



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research and Innovation, Awareness

The Director

Brussels
LB/nb/agri.ddgl.b.4 (2021) 2128764

Dear,

Thank you for your note of 30 January 2020 (our reference Groves (2020) 649905) and your reminder of 1 March 2021 (our file reference (2021) 1552400) requesting clarification on the organic certification of certain foodstuffs intended for a particular population. Please accept my apologies for the very late reply.

First of all, you wish to know whether ‘anti-regurgitation milk’ classified as food denial for special medical purposes as defined in Article 1(1)(c) of Regulation (EU) No^{609/2013} 1 can be certified as organic under current and future organic rules. You state that this anti-regurgitation milk consists of certified organic infant milk enriched with minerals, vitamins or micronutrients to which also organic carob meal is added.

In addition, you would like to know whether milk preparations for young children (milk intended for children aged 12 to 36 months) can be certified as organic under current and future organic rules. You state that, in accordance with French legislation, these milk preparations for children are enriched with minerals, vitamins or micronutrients.

Finally, in the event that the above two product categories could not benefit from organic certification under future organic rules, you would suggest that the Commission adopt delegated acts to cover these two categories of products.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?URI=CELEX:02013R0609-20170711&qid=1615299443435&from=EN>

(1) (f) of current organic Regulation (EC) No 889/2008¹ and point 2.2.2 (f) of Part IV of Annex II to future Regulation (EU) 2018/848² lay down detailed rules according to which certain products and substances may be used in the processing of foodstuffs:

According to those provisions³, minerals (including trace elements), vitamins, amino acids and micronutrients may be used provided that:

- i) their use in foodstuffs for everyday consumption is ‘specifically legally required’, that is to say directly imposed by provisions of Union law or provisions of national law compatible with EU law, with the consequence that food may under no circumstances be placed on the market as food for everyday consumption if minerals, vitamins, amino acids or micronutrients are not added; or
- ii) in the case of foods placed on the market as having special health, nutritional or nutritional characteristics or effects, or in relation to the needs of particular categories of consumers:
 - in products referred to in Article 1(1) (a) and (b) of Regulation (EU) No 609/2013 of the European Parliament and of the Council, their use is authorised by that Regulation and by acts adopted on the basis of Article 11(1) of this Regulation for the products concerned, or
 - in products covered by Commission Directive 2006/125/EC (2), their use is authorised by that Directive.

According to your note, the product which you describe as ‘anti- regurgitation milk’ is not covered by Article¹ (1) (a) and (b) of Regulation (EU) No 609/2013 but by Article 1⁽¹⁾ (c) of Regulation (EU) No 609/2013 and is therefore not covered by the exception provided for in point 2.2.2 (f) (ii) of Part IV of Annex II to Regulation (EU) 2018/848; it cannot therefore be certified as organic.

Concerning milk preparations for young children (“milks” intended for children aged between 12 and 36 months),

Commission to the European Parliament and the Council published in 2016⁴ on preparations for young children, which was based on the opinion of the European Food Safety Authority (EFSA) of 2013, the co-legislators decided not to introduce specific provisions for the composition of milk preparations for young children and to consider them as ‘normal’ foods. please explain that France has adopted national rules requiring enrichment with minerals, vitamins or micronutrients. For these ‘milks’ intended for children aged between 12 and 36 months ‘conventional’, Member States may lay down such national rules; however, in this case, Member States may not restrict or prohibit the placing on the market of “milks” intended for 12-36 “conventional” children who comply with the requirements of the general legislation on

food, but which does not meet the French requirements for them
composition

For organic production, please note that these “milks” intended for children aged between

¹ [https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:02008R0889-20200107 & qid = 1615299890712 & from = EN](https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:02008R0889-20200107&qid=1615299890712&from=EN)

² [https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:02018R0848-20201114 & qid = 1615301070415 & from = EN](https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:02018R0848-20201114&qid=1615301070415&from=EN)

³ The provisions of Article 27 (1) (f) of Regulation (EC) No 889/2008 are identical in substance and are not repeated in this letter.

⁴ <https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52016DC0169&from=EN>

12 and 36 months are not covered **by the exception provided for in point 2.2.2 (f) (ii)**. These ‘milk’ intended for children aged 12 to 36 months enriched to comply with French national requirements could therefore potentially benefit from organic certification only **if they were covered by the exception provided for in point 2.2.2 (f) (i) and therefore** regarded as ‘foodstuffs for everyday consumption’, **in other words milk**. According to your note, France has adopted provisions of national law requiring minerals, vitamins, amino acids or micronutrients to be added to milk preparations for young children but not to milk in general. However, **the exception in point 2.2.2 (f) (i) to enrich organic products with minerals, vitamins, amino acids or micronutrients can only be applied if food**, milk in this particular case, cannot be placed on the market as food for everyday consumption if minerals, vitamins, **amino acids** or micronutrients are not added to it. Accordingly, milk preparations for young children (milk intended for children aged 12 to 36 months) enriched with minerals, vitamins, amino acids or micronutrients in accordance with the requirements of French national legislation for these products cannot be certified organic under current or future biological regulations.

As regards your suggestions to adopt a delegated act aimed at enabling organic certification of the above products, the Commission is indeed empowered to adopt delegated acts in accordance with Article 16 (2) (b) of Regulation (EU) 2018/848 amending point 2.2.2 of Part IV of Annex II as regards the types and composition of products and substances authorised for use in processed food and the conditions under which they may be used.

However, it should be stressed that the production of processed organic food is based on a number of specific principles set out **in particular in Article 7** of Regulation (EU) 2018/848, including: (b) the restriction of **the use of micronutrients, including minerals and vitamins**.

Moreover, as communicated to the delegates of the Member States of the Committee on Organic Production, the Commission’s priorities for proposing secondary legislation in 2021 are to complete the legislation on controls and international trade. To **this end, there is a need to discuss with the other Member States whether or not they are interested in extending the scope for organic certification to such products.**

This opinion is provided on the basis of the facts set out in your note of 30 January 2020 and expresses the views 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.

Veillez agréer, Madame, l'expression de ma considération distinguée.

