the presence of the microorganism, and
- 3) the relevant metabolite is expected to occur in the environment in concentrations considerably higher than under natural conditions.

This data gap is pertinent in respect of the representative uses in the field, walk-in tunnels and greenhouse assessed for *Beauveria bassiana* strain 203. It should be noted that PEC in soil and in surface water were calculated only for metabolite beauvericin considering its presence in the product and are presented in Appendix A. For the indoor uses, environmental exposure to the relevant metabolite(s) produced by *Beauveria bassiana* strain 203 can be considered negligible.

A literature search was conducted on the fate and behaviour of the secondary metabolites/toxins in the environment, but no studies relevant for the metabolites produced by *Beauveria bassiana* strain 203 were retrieved.

5. Ecotoxicology

Insufficient data and strain specific information were available to address toxicity, infectivity and pathogenicity to **birds** from *Beauveria bassiana* strain 203. Exposure can be via ingestion of the granules as grit as well as through infected target insects. Consequently, a data gap leading to an assessment not finalised was identified for the toxicity, infectivity and pathogenicity to birds from *Beauveria bassiana* strain 203 for representative uses in open field and open structures (walk-in tunnels). The RMS was of the opinion that a read-across taking into account phylogeny and physiology traits among other *Beauveria bassiana* strains and strain 203 could be considered appropriate. The RMS was of the opinion that data on other strains demonstrated a low risk to birds. Low risk is identified for representative uses in permanent greenhouses and for the indoor use as the exposure to birds is expected to be negligible from these uses.

As concluded in Section 2, sufficient information is available to finalise the assessment of infectivity and pathogenicity of *Beauveria bassiana* strain 203 in **mammals**. On the basis of the available data, a low risk to wild mammals was concluded (relevant for all representative uses).

Insufficient data and strain specific information were available to address toxicity, infectivity and pathogenicity to **aquatic organisms** from *Beauveria bassiana* strain 203. Consequently, a data gap leading to an assessment not finalised was identified for the toxicity, infectivity and pathogenicity to aquatic organisms from *Beauveria bassiana* strain 203 for the representative use in permanent greenhouses. The RMS was of the opinion that a read-across taking into account phylogeny and physiology traits among other *Beauveria bassiana* strains and strain 203 could be considered appropriate. The RMS was of the opinion that data on other strains demonstrated a low risk to aquatic organisms. Low risk was identified for representative uses in open field (i.e. open structures (walk-in tunnels) and for indoor uses) as the exposure to aquatic organisms is expected to be negligible as spray drift and run-off is not expected.

In an acute oral toxicity test on infectivity in **honey bees** from exposure to *Beauveria bassiana* strain 203 effects were observed. Assessment of pathogenicity was not performed in the study. Based on the available information infectivity and pathogenicity to honeybees cannot be excluded. In some

⁵ Commission Regulation (EU) 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

studies with caged honeybees exposed to other strains of *Beauveria bassiana* there was evidence of high mortality. In a field study with another strain of *Beauveria bassiana*, infectivity was observed. Palm tree attractiveness to bees cannot be excluded for the representative uses in open field and walk-in tunnels. Consequently, a high risk to bees is concluded for representative uses in open field and open structures (walk-in tunnels). In the case of bees and bumblebees, the RMS is of the opinion that it is important to clarify that studies from the scientific literature present a mix of results in which sometimes no-effects or negative effects are found when studying the effect of different *Beauveria bassiana* strains on bees. Additionally, the RMS is of the opinion that date palms are not pollinated by bees. While it is agreed that palms are considered to be mainly wind pollinated, this does not exclude that bees would visit flowers. Low risk identified for representative uses in permanent greenhouses and for indoor use as the exposure to bees is expected to be negligible from these uses.

In the available studies with **non-target arthropods** exposed to *Beauveria bassiana* strain 203, a high mortality was observed. An assessment of infectivity and pathogenicity was not performed. Based on the available information toxicity, infectivity and pathogenicity to non-target arthropods exposed to *Beauveria bassiana* strain 203 cannot be excluded. Consequently, a high risk to non-target arthropods is concluded for representative uses in open field and open structures (walk-in tunnels). Exposure is only expected to non-target arthropods in-field while off-field exposure is considered negligible due to the method of application. Low risk identified for representative uses in permanent greenhouses and for indoor use as the exposure to non-target arthropods is expected to be negligible.

