EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate E - Food and feed safety, innovation
E.2 - Food processing technologies and novel foods

Brussels,
DG SANTE/E2/RP/amf (2019)2663427

Dear Dr Kolba,

Subject: Status of Cannabis sativa, cannabidiol and cannabinoids-Forthcoming discussion in the working group "novel foods"

I refer to your letter of 12 March 2019 (Ares(2019)1717136) to the Commission regarding the above mentioned subject.

First of all, please accept our apologies for the delay in responding to your letter.

At the outset, it should be recalled that according to Article 2 of Regulation (EC) No 178/2002[1], food shall not include medicinal products within the meaning of Directive 2001/83/EC on the Community code relating to medicinal products for human use[2]. In addition, Article 7(3) of Regulation (EU) No 1169/2011 on the provision of food information to consumers[3] stipulates that food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties. Moreover, to date, *Cannabis sativa* L. extracts (e.g. cannabidiol) is not listed in Commission Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods[4].

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1

[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. OJ L 311, 28.11.2001, p. 67)

[3] Regulation (EC) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18.

[4] Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. OJ L 136, 25.5.2012, p. 1

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Pursuant to Article 4(1) of Regulation (EU) 2015/2283 on novel foods[5] (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 after considering all the information available food business operators are still unsure whether a particular food falls within the scope of the novel food regulation, they shall consult the Member State where they first intend to place the novel food. For that purpose, the Commission has adopted Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for determination of novel food status[6], which lays down the information requirements that need to be included in the consultation request, including provisions on the confidentiality of the request, and the procedural steps business operators must follow for the consultation process.

To date, no request on the novel status of *Cannabis sativa* L. extracts pursuant to the requirements of Commission Implementing Regulation (EU) 2018/456 has been submitted to any of the EU Member States.

In light of the above, the Member States have held several discussions on the subject at the meetings of the governmental expert working group on novel foods organised by the Commission. On request by the European Industrial Hemp Association (EIHA) and Cannabis Trade Association UK, the Commission invited these stakeholders on 16 October 2018, to express their views on the novel food status of hemp and hemp derived products and in particular to present documentation which would help establish a history of consumption for these products. Following those presentations, and on the basis of the available information in the public domain, the Member states indicated that the history of consumption of these extracts has not been demonstrated including for food supplements. Some exceptions apply for some hemp-derived products such as hemp seed oil.

In consequence, the novel food catalogue[7], which serves as an orientation only on whether a product will need an authorisation under Regulation (EU) 2015/2283, was amended on 20 January 2019 as a result of the discussion at the working group meeting on novel food held on 15 January. It mentions that '*EU countries may restrict the marketing of a product through specific legislation*'.

In a subsequent working group meeting on novel foods held on 12 March 2019, the above stakeholders were also invited to present further information on these products. As a result of that meeting, the current situation on the novel food status of these extracts has not changed. This means that in addition to being subject to Regulation (EC) No 178/2002[8], food containing *Cannabis sativa* L. extracts (e.g. cannabidiol) falls within the scope of the novel food regulation unless the history of consumption of these products

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[5] Regulation (EU) 2015/2283 on novel foods of the European Parliament and of the Council of 25 November 2015, 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

[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

[7] Please kindly see the explanations accompanying the catalogue at https://ec.europa.eu/food/safety/novel_food/catalogue_en

[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1

before 15 May 1997 can be demonstrated. Therefore, a pre-market authorisation is required following the requirements of the novel food regulation

Yours sincerely,

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