

The Need for Clarification on the ECDD's statement regarding the Preparations containing cannabidiol not more than 0.2 Percent of delta-9-Tetrahydrocannabinol.

Thank you Mr. Chairman, I'm Birgit Karner the Chief Administration Officer of the Society for the Advancement of Global Understanding.

The ECDD conducted a critical review of cannabis and cannabis-related substances and recommended that a footnote be added to read: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-THC are not under international control." It is our belief that the proposed language in Recommendation 5.5 should be revised to clarify how preparations of CBD with no more than 0.2 percent THC will be measured. ECDD's recommendation may cause confusion among Member States and, more importantly, lead to consumers being unknowingly exposed to high amounts of THC.

1. ECDD's Recommendation Creates Confusion as to Its Application.

Terminology used in regulatory language must be clear and precise to ensure uniform interpretation of such regulations. The ECDD's limit of 0.2% THC in a "preparation" requires clarification, since it could be interpreted in multiple ways. "Preparation" under the Single Convention is broadly defined as "a mixture, solid or liquid, containing a drug." It therefore **encompasses both a drug substance and a finished drug product**. However, a **finished product** containing 0.2% THC will have very different abuse potential than a **product** with a drug substance containing 0.2% THC. In the latter case, the THC content of the finished product generally will be significantly diluted by the medium. Should Member States interpret the 0.2% THC recommendation to apply to a finished product, rather than the Active Pharmaceutical Ingredient (API)

or drug substance itself, **there is a significant risk of exposing the public to meaningfully increased health and safety risks due to high levels of THC ingestion.**

2. The Application of ECDD's 0.2% THC Application Carries Significant Consequences for Consumers' Health, Safety, and Livelihoods.

The impacts of ingesting even relatively small amounts of THC have been evaluated in the United States in their marijuana policy at the state and federal level, resulting in regulatory limits on the allowable amount of THC per serving in certain THC delivery mechanisms. For example, in the U.S., individual states such as Alaska, Massachusetts, and Oregon, have limited the amount of THC allowed in a serving of a cannabis edible to no more than **5 mg of THC**, recognizing that 5 mg of THC is sufficient to produce psychoactivity. A single dose of the FDA-approved prescription dronabinol product Marinol® is 2.5mg THC, and studies have demonstrated **psychoactive side effects even at that level.**

A consumer who ingests 3 ml of a CBD oil preparation containing 0.2% THC by volume may consume 5.5mg-6mg THC, an amount in excess of both the states' maximum single serving size and the prescription dosage of Marinol®.

Further, a safety risk would result in unintentionally consuming THC in CBD products resulting in unanticipated impairment. The impacts of consuming THC are more significant for vulnerable populations. Both the FDA and the Surgeon General in the U.S. have publicly issued warnings about the risks of THC and CBD to women who are pregnant or breastfeeding.

3. ECDD Should Clarify Its Recommendation that the Term “Preparation” Applies to the Drug Substance or Total Cannabinoid Content, Not a Finished Product

The ECDD’s use of the term “preparation” has caused significant confusion among Member States and will have adverse impacts on public health and safety. A consumer will experience a very different effect from a product containing a drug substance with 0.2% THC (that is diluted in the finished product), rather than from a finished product that itself contains 0.2% THC, depending on the amount taken, the manner of administration, and the frequency of use. Failure to clarify the meaning of the term “preparation” may result in potential impairment in unsuspecting individuals, who are unaware they are consuming an intoxicant.

Thank you again for allowing me to speak.