For the representative uses in permanent greenhouses and for indoor uses, an assessment to the soil compartment is not considered relevant (see Section 4). However, exposure to the soil for the uses in the field and open structures (walk-in tunnels) is expected. Insufficient data were available on **earthworms** to indicate if *Beauveria bassiana* strain 203 would be toxic, infectious or pathogenic to earthworms. Consequently, a data gap leading to an assessment not finalised was identified for the toxicity, infectivity, pathogenicity of *Beauveria bassiana* strain 203 to earthworms for the representative uses in open field and open structures (walk-in tunnels). Insufficient data were available on **soil microorganisms** to indicate if *Beauveria bassiana* strain 203 would cause adverse effects to soil microorganisms for the representative open field uses and open structures (walk-in tunnels). Consequently, a data gap leading to an assessment not finalised was identified for the toxicity of *Beauveria bassiana* strain 203 to soil microorganisms for the representative uses in open field and open structures (walk-in tunnels). The RMS is of the opinion that it is widely documented in the scientific literature that earthworms and other soil organisms are well adapted to deal with and even spread entomopathogen fungi as *Beauveria bassiana* and its metabolites. Further the RMS proposed to add the statement that once common microorganisms such as *Beauveria bassiana* reach the soil, they enter into the soil food web in which they have to compete with other microorganisms and they may serve as food for other soil organisms. A risk to soil organisms was therefore considered negligible by the RMS.

Data were not available on beauvericin and other secondary metabolites to perform a hazard characterisation (data gap). The risk assessment of toxins/secondary metabolites such as beauvericin could not be finalised for non-target terrestrial organisms for the representative uses in open field and open structures (walk-in tunnels) (see Sections 1 and 4.2). For the representative uses in permanent greenhouse and indoor, the exposure to non-target terrestrial organisms from secondary metabolites is considered negligible.

For non-target aquatic organisms, exposure of beauvericin and other secondary metabolites/toxins to surface water cannot be excluded for the representative use in permanent greenhouse. A published scientific paper was available with the aquatic invertebrate mysid shrimp (*Mysidopsis bahia*) deriving a toxicity endpoint from the secondary metabolite beauvericin. A low risk was identified for aquatic invertebrates exposed to beauvericin (for all representative uses). Insufficient information was available on the potential effects of the secondary metabolite beauvericin on fish and algae for the use in permanent greenhouses resulting in a data gap and an issue not finalised. Insufficient information was available on the potential effects of other secondary metabolites/toxins on non-target aquatic organisms (see Section 1 and 4.2). Toxicity data were not available to perform a hazard characterisation resulting in a data gap and an issue not finalised. For representative uses indoor, in field and open structures (walk-in tunnels), the exposure to surface water is considered negligible due to the method of application.

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>Beauveria bassiana</i> strain 203	The applied inoculum density decreases to upper natural background levels within 0.5—1.5 years after application. These values indicate the fungi can be considered as persistent	Data gap for infectivity and pathogenicity to earthworm and for potential adverse effects to soil microorganisms for representative field- and walk-in tunnel uses
Relevant toxins or secondary metabolites (except beauvericin)	Data gap (relevant for field and walk in tunnel uses)	Data gap for the potential effects of toxins/secondary metabolites to soil organisms for the representative uses in open field and walk-in tunnels
Beauvericin	Data gap (relevant for field and walk in tunnel uses)	Data gap for the potential effects of beauvericin to soil organisms for the representative uses in open field and walk-in tunnels

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
Relevant toxins or secondary metabolites (including beauvericin)	Data gap (relevant for all uses except indoors)	Data gap (relevant for field and walk in tunnel uses)	No data, however may be assumed to be involved in the mode of action	Data gap

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

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
<i>Beauveria bassiana</i> strain 203	Data gap for the infectivity and pathogenicity to aquatic organisms for the representative use in permanent greenhouses
Relevant toxins or secondary metabolites (except beauvericin)	Data gap for the potential effects of the secondary metabolite on aquatic organisms for the use in permanent greenhouses
Beauvericin	Data gap for the potential effects of beauvericin on fish and algae for the use in permanent greenhouses

Table 4: Air

Compound (name and/or code)	Toxicology
<i>Beauveria Bassiana</i> strain 203	No mortality, no toxic effects and no pathogenicity were observed in rats following intratracheal instillation of <i>Beauveria Bassiana</i> strain 203 at 1.8×10^8 CFU/rat
Toxins/secondary metabolites (including beauvericin)	Data gap

CFU: colony forming unit.

