



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B – Sustainability
The Director

Brussels
PP/ant/agri.b.4(2023)1204540

Dear [REDACTED],

I would like to thank you for your email of 22 December 2022¹, in which you ask for clarification with respect to the possible use of ethyl acetate to extract astaxanthin oleoresin from organic algae.

In your email, you consider that there are two “*possible interpretations*” referring to the provisions of point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848 on organic production², which allow the use of substances as flavourings in accordance with Regulation 1334/2008⁽³⁾ as follows:

(b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation;”.

You assume that: “*According to Regulation of the European Parliament and Council n. 2018/848 Annex II, Part IV point 2.2. 2 it is possible to use substances according to Regulation 1334/2008. In Annex 1, Part A, Table 1 of this regulation, ethyl acetate is listed. (on page 92, type from top) The code is FL 09.001 ethyl acetate*”.

I would like to start by recalling the provisions of Article 9(3) of Regulation (EU) 2018/848, which read as follows: “*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.*”

¹ Ares (2023)27650

² [CL2018R0848EN0020010.0001.3bi_cp 1..1 \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2018/848/20181220/oj)

⁽³⁾ [http://data.europa.eu/eli/reg/2008/1334/2022-09-26](https://data.europa.eu/eli/reg/2008/1334/2022-09-26)

Furthermore, it should also be kept in mind that, given its properties and specifications, the same chemical substance can often be used for different purposes; in the case you are presenting, ethyl acetate can be used in conventional production as flavouring in compliance with Regulation (EC) No 1334/2008 or as solvent in foodstuffs in compliance with Directive 2009/32/EC⁽¹⁾.

Therefore, for the purpose of using it as a flavour in organic production, your consideration is incorrect. Please take into account that the provisions of point 2.2.2(b) of Part IV of Annex II to Regulation (EU) 2018/848 are referring to natural flavourings “*in accordance with Article 16(2), (3) and (4) of that Regulation*” and not to all possible flavourings authorised under the flavourings Regulation.

Hence, even if ethyl acetate is listed among the flavourings authorised under Regulation (EC) 1334/2008, in order to be used in organic production, it must also be in compliance with the abovementioned provisions.

Please also note the requirements applicable in accordance with Regulation (EC) No 1334/2008 in particular points (c) and (d)(i) of Article 3(2): “*2. For the purposes of this Regulation, the following definitions shall also apply: ... (c) ‘natural flavouring substance’ shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;*

(d) ‘flavouring preparation’ shall mean a product, other than a flavouring substance, obtained from: (i) food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II;”

And according to Article 16(2): “*The term ‘natural’ for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances. 3. The term ‘natural flavouring substance(s)’ may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances. 4. The term ‘natural’ may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95 % by w/w from the source material referred to. The description shall read ‘natural “food(s) or food category or source(s)” flavouring’.*” A detailed reply on this subject is also available in CIRCA BC ARES (2022)415136.

However, you ask whether the use of ethyl acetate for the extraction of astaxanthin oleoresins from organic algae would be possible, when this is not a use as flavour but as solvent. I understand that the intention would be to certify and label as organic the astaxanthin oleoresins from organic algae to be placed on the market as food supplement.

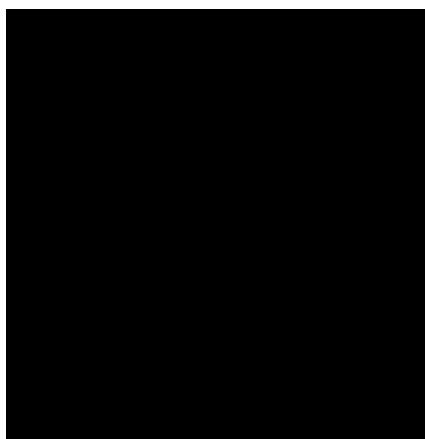
Assuming that this is the product you have in mind, I would like to bring to your attention the importance of examining the detailed nature of the product, its specifications and function before taking any decision.

Astaxanthin-rich oleoresin from *Haematococcus pluvialis* is an authorised novel food, which is listed in Commission Implementing Regulation (EU) 2017/2470⁽⁴⁾. As regards the extraction solvent that you are referring to, the specifications laid down in that Regulation clearly indicate the following: “*The algal cells are harvested and dried; the oleoresin is extracted using either super critical CO2 or a solvent (ethyl acetate).*”

Therefore, in accordance with Article 24 of Regulation (EU) 2018/848, the solvent used - ethyl acetate - should be assessed and if approved as processing aid be listed in Annex V to Regulation (EU) 1165/2022. At present, its use as a solvent is not allowed in organic production. If you consider that the substance should be assessed and allowed in organic farming, in compliance with above-mentioned Article 24, you should transmit to my Services and to the other Member States a request accompanied by a dossier⁽⁵⁾ and my Services will ask the Expert Group for Technical advice on Organic Production (EGTOP) to assess whether such a substance could be allowed to be used in organic production in line with organic principles and objectives.

This opinion is provided on the basis of the facts set out in your email of 22 December 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,



⁽⁴⁾ [COMMISSION IMPLEMENTING REGULATION \(EU\) 2017/ 2470 - of 20 December 2017 - establishing the Union list of novel foods in accordance with Regulation \(EU\) 2015/ 2283 of the European Parliament and of the Council on novel foods \(europa.eu\)](#)

⁽⁵⁾ Templates for dossiers are available at [EGTOP dossiers \(europa.eu\)](#)