

THC regulations regarding industrial hemp in the EU

Summary:

- 1961: The single Convention on Narcotic Drugs was the first international treaty to include Cannabis as a controlled substance.
- 1963: The discovery of THC.
- 1970: A common market organization for the flax and hemp sector in the EU was established.
- 1971: General guidelines for aid concession regarding hemp and flax.
- 1972: Protocol amending the Single Convention on Narcotic Drugs included Delta-9-THC (hereinafter „THC“). Provisions were made to exclude industrial hemp (non-drug Cannabis) as a „narcotic“ substance. Article 28 specifically excludes industrial hemp from these regulations, stating: „This convention shall not apply to the cultivation of the Cannabis plant exclusively for industrial purposes (fibre and seed) or horticulture purposes“.
- 1982: It was noted in the EU Directive 1420/82 for the first time that „the increasing abuse of narcotics in the Community is likely to endanger human health“ and that THC safeguards have to be determined for industrial hemp.
- 1984: For the first time specific THC limits for industrial hemp were determined in Europe. For the marketing years until 1987 a limit of 0,5 %, for subsequent marketing years a limit of 0,3 % was set. "Protection of public health" was the justification for this decision.
- 1999: The limit was lowered from 0,3 % to 0,2 %, to prevent the cultivation of illicit drug type Cannabis in industrial hemp crops.
- 2013: The European Commission eliminated the requirement for Member States to report THC data from field hemp samples to the Commission. This went into effect on 29 April with the implementation of EC 393/2013. Since then, each Member States has been left to determine if a hemp variety is permitted or not.
- 2016: Commission Implementing Decision (EU) 2016/17 attempted to ban the FINOLA variety of hemp in the UK. This went into effect on 7 January 2016, and was formally retracted by the UK on 2 March 2016.

Scientific distinction between hemp and marijuana

The first scientific study to deal with a taxonomic distinction between hemp and marijuana was published; "A Practical and Natural Taxonomy for Cannabis, Taxon Vol. 25, No. 4 (Aug., 1976), pp. 405-435" by Ernest Small and Arthur Cronquist. The two authors adopt a concentration of 0,3 % Δ 9-THC (dry weight basis) to distinguish between „hemp“ (non-drug Cannabis) and „marijuana“ (drug Cannabis).

Evaluation

The THC limits set by the EU in the year 1984 to distinguish between „industrial hemp“ and „drug type Cannabis“ are comprehensible from a scientific point of view.

However, this is not the case for the decision that was made in 1998, which led to a decrease in the THC limit from 0,3 % to 0,2 % in 1999. Again this further lowering of THC level was justified to prevent the cultivation of illicit drug type Cannabis and in industrial hemp crops. Yet no evidence was presented to support this opinion. According to drug market statistics, more people have begun to use drug Cannabis since the end of the last century when the limit for hemp THC was lowered to 0,2 %. This includes the use of drug Cannabis for both medical and recreational purposes. Moreover, THC levels have increased significantly in drug Cannabis samples during the last two decades. This means that lowering the THC limit for industrial hemp has had no effect on illicit drug use.

The intention to prevent the cultivation of drug type Cannabis by lowering THC level to 0,2 % for industrial hemp is also not reasonable by botanical means as explained in the following. *Cannabis sativa* is naturally dioecious, with separate male and female plants. Drug Cannabis producers actively remove all male plants to prevent pollination, as the production of seed reduces the production of THC. This method of seedless cultivation („sinsemilla“) produces the highest possible quality of the desired drug product, with high levels of THC (>15 %) and also increases female flower yields considerably. By contrast, hemp that is grown for seed requires male plants, to provide pollen for seed production.

Cross-pollination of drug type Cannabis (marijuana) with hemp pollen would significantly reduce THC production in the marijuana plants and reduce „drug quality“ by producing unwanted seeds in the marijuana flowers. Cross-pollination of hemp with marijuana pollen could increase the THC content of hemp, but only after several generations of careful selection. Thus, marijuana that is cultivated in a hemp field would be pollinated by hemp, produce seed and contain less THC than in comparison to unpollinated plants. Such product would be less valuable in modern markets for high THC products.

