



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation  
Unit E4- Pesticides and Biocides

Brussels,  
SANTE/E4/MN/sik (2019) 1326609

Dear Mr Ehlers,

**Subject: Your letter of 31 January 2019 concerning the use of nematodes in biocidal products**

I refer to your letter of 31 January 2019 concerning the use of entomopathogenic nematodes for biological control of insect pests. In this letter you enquire whether the use of nematodes to exert a controlling effect on insects would require an authorisation in accordance with Regulation (EU) No 528/2012.

Article 3(1)(c) of Regulation (EU) No 528/2012 provides a definition of 'active substance': a substance or a micro-organism that has an action or against harmful organisms. Article 3(1)(b) of this regulation provides a definition of micro-organism and includes, among others, microscopic parasitic helminths.

Helminths is a general term meaning worms. According to the definition in the regulation these worms could be considered micro-organisms if the organisms are both parasitic and microscopic. Nematodes can be considered relative large, multicellular organisms that are not microscopic. This implies that nematodes used to exert a controlling effect against harmful organisms are not considered an active substance in the context of Regulation (EU) No 528/2012 and biocidal products containing these nematodes do not require an authorisation.

We hope that this letter helps to clarify the legal situation of your product.

Yours sincerely,

  
Klaus Berend

Cc: ECHA: Mr Hugues Kenigswald, Ms Leena Yla-Mononen, Mr Erik van de Plassche

Mr R. Ehlers  
e-nema  
Klausdorfer Strasse 28-36  
D-24223 Schwentinental  
Germany  
E-mail : [info@e-nema.de](mailto:info@e-nema.de)