

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2014-5121  
**Application:** Changes to TGAI Product Chemistry – New Source (Site) Same Registrant  
**Product:** *Beauveria bassiana* strain ANT-03 Technical  
**Registration Number:** 31230  
**Active ingredients (a.i.):** *Beauveria bassiana* strain ANT-03  
**PMRA Document Number :** 2552769

### Purpose of Application

The purpose of this application was to add a new alternate manufacturing site for *Beauveria bassiana* strain ANT-03 Technical.

### Chemistry Assessment

The registrant has submitted sufficient data to assess the proposed new manufacturing site and new manufacturing methods. Analysis for the secondary metabolite, beauvericin, will be required for every batch of technical grade active ingredient (TGAI) produced as part of the standard quality control procedures.

### Health Assessments

Toxicology and occupational exposure assessments were not required for this application.

The registrant has submitted sufficient data to address the concerns regarding the content of secondary metabolites contained in the TGAI resulting from the proposed new manufacturing site and new manufacturing methods. The data demonstrated that risks to human health are acceptable from the dietary exposure to *Beauveria bassiana* strain ANT-03 Technical when applied to food crops as a microbial pest control agent.

### Environmental and Value Assessments

Environmental and value assessments were not required for this application.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the addition of a new alternate manufacturing site for *Beauveria bassiana* strain ANT-03 Technical.

### References

PMRA Document Number	References
2470752	2014, Supplemental Product Chemistry for <i>Beauveria bassiana</i> strain ANT-03 Technical, DACO M2.8, M2.9.2, M2.9.3, M2.10. CBI
2470750	2014, New Manufacturing Site for TGAI, DACO M2.2, M2.11, M2.12, CBI
2534914	2015, Estimation de l'activit et garantit du produit, DACO M2.9.2. CBI
2534915	2015, Certificat d'analyse, DACO M2.9.3, CBI
2534913	2015, Response to PMRA On Hold Letter, DACO M2.8, M2.9.2, M2.9.3. CBI
2552720	2015, Certificates of Analysis 1 – 5, DACO M2.9.3, CBI
2552721	2014, European Food Safety Authority, Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed, DACO M7.0.
2552727	2007, High-throughput synergy screening identifies microbial metabolites as combination agents for the treatment of fungal infections, PNAS, March 13, 2007, 104(11), DACO M7.0
2552728	2010, Beauvericin Ameliorates Experimental Colitis by Inhibiting Activated T Cells via Downregulation of the PI3K/Akt Signaling Pathway, PLOS ONE, December 2013, 8(12), DACO M7.0
2552729	2013, European Food Safety Authority, Conclusion on the peer review of the pesticide risk assessment of the active substances <i>Beauveria bassiana</i> strains ATCC-74040 and GHA1, DACO M7.0.

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2016**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.