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From:	Commission Services
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Subject:	Overview of the EU acquis applicable to cannabis in its different forms and components

Delegations will find in the annex a non-paper from the Commission services, dated 19 February 2021, providing an overview of the EU acquis applicable to cannabis in its different forms and components.

Commission services non-paper[1]

Overview of the EU acquis applicable to cannabis in its different forms and components

(19 February 2021)

1. Introduction

In the context of the work of the Horizontal Drugs Group, the Finnish Presidency asked the Commission to provide a factual overview of the EU *acquis* applicable to cannabis in its different forms and components.

The Commission services responded to this request and provided a factual description of the existing EU *acquis* regarding the recreational and medical use of cannabis, agricultural aspects and its use in other areas[2]. The Croatian Presidency collected a number of follow-up questions and requests for clarification, which were forwarded to the Commission services. Moreover, on 19 November 2020, the Court of Justice of the European Union delivered a judgment on the marketing of cannabidiol in Case C-663/18[3], which has implications for this issue. Finally, the vote of the WHO recommendations on cannabis and cannabis-related substances took place on 2 December 2020 in the Commission on Narcotic Drugs[4].

The aim of this non-paper is therefore to reflect the above-mentioned developments since its initial version was released to the Member States. At the same time, it addresses those points raised by the Member States, which do not require an interpretation of the International Drug Control Conventions, of the EU *acquis*, or of the case-law in order to respect the technical nature of the non-paper and its scope, meant to provide an overview of the EU *acquis* applicable to cannabis.

2. International legal framework

The International Drug Control Conventions are the Single Convention on Narcotic Drugs of 1961, as amended by the Protocol amending the Single Convention on Narcotic Drugs[5], the Convention on Psychotropic Substances of 1971[6], and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[7]. At the outset, it must be stated that only the EU Member States are parties to all three International Drug Control Conventions. The Union is only a party to the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[8].

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1 This non-paper expresses the view of the Commission services and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

2 WK 14407/2019 of 20 December 2019.

3 Judgment of the Court of Justice of 19 November 2020, B S and C A, C-663/18, ECLI:EU:C:2020:938.

4 CND Draft Report, Implementation of the international drug control treaties, https://undocs.org/E/CN.7/2020/L.1/Add.9

5 United Nations Treaty Series, vol. 976, No. 14152.

6 United Nations Treaty Series, vol. 1019, No. 14956.

7 United Nations Treaty Series, vol. 1582, No. 27627.

8 Council Decision 90/611/EEC of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, OJ L 326, 24.11.1990, p. 56–57.

The fact that the Union is a party to only one International Drug Control Convention does not mean that they do not have any significance for the EU *acquis*. The EU *acquis* contains references to the schedules of those Conventions. Any changes to the schedules or tables annexed to the International Drug Control Conventions are capable of affecting EU common rules or altering their scope within the meaning of Article 3(2) TFEU. This is irrespective of whether the substance in question is already placed under control at EU level.

The Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, defines drugs as meaning any of the substances in Schedules I and II of the Convention, whether natural or synthetic[9].

Schedule I of the Single Convention on Narcotic Drugs includes an entry concerning "*Cannabis and cannabis resin and extracts and tinctures of cannabis*". "*Cannabis and cannabis resin*" was also included in Schedule IV of the Convention containing substances that are considered especially dangerous; however, this entry has been deleted following the vote in the Commission on Narcotic Drugs on 2 December 2020.

Pursuant to Article 1(1)(b) of the Convention, "*"Cannabis" means 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*".

Cannabis plant is defined in Article 1(1)(c) as any plant of the genus Cannabis.

3. Use of cannabis

The Single Convention on Narcotic Drugs limits the cultivation of the cannabis plant for the production, its manufacture, export, import, distribution of, trade in, and the use of cannabis or cannabis resin exclusively to medical and scientific purposes[10]. This limitation covers the plant in its entirety, the flowering and fruiting tops and the seeds and leaves of the cannabis plant, when accompanied by the tops.

