Review report for the active substance *Trichoderma atroviride strain SC1*

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 19 May 2016

in view of the approval of *Trichoderma atroviride strain SC1* as low risk active substance in accordance with Regulation (EC) No 1107/2009

1. **Procedure followed for the evaluation process**

This review report has been established as a result of the evaluation of the new active substance *Trichoderma atroviride* strain SC1, made in the context of the work provided for in Articles 7 to 13 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 7 of that Regulation, the authorities of France received on 6 November 2012 an application from BI-PA NV, hereafter referred to as the applicant, for the approval of the active substance *Trichoderma atroviride* strain SC1 for use in plant protection products. The French authorities indicated to the Commission on 5 February 2013 the results of their examination of the completeness of the dossier satisfying the requirements of Article 8, according to the provisions of Article 9 of the Regulation. Subsequently, and in accordance with the requirements of Article 9(3), a dossier on *Trichoderma atroviride strain SC1* was distributed to the Member States, the European Food Safety Authority (EFSA) and the Commission.

Thereupon, France as rapporteur Member State started the detailed examination of the dossier provided by the applicant. According to the provisions of Article 11, the rapporteur Member State shall prepare and submit it to the Commission and EFSA within twelve months a report (the draft assessment report), assessing whether the active substance can be expected to meet the criteria provided for in Article 4 of the Regulation.

France submitted that draft assessment report to the Commission and EFSA on 27 May 2014.

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1 Does not necessarily represent the views of the Commission services.
On 10 June 2014, EFSA circulated the draft assessment report to Member States and the applicant and, in addition, organised a public consultation on it, in line with the provisions of Article 12(1) of the Regulation.

EFSA organised a consultation to review the draft assessment report and the comments received thereon (peer review) in accordance with the provisions of Article 12(2) and 12(3). In this framework, EFSA decided to request additional information from the applicant and to conduct specific consultations of experts from Member States and the rapporteur.

According to the provisions of Article 12(2) of the Regulation, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain SC1 (approved: 20 April 2015)²]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 13 of that Regulation, the Commission produced a draft review report and a draft Regulation on *Trichoderma atroviride* strain SC1. The Commission referred the draft review report to the applicant for commenting on 9 December 2015 and on 10 December 2015 to the Standing Committee on Plants, Animals, Food and Feed, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 19 May 2016.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and background documents A and B, these documents are also considered to be part of this review report.

2. **Purposes of this review report**

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) 2016/951³ concerning the approval of *Trichoderma atroviride* strain SC1 as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing *Trichoderma atroviride* strain SC1 they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

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In line with the data requirements laid down in that Regulation, this review report provides for the evaluation of any foreseeable risk. Risks which are not plausible but were raised during the assessment because they could not be excluded for epistemological reasons are not part of the review.

This review report will be made available to the public by the Commission.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.


The overall conclusion from the evaluation is that it may be expected that plant protection products containing _Trichoderma atroviride_ strain SC1 will fulfil the safety requirements laid down in Article 4(1) – (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each _Trichoderma atroviride_ strain SC1 containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011. This might in particular be the case for the risk to consumers from metabolites produced after application of the active substance, which is considered low for the uses supported by available data, but might be different for uses where there is a higher metabolite secretion.

The review established that no significant level of toxins is expected in the end-use product, and therefore the risk to operators and bystanders is very low. Due to the lack of significant toxicity, infectivity or pathogenicity of the microorganism and the absence of growth at 35°C and above, it was considered not necessary to derive reference values for _Trichoderma atroviride_ strain SC1.

With particular regard to residues, no data have been submitted by the applicant. However, for the uses supported by data currently no harmful effects on human or animal health from the residues are expected, taking into account the route and rate of application and the weight of evidence that _Trichoderma atroviride_ strain SC1 does not produce relevant metabolites of significant toxicity or at levels leading to exposure levels higher than negligible.
On the same basis, the review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report and taking into account available information on Trichoderma atroviride strain SC1 and the relationship with other Trichoderma species when considering population viability and dispersal power.

In the view of EFSA some elements of the risk assessment are inconclusive. However, the review established that the risk under realistic conditions is considered negligible or very low for the following issues:

- Several species of the genus Trichoderma are known for producing toxins which might affect human health (e.g. trichothecenes, peptaibols). From open literature, Trichoderma atroviride strain SC1 is not known to produce trichothecenes and it is not closely related to the Trichoderma brevicompactum-group, which all known producers of trichothecenes belong to.

Moreover, several strains of the species Trichoderma atroviride have already been assessed under the provisions of Regulation (EC) No 1107/2009. Neither these nor other strains of the species are known to produce metabolites (especially toxins) resulting in unacceptable effects on human health and/or the environment during or after application.

