Document 025

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/ (2020)4016897

MIR-LEK sp. z o.o.
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Dear ,

Subject: Validity of your application for authorisation of Hemp tea submitted to the Commission under Article 10 of Regulation (EU) 2015/2283 on novel foods (NF 2020/1747).

On 16 April 2020, the company 'MIR-LEK sp. z o.o.' made a request to the European Commission to place 'Hemp tea containing cannabidiol' on the Union market as a novel food within the meaning of Article 10(1) of Regulation (EU) 2015/2283 on novel foods[1].

Pursuant to Article 6 of Commission Implementing Regulation (EU) 2017/2469[2], the Commission shall verify the validity of an application. The assessment of the validity of an application requires, at first, the assessment of whether the application falls within the scope of Regulation (EU) 2015/2283.

Prior to taking a final decision on the invalidity of the above mentioned application, the Commission hereby communicates its preliminary conclusions and gives the applicant the opportunity of making known its views thereon.

The definition of 'food' set out in Article 2 of Regulation (EC) No 178/2002[3], to which Articles 2 and 3 of Regulation (EU) 2015/2283 make reference, when defining the scope of application of the novel food regime, excludes (under lit. g) substances that are 'narcotic or

[1] 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

[2] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food, OJ L 351, 30.12.2017, p. 64.

[3] 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

psychotropic' within the meaning of the applicable United Nations Single Convention on Narcotic Drugs of 1961[4] (hereafter 'Narcotics Convention').

Article 1(1)(b) of the Narcotics Convention defines the term 'Cannabis' as meaning 'the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated'. Article 1(1)(j) qualifies as 'drugs' in the framework of the Narcotics Convention any of the substances falling within the scope of Schedules I and II of the Narcotics Convention. Schedule I of the Narcotics Convention includes 'Cannabis and cannabis resin, and extracts and tinctures of cannabis'.

Although cannabidiol that can be obtained from the *Cannabis sativa* L plant are not explicitly mentioned in the schedules of the International Drug Control Conventions, they are, in the Commission's preliminary view, covered by the description of the production method laid out in Schedule I of the Narcotics Convention (i.e. 'extracts and tinctures of cannabis'). It follows that cannabidiol, when extracted from 'cannabis', has to be considered as a substance falling within the scope and under the control mechanisms of that Convention and that is qualified as 'drug' thereunder. Therefore, the Commission has come to the preliminary conclusion that such cannabidiol cannot be regarded as food pursuant to Article 2(g) of Regulation (EC) 178/2002.

Having examined your application, we understand that the substance for which you seek authorisation as a novel food is obtained by an extraction process from hemp (*Cannabis sativa* L.) leaves and flowers.

Based on the assessment outlined above, the Commission therefore preliminarily concludes that the substance for which you seek authorisation must be qualified as an extract from Cannabis pursuant to Schedule I of the Narcotics Convention, cannot be qualified as 'food' pursuant to Article 2(g) of Regulation (EC) 178/2002 and, consequently, falls outside the scope of Regulation (EU) 2015/2283.

You are invited to provide comments on the Commission's conclusions outlined above within a period of 2 months from the receipt of this letter.

After the lapse of that period, the Commission will adopt a final decision on the validity of your application, which will take into account the comments you submitted.

Yours sincerely,

[redacted]

[4] United Nations Treaty Series, vol. 978, No 14152.