In accordance with its Article 28(2), the Single Convention on Narcotic Drugs does not apply to the cultivation of the cannabis plant, when it is cultivated exclusively for industrial purposes (fibre and seed) or horticultural purposes.

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 drug trafficking[11] obliges Member States to take the necessary measures to ensure that, when committed without right, the conduct described in Article 2(1) of the Framework Decision is punishable[12], except when it is committed by its perpetrators exclusively for their own personal consumption as defined by national law[13].

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9 See Article 1(1)(j) of the Single Convention on Narcotic Drugs.
10 Article 4(c) of the Single Convention on Narcotic Drugs.
11 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004F0757
12 Article 2(1)(b) of Council Framework Decision 2004/757/JHA.
13 Article 2(2) of Council Framework Decision 2004/757/JHA.

The most common mode of recreational consumption of cannabis is smoking or smoking with tobacco[14]. In this case, cannabis-based herbal products placed on the market, that can be used for smoking, need to comply with the provisions of Directive 2014/40/EU on tobacco and related products (TPD)[15], which defines "herbal products for smoking" as "a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process". The TPD in itself does not lay out provisions on whether a product or its ingredients are legal or not, but instead intends to regulate products which can be legally placed on the market.

These products are specifically regulated by Articles 21 and 22 of the TPD with specific provisions for product labelling and ingredients reporting. Prior to placing a new product on the market, manufacturers and importers need to submit to the national competent authorities a list of ingredients and respective quantities by brand name and type[16].

4. The case of cannabinoids and, in particular, of cannabidiol ("CBD")

Cannabinoids are various naturally-occurring, biologically active, chemical constituents of the cannabis plant. The most notable cannabinoid is tetrahydrocannabinol (THC), the primary psychoactive compound in cannabis. Cannabidiol is another major, non-psychoactive cannabinoid.

Cannabinoids, as a class of compounds, are not listed in the schedules of the International Drug Control Conventions as such.

Tetrahydrocannabinol, its isomers and stereochemical variants as well as delta-9-tetrahydrocannabinol and its stereochemical variants are listed in Schedule I and Schedule II of the Convention of Psychotropic Substances of 1971, respectively. Pursuant to Article 1(e) of this Convention, these are thus to be considered as psychotropic substances.

In light of the judgment in Case C-663/18 and current state of scientific knowledge, it appears that cannabidiol, whether obtained as an extract of the *Cannabis sativa* plant or artificially synthetised, should not be considered as a drug within the meaning of the Single Convention on Narcotic Drugs provided that it does not have any psychotropic effect[17].

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14 Eurobarometer 2020 on tobacco and related products still to be published.

15 https://eur-lex.europa.eu/eli/dir/2014/40/oj.

16 According to the submitted information, herbal products for smoking, which contain or may be otherwise associated with cannabis, were reported in more than 20 Member States to date with a particular increase of products reported in the last two years (2019 and 2020).

17 The Commission services are assessing the implications of this judgment for other non-psychoactive cannabinoids.

5. Medical use

The requirements and procedures for the marketing authorisation of medicinal products for human use, as well as the rules for monitoring authorised medicinal products, are laid down in 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[18] and in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[19]. They also include harmonised provisions for the manufacture, wholesale or advertising of medicinal products for human use.

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[20] provides for common rules for the conduct of clinical trials to test the safety and efficacy of medicines under controlled conditions in the EU.

According to this comprehensive EU legal framework on pharmaceuticals, medicinal products for human use may be authorised either centrally, for the whole EU, by the European Commission, after independent scientific assessment by the European Medicines Agency (EMA), or nationally, for the territory of a Member State, by the national competent authority. The EU law determines for which medicinal products the centralised procedure is compulsory.

National competent authorities may recognize national authorisation of another Member State through the mutual recognition procedure[21]. An applicant may also seek national authorisations in several Member States in parallel through the decentralised procedure[22].

