



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach
The Director

Brussels
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I am writing to bring to your attention a case, which has been signalled to the Commission by the Federal Institute for Agriculture and Food (BLE) of Germany (ARES(2020)4754217).

In accordance with an Italian note of 2017 published on the SINAB webpage at the following address:

<http://www.sinab.it/normativa/nota-n-37454-del-10-maggio-2017>

the Italian Ministry of Agriculture recognised the declaration provided by the company DSM Food Specialties B.V. concerning their product Preventase M, asparaginase from *Aspergillus niger*, as having been provided in line with Annex XIII of Commission Regulation (EC) No 889/2008¹ and consequently in compliance with requirements of Article 9(3) of Council Regulation (EC) No 834/2007².

In their declaration, DSM certified, among others, that the product Preventase M had been produced with an *Aspergillus niger* strain classified by the authorities in The Netherlands and France as a “self-cloned micro-organism”.

In 2013, ‘DSM Food specialties’ submitted an application for authorization of the food enzyme asparaginase from *Aspergillus niger* (ASP) in accordance with Regulation (EC) No 1331/2008 as an enzyme from a genetically modified microorganism. This application is currently subject to a scientific risk assessment by EFSA (EFSA-Q-2013-00895). As regards the use in the organic production, Article 9 (1) of Regulation (EC) No 834/2007 establishes that GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production. The definition of ‘GMO’ under Regulation (EC) No 834/2007 is that

¹ [Commission Regulation \(EC\) n° 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation \(EC\) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control \(OJ L 250, 18.9.2008, p. 1\).](#)

² Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.07.2007, p. 1)



given in Directive 2001/18/EC and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive. Self-cloned micro-organisms fall under this definition of GMOs. Therefore, products produced by self-cloned GMOs shall not be used in organic production.

In the light of the above, I would kindly ask you to follow up on this case and send us any updated information as well as your opinion. I also thank you for sharing all relevant information with other Member States' delegates in one of the future meetings of the Committee on organic production to follow up appropriately the matter.

Yours faithfully,

