Ministero dell'agricoltura,
della sovranità alimentare e delle foreste
Dipartimento della sovranità alimentare e dell'ippica
DG PQA – PQA II

A

Organismi di Controllo
LORO SEDI

E p.c.

ICQRF PREF II, PREF III, PREF IV
TERR1
SEDE

Regioni e Province Autonome
LORO SEDI

ACCREDIA
info@accredia.it

Componenti tavolo tecnico
sull'agricoltura biologica
LORO SEDI

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Oggetto: Certificazione di prodotti probiotici ai sensi del Reg. (UE) 2018/848

Con la presente si forniscono chiarimenti in relazione a quanto in oggetto, a seguito della notifica INEU-119/2026 aperta dalla Francia in relazione ad un prodotto certificato in Italia.

In particolare la Francia segnala l'irregolarità della certificazione ai sensi del Reg. (UE) 2018/848 di un prodotto contenente microrganismi come ingredienti, e non come additivi alimentari. Tale certificazione non risulterebbe conforme, alla luce di quanto previsto dalla nota Ref.Ares(2020)6689462 – 13/11/2020 (allegata alla presente), a quanto previsto dal Reg. (UE) 2018/848, Allegato II, Parte IV, punto 2.2.2 a) '*Nel settore della trasformazione degli alimenti, possono essere utilizzati … preparazioni a base di microrganismi … normalmente utilizzate nella trasformazione degli alimenti'*.

Il prodotto oggetto della segnalazione è commercializzato come probiotico e contiene probiotici/fermenti lattici insieme a 'fibre vegetali' biologiche.

Considerato quanto sopra e anche alla luce di quanto riportato nella nota Ref.Ares(2024)7286961 – 14/10/2024 (allegata alla presente), che chiarisce che i microrganismi non rientrano nel campo di applicazione del Reg. (UE) 2018/848, si ritiene che un prodotto commercializzato come 'probiotico/fermenti lattici' non possa essere certificato ai sensi del Reg. (UE) 2018/848 e riportare il logo UE.

Il Dirigente
Stefania Mastromarino
(*firmato digitalmente ai sensi del C.A.D.)*

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

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

Brussels,
PP/sn/agri.ddg1.b.4(2019)6251296

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

[redacted]

(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,

Ref. Ares(2024)7286961 - 14/10/2024

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B – Sustainability
The Director (acting)

Brussels
[redacted]

Dear [redacted],

I would like to thank you for your email of 27 March 2024 ([1]), which contains a follow-up question to the questions you asked previously concerning probiotics in organic food and feed production ([2]). As we agreed, your letter was discussed with other Member States in the expert group for organic production (GREX). It is for this reason my answer has taken some time.

In your letter, you provide some concrete examples of products labelled as organic and ask my services to evaluate whether such food supplements are compliant with the EU legislation. I am afraid my services cannot evaluate the compliance of specific products as the assessment of these products on the ground is your responsibility. However, taking into account also the discussion that occurred in the recent meetings of the Expert Group on Organic Production, I would like to highlight the following elements:

I would like to start by drawing your attention to the first answer included in chapter "Scope" of the FAQ document on organic rules, which is available here: e5b18da2-e7a7-4535-8425-db81ebe7e5ba_en (europa.eu):

1) Can food supplements be organic?

Food supplements are food in accordance with the definition provided for Article 2(j) of Regulation (EC) No 178/2002 (General Food Law). Article 2(1) of Regulation (EU) No 2018/848 defines the scope of the organic legislation as applying to: "the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

([1]) Ares(2024)2306886

([2]) Ares(2024)1417698

[redacted]

(b) processed agricultural products for use as food;

(c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Hence, only food supplements produced from agricultural ingredients fall under the scope of the organic regulation and can be labelled as organic Food supplements produced from vitamins and minerals do not fall under the scope of the EU organic legislation and cannot be labelled as organic.

Only food supplements produced from agricultural ingredients fall within the scope of Regulation (EU) 2018/848 ([3]) and can be labelled as organic. When the product is a food supplement composed mainly of micro-organisms([4]), it cannot be labelled as organic. Indeed, micro-organisms are not covered by Article 2 of Regulation (EU) 2018/848. In addition, preparations of micro-organisms must not be calculated as agricultural ingredients for the purpose of the calculation referred to in Article 30(5) of Regulation (EU) 2018/848 in accordance with point 2.2.4(b) of Part IV of Annex II to Regulation (EU) 2018/848.

In relation to your detailed questions on micro-organisms, please see also our previous letters([5]), which are available in CIRCABC.

Concerning the labels you provided in your emails, I would recommend you inform the national authority responsible for the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods ([6]) as already mentioned in my previous letter ([7]). As explained in this letter, please note that no health claim on "probiotic" is currently authorised for use on food on the EU market.

The present opinion is provided on the basis of the facts as set out in your email of 27 March 2024. It expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law, under the Treaty

([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,ELI: http://data.europa.eu/eli/reg/2018/848/2023-02-21).

([4]) for the purpose of this letter the reference to micro-organisms excludes yeasts as food or feed referred to in Annex I to Regulation (EU) 2018/848.

([5]) ARES(2020) 7629710 and 6689462

([6]) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L30.12.2006, p.9, ELI: http://data.europa.eu/eli/reg/2006/1924/oj).

([7]) Ares(2024)1417698

on the Functioning of the European Union, it is ultimately for the Court of Justice of the European Union to provide a definitive interpretation of the applicable Union law.

Yours sincerely,