The data requirements and standards for the authorisation of medicines in the EU are the same for centrally and nationally authorised products.

The pharmaceutical legislation in the EU is comprehensive, and applies to any substance having properties for treating a disease or any substance modifying physiological functions by exerting a pharmacological or metabolic action. Consequently, cannabis derived medicinal products fall under the existing definition of a medicinal product laid down in the EU legislation. All generally applicable requirements to medicinal products apply also to those based on cannabis, including the rules on clinical trials or good manufacturing practices. The authorisation of medicinal products containing cannabis or cannabinoids does not differ from other medicines and can only be granted if safety, quality and efficacy of the product concerned are confirmed during the assessment.

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18 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF.

19 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF.

20 https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf. Clinical Trials Regulation EU No. 536/2014 is set to replace the Clinical Trials Directive 2001/20/EC once it comes into application.

21 See Chapter IV of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

22 Introduced by Directive 2004/27/EC amending Directive 2001/83/EC.

Directive 2001/83/EC recognises the category of traditional herbal medicinal products, which are eligible for simplified registration procedure. The advantages of this procedure is that no clinical tests and trials on safety and efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated on the basis of existing scientific literature. This procedure is however only accessible for products that have been used for at least 30 years, including at least 15 years within the EU, are intended to be used for self-medication (without the supervision of a medical practitioner) and are not administered by injection.

6. Food, feed and veterinary products

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[23], hereunder referred to as the General Food Law, excludes from the definition of food "*narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971*"[24].

The definition of 'food' contained in the General Food Law is applicable in most other acts of European food law. This means that what is classified as 'narcotic' in the Convention of 1961 or 'psychotropic' in the Convention of 1971 has a direct impact on whether or not these substances can be considered as 'food' under EU law. Moreover, the conditions under which certain parts of the plants (e.g. flower) or products derived from the *Cannabis sativa* plants are considered as 'narcotic' drugs have also to be assessed in line with the Conventions.

When some parts of the hemp plant or hemp derived products are placed on the market as 'food' in line with the General Food law, numerous other regulations pertaining to the EU food legislation may apply. The most relevant acts are listed below.

Novel Food

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods[25] imposes that 'foods' that have not been consumed to a significant degree in the EU before 15 May 1997 are subject to a safety assessment and an authorisation before their placing on the EU market.

In conformity with the General Food Law quoted above and the judgment of the Court of Justice in Case C-663/18, cannabidiol can be qualified as 'food' in so far as it does not have psychotropic effect and provided that also the other conditions of Article 2 of Regulation (EC) No 178/2002 are met. Applications for the authorisation of cannabidiol as a 'novel food' may therefore be considered valid, if all other validity conditions are complied with.

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23 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178.
24 Article 2(g) of Regulation (EC) 178/2002.
25 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32015R2283.

Flavourings

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[26] lays down the rules applicable to products that are added to food in order to impart or modify odour and/or taste. Different types of flavourings are defined by the Regulation and a number of them are subject to a pre-market authorisation including a safety assessment. However, some types of flavourings can be placed on the market without a prior evaluation and approval (e.g. flavouring preparations obtained from food), unless the Commission, a Member State or the European Food Safety Authority (EFSA) express doubts about the safety of that product.

Whether products fall in this category depends on whether the source material used for their production qualifies as 'food' under the Flavourings Regulation. The Regulation specifies that only source materials for which there is significant evidence of use for the production of flavouring shall be considered as food for its purposes.

Additives

None of the currently authorised food additives originates from the cannabis plant. If food additives would be produced from hemp plants, they would be subject to the rules of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[27].

