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Subject: Notification 2023/355/BG

Act amending and supplementing the Law on Control of Narcotic Substances and Precursors

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015

Madam,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535¹, the Bulgarian authorities notified to the Commission on 8 June 2023 the draft “**Act amending and supplementing the Law on Control of Narcotic Substances and Precursors**” (hereafter “the notified draft”).

According to the notification message, the notified draft *regulates the type, procedure and rules for the cultivation and processing of plants of the hemp (cannabis) genus intended for the production of non-psychoactive products.*

The examination of the notified draft has prompted the Commission to issue the following comments.

The Commission notes that the amendments to Article 29 of the basic act that would be introduced by Section 1 of the notified draft would result in an increase of the permitted levels of Tetrahydrocannabinol (THC) concentration from 0.2 to 1% by weight of THC insofar as this concerns cultivation of hemp plants “*intended for the production of*

¹ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1.

products without psychoactive effects". The Commission also notes that Section 2 of the notified draft provides for the inclusion of the following statement in Article 30 of the basic act: *with the exception of plants and products derived from their processing under Article 29*. Article 30 of the basic act contains a prohibition of production, processing, trade, storage, import, export, re-export, transit, transfer, transport, offering, acquisition, use and possession of plants, drugs and their preparations as included in the national list of plants and substances posing a high risk to public health because of the harmful effect of their misuse, prohibited for human use, and veterinary medicine. The amendments and the clarifications provided by the Bulgarian authorities in the notifying message on the difference between industrial hemp and marijuana seem to imply that the products coming within the scope of the definition provided in Article 29 are not to be considered as "drugs".

The Commission further notes Section 3, paragraph 2, of the notified draft, according to which: *"Hashish" means the mechanically separated resin of the hemp plant or the hemp plant itself containing more than 1 (one) percent by weight of tetrahydrocannabinol, subject to mechanical treatment, as a result of which its individual parts cannot be distinguished*.

The Commission would like to remind Bulgaria that the International Drug Control Conventions, in particular the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol², and the 1971 United Nations Convention on Psychotropic Substances³, do not provide for a threshold of THC below which cannabis plants and products derived therefrom would not qualify as psychotropic substance, which is a drug and, in turn, qualify THC as a drug in its own right within the meaning of EU law⁴.

In light of the definition of 'hashish' provided for in the notified draft, which appears to exclude the resin extracted from hemp plants with a content of less than 1% from the qualification of drugs, we would like to stress that, in accordance with Article 1(1) letter b) and d) of the 1961 United Nations Single Convention on Narcotic Drugs, 'cannabis'⁵ and 'cannabis resin'⁶ are considered as drugs, as per their inclusion in Schedule 1 of the Convention.

Furthermore, the definition of hashish included in the notified draft deviates from applicable definitions in international and EU law and appears to allow the processing of hemp flowers without specific controls besides an authorisation from the national

² Single Convention on Narcotic Drugs, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961 https://www.unodc.org/pdf/convention_1961_en.pdf

³ Convention on Psychotropic Substances https://www.unodc.org/pdf/convention_1971_en.pdf

⁴ Namely Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, OJ L 335, 11.11.2004, p. 8.

⁵ *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*

⁶ *the separated resin, whether crude or purified, obtained from the cannabis plant*

administration if the hemp is from a variety with an average level below 1% THC. In line with Article 2 of the Council Framework Decision 2004/757/JHA⁷, Member States are required to take the necessary measures to ensure that crimes linked to illegal trafficking in drugs, including cannabis and cannabis resin as defined above, are punishable.

Insofar as the definitions laid down by the notified draft deviate from the applicable international rules, the Commission underlines the potential risk of the notified draft being interpreted as permitting the marketing of certain products, which could classify as “drugs”, which would be contradictory to the rules laid down by Council Framework Decision 2004/757/JHA.

Moreover, the Commission notes the reference made in Section 4 of the notified draft to the Common Agricultural Policy’s (CAP) Strategic Plans for the period 2023-2027. The Commission reminds the Bulgarian authorities that EU law permits and provides for the eligibility for CAP direct payments⁸ for the use of certain hemp seed varieties, but only when the THC content is below 0,3%⁹.

In addition, in relation to final products that could be derived from hemp/cannabis plant, as included in Section 2 of the notified draft measure, the Commission would like to stress the relevance of sectoral legislations, notably:

The definition of ‘food’ laid down by Article 2 of Regulation (EC) No 178/2002¹⁰ (the General Food Law) excludes (in point g) ‘narcotic or psychotropic substances’ within the meaning of the applicable UN Single Convention on Narcotic Drugs of 1961, and the UN Convention on Psychotropic Substances, 1971.

In this connection, while cannabidiol (CBD) has been considered by the Court in case C-663/18¹¹ as not qualifying as a drug, Regulation (EU) 2015/2283 on novel foods¹² applies to foods that were not used for human consumption to a significant degree within the Union before 15 May 1997 and that fall under at least one of the categories listed in

⁷ Please see the reference in footnote 4

⁸ The Common Agricultural Policy, [The Common Agricultural Policy: an overview | European CAP Network \(europa.eu\)](https://ec.europa.eu/eip/en/the-common-agricultural-policy)

⁹ See Art. 4(4) of Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013, OJ L 435, 6.12.2021, p. 1.

¹⁰ 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.

¹¹ Case C-663/18- Judgment of the Court (Fourth Chamber) of 19 November 2020, Criminal proceedings against B S and C A, Request for a preliminary ruling from the Cour d'appel d'Aix-En-Provence, ECLI:EU:C:2020:938.

¹² 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 (Text with EEA relevance), OJ L 327, 11.12.2015, p. 1.

Article 3(2)a) and therefore to CBD as food insofar as it falls under a relevant category. CBD is currently not authorised as a novel food.

In addition, some hemp-derived foods are not considered as ‘novel’: this is the case of e.g. hemp seeds, hemp seed oil and other hemp seed-derived food as a history of consumption prior to 1997 has been demonstrated but they may be subject to maximum levels for delta-9-THC, such as those established for by Commission Regulation (EU) 2023/915¹³ in Annex I, Section 2, entry 2.6.

In relation to cosmetics, Regulation (EC) 1223/2009¹⁴ lists in Annex II, entry 306, “*Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961*” as part of the substances prohibited in cosmetic products.

On CBD and following the above-mentioned Court judgment, the Commission intends to request the EU Scientific Committee on Consumer Safety (SCCS) to perform a safety assessment for CBD when used in cosmetic products, in light of the potential risk to consumer’s health due to the limited available information on its safety in such products. To that end, the Commission has opened a call for data on the safety of CBD to be submitted by any interested parties in order to prepare the mandate of the SCCS. The call is open until 1 October 2024.¹⁵ The national authorities are invited to follow the developments in this sector.

The Bulgarian authorities are invited to take these comments into account.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission

Kerstin JORNA
Director-General

Directorate-General for Internal
Market, Industry, Entrepreneurship
and SMEs

¹³ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (Text with EEA relevance), OJ L 119, 5.5.2023, p. 103.

¹⁴ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast), OJ L 342, 22.12.2009, p. 59.

¹⁵ Call for data on ingredients used in cosmetic products- [Call for data on ingredients used in cosmetic products \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/pages/press-room-detail.aspx?lang=en&id=12345)