EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Deputy Director-General, in charge of Directorates E and G

Brussels
AGRI.E.2/Art.4(1)b – p(2025)8877179

Dear Art.4(1)b – privacy,

Thank you for your e-mail of 25 July 2025 ([1]) by which you ask for an interpretation of the EU legislation concerning the use of botanical materials in the preparation of spirit drinks.

In particular your key questions are the following:

1) Article 6(1) of Regulation (EU) 2019/787 ([2]) specifies that ethyl alcohol and distillates used in the production of spirit drinks shall be exclusively of agricultural origin, within the meaning of Annex I to the Treaty. You ask whether this implies that such alcohol could be derived from non-food agricultural sources, including potentially toxic botanical materials. Upon request from our side, you further clarified that Annex I to the Treaty enumerates various categories of agricultural products, including live trees and other plants (Chapter 6) as well as medicinal plants (Chapter 12) and does not explicitly exclude toxic plants. You explained that this inquiry is intended to clarify whether distillates of agricultural origin may be lawfully produced from medicinal plants, even where such plants could possess toxic properties.

2) Furthermore, given that Regulation (EU) 2019/787 provides that spirit drinks may be produced by using the methods outlined in Article 2(d), including maceration or similar processing of plant materials in ethyl alcohol of agricultural origin (EAAO), you ask:

([1]) Our reference: Ares(2025)6047582

([2]) Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 (OJ L 130, 17.5.2019, p. 1–54).

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a. whether the resulting product should be considered intended for direct consumption and could therefore not be classified as a flavouring, and

b. whether the botanical material in this context could fall within the scope of Regulation (EU) 2015/2283 on novel foods. Upon request from our side, you clarified that your current issue concerns golden root (*Rhodiola rosea*), which is permitted only in food supplements. You specified that, in other contexts, it is considered an unauthorised novel food. However, you informed us that you frequently receive inquiries about the use of various plants in alcoholic beverages, including spirit drinks.

3) Finally, in the context of the addition of flavourings (in line with Regulation (EC) No 1334/2008 ([3])), agricultural products or other foodstuffs, you ask :

a. Where plant material is first macerated in EAAO and the resulting infusion is added to EAAO, whether the infusion would be regarded as a flavouring preparation under Regulation (EC) No 1334/2008. Upon request from our side, you clarified that Article 2(d)(i) of Regulation (EU) 2019/787 distinguishes between maceration or similar processing of plant materials in EAAO (relating to question no. 2.a above) and the addition of flavourings in compliance with Regulation (EC) No 1334/2008. Your interpretation is that, if the infusion is intended for direct use, it does not qualify as a flavouring preparation and would therefore fall outside the scope of authorisation under Regulation (EC) No 1334/2008. However, if it is not considered a flavouring, it would potentially require assessment and approval under the Novel Food Regulation (EU) 2015/2283 ([4]). You seek clarification on these points, particularly as you do not observe such practices always being considered in the EU market for spirit drinks. Hence, you wish to verify whether it is necessary to account for them in the context of spirit drinks at all.

b. And, in such cases, if the botanical in question is not considered food, or its use as a flavouring preparation was not documented prior to 2009, whether this would require authorisation under Regulation (EC) No 1334/2008

Based on the information provided, it cannot be ascertained whether the described products are alcoholic beverages or flavouring preparations.

In principle, since "maceration" is listed under the traditional food preparation processes in Annex II to Regulation (EC) No 1334/2008, and given the definition of flavouring preparations, alcohol of agricultural origin (ethyl alcohol or distillates) macerated or infused with such botanical product might theoretically be regarded as a flavouring preparation under Article 3(2)(d) of Regulation (EC) No 1334/2008.

([3]) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

([4]) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

Moreover, by definition, as outlined in Article 3(2)(a)(i) of Regulation (EC) No 1334/2008, the product should be considered as '*not intended to be consumed as such, but added to food to impart or modify odour and/or taste*'.

If this product is regarded as a flavouring preparation, then the Novel Food Regulation does not appear to be applicable.

Finally, Article 3(3) of Regulation (EC) No 1334/2008 states that: '*For the purpose of the definitions listed in paragraph 2(d), (e), (g) and (j),* ***source materials for which hitherto there is significant evidence of use for the production of flavourings shall be considered as food for the purpose of this Regulation.'***

Therefore, based on the combined reading of all above provisions in conjunction with Article 8(1)(a) and Article 9(b) of Regulation (EC) No 1334/2008, it can be concluded that, if there is significant evidence of use of the specific botanicals for the production of flavourings then they can be considered as 'food' and an evaluation and approval of the product is not required pursuant to Article 8(1)(a). If there is no such evidence, then they are not considered as 'food' and an evaluation and approval of the product is required as per Article 9(b).

However, if the product is not regarded as a flavouring preparation, it may fall under the Novel Food Regulation (EU) 2015/2283. In accordance with the Novel Food Regulation (EU) 2015/2283, 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997 and that falls under at least one of the categories listed in Article 3(2)(a) of Regulation (EU) 2015/2283.

Regarding a novel food status of *Rhodiola rosea*, as indicated in the EU Novel Food status Catalogue ([5]), root and herb of *Rhodiola rosea* are, as you stated, not novel when used solely in food supplements and therefore are not subject to the pre-market authorisation in accordance with the Novel Food Regulation as, according to the data from Member States' competent authorities, root and herb of *Rhodiola rosea* were used in food supplements in the EU before 15 May 1997. However, any other food uses of root and herb of *Rhodiola rosea*, may, as you state, be novel and would require an authorisation under the Novel Food Regulation (EU) 2015/2283 before being placed on the Union market.

It should be noted that in accordance with Article 4 of the Novel Food Regulation, food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation. If unsure, they should consult the Member State where they intend to first market this novel food. Commission Implementing Regulation (EU) 2018/456 ([6]) outlines the required information for consultation requests, including confidentiality provisions, and procedural steps for food business operators to follow. Therefore, we recommend directing a query to the competent authority in the Member State where the food business operator intends to enter the market, providing them with necessary and detailed information to determine whether a product falls under the Novel Food Regulation.

([5]) https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search

([6]) Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 77, 20.3.2018, p. 6) ELI: http://data.europa.eu/eli/reg_impl/2018/456/oj

The list of national competent authorities can be found on https://food.ec.europa.eu/document/download/288ca174-a585-47bf-bb9c-80fe4fc87247_en?filename=fs_novel-food_leg_list_comp_auth_reg_2018_en.pdf

The present opinion is provided on the basis of the facts as set out in your e-mail of 25 July 2025, 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 Court of Justice of the European Union to provide a definitive interpretation of the applicable Union law.

Yours sincerely,

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