Contaminants

Council Regulation 315/93/EEC of 8 February 1993 laying down Community procedures for contaminants in food[28] sets out the basic principles of EU legislation on contaminants in food. Commission Regulation (EC) No 1881/2006 of 19 December 2006 is setting maximum levels for certain contaminants in foodstuffs.[29]

Contaminants include inherent plant toxins such as THC. The presence of THC in hemp-derived foods (e.g. hemp seeds, hemp seed flour, hemp seed oil) are subject to the rules regarding contaminants contained in food.

For the time being, there are no maximum levels for THC in hemp derived foods established at EU level. Some Member States have established in their national legislation maximum levels (Belgium, Italy).

On the basis of work carried out by EFSA on THC as contaminant and exchanges in the "Agricultural Contaminants in food" working group of the Standing Committee on Plants Animals Food and Feed, discussions on the setting of EU maximum levels for delta-9-THC (as a sum of delta-9-THC and delta-9-THCA) in hemp seeds, hemp seed flour and hemp seed oil are ongoing and expected to be finalised in the course of 2021.

26 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1334.
27 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R1333.
28 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993R0315-20090807.
29 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150731.

Recommendation on the monitoring of THC in food

EFSA adopted a scientific opinion on THC in milk and other food of animal origin[30]. Only limited data on the presence of delta-9-THC in food of animal origin and from the transfer rate from feed to food of animal origin were available. The Agency noted that more data are needed on the presence of delta-9-THC in hemp-derived foods and foods containing hemp or hemp-derived ingredients. Therefore, a Commission Recommendation on the monitoring of the presence of delta-9-THC, its precursors and other cannabinoids in food[31] was adopted in 2016 in view of generating the data.

Health and Nutrition Claims

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[32] regulates the use of nutrition and health claims for foods. Only those health claims for which an authorisation has been granted may be used. To date, no claims have been submitted for authorisation on cannabinoids specifically and thus no claim can be used on these substances. However, there are claim submissions for authorisation on the effects of hempseed oil (*Cannabis sativa*) and on *Eupatorium cannabinum* (leaves). The treatment of health claims on these botanical substances has been temporarily suspended and therefore a final decision on their authorisation has not been taken yet by the Commission. Health claims, which were put 'on hold', may continue to be used on a temporary basis in accordance with Regulation (EC) No 1924/2006, which provides that such health claims may be made under the responsibility of food business operators provided that they comply with the said Regulation and with existing national provisions applicable to them.

Food supplements

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[33] only lays down compositional rules with regard to vitamins and minerals. The use of 'other substances' is not harmonised at EU level.[34] Therefore, Member States may adopt national rules in compliance with the Treaty.

It should be noted that the Member States' competent authority may determine the classification of a particular product as a medicinal product or as a food and thus possibly as a food supplement. According to established case-law, this is done on a case-by-case basis taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

30 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA Journal 2015;13(6):4141, 125 pp. doi:10.2903/j.efsa.2015.4141.

31 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016H2115.

32 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1924

33 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0046.

34 The use of foods containing cannabinoids from hemp was discussed with the Member States in 2012. A summary is available here: https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_gfl_sum_30042012_en.pdf.

Use of cannabis as active substance in veterinary medicinal products

Authorisation of cannabis as an active substance in a veterinary medicinal product is generally possible in application of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[35]. For the time being, however, there is no centrally authorised veterinary medicinal product with cannabis as active substance.

For the use in food-producing animals, a maximum residue limit has to be defined according to Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin[36]. Currently, there is only one entry in the list for Apocynum Cannabinum.

Use of cannabis derived products in animal nutrition

Cannabis-derived products for use as animal feed can be either classified as a feed material or feed additive. The definition of 'feed additive' is laid down in Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[37], and that of 'feed material' in Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed[38]. A precondition for the classification within the feed legislation is that the product at stake is not a 'veterinary medicinal product' as defined in Directive 2001/82/EC[39].

