EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

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

Brussels,
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Dear [redacted],

Thank you for your e-mail of 21 May 2018 and 24 June 2019 (Int. Ref. ARES (2018)2620214 and (2019)4000291) in which you provided additional information to your previous request for clarification of 31 January 2018. Please accept my apologies for the very late reply.

In particular, you expressed two main questions: 1st) whether micro-organisms used in dairy products for adding extra values to enhance digestion or to act via lactase enzyme in milk (normally called probiotics) or affecting taste and consistency of a product, can be used in organic products; and 2nd) whether the reference to "particular nutritional purposes" now should be read "food for specific groups" or if not, which is the meaning of "particular nutritional purposes".

Article 19 of Regulation (EC) No 834/2007[1] lays down general rules on the production of processed food, and in particular its paragraph (2)(b) "*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***".

Article 21 lays down specific criteria for certain products and substances to be used in processing. Indeed, it provides also for an authorisation procedure of products and substances to be used in organic production and for their inclusion in a restricted authorised list, demanding such products and substances to be compliant with objectives and principles of organic regulation and with the following:

*"(i) alternatives authorised in accordance with this chapter are not available;*

[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. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02007R0834-20081010&qid=1396976187958&from=EN

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*(ii)* ***without having recourse to them, it would be impossible to produce or preserve the food*** *or to fulfil given dietary requirements provided for on the basis of the Community legislation.*

*In addition, the products and substances referred to in Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where such products and substances from such sources are not available in sufficient quantities or qualities on the market."*

These provisions have been further specified in Article 27(1)(b) of Commission Regulation (EC) No 889/2008[2], which lays down the substances which can be used in the processing of organic food:

*"(a) substances listed in Annex VIII to this Regulation;*
*(b) preparations of micro-organisms and enzymes* ***normally used in food processing****; however, enzymes to be used as food additives have to be listed in Annex VIII, Section A;*
…. "
From the provisions above, and considering that preparations of micro-organisms and enzymes are not micro-nutrients, it follows that preparations of micro-organisms in organic food are authorised when normally used in food processing.

Micro-organisms which are normally used in food production are only those micro-organisms which are essential to food manufacture, hence, technologically needed as it would be impossible to produce or preserve the food without them. However, under "normal use" any case could be considered where the use of a certain input is linked to a legal requirement, as such use would become unavoidable to market a certain product and therefore it would become normal use.

It should be recalled in this context, that the use of micro-organisms for the production of novel food, which could not be directly assessed as normal use, has to be evaluated on a case by case basis to verify their possible approved use in organic productions.

Finally, as in the examples you provided, the preparations of micro-organisms are used for certain nutritional purposes (e.g. lactose-free products, alleged "probiotics", etc..); in those cases and in the case of uses which could just affect taste and consistency of products, the micro-organisms should be examined on a case by case basis to verify whether their use would be technologically essential to produce that specific food or food supplement and therefore, normally used, and if not, they should be assessed in compliance with Article 21 of Regulation (EC) 834/2007 for potential inclusion in Annex VIII.

I refrain from addressing your question concerning "particular nutritional purposes" as it is linked to the ongoing EU Court case C-815/19 concerning *Lithothamnium calcareum* on which a judgement is expected soon.

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[2] Commission Regulation (EC) No 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. 1–84).

The present opinion is provided on the basis of the facts as set out in your e-mails of 21 May 2018 and 24 June 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,