EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

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

Brussels,
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[redacted]

Thank you for your e-mail of 27 September 2019 (Int. Ref. ARES (2019)6052180) in which you request a clarification on a milk product for infants and whether or not it is compliant with the EU organic legislation. Please accept my apologies for the very late reply which had been linked to the outcomes of other related discussion on use of micro-organisms in food occurring in the Committee on Organic Production.

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) provides that "*only additives, processing aids, flavourings, water, salt,* ***preparations of micro-organisms and enzymes****, minerals, trace elements, vitamins, as well as amino acids and 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 27(1)(b) of Commission Regulation (EC) No 889/2008[2] authorises *inter alia* the following substances 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.

Such micro-organisms and enzymes may of course only be used in food processing when they are allowed to be used according to the legislation applicable to all food.

[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

[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 25, 22.2.2016, p. 1).

[redacted]

The example you provided in your letter appears to be an organic milk-based infant formula of which ingredients include *"**bifidobacteria cultures (B.breve, B.bifidum, B.infantis, B.longum)"**.*

Bifidobacterium spp. bacteria are included in the Qualified presumption of safety (QPS) EFSA list[3] and therefore, they do not need to undergo a full safety assessment to be used in food.

Please note that the relevant horizontal EU legislation (i.e. Commission Delegated Regulation (EU) 2016/127[4] on infant and follow-on formula) provides that the voluntary addition to infant formula and follow-on formula of ingredients not covered by specific requirements of that Regulation, such as QPS bacteria, should be possible. In this case, however all ingredients used in the manufacture of infant formula and follow-on formula should be suitable for infants and their safety and suitability should have been demonstrated, when necessary, by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities (of the Member States in which the food business operators intend to market the products) to consider, on a case-by-case basis, whether this is the case (see in particular Art. 3 of Regulation (EU) 2016/127).

To note also that up to now, there are no authorised health claims on bifidobacteria cultures or on probiotics. Therefore, while bifidobacteria cultures may be used in infant formula and follow-on formula, in line with the provisions of Commission Delegated Regulation (EU) 2016/127 described above, it is not possible to state, suggest or imply that a relationship exists between the food and health in the labelling, presentation or advertising of the food.

In conclusion in the case you provided, under the organic legislation provisions, the use of preparations of micro-organisms is in compliance with organic provisions when it can be considered as "normal use".

With respect to the other components, please note that Article 27(1)(f) of Commission Regulation (EC) No 889/2008 on processed food production rules provide for the following:

"*In the processing of food, the following products and substances may be used: (f) minerals (trace elements included), vitamins, amino acids and micronutrients provided that:*

"…..

(ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:
- in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council their use is authorised by

[3] https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fdoi.org%2F10.5281%2Fzenodo.1146566&data=02%7C01%7C%7Cfaa4878a8499474e170708d7aa45e695%7C406a174be31548bdaa0acdaddc44250b%7C1%7C0%7C637165089500946416&sdata=NWtc%2Fv5kj0J4tmbpoYT8hiWMNxHBzCA2769cuGjjbP0%3D&reserved=0

[4] Commission Delegated Regulation (EU) No 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 181, 29.6.2013, p.35)

that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or
- in products regulated by Commission Directive 2006/125/EC, their use is authorised by that Directive
- in products regulated by Commission Directive 2006/141/EC, their use is authorised by that Directive."

Therefore, the use of vitamins, amino-acids and micronutrients in food intended for infants and young children is authorised in the organic production of such food when in compliance with provisions laid down under Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013[5] which entered into application on 22 February 2020.

The present opinion is provided on the basis of the facts as set out in your e-mail of 27 September 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,

[5] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p.35)