Regulation (EC) No 767/2009 lays down the general principles for the safety of feed. If a product is considered as feed material, it may be only placed on the EU market if it is either listed in the EU Catalogue of feed materials[40] or the Register of feed materials as referred to in Article 24 of that Regulation. The name of a feed material listed in the Catalogue may be used only on condition that all relevant provisions of the Catalogue are complied with. The Catalogue lists hemp flour (ground from dried leaves), hemp fibre (by-product from hemp processing), seeds, expeller and oil from C*annabis sativa L*. All hemp based feed materials must come from varieties of *Cannabis sativa L.* with a tetrahydrocannabinol content < 0.2% according to Regulation (EU) No 639/2014 (see hereunder).

In case the product is considered to be a feed additive, e.g. due to a chemical extraction process of cannabidiol, a pre-market authorisation procedure according to Regulation (EC) No 1831/2003 is necessary. As of today, there is no hemp derived feed additive authorised in the EU.

35 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0082. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC will become applicable on 28 January 2022

36 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010R0037.

37 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003R1831.

38 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1563192102685&uri=CELEX:32009R0767.

39 Commission Recommendation of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (2011/25/EU) (OJ L 11, 15.1.2011, p. 75).

40 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02013R0068-20170711.

7. Cosmetics

According to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[41] (hereunder referred to as the 'Cosmetics Regulation'), prohibited substances are listed under Annex II. Although most of the entries in Annex II correspond to specific substances, entry 306 of Annex II states "*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*".

The interpretation of entry 306 on Cannabis has great practical importance for the database of cosmetic ingredients ('CosIng'). It is a non-legally binding, publicly available database of cosmetic ingredients run by the Commission services. In practice, CosIng is widely relied on by the industry to identify the legal status of substances (whether they are banned, restricted, etc.).

Ingredients that are only derived from seeds or leaves (when not accompanied by the flowering or fruiting tops) of cannabis (for example *Cannabis sativa* seed oil/extract/powder/etc.) should not be prohibited, as they are not covered by the definition of cannabis set out in Article 1(1)(b) of the Single Convention on Narcotic Drugs. As regards cannabidiol extracted from the entirety of the *Cannabis sativa* plant, it will be necessary to assess the impact of the judgment of the Court of Justice in Case C-663/18 on the Cosmetics Regulation.

Essential oils from Cannabis, isolated from the resin, should not be used in cosmetics when derived from prohibited substances.

THC is covered by the entry *"Cannabis and cannabis resin and extracts and tinctures of cannabis"* in Schedule I of the Single Convention on Narcotic Drugs. Therefore, THC is a controlled substance and cannot be used in cosmetics.

8. Agricultural aspects

Hemp seed and varieties

The production and marketing of hemp (*Cannabis sativa L.*) seed for agricultural production is covered by Council Directive 2002/57/EC on the marketing of seed oil and fibre plants.[42] According to the Directive only officially certified hemp seed may be marketed in the EU for agricultural production, excluding ornamental purposes. Cannabis seeds intended for ornamental purposes is not covered by the Directive so they can be marketed without respecting the provisions of Directive 2002/57/EC (e.g., on germination, analytical purity, and certification). However, the rules of Council Directive 98/56/EC on the marketing of propagating material of ornamental plants[43] would need to be respected.

41 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549621036385&uri=CELEX:02009R1223-20180801
42 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002L0057
43 https://eur-lex.europa.eu/eli/dir/1998/56/oj.

Moreover, only varieties of hemp that are distinct, stable, sufficiently uniform and of satisfactory value for cultivation are included in the Common Catalogue of varieties of agricultural plant species, under Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species[44] and can be marketed in the EU for agricultural production. There are currently 68 authorised hemp seed varieties (2019)[45].

Hemp seed intended for agricultural production harvested in third countries can only be imported in the EU on the basis of EU equivalence[46]. Third countries seeking to export to the EU must meet the same requirements for seed production, certification, labelling and packaging as seed harvested in the EU and complying with EU rules.

However, the marketing of any propagating material (plantlets) of hemp is not covered by EU legislation except for ornamental purposes (Directive 98/56/EC).

