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Science-Based THC Limits 'Urgently Needed' For EU To Compete In Global CBD Market

by David Ridley

"We urgently need the adoption of an EU wide regulation on sound scientific THC limits in food," insisted EIHA president and Hempro International CEO Daniel Kruse at the association's 18th annual conference, "Hemp for Europe: Emerging opportunities for the Green Recovery."

"There has never been a recorded human or animal health issue with tetrahydrocannabinol (THC)," claimed European Industrial Hemp Association president Daniel Kruse, referring to the experience of 23 years of commercial hemp production in Canada.

"All kinds of substances have a lethal dose, measured by the median lethal dose (LD50) level," continued Kruse, who is also CEO of Hempro International. "Even water, sugar, vitamin C and solanine, which means that potatoes can get you killed."

The permitted maximum levels for THC in hemp foods – including cannabidiol (CBD) food supplements – in the European Union "are unnecessarily low and not supported by scientific evidence," Kruse insisted, speaking at the 18th Annual EIHA conference, "Hemp for Europe: Emerging opportunities for the Green Recovery."

In Canada, where the recreational use of cannabis was legalized in 2018, the Tolerable Daily Intake (TDI) levels for THC are set at 14µg per kg body weight per day, he pointed out, compared to only 1µg per kg body weight per day in the EU.

Meanwhile in Switzerland, the TDI is 7µg

How toxic is THC?

According to the World Health Organization, the toxicity of THC is "very low" compared to

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per kg body weight per day, and 6µg per kg body weight per day in both Australia and New Zealand.

This low EU level, combined with a "very unclear (regulatory) situation all over the world," created an unlevel playing field compared to other markets

"We urgently need the adoption of an EU wide regulation on sound scientific THC limits in food," Kruse insisted. "As operators we have to be able to compete on same level with Canada, the US and South America."

Toxicology Study

To achieve harmonization, Kruse said that toxicology studies are needed, as well as an open discussion on TDI levels for THC in food with European regulators.

Kruse pointed to the EIHA's toxicological studies on CBD and THC launched as part of its Novel Food Consortium, which aims submit a joint Novel Food application and share the costs. (Also see "European Hemp Players Join Forces To Make Legal CBD Market A Reality" - HBW Insight, 18 Jun, 2020.)

most other recreational and pharmaceutical drugs.

Following oral administration, the median lethal dose (LD50) of delta-9-tetrahydrocannabinol was 800 mg/kg in rats, up to 3000 mg/kg in dogs and up to 9000 mg/kg in monkeys, reported a WHO Expert Committee on Drug Dependence Pre-Review in 2018.

"It has been calculated that a lethal dose in a 70 kg human would be approximately 4 g and that such a dose could not be realistically achieved in a human following oral consumption, smoking or vaporizing the substance, as delta-9-tetrahydrocannabinol has a large margin of safety," it continued.

"The absence of mortality with delta-9-tetrahydrocannabinol may reflect the low density of cannabinoid CB1 receptors in brainstem regions that control vital cardiovascular or respiratory functions," it added.

CBD food products must be authorized by the Commission and undergo a pre-market safety assessment by the European Food Safety Authority (EFSA) before they can be legally marketed in the EU. The FSA carries out the assessment for the UK market.

To support these applications, EIHA will invest €3.5m (\$3.9m) over the next two-to-three years in "unprecedented" toxicology studies on CBD and THC. The ingredients tested will cover a whole range of cannabinoid-containing ingredients, e.g. isolate, gold, regular and raw.

Announcing the project, EIHA managing director, Lorenza Romanese, said that by covering the whole possible range of toxicology studies for both molecules, CBD and THC, the Consortium



project "represents the most comprehensive response that we can give to authorities."

"It is science-based, and it is the only way in which we can inverse the unfair status quo," Romanese insisted. "We cannot guarantee the success of the application, but what we can ensure is that we will put all of our efforts into this project that will change history."