From the available toxicological studies, it can be expected that there is no significant level of toxins in the end-use product. Some peptaibols are known to be produced during the growth of Trichoderma atroviride strain SC1, in particular following exposure to potential pathogens. Accumulation of these toxins up to a critical level is, however, not expected to occur under natural conditions of growth (characterized by limited availability of nutrients and energy). In addition, no incidence on Trichoderma toxins from natural or agricultural environments to humans, other non-target organisms, or the environment was so far described in the literature.

- It was demonstrated that Trichoderma atroviride strain SC1 following application in different soils did not prevail and was not present in higher abundances than populations naturally occurring in soil. Therefore, the review concluded that there is only a negligible or very low risk that toxins or other metabolites might be secreted at levels higher than the natural background or dangerous for human and animal health, groundwater or the environment.

Some further issues were identified by EFSA concerning all possible metabolites which are known be produce by other Trichoderma species or which hypothetically might be produced by a microorganism under any relevant environmental conditions. The data required go beyond the concept of "foreseeable risk" and the scope of the data requirements according to Regulation (EU) No 544/2011 part B and in particular the requirements of paragraph 2.8. They are therefore not considered relevant for the decision whether or not Trichoderma atroviride strain SC1 may be approved under the conditions of that legislation.
4. **Identity and Physical/chemical properties**

The main identity of *Trichoderma atroviride* strain SC1 is given in Appendix I.

The isolate is deposited at the Centraalbureau voor Schimmelcultures (CBS) Fungal Biodiversity Centre in Utrecht, Netherlands under the Reference Number CBS 122089.

The minimum initial population in the MPCA (microbiological pest control agent) shall be $1 \times 10^{10}$ CFU/g.

The review has established that for the active substance notified by the applicant BI-PA NV there are no relevant toxins which are of toxicological, ecotoxicological and/or environmental concern.

5. **Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing *Trichoderma atroviride* strain SC1.**

On the basis of the proposed and supported uses (as listed in Appendix II), the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers.

Conditions of use shall include risk mitigation measures where appropriate.

7. **List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the approval of *Trichoderma atroviride* strain SC1 under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 14).
8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for *Trichoderma atroviride* strain SC1.
# APPENDIX I

## Main identity

**TRICHODERMA ATROVIRIDE STRAIN SC1**

<table>
<thead>
<tr>
<th>Name of the organism:</th>
<th>Trichoderma atroviride strain SC1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species, subspecies, strain:</td>
<td><em>Trichoderma atroviride</em> strain SC1</td>
</tr>
<tr>
<td>Identification / detection:</td>
<td>Real-time PCR using standard a strain specific TaqMan probe</td>
</tr>
<tr>
<td>Culture collection:</td>
<td>Deposited under the accession number CBS 122089 in the collection of the CBS in Utrecht, The Netherlands</td>
</tr>
<tr>
<td>Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (viable granules; g/kg):</td>
<td>Minimum concentration: $1 \times 10^{10}$ CFU/g</td>
</tr>
<tr>
<td>Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:</td>
<td>None</td>
</tr>
<tr>
<td>Is the MPCA genetically modified; if so provide type of modification</td>
<td>No</td>
</tr>
</tbody>
</table>
# APPENDIX II

## List of uses supported by available data

*TRICHODERMA ATROVIRIDE STRAIN SC1*

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Member State or Country</th>
<th>Product name</th>
<th>F or G</th>
<th>Pests or group of pests controlled</th>
<th>Formulation</th>
<th>Application</th>
<th>Application rate per treatment</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grapes, established vines (VITVI)</td>
<td>Europe</td>
<td>Vintec</td>
<td>F&lt;sup&gt;1&lt;/sup&gt;</td>
<td><em>Phaeomoniella chlamydospora</em> <em>Phaeoacremonium aleophyllum</em> <em>Diplodia seriata</em> <em>Eutypa lata</em></td>
<td>WG 150 g/kg 1.0 x 10&lt;sup&gt;13&lt;/sup&gt; CFU/kg</td>
<td>Spraying onto pruning wounds</td>
<td>Winter dormancy period</td>
<td>1 - 2</td>
<td>1 week</td>
</tr>
<tr>
<td>Grapes, nursery (VITVI)</td>
<td>Europe</td>
<td>Vintec Nursery</td>
<td><em>Phaeomoniella chlamydospora</em> <em>Phaeoacremonium aleophyllum</em></td>
<td>WG 150 g/kg 1.0 x 10&lt;sup&gt;13&lt;/sup&gt; CFU/kg</td>
<td>Dipping of root stock and scions</td>
<td>Grafting period</td>
<td>1 - 4</td>
<td>1 day</td>
<td>0.030 2 x 10&lt;sup&gt;12&lt;/sup&gt; (product: 0.2)</td>
</tr>
</tbody>
</table>

**Remarks:** (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use of g/kg or g/L.

(i) g/kg or g/L.
situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions