



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B – Sustainability
The Director

Brussels
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Dear Ms Jakubauskiene,

I would like to thank you for your email¹ of 3 May 2022, in which you request a reply to your email of 21 March 2022² asking for clarifications with respect to the use of food enzymes preparations. Please accept my apologies for the belated reply.

Specific replies are provided below to each of your questions:

1) On the condition that enzyme products used for dairy production are evaluated, should supplementary processed materials e.g. carrier, stabilizer - glycerol be evaluated as well?

I would like to start by recalling the specific principles applicable to the processing of organic food laid down in Article 7 of Regulation (EU) 2018/848³, which *inter alia* provides for: “(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 cases of essential technological need or for particular nutritional purposes;*”

In addition, point 2.2.1. of Part IV of Annex II to Regulation (EU) 2018/848 states: “*Only food additives, processing aids and non-organic agricultural ingredients authorised pursuant to Article 24 or Article 25 for use in organic production, and the products and substances referred to in point 2.2.2 may be used in the processing of food, with the exception of products and substances of the wine sector, for which point 2 of Part VI shall apply, and with the exception of yeast, for which point 1.3 of Part VII shall apply.*”

¹ ARES (2022)3433545

² ARES(2022)2051005

³ [Regulation \(EU\) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation \(EC\) No 834/2007 \(OJ L 150, 14.6.2018, p. 1\).](#)

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Moreover, for the sake of clarity, I would also like to recall Article 9(3) of Regulation (EU) 2018/848, which states: “*For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, **provided that their use in non-organic production has also been authorised** in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law*”.

In particular, the use of food enzymes is allowed in organic processed food under point 2.2.2. of Part IV of Annex II to Regulation (EU) 2018/848: “*(a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production*”.

In this context, it is important to mention as well the EU horizontal legislation concerning enzymes, i.e. Regulation (EC) 1332/2008⁴, where a definition of preparation is also provided under its Article 3(2)(b) as follows: “*‘food enzyme preparation’ means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution*”.

Also to be considered is the definition of processing aid under Article 2(b) of Regulation (EC) 1333/2008⁵ on food additives, as follows: “*‘processing aid’ shall mean any substance which: (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;*”.

I would further like to bring to your attention that Annex I to Regulation (EC) 1333/2008 lists the functional classes of food additives, such list includes carriers and stabilisers.

Consequently, in accordance with point 2.2.2. of Part IV of Annex II to Regulation (EU) 2018/848, when the enzyme is indeed used as a processing aid normally used in food processing, the food enzyme preparation to be used as processing aid can be used in organic production, when it is not produced from or by Genetically Modified Organisms in line with Article 11 of Regulation (EU) 2018/848.

In this case, it is sufficient that the food additives including those used as carriers present in the preparation are normally used and authorised for use in food enzymes and thus included in Annex III to Regulation (EC) No 1333/2008, which lays down the Union list of food additives approved for use in food additives, food enzymes, flavourings and nutrients and their conditions of use.

⁴ Regulation (EC) 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) no 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)

⁵ Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p.16)

For the categorisation of food enzymes, please consider also the DG SANTE Guidance available here: [*fs food-improvement-agents_enzymes-guidance-categorisation.pdf \(europa.eu\)](https://fs.food-improvement-agents.enzymes-guidance-categorisation.pdf).

When the food enzyme is used for its technological function as an ingredient (i.e. as an additive), approved in compliance with the horizontal legislation, it shall have to be further assessed and, when appropriate, authorised for use in organic production pursuant to Article 24 of Regulation (EU) 2018/848. However, also in this case, carriers and other food additives normally used in the preparation of the food enzyme itself, and already approved under horizontal legislation, will not need to be authorised in organic, except in the case of food additives having a technological function in the final food.

In this last case, indeed, also the food additive used in the enzyme preparation shall be considered as a food additive of the food, and not a food additive of the added food enzyme, and must then comply with the conditions of use for that food as provided for in the horizontal legislation⁶ and be assessed under the Article 24 of Regulation (EU) 2018/848.

Finally, in case the preparation of the food enzyme itself should be subject to organic certification and placed on the market as “organic enzyme preparation” being a product in the scope as “processed agricultural products for use as food” under Article 2 of Regulation (EU) 2018/848, all components of such food enzyme preparation (e.g. carriers, stabilisers) will have to be assessed and if appropriate, approved under the organic legislation.

2) Should the following supplementary processed materials / additives be assessed according to Annex V to R2021 / 1165 that provides a list of products and substances for production of organic food and yeast used for food or feed:

Authorized food additives and processing aids referred to in Article 24 (2) (a) of Part A R2018 / 848:

Section A1 - Food additives, including carriers;

Section A2 - Processing aids and other products authorized for use in the processing of organically produced ingredients of agricultural origin.”?

Yes, but only in the cases explained above.

-3) Should the R 2018 / 848 Annex II part IV paragraph 2.2.2 be applied solely for the enzyme preparations

„The following products and materials may be used in food processing:

(a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes used as food additives are authorized for use in organic production in accordance with Article 24“?

⁶ Article 18 of Regulation (EC) 1333/2008: “Where a food additive in a food flavouring, food additive or food enzyme is added to a food and has a technological function in that food, it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme, and must then comply with the conditions of use for that food as provided for.”

See above.

This opinion is provided on the basis of the facts set out in your e-mail of 21 March 2022 and expresses the opinion 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 Court of Justice of the European Union to provide a definitive interpretation of the applicable Union law.

Yours sincerely,

A handwritten signature in blue ink, consisting of a large, stylized 'P' followed by a horizontal line and a vertical stroke.

Michael PIELKE i.o. Pierre
BASCOU absent