Swiss CBD company takes issue with EFSA's delay of novel food applications

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A Swiss CBD company has questioned the approach of European authorities in demanding further data in order to advance **novel food applications**, describing it as an issue that might signal the end of hemp-extracted cannabinoids as a viable sector in the EU.

Linnea, a Swiss provider of ingredients for the pharmaceutical, cosmetics, and dietary supplement industries, has two applications now on hold with the European Food Safety Authority (EFSA).

Linnea CEO Susanne Caspar told CBD-Intel that the company was unsure it was even possible to provide the information requested by EFSA due to the nature of its business.

"The question is: Can we really provide the information they need?" Caspar said. "After two weeks since our application was put on hold, we started to discuss what it really meant." For example, she said, EFSA asks for clinical trials on humans, which require a dosage form or finished products from a patient, whereas Linnea produces only active pharmaceutical ingredients (APIs).

The company sells its APIs to pharmaceutical companies or producers of finished products, so it cannot easily perform clinical trials on CBD isolate because it does not have a final delivery form. Theoretically, API companies like Linnea could administer the CBD extract without any further processing, but this then raises its own significant questions about feasibility and applicability.

Caspar added that, assuming the more likely option of using finished products in tests, the company would need to check with its clients to see whether they are interested in going further with these clinical trials and then discuss the costs.

"There is the possibility that our clients may no longer be interested in placing their CBD products through a novel food application when they start a clinical trial," she said. "Instead, they may want finished products registered by the health authority and to enter the pharmaceutical system."

High cost, piles of data and years of testing time

Currently, the cost profile for the tests look prohibitive. For example, the trial on rat reproductivity consists of demonstrating product safety on three generations of rats. This trial would take around 18 months, and the study alone would cost at least €1m, according to Linnea's estimate.

The other data, which is likely to require human testing, would come at an even higher cost and bring other difficulties along with it. "I am not convinced that an ethical committee will allow you to do trials on humans for food purposes," Caspar said.

There is no way Linnea as an API company could afford the overall cost of filling the data gaps requested by EFSA on its own, she said, as the cost could easily run into millions of euros. The firm wants to meet with other companies that have applications on hold to see if some sort of consortium could be created to address EFSA's specific concerns.

Linnea previously worked with associations in the UK to get toxicology data, and is discussing how that could fit into the European applications and feed into such a consortium.

Companies with applications on hold also have to understand how EFSA wants to evaluate synthetic CBD and natural CBD, and Linnea in particular needs to know whether EU authorities plan to conduct different trials for each product.

Caspar said she cannot fathom the large amount of safety data being requested for a food product.

"EFSA's requests are complicated to satisfy and unusual for the food system," she said. "To register a pharmaceutical product in the pharmaceutical system, you must have human clinical trials. However, these products have been used for decades in the food marke; such requests are very unusual for food product applications. It seems that EFSA is not very amenable to approving the applications for CBD products."

There is also the time element to be considered. Getting data from clinical trials on humans could require at least a year because tests have to go through an ethics commission for approval. What's more, clients have to be selected to provide products, and if there is a need for long-term toxicity data, that could take years.

European companies could take their business elsewhere

Caspar said there will likely be other questions from EFSA before the process is over. As part of its initial application, Linnea had already submitted data it thought addressed EFSA concerns.

"We had all our documents ready," she said. "For instance, we had our drug master file, which is very important for those that want to register a finished product." Caspar explained that Linnea had already submitted all the necessary documents, including long-term stability data, in Brazil and in Argentina, where Linnea has products, and registered them with health authorities.

She said Linnea put together a dossier of data for EFSA to submit the company's novel food request, and that EFSA read it, accepted the application, and began revising it. Then the agency published the questions on toxicity. "But we are quite sure that more open questions will follow," she said.

Instead of dealing with all this, companies could start to look elsewhere – as Linnea is starting to do.

"I am really not convinced the EU will authorise CBD as a novel food," Caspar said. "At the very least, it will take time."

Linnea will continue to develop CBD APIs for several clients outside the EU, though it declined to disclose names, citing commercial confidentiality. The company did say, however, that it has a novel food application lodged in the UK and is expecting a positive result from that as soon as next year.

High standards are a must for high-quality results

Linnea is also developing **cannabigerol (CBG)** products, researching other **minor cannabinoids**, and considering the development of medical cannabis products with higher levels of THC for the Swiss market when it **changes regulations** controlling the medical cannabis regime on 1st August.

Caspar also thinks cannabis legalisation in markets such as **Germany** will impact hemp-derived CBD – though exactly how they will co-exist will depend on the final regulatory framework countries adopt for **medical and recreational** markets.

For now, Caspar doesn't think products will be sold in hemp shops, but perhaps in pharmacies, where there can be some sort of control over them. "There should be authority ensuring standardisation of products because this will be the best for the patients – something that is not currently happening," she said.

"The market will grow faster if CBD is sold as a novel food. But it is important to have control of the product, what companies are producing, and how it is made, to ensure people have a high-quality product. Otherwise, people will order it online without knowing its ingredients."

– Dario Sabaghi *CBD-Intel contributing writer*

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