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 search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and its relevant metabolites for non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated).
- Determination of shelf life of the formulation (including data on beauvericin content) (relevant for all representative uses; see Section 1).
- Production of secondary metabolites by *BEAUVERIA BASSIANA* STRAIN 203 (in the product and after application) should be further investigated, possibly triggering the need for further toxicological assessment of these metabolites to conclude on risk assessment for humans (relevant for all representative uses; see Sections 1 and 2).
- Further investigation of the genotoxic potential of beauvericin, based on equivocal *in vitro* and *in vivo* data (relevant for all representative uses; see Section 2).
- Data addressing the transfer of beauvericin and of viable residues on date fruits during treatments, the possible colonisation and secondary metabolite production by *Beauveria bassiana* strain 203 on date fruits after application (relevant for the representative use in *Phoenix dactylifera*; see Section 3).
- Satisfactory information to demonstrate that, under the conditions of use, any relevant secondary metabolites/toxins that are produced by *Beauveria bassiana* strain 203 will not occur in the environmental compartments in concentrations considerably higher than under natural conditions. Further data on the persistence, transformation and mobility of these compounds may be needed in order to assess the potential level of environmental exposure including groundwater (with the exception for the aquatic and soil compartments exposed to beauvericin present in the formulated product) (relevant for all representative uses evaluated except for indoor uses; submission date proposed by the applicant: unknown; see Section 4).
- Further data to address the potential toxicity, infectivity and pathogenicity to birds (relevant for the representative field and walk-in tunnel uses; see Section 5).
- Further data to address toxicity, infectivity and pathogenicity to aquatic organisms (relevant for representative use in permanent greenhouses; see Section 5).
- Further data to address toxicity, infectivity and pathogenicity to earthworms and the potential adverse effects to soil microorganisms (relevant for representative field and walk-in tunnel uses; see Section 5).
- Further hazard characterisation and assessment of the risk to non-target terrestrial organisms from toxins/secondary metabolites such as beauvericin (relevant for the representative uses in open field and walk-in tunnels; see Section 5).
- Further hazard characterisation and assessment of the risk to fish and algae from the secondary metabolite beauvericin (relevant for the representative use in permanent greenhouses; see Section 5).
- Further hazard characterisation and risk assessment to aquatic organisms from toxins/secondary metabolites (other than beauvericin), (relevant for the representative use in permanent greenhouses; see Section 5).

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

- In the absence of a quantitative risk assessment, the use of PPE and RPE for the operators and workers might be considered to reduce the non-dietary exposure (dermal and inhalation) to the microorganism and its metabolites (see Section 2).

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 546/2011⁶ 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.