The intentions to minimize illicit and harmful drug production by the EU are understandable. But this has not been achieved by lowering the THC limits in industrial hemp from 0,3 % to 0,2 %. Instead, hemp varieties in the EU have been subjected to a haphazard application of this regulation. Several industrially valuable hemp varieties, especially from East Europe, have been eliminated from the market by lowering the THC limit to 0,2 %. The decision to lower content from 0,3 % to 0,2 % was either based on a misunderstanding of botanical genetics or the stated „official reason“ was not the real intention at all.

The „EU Drug Markets Report: In-Depth Analysis“ by the „European Monitoring Centre for Drugs and Drug Addiction and Europol“ depicts the mean potency of Cannabis products in several European countries. It is obvious, that the average levels of THC in illicit Cannabis vary between 1 % and 13,4 % from 2010 to 2014. This evidence shows that reducing the THC limit of industrial hemp from 0,3 % to 0,2 % after 1999 has had no noticeable effect on illicit Cannabis production. By reintroducing the former European THC limits of 0,3 % for industrial hemp, there is sufficient room to distinguish between illicit drug type Cannabis and industrial hemp.

In 2013, The European Commission eliminated the requirement for Member States to report THC data from field hemp samples to the Commission with the implementation of EC 393/2013.

This went into effect on 29 April. Since then, each Member States has been left to determine if a hemp variety is permitted in that specific Member State or not.

So, instead of one central authority, the hemp industry now faces 27 different authorities that are responsible for administering complex sampling regulations for hemp in the EU, and potentially 27 different interpretations of the EU's field sampling regulation.

Regulation 393/2013 also returned two hemp varieties to the list of EU approved varieties, after they were mistakenly removed in previous years. Unfortunately, shifting this responsibility to the member state level has not insured the good administration of regulations related to hemp and THC. For example, in 2016, the United Kingdom tried to ban the FINOLA variety of hemp with Commission Implementing Decision (EU) 2016/17, which was accepted by the EC on 7 January 2016. The evidence for this ban came from two poorly controlled samples in Northern Ireland; one in 2013 and one in 2014. Subsequent to a judicial review, the United Kingdom's Department of Environment, Food and Rural Affairs (DEFRA) admitted to a serious mistake and had to ask the EC to cancel Decision 2016/17 shortly after it had been submitted. With THC limits of 0,3 % the benchmark for the sample procedure and evaluation (detection limit, uncertainty measurement) would be more practical and still a solid differentiation between illicit drug type Cannabis and industrial hemp possible.

To ensure that hemp varieties provide adequate safeguards in the long term, certifications are required. Seed certifications are a quality assurance system whereby seeds intended for marketing are subject to official control and inspection. The Seed Certification Scheme is an official system supported by EU and national legislation and international protocols to ensure that seed is produced, multiplied and marketed according to predetermined standards and systems, which is also applied to every hemp variety on the market. This is the most efficient way to control hemp cultivation and field testing should be only done if the authorities have a reason to believe that a farmer is not using certified seeds.

Another important point is, that in all EU directives regarding industrial hemp, THC limits are always mentioned in conjunction with subsidiary payments. Requirement for these subsidies is the compliance to the 0,2 % THC limit, in case of deviation from this limit, the farmer will not receive EU aid for this acreage.

Although the current limit (0,2 %) refers obviously only to subsidies, almost all European countries have oriented their hemp cultivation regulation (and exemption permits in the particular national narcotic acts) on the THC limit of the relevant EU directive.

For example the industrial hemp cultivation in Austria is one exception. According to the Austrian Narcotic Substance Act (§35 Annex I Suchtmittelgesetz (SMG)) industrial hemp cultivars may be grown, which are either noted in the Austrian or in the European variety catalogue **or** do not exceed a THC limit of 0,3 %. Therefore it remains the decision to the farmer, whether he applies for the European subsidy and chooses a cultivar which is present in the EU variety catalogue (< 0,2 %), or he renounces the aid and cultivates a variety of his own choice (with a THC limit up to 0,3 %) according to the Austrian narcotic act.

The 0,2 % limit from the EU directives, which originally was only intended to regulate the support of cultivation for industrial hemp, and its adoption by the national narcotic acts and laws has become a restriction for the whole hemp industry. Without an official change of the THC limits on EU level, industrial hemp with the former safeguards of 0,3 % can not be bred and used for sowing in most European countries. National authorities (e. g. the German BfArM) will not change their current

rules and regulations without a clear signal from Brussels. On the other hand the restoring of the former THC limit of 0,3 % should have a direct impact on the THC regulations and differentiation between illicit drug type Cannabis and industrial hemp in the national narcotic acts (e. g. BtmG) and drug laws in European countries.

The hemp food market is showing intensive growth and hemp foods have the potential to provide not only a so called “super food” but also an important contribution to basic nutrition for the (European) population. The raw material for hemp foods, the hemp seeds, can be grown environmentally friendly and sustainable all over Europe.

To produce high (food) quality hempseeds in a realistic, economic yield-ratio the European hemp industry needs specifically cultured varieties and those seed for sowing. Obviously, based on botanical principles, “seed varieties” produce significantly more branches, bracts and flowers in the upper third of the plant compared to “fiber varieties”. Cultivars for seed, bred or grown to produce a dense elongated cluster of flowers (hence fruit) are always going to be higher in THC simply because sampling is unbalanced towards more flowers (hence more branches and bracts). This disadvantaging effect is reinforced by early-season flowering, which would tend to result in dropping of lower foliage with less THC. Fiber and dual purpose cultivars, with less amount of flowers, are at an advantage when same (unprecise) period of test method is applied. Additionally, and of particular importance, monoecious cultivars are advantaged because male flowers (less THC) that are present dilute the THC content.

This brings the evaluation to an important point: The international level playing field! E. g. Canada, second largest grower of hemp seeds and largest producer of hemp foods worldwide, has an Δ 9-THC limit of 0,3 % on the field (based on the former EU limit from 1987 till 1999). And, together with their THC limit of 10 ppm (10 mg/kg) in food intermediate products, there have not been any health problems reported in the last 12 years of the North-American hemp food market. Regulations similar to Canada are planned in the USA and India. China (still the largest grower of hemp seeds) and South America have even less strict regulations.

Conclusion: Due to the limitation of 0,2 % THC on the field, the hemp food industry in Europe has already a significant competitive disadvantage and this will become bigger in subsequent years.

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References:

- Small, E. and Antle, T. (2003), „A Preliminary Study of Pollen Dispersal in Cannabis sativa in Relation to Wind Direction“, Journal of Industrial Hemp, Vol. 8(2) 2003
- European Monitoring Centre for Drugs and Drug Addiction and Europol (2016), EU Drug Markets Report: In-Depth Analysis, EMCDDA–Europol Joint publications, Publications Office of the European Union, Luxembourg
- Council regulation (EEC) No 1430/82 of 18 May 1982 providing for restrictions on the importation of hemp and hemp seed and amending Regulation (EEC) No 1308/70 in respect of hemp
- Council Regulation (EEC) No 2059/84 of 16 July 1984 laying down general rules relating to the import restrictions on hemp and hemp seed and amending Regulation (EEC) No 619/71 in respect of hemp
- Council Regulation (EC) No 1251/1999 of 17 May 1999 establishing a support system for producers of certain arable crops
- Council Regulation (EC) No 1672/2000 of 27 July 2000 amending Regulation (EC) No 1251/1999 establishing a support system for producers of certain arable crops, to include flax and hemp grown for fibre
- Implementing Decision (EC) No 393/2013 of 29 April 2013, returning two hemp varieties and eliminating the requirement for Member States to report THC hemp values to the European Commission
- Implementing Decision (EC) No 2016/17 of 7 January 2016 attempted to ban the FINOLA variety of oilseed hemp in the UK
- Austrian Narcotic Substances Act (SMG): § 35, Annex I

Appendix:

- I. Small, E. & Cronquist, A. 1976. A Practical and Natural Taxonomy for Cannabis. Taxon 25 (4), Aug 1976: 405-435.
- II. European Monitoring Centre for Drugs and Drug Addiction and Europol (2016), EU Drug Markets Report: In-Depth Analysis, EMCDDA–Europol Joint publications, Publications Office of the European Union, Luxembourg
- III. Excerpts of relevant EU directives

Appendix I

Excerpt from "A Practical and Natural Taxonomy for Cannabis" (1976)

The part where the 0,3 % shows up is in the discussion of where to draw the chemical line between hemp and marijuana in this paper:

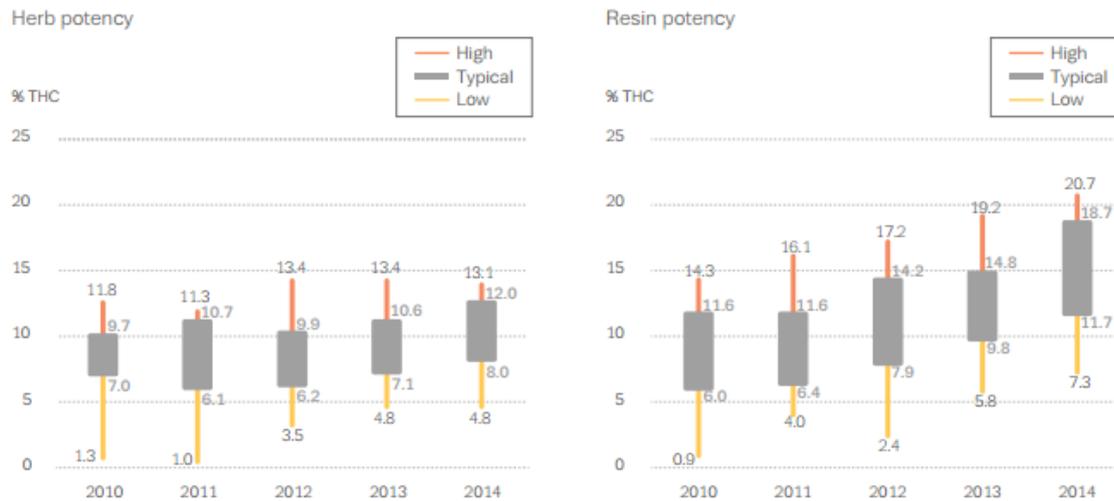
It will be noted that we arbitrarily adopt a concentration of 0.3% Δ^9 -THC (dry weight basis) in young, vigorous leaves of relatively mature plants as a guide to discriminating two classes of plants. This is based on standard-grown material in Ottawa in gardens, greenhouses and growth chambers, and of course on our analytical techniques. Dr. C. E. Turner, who has conducted extensive chemical analysis of *Cannabis* at the University of Mississippi, has agreed (pers. com.) that this is a reasonable figure to discriminate two classes of plants. We found that generally approximately 2% of the dry weight of young leaves of mature plants, or of the average dry weight of the softer parts of the female flowering plant (leaves, small twigs, flowers) is comprised of cannabinoids. Since CBD (cannabidiol, the most common non-intoxicant cannabinoid) and THC collectively usually compose the bulk of the cannabinoids present, one can crudely adjust literature reports of cannabinoid concentration for comparison with our values on the basis that the concentration of CBD and THC should sum to roughly 2%.

It has been shown that two widespread classes of plants can be discerned with respect to intoxicant properties (Small and Beckstead, 1973a, 1973b). Plants orig-

Appendix II

European Monitoring Centre for Drugs and Drug Addiction and Europol (2016), EU Drug Markets Report: In-Depth Analysis, EMCDDA–Europol Joint publications, Publications Office of the European Union, Luxembourg

FIGURE 3.6
Trends in cannabis potency and retail price in the EU, 2010–14



Appendix III

Detailed analysis of the relevant EU directives

| Year | Directive | Topic | Effects |
|------|-----------|--|---|
| 1970 | 1308/70 | Common market organization for the flax and hemp sector | Cornerstone of hemp in the European Union |
| 1971 | 619/71 | General guidelines for aid concession regarding hemp and flax | Guidelines for subsidies |
| 1982 | 1430/82 | Import restrictions on hemp bast and seed, limiting of varieties | General THC safeguards were requested |
| 1984 | 2059/84 | Restriction of aid for cultivation, measuring THC, import restrictions on hemp bast and seed | THC limits were lowered from 0,5 % down to 0,3 % |
| 1999 | 1251/99 | Laying down general rules for granting aid for hemp | THC limits were lowered again from 0,3 % to 0,2 % |
| 2000 | 1672/2000 | Establishing a support system for producers of hemp | Subsidies only for 0,2 % THC hemp varieties |

Directive 1430/1982

Aid shall be granted only for hemp grown from seed of varieties providing certain safeguards to be determined in respect of the content of intoxicating substances in the harvested product.

Motivation

Whereas the increasing abuse of narcotics in the Community is likely to endanger human health; Whereas the stalk of true hemp may in some cases contain intoxicating substances; whereas, however, the cultivation of hemp in the Community is of considerable significance in some regions; whereas, to prevent the danger referred to above from being increased by the cultivation of hemp in the Community and by imports of raw hemp and hemp seed, the aid granted under Article 4 of Council Regulation (EEC) No 1308/70 of 29 June 1970 on the common organization of the market in flax and hemp (3), as last amended by the 1979 Act of Accession, **should be limited to varieties providing adequate safeguards in terms of human health, and imports of hemp and hemp seed which do not provide adequate safeguards should be prohibited.**

Directive 2059/1984

For hemp, aid shall be granted only to the grower and only for hemp grown from certified seed of varieties contained in a list to be drawn up in accordance with the procedure laid down in Article 12 of Regulation (EEC) No 1308/70. This list shall include only varieties for which a Member State has found by analysis that the weight of THC (tetrahydrocannabinol) in the weight of a sample maintained at a constant weight is:

- for the purpose of granting aid for the marketing years 1984/85 to 1986/87, not more than 0,5 %,
- for the purposes of granting aid for subsequent marketing years, not more than 0,3 %.

The sample shall consist of the upper third of a representative number of plants selected at random at the end of their flowering period and with stalks and seeds removed.

Motivation

Whereas the second subparagraph of Article 4 (1) of Regulation (EEC) No 1308/70 states that aid shall be granted only for hemp grown from seed of varieties providing certain safeguards to be determined in respect of the intoxicating substance content in the harvested product;

whereas Article 3 (1) of Council Regulation (EEC) No 619/71 (4), as last amended by Regulation (EEC) No 1 775/76 (s), should therefore be amended to specify **that aid shall be granted only for hemp grown from certified seed of varieties the average tetrahydrocannabinol (THC) content of which has been found not to exceed certain acceptable limits;**

whereas, for the satisfactory operation of the aid system, it should be specified that a list of varieties meeting the required conditions be drawn up; **Whereas, pursuant to Article 2 of Regulation (EEC) No 1430/82, imports of hemp and hemp seed for which adequate health safeguards cannot be guaranteed should be prohibited.**

Directive 1251/1999

For hemp grown for fibre, the area payment shall be made only where: the varieties used have a tetrahydrocannabinol content not exceeding 0,2 %. However, that limit shall be set at 0,3 % for the 2000/2001 marketing year, the entire crop is sold under contract to authorised primary processors for uses other than human nutrition.

The Member States shall fix a maximum area eligible for area payments for hemp for each production area so that they can ensure verification of the tetrahydrocannabinol content of the crops grown on at least 30 % of the areas for which area payment applications have been made. To ensure that the maximum areas fixed are not exceeded, the Member States shall introduce a system of prior approval for the cultivation of hemp restricting sowing under this scheme to those areas.

Motivation

Specific measures should be laid down for hemp, to ensure that illegal crops cannot be hidden among the crops eligible for area payments, thereby disturbing the common market organisation for hemp. Provision must therefore be made for area payments to be granted only for areas sown to varieties of hemp known to have a low psychotropic content. In addition, the Member States should restrict the areas sown to hemp in each production area to ensure that compliance with the maximum levels of psychotropic substances can be closely monitored on the areas covered by payment applications. A system of prior approval should therefore be introduced to ensure that the maximum areas fixed by the Member States are not exceeded.

Directive 1672/2000

For hemp grown for fibre, the area payment shall also be made only where the varieties used have a tetrahydrocannabinol content not exceeding 0,2 %.

Motivation

Specific measures should be laid down for hemp, to ensure that illegal crops cannot be hidden among the crops eligible for area payments, thereby disturbing the common market organisation for hemp. Provision must therefore be made for area payments to be granted only for areas sown to varieties of hemp offering certain guarantees with regard to the psychotropic substance content.