



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT
Directorate B. Quality, Research & Innovation, Outreach
Director

Brussels,
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Dear [REDACTED],

Thank you for your email of 25 January 2019 (Int. Ref. ARES (2019)437564) asking for clarification on the requirements for the approval in organic production of the compound pullulan (E1204), which is used by your company for the production of empty capsules for dietary supplements and pharmaceuticals.

First of all, I would like to bring your attention that according to Article 1(2) of Regulation (EC) No 834/2007¹ the organic legislation applies to "products originating from agriculture, including aquaculture, where such products are placed on the market [...]: (a) live or unprocessed products; (b) processed agricultural products for use as food".

Article 6 of the same Regulation provides for specific principles applicable to the production of processed organic food and among others: "*(b) the restriction of the use of food additives, of non organic ingredients with mainly technological and sensory functions and of micronutrients and processing aids, so that they are used to a minimum extent and only in case of essential technological need or for particular nutritional purposes; (c) the exclusion of substances and processing methods that might be misleading regarding the true nature of the product; (d) the processing of food with care, preferably with the use of biological, mechanical and physical methods.*"

Article 19 lays down general rules on the production of processed food and in particular requires in its paragraph 2(b) that "*only additives, processing aids, flavourings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses may be used, and only in so far as they have been authorised for use in organic production in accordance with Article 21; .*

In order to authorise a substance or product for use in organic production, it must be verified whether the product or substance and its possible uses are in line with the

¹ 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, 20.7.2007, p. 1).

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objectives and principles of organic production and with the criteria laid down in Article 21. The substance is then evaluated by the Expert Group for Technical Advice on Organic Production (EGTOP). Should EGTOP provide a positive advice on the use of the substance, the Commission may propose to the Committee on organic production to add this substance in the relevant Annex to Regulation (EC) No 889/2008².

Please note that only Member States may request the Commission to authorise a product or substance in organic food production by submitting a complete dossier giving reasons for its authorisation. I suggest you to contact the competent authority of one Member State to examine the case and if possible, present a request in accordance with above-mentioned rules.

The present opinion is provided on the basis of the facts as set out in your letter of 25 January 2019 and expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours sincerely,



Nathalie SAUZE- VANDEVYVER

² 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).