- 1) With regard to dietary exposure, since the exposure to secondary metabolites (in the product and after application) has not been determined, and that their potential toxicity has not been fully characterised and the genotoxic potential of beauvericin could not be excluded, a higher tier risk assessment cannot be finalised, while tentative estimates cannot rule out a concern with regard to the use in *Phoenix dactylifera* (see Sections 2 and 3).
- 2) With regard to non-dietary exposure, since the exposure to secondary metabolites (in the product and after application) has not been determined, and that their potential toxicity has not been fully characterised and the genotoxic potential of beauvericin could not be excluded, the risk assessment for operators, workers residents and bystanders cannot be concluded (see Section 2).
- 3) The risk assessment to birds cannot be finalised as satisfactory information to address the potential toxicity, infectivity and pathogenicity to birds was not provided (relevant for representative field and walk-in tunnel uses; see Section 5).
- 4) The risk assessment to aquatic organisms cannot be finalised as satisfactory information to address the toxicity, infectivity and pathogenicity to aquatic organisms was not provided (relevant for representative use in permanent greenhouses; see Section 5).
- 5) The risk assessment to soil organisms cannot be finalised as satisfactory information to address the toxicity, infectivity and pathogenicity to earthworms and the potential adverse effects to soil microorganisms was not provided (relevant for representative field and walk-in tunnel uses; see Section 5).
- 6) Hazard characterisation and assessment of the risk not finalised to non-target terrestrial organisms from toxins/secondary metabolites such as beauvericin (relevant for the representative uses in open field and walk-in tunnels; see Section 5).
- 7) Hazard characterisation and assessment of the risk not finalised to fish and algae from the secondary metabolite beauvericin (relevant for the representative use in permanent greenhouses; see Section 5).
- 8) Hazard characterisation and assessment of the risk not finalised to aquatic organisms from toxins/secondary metabolites (other than beauvericin), (relevant for the representative use in permanent greenhouses; 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 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 a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does

⁶ 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.

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.

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.)

Table 5: Overview of concerns

Representative use		<i>Phoenix canariensis</i> (field use),	<i>Phoenix canariensis</i> (walk-in tunnel)	<i>Phoenix canariensis</i> (permanent greenhouse)	<i>Phoenix canariensis</i> (indoor)	<i>Phoenix dactylifera</i> (field application)
Operator risk	Risk identified					
	Assessment not finalised	X	X	X	X	X
Worker risk	Risk identified					
	Assessment not finalised	X	X	X	X	X
Resident/ bystander risk	Risk identified					
	Assessment not finalised	X	X	X	X	X
Consumer risk	Risk identified					X ¹
	Assessment not finalised					
Risk to wild non-target terrestrial vertebrates	Risk identified					
	Assessment not finalised	X ^{3,6}	X ^{3,6}			X ^{3,6}
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X	X			X
	Assessment not finalised	X ^{5,6}	X ^{5,6}			X ^{5,6}
Risk to aquatic organisms	Risk identified					
	Assessment not finalised			X ^{4,7,8}		
Groundwater exposure to active substance	Legal parametric value breached					
	Assessment not finalised					
Groundwater exposure to metabolites	Legal parametric value breached ^(a)					
	Parametric value of 10 µg/L ^(b) breached					
	Assessment not finalised					

The superscript numbers in this table 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).

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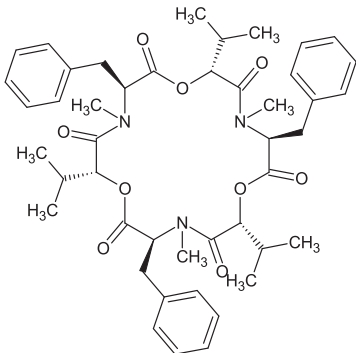
Abbreviations

bw	body weight
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
InChIKey	International Chemical Identifier Key
MPCA	microbial pest control agent
MPCP	microbial pest control product
PEC	predicted environmental concentration
PPE	personal protective equipment
RMS	rapporteur Member State
RPE	respiratory protective equipment
SMILES	simplified molecular-input line-entry system
TTC	threshold of toxicological concern

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.2020.6295>

Appendix B – Used compound codes

Code/trivial name ^(a)	Chemical name/SMILES notation/InChiKey ^(b)	Structural formula ^(c)
Beauvericin	(3<i>S</i>,6<i>R</i>,9<i>S</i>,12<i>R</i>,15<i>S</i>,18<i>R</i>)-3,9,15-tribenzyl-6,12,18-triisopropyl-4,10,16-trimethyl-1,7,13-trioxa-4,10,16-triazacyclooctadecane-2,5,8,11,14,17-hexone <chem>CC(C)[C@H]4OC(=O)[C@H](Cc1ccccc1)N(C)C(=O)[C@H](OC(=O)[C@H](Cc2ccccc2)N(C)C(=O)[C@H](OC(=O)[C@H](Cc3ccccc3)N(C)C4=O)C(C)C)C(C)C</chem> GYSCAQFHASJXRS-FFCOJMSVSA-N	

SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019)

(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019)