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CBD and transparency: Not all CBDs are the same

By Barbara Brockway 24-Jun-2020

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As the laws surrounding the use of cannabis and related products change, Barbara Brockway asks, how c

cosmetics companies be sure that they are using the right ingredient from the right source?



CBD has already become a familiar term, despite people being unsure of the exact nature of CBD oils and relationship to *Cannabis sativa*.

In April's SPC article *CBD & skin: A scientific history*, Rouah Al-Wakeel introduced CBD and the endocann system (ECS), explaining how its primary function is to maintain the body's equilibrium^[1].

She went on to write about cannabinoids in skin, mentioning the many cannabinoid receptors found in skin how skin naturally synthesises its own endocannabinoids (anandamide and 2-AG).

These two skin cannabinoids bind to skin cannabinoid receptors and suppress cellular proliferation, trigger differentiation and control the release of inflammatory mediators.

Skin endocannabinoids can also initiate lipid production and reduce pain and itching^[2].

The current literature indicates that CBDs may be beneficial for acne and atopic dermatitis, however, studies to be small and so non-conclusive^[3].

The shortage of authoritative studies has divided scientific opinion and left many toxicologists feeling that insufficient information on the pharmacokinetics and toxicity of topical CBD.

Dermal absorption of CBD from cosmetics, even after repeated use, would be expected to be low, because of its lipophilic nature, however more studies are needed to be certain.

To help address the need for good scientific information, The International Cannabis and Cannabinoids Institute (ICCI), has been established. It is bringing together global experts from academia, health care and industry to research the various uses of medical cannabis and investigate anecdotal claims about health benefits.

It is expected that its studies will continue to fuel the trend for cannabinoids (phytocannabinoids), CBD oil, synthetic cannabinoids and their derivatives in cosmetics.

Sources of CBD are set to rise

More CBD is used in food supplements than in cosmetics however, the demand for CBD in skin care is growing. It is estimated that the legal usages of *Cannabis sativa* will rise to over \$60 billion in the next few years^[4], due to the lessening of legal constraints on hemp cultivation.

The US 2018 Farm Bill now fully legalises the cultivation and sale of hemp, subject to state and federal regulations. Consequently, cannabis is now grown legally in over ten USA states^[5] (with more states expected to follow).

The regulations controlling cannabis cultivation are being readdressed globally and everyone wants a slice of the lucrative market.

Cosmetic grade hemp and CBD oil may be coming into Europe from almost anywhere. It could have originated in countries from China to Chile, from North Korea to New Zealand as well as from Russia and the US.

**The US 2018 Farm Bill now fully legalises the cultivation and sale of hemp
subject to state and federal regulations**

Choosing from the myriad of cannabis products

This upsurge in the availability of cannabis related materials has left cosmetic formulators choosing from a wide range of different natural *Cannabis sativa*-derived cannabinoids and extracts, not to mention synthetic cannabinoid products. This begs the question; which cannabinoids can and should, cosmetic formulators be using?

Al-Wakeel pointed out that the medical potency of the different commercial CBD products relates to their composition in terms of both concentration and constituent cannabinoids. She mentioned "the entourage effect" where efficacy can be boosted through synergy with other natural companion substances and she described three main commercial CBD products as follows:

Full Spectrum: All the natural *Cannabis sativa* cannabinoids with <0.3% the psychoactive Tetrahydrocannabinol (THC);

Broad Spectrum: With just the following cannabinoids: Cannabidiol (CBD), Cannabinol (CBN), Cannabidiol (CBDV), Cannabigerol (CBG) and Cannabichromene (CBC);

And **Isolate:** >99% CBD.

If only the situation was as simple as just choosing from the three above. The true situation is even more complicated.

Before considering the potency or better still, the cosmetic value of a cannabis-derived cosmetic ingredient, it is important to know the law.

In the EU, it is essential to know if the CBD was derived from the correct part of an EU registered cultivar (i.e. a licensed grower)? Because despite strict EU regulations stating "cosmetic ingredients must be made using industrial hemp varieties (low in THC), which are registered on the European Commission's Plant Variety Database and have been grown by licenced growers", cannabis materials from other cultivars are finding their way into the market.

Low or no THC

As I write this article under coronavirus lockdown, Switzerland allows cosmetics with CBD, if the THC content is less than 1%.

European countries have their own restrictions. France insists there is zero THC in CBD isolates and thinks logically, isolates should be just pure CBD.

Austria and Luxembourg allow CBD products with a THC content of up to 0.3% and CBD is totally illegal in Slovakia and Lithuania.

As there is so much contradictory information about the THC levels allowed in the EU, I asked Amanda Isc Bloom Regulatory to clarify the situation.

She said, "It is a common misconception that the CBD used in cosmetics destined for the EU must contain less than 0.2% THC. From a practical point of view, it will only be feasible to use industrial varieties of cannabis for which the level of THC in the plant must be below 0.2%."

However, THC is actually prohibited in cosmetic products and so cosmetics need to avoid containing THC.

Isom went on to say: "Using CBD and cannabis materials in a cosmetic is a complex area. Not only must companies ensure compliance with the specific sector legislation for the destination market, but they must also be mindful of local legislation on controlled substances. And this often hinges on issues of purity and traceability."



Materials from Cannabis sativa flowering or fruiting tops are permitted

It is especially important to know the part(s) of the plant used to make the CBD as EU regulations demand

cosmetic grade CBD originates only from seed and or the leaves.

It is worth mentioning in passing that the United Nations Conventions on International Drug Control, define controlled cannabis as "the flowering or fruiting tops of the cannabis plant". They do not include materials from *Cannabis sativa* seed or leaves, as controlled substances.

This position is mirrored in the EU cosmetic regulations - and will be the UK regulations immediately post which allow cosmetics to contain CBD, "however it shall be prohibited from use in cosmetic products, if it prepared as an extract or tincture or resin of Cannabis in accordance with the Single Convention"^[6].

CBD can therefore originate from the seeds and or the leaves of the plant, provided no material from cannabis fruiting tops is present.

To be certain of compliance to EU cosmetic regulations, only use CBD from supply chains that can demonstrate the biomass originated just from the leaves of EU approved cultivars <0.2% THC, as anything else could be deemed illegal.

CBD is not a controlled substance

The US definition of marijuana in the Controlled Substances Act (CSA) has been amended to exclude hemp derivatives. They define hemp as follows: "*Cannabis sativa* and any part of that plant, including the seeds and derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with delta-9 tetrahydrocannabinol concentration of not more than 0.3 % on a dry weight basis."

To reduce confusion, the WHO Expert Committee on Drug Dependence have requested that the convention that CBD preparations are not under their international drug control^[7].

FDA & EU Regulations concerning CBD

Meanwhile, the US Food and Drug Administration (FDA) has only approved pharmaceutical-based CBD and does not consider CBD as a food or dietary supplement. The FDA is genuinely concerned about companies selling products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act).

It says it is taking steps to aid the lawful marketing of appropriate cannabis and cannabis-derived products and remains committed to protecting public health.

Companies who are not thoroughly checking the levels of THC and the origins of their cannabis and cannabis-derived ingredients are risking severe penalties.

The FDA and the Federal Trade Commission (FTC) are acting. They have already sent warning letters to US companies marketing CBD dietary products with overstated health claims^[8].

Remembering too, that the cosmetic use of CBD in Europe needs to satisfy (EU) Regulation No 1223/2009 (Cosmetics Regulation), which defines a cosmetic product as any substance or mixture intended to be placed in contact with external parts of the human body for the purposes of cleaning, perfuming, changing its appearance, protecting, keeping in good condition or correcting body odours. Claims evoking pain and itch reduction, cell differentiation and controlling the release of inflammatory mediators, would not be appropriate for a cosmetic product.

It is worth mentioning again here that the cannabis listed in the Single Convention is material from the flowering and fruiting tops (and not the cosmetic grade materials deriving from the seed and or the leaves) as Annex I of the EU Cosmetic Regulation includes any substance referred to in Tables I and II of the Single Convention on Narcotic Drugs of 1961 (the Single Convention) as substances, which are prohibited from use in cosmetics.

CBD quality

CBD oils can be all described as concentrated *Cannabis sativa* leaf/seed extracts, which are then dissolved in edible oil(s). It is not the purity but the impurities in CBD oils that matter.

Hemp is a phytoremedial crop used to repair ground contamination^[9] so some of the hemp, which is illegal in some countries, finding its way into supply chains, will have been grown on soils contaminated with toxic substances. Heavy metals, and pollutants such as monocyclic and polycyclic hydrocarbons (known carcinogens) etc, along with pesticides and other agrochemicals, can all become contaminants.

There is no recognised quality standard or extraction procedure for CBD. For safety, the grade and suitable solvents need to be known. Ethanol and isopropyl alcohol are amongst the most popular solvents used and supercritical CO₂ extracted *Cannabis sativa* are also available.

Extracts may be further refined by chilling (winterisation) and filtering to remove precipitate material before dissolving in the edible oils.

With no safety standard certification for cannabis-based products, the situation is open to abuse. The BBC consumer programme *Trust Me, I'm a Doctor* sent 12 popular CBD oil products to the ICCL for analysis, with collaboration with the University of Prague, found that three of the products contained less CBD than was claimed. One, which should have had 2.75% CBD, contained only 1.7% CBD. Another, which should have had 5%, contained 2.9% CBD. A third product claiming to contain 500mg in 10ml of CBD (5% CBD), contained only 0.00075%.

When the ICCL looked at the quality of CBD products available in the EU they were concerned that the levels of THC were not listed and hydrocarbons, pesticides and other recognised impurities could be present^[10].

An independent 2019 report commissioned with FERA Science confirms its concerns^[11].

The results showed levels of contamination amongst UK CBD products – all of which were imported. They included heavy metals rhodium, manganese, chromium, and copper along with polycyclic aromatic hydrocarbons (including benzo[a]anthracene, chrysene, benzo[b]fluoranthene, and benzo[a]pyrene). Some CBD products also contained polychlorinated biphenyls (both dioxin-like and non-dioxin like PCBs), and furans.



Crime adds to supply chain risk for cannabis-based cosmetic materials

The lucrative CBD market is swamped with material. As a result, very few of the supply chains currently operating across Europe are compliant. Back in 2017, the United Nations Office on drugs and crime estimated that there were 183 million cannabis users and that cannabis was being grown illegally in 135 countries^[12].

Highly sophisticated underground supply chains have developed over the decades of abuse. The likely involvement of hardened criminals means, more than ever, suppliers' documents stating that a CBD/*Cannabis sativa*-based ingredient was made only from the leaf and or seed of an EU registered plant variety, cannot be assumed reliable. Documents can be easily falsified as food scandals, when horse meat was found in beef products prove^[13].

Even in the most tightly managed systems, documents alone are not proof of compliance. Blockchain supply chain ledgers secure digital information but if the digital information contains misinformation then blockchain simply secures the lie.

Also, when brands are challenged by the authorities, being confused about the legal status of CBD is not an acceptable defence in the eyes of the law.

Large fines mean it has never been more important to know the source of the CBD. Brands must be confident in their supply chain and have recourse, in the event of non-compliance to CBD regulations.

With the US supplying 40% of the global market share and Asian sales expected to reach US\$1.7bn by 2025, CBD will be entering the EU market in increasing amounts.

No brand would openly admit to using illegal, unethical, unsustainable sources. However, all the while the authorities allow isolates to be imported with only a CAS number, no certificate of origin or supporting paper to confirm the cultivar, illegal Cannabis sativa products will enter and be used in the EU.

Transparency and traceability in global supply chains

Isom points out that "the horizontal link between the EU Cosmetics Regulation and the International Single Convention on Narcotic Drugs means that it is not permissible to use the flowering tip of the cannabis plant for cosmetics, even if it is obtained from Hemp varieties. Therefore, in order to be able to demonstrate compliance is especially important to not only obtain CBD that is not processed from the flowering tip part of the plant but to be able to show the full traceability from the processed extract to use in the final product."

Technology is available to give traceability throughout the entire supply chain from crop-to-shop. The digital revolution has made track-and-trace part of consumers' everyday experience for parcel deliveries.

As already mentioned, digital documents can be secured using blockchain distributed ledger systems. Smartphones are allowing consumers to instantly access information shared via the cloud. Sadly, in practice, few brands feel the need to use these technologies.

One exception is the UK based company, TTS Pharma^[15]. It finds itself alone in seriously investing in vertical integration to control every step from farm to product. Unlike products from unregulated sources, TTS Pharma products provably satisfy the UK and European regulations. It has established its own fully traceable track and trace supply chain system (CHOTrak). It therefore knows that the seed is on the EU Approved list and cultivated followed ethical and organic practices.

Labelling legal CBD using DNA Technology

The 2020 Covid-19 (SARS-CoV-2) pandemic has turned almost everyone into virologists and molecular biologists and thanks to the media, the terms RNA and PCR have become commonplace. Hundreds of thousands of people have undergone the swab test for Covid-19, where samples were taken from their nose or from the back of the throat. In this test, coronaviral RNA is extracted from the swabs and mixed with the enzyme, reverse transcriptase (RT), which converts coronaviral RNA, into its complementary, cDNA nucleic acid sequences. The coronavirus cDNA is then amplified by the Polymerase Chain Reaction (PCR).

Amazingly, the exponential nature of PCR enables some test methods to detect down to as little as just 40 copies of coronavirus SARS-CoV-2 RNA per ml. This same PCR technology is being used to secure a wide range of supply chains from textiles to electronic components destined for fighter jets; and is now being used to authenticate CBD.

PCR selective DNA amplification

The PCR reaction is a powerful, everyday laboratory tool that enables, not just traces of coronaviral cDNA to be amplified but also to reveal traces of incriminating DNA found at crime scenes. This same technology can be adapted to enable the use of DNA as molecular tags. Because PCR is so sensitive, these DNA molecular tags can tag CBD throughout supply chains at concentrations of just parts per billion.

PCR amplification begins when double stranded DNA is melted into its two separate DNA strands. Primer sequences, in the assay media, bind to the single strands and enable the enzyme, DNA Polymerase to catalyze replication of both strands. The resulting two new double strands of DNA can then be melted into their single strands ready for the next cycle to begin again. In this manner PCR exponentially increases the amount of DNA.

Primers are short nucleic acid sequences, which are complementary to the three-prime end sequences or

target, DNA. Due to their specificity, in the case of the Covid-19 test kits, only coronavirus SARS-CoV-2 c[...]
amplified.

Similarly, when authenticating molecular tagged CBD, the primers included in the assay will be those spec[...]
the target DNA tags ensuring they are the only DNA amplified. DNA polymerase catalyses up to 155 nucle[...]
per second. Super-fast PCR can achieve amplification of short DNA sequences in less than 15 seconds.

Fluorescent dyes included in PCR reagents make these tests even more sensitive. In the case of Covid-19
samples testing positive for the virus are those which show increasing fluorescence reaching a validated tl[...]

**After decades of illegal cannabis use, and lack of scientifically supported fa[...]
the regulations controlling cosmetic the use of *Cannabis sativa* are unusua[...]
strict**

SigNature DNA tagging legal cannabis

The use of DNA tagging for cannabis has been developed and implemented by Applied DNA Sciences, us[...]
SigNature DNA molecular tags. These molecular tags are the auditors' friend as they forensically authentic[...]
material at every stage of its journey from farm to face cream.

SigNature DNA has been used to authenticate materials in global supply chains, not just for the textiles an[...]
electronic components mentioned earlier, but the tags are also used to authenticate items as diverse as
pharmaceuticals, fertilisers, leather, down, inks and a wide range of polymers.

These SigNature DNA molecular tags act much like a bar code as unique identifiers associated to original
a specific claim being made by a manufacturer or brand. DNA item identification can be included in Block[...]
shared documents, using Applied DNA's CertainT platform. The physical presence of the SigNature DNA c[...]
molecular tagged consignment indisputably links the material to accompanying digital documents. Transp[...]
track and trace informatician be achieved by sharing the GPS located portable PCRs' results via the clouc[...]

CBD is expected to continue to be popular in cosmetics; especially with the ICCI encouraging anecdotal c[...]
be investigated.

Unfortunately, along with the huge profit potential of the fast-growing CBD market, comes huge risk. Unsc[...]
players have joined the enthusiasts and global cosmetic brands making CBD products. Even law-biding p[...]
will be tempted to deceive, if for example, THC tests show they have accidentally grown a Schedule I con[...]
substance, which by law must be destroyed.

After decades of illegal cannabis use, and lack of scientifically supported facts, the regulations controlling
the use of *Cannabis sativa* are unusually strict.

In the EU, cosmetic phytocannabinoids must only come from the seeds and or leaves of registered cultiva[...]
have been cultivated by licensed growers. All the while authorities continue to allow isolates with only a C[...]
number and no documented evidence of their origin to enter the EU, unacceptable risks are being put on t[...]
Responsible Person and brands, before being passed onto the consumer.

Brands looking to remove the risk of prosecution should therefore only purchase from suppliers using trac[...]
trace systems such TTS Pharma. The same DNA technologies detecting coronavirus can be used to auth[...]
CBD oils.

Applied DNA Sciences' uses SigNature DNA molecular tags as part of its CertainT platform, which offers
forensically verifiable supply chain transparency, providing sources of identification for Blockchain or other[...]

systems.

By combining the new DNA and digital technologies, supply chains can be made fully transparent - from 'face cream'. Formulators should only be using cosmetic *Cannabis sativa* derived materials with fully transparent supply chains.

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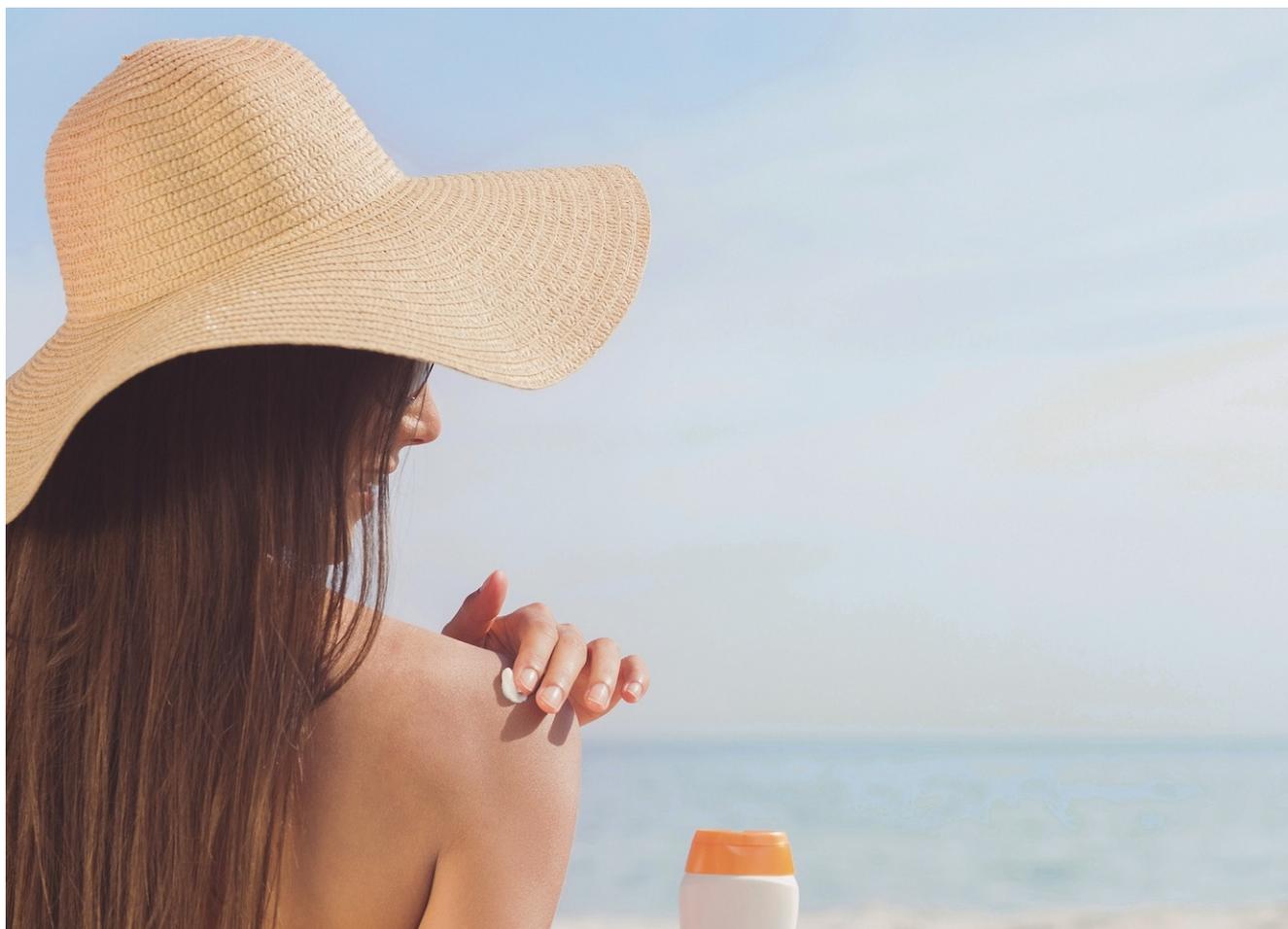
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