The EU seed legislation does not lay down any requirements for the THC content of hemp seed as such, however Member State are - during the variety testing - checking the threshold laid down for direct payments (see below, Commission Delegated Regulation (EU) No 639/2014).

EU legislation on marketing of seeds is based and aligned with the OECD Seed Schemes on seed moving in international trade. Discussion has started to update the OECD hemp seed certification standards to meet developments in relation to feminised seed breeding and production of cannabidiol.

Direct payments

As for any other crop, farmers can be granted decoupled area-based direct payments for growing industrial hemp, provided that they meet all the eligibility conditions to receive direct payments, and in particular that the variety cultivated has a THC content not exceeding 0.2%, in line with Article 32(6) of Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy[47]. Moreover, in Member States where the sector undergoes certain difficulties, hemp farmers can in addition be granted Voluntary Coupled Support (VCS). VCS for hemp is currently only implemented in France, Poland and Romania. The amount of area payments for hemp cultivation may vary per Member State, as it should be limited to the extent necessary to maintain the current level of production.

There is currently a debate on the 0.2% THC limit in relation to its possible impact on the cannabidiol content of the hemp plants, and considering the fact that the cannabidiol market is now developing. In the context of the current discussions on the Common Agricultural Policy reform, the European Parliament has proposed to increase the THC limit to 0.3%. This will be discussed within the ongoing trilogue meetings.

44 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1563197508073&uri=CELEX:32002L0053.

45 http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search//public/index.cfm?event=SearchForm&ctl_type=A.

46 Article 20(1)(b) of Directive 2002/57.

47 https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32013R1307.

Article 9 of Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014[48] establishes the requirement to use certified seed of varieties listed in the 'Common Catalogue of Varieties of Agricultural Plant Species'. It also establishes that each cultivated hemp variety receiving direct support from the common agricultural policy has to be checked every year for its THC content according to a fixed method. If for two years in a row the average of all the samples of a given variety exceeds the THC content of 0.2 %, the Member State shall prohibit the marketing of such variety. These rules only apply to hemp subject to and benefiting from common agricultural policy support.

In addition, following the judgments of the Court of Justice in Cases C-462/01[49] and C-207/08[50], the common agricultural policy rules on hemp must be interpreted as precluding national legislation that has the effect of prohibiting the cultivation and possession of industrial hemp covered by those Regulations. In other words, as the common agricultural policy regulations already provide strict conditions to prevent illegal use of the hemp plants, Member States cannot prohibit the cultivation of industrial hemp on their territory and deprive the farmers of this opportunity.

Imports of hemp

All imports of hemp are currently subject to an import licence requirement on the basis of Article 189 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products[51], and of Commission Delegated Regulation (EU) 2016/1237 of 18 May 2016[52] and Commission Implementing Regulation (EU) 2016/1239 of 18 May 2016[53]. In addition:

- Raw true hemp falling within CN code 5302 10 must have a THC content not exceeding 0.2%;
- Hemp seeds for sowing must be accompanied by proof that the THC content of the variety concerned does not exceed 0.2%;
- Hemp seeds other than for sowing may only be imported by importers authorised by the Member State. Authorised importers have to submit proof that the seeds have been placed in a condition that excludes use for sowing, or mixing with seed other than hemp (within a maximum limit of 15% or 25% in exceptional cases) for the purposes of animal nutrition, or exporting to a third country.

Besides, Article 189 of Regulation (EU) No 1308/2013 allows Member States to apply more restrictive rules in compliance with EU Treaties and international obligations.

Within the common agricultural policy reform, the Commission has proposed to remove the provisions related to hemp imports[54].

48 https://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex%3A32014R0639.
49 ECLI:EU:C:2003:33.
50 ECLI:EU:C:2008:407.
51 https://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex%3A32013R1308.
52 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1237.
53 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1239.
54 COM/2018/394 final.