European CBD Company Reacts to the EFSA's Decision to Halt Novel Foods Process

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On June 7, the European Food Safety Authority (EFSA) **announced that it had paused its processing of all CBD novel foods applications**.

The decision was made because the EFSA's scientists could not agree that CBD was safe to consume.

"EFSA's scientists cannot currently establish the safety of cannabidiol (CBD) as a novel food due to data gaps and uncertainties about potential hazards related to CBD intake," **the agency said at the time.**

The decision certainly came as a shock to one of the affected CBD companies, **Linnea**, which had two novel foods applications with the EFSA, one for its 99% pure CBD isolate and another for its CBD full spectrum extract product. Both applications had already come with substantial toxicology data.

"For our two CBD Novel Food applications we had undertaken our own long term stability studies, a toxicology study together with one customer for our CBD extract and for the 99% pure CBD isolate, we also used a lot of desktop toxicology data," Susanne Caspar, CEO of the Locarno-, Switzerland, based company, told *Analytical Cannabis* in an email.

The company was also part of a CBD data consortium in the UK headed by the Association of the Cannabinoid Industry (ACI), which undertook further rodent toxicology studies to assess CBD's safety.

Yet, apparently, this existing data is not thorough enough to satisfy the EFSA, which is now requesting human toxicology CBD data.

"We are very surprised by the level of toxicology data EFSA is now asking for," Caspar continued.

According to Caspar, the EFSA is now asking its novel foods applicants for more toxicological data to help fill the "data gaps" for CBD's safety.

"We think the toxicology data is of course necessary however they are now requiring this data be on humans as well. This is standard in the pharmaceutical world but normally not in the food world."

"We believe the existing safety data on CBD is good and should be sufficient, but it seems this doesn't match EFSA's expectations," she added.

"Internally we are now evaluating the additional costs and studies that will need to be done to satisfy these new EFSA requirements. We understand there is a good chance this may lead to further, high-cost toxicology, so we need to discuss how to take this forward, either as individual companies or as consortia."

In its June 7 announcement, the EFSA did say that it would be holding an online info-session, open to all novel food applicants and other individuals, to further explain the

session, open to all novel food applicants and other individuals, to further explain the situation and what is now required of the affected companies. The session is due to take place on June 28.

"At this stage we don't know what they exactly expect," Caspar continued. "We will attend the EFSA information session on June 28th and secure further guidance from them in this online session."

"We hope this new EFSA hurdle will not take long to overcome for both the industry and businesses like ourselves, and especially for the benefit of the consumer and patient as this is another setback in their access to quality standardized CBD," she added.