EFSA's Request For Human CBD Toxicology Data Is 'Unusual' For a Food Authority

BY PETER JUNE 27, 2022 IN BUSINESS OF CANNABIS EUROPE, CBD, OPINION, REGULATION

Susanne Caspar CEO of Swiss botanical extraction company Linnea SA analyses Europe's latest CBD deliberations.

WE were not surprised by the European Food Safety Authority's (EFSA) decision to halt the Novel Food application process for cannabidiol (CBD) products.

As a company with 40 years experience producing botanical extracts mainly for the pharmaceutical, food and cosmetics industries we have encountered and overcome many regulatory hurdles.

Many players in the CBD market fail to grasp its regulatory complexities; they fail to understand that the Novel Food process cannot be dealt with in a matter of months.

We have been attempting to secure Novel Food approval for one, non-cannabinoid, product for the last three years. In that time we have been asked 23 supplementary questions from a multitude of European Commission entities.

10-Year Novel Food Wait

Novel Food is not a speedy process, at least one or two substances have been gridlocked in the process for the last 10 years!

In February we saw our 5% CBD whole plant extract validated by EFSA, along with our isolate at 99% CBD. Only for them both to be then paused alongside a further 18 applications on June 7.

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 5% full extract, and for the 99% CBD isolate we also used a lot of desktop toxicology data.

When the UK said this may not be sufficient we joined the ACI consortium which has undertaken further rodent toxicology studies for the isolate and this has now been submitted to the FSA.

While this may be enough to satisfy the FSA in the UK – and we hope that is the case – we are not sure if it will satisfy the authorities in Europe.

Our findings will be passed on to the EFSA, but it appears from its recent announcement that it also requires toxicology data on the potential impacts of CBD on humans, too.

'Existing Data Sufficient'

We believe the existing safety data on CBD is good and should be sufficient, but it seems this doesn't match EFSA's expectations. While there is data from many clinical trials on CBD – we did the worldwide data research – it does not seem to be enough for them.

At this stage we don't know what they exactly expect. We will secure further guidance from EFSA's on-line information session later this month (June 28).

But the question that will then need to be asked is how we secure this additional data, and how long will it take – weeks or years? Only after we get this information will we know.

However, we understand there is a good chance this may lead to further, high-cost toxicology studies and

take maybe a longer time, so we will need to discuss how to take this forward, either as individual companies or as consortia.

As a company which spans a range of industries from pharmaceutical to food we do find EFSA's latest proclamation very unusual for an authority responsible for food.

The request for these data is normally the responsibility of health authorities if a product is to receive a pharmaceutical marketing authorisation.

Food Or Pharma?

This dichotomy between treating CBD as either a pharmaceutical or as a food product may well lie behind Europe's twists and turns over the status of CBD.

Remember it was only the decision of the European Court of Justice in December 2020 which saw the EC remove its previous designation of CBD as a narcotic.

France and Italy usually have a stronger tendency towards food products than, for example, a country like Germany, which prefers to see some substances submitted as novel foods under the control of the BfArM.

Here at Linnea we prepare our cannabinoid products like we have prepared all our other products for the last 40 years – as a pharmaceutical.

We are aligned with the Swiss medical regulations and we are a GMP producer.

Nevertheless we see CBD as being suitable for either of the two camps – food supplement or pharmaceutical, depending on the indication and dosage.

CBD and CBG can help with indications for real clinical problems. Our CBD extract is used in Brazil for children with epilepsy and we have complied with its pharmaceutical regulations.

Sometimes in the CBD supplements industry you get really poor quality products which bear no similarity to that which is claimed on the label.

We believe the global CBD industry will continue to grow – we are making headway in Latin America and Asia – although each jurisdiction will be different.

The direction of travel for Europe is towards higher quality products and that is why we believe CBD should be treated as a Novel Food, no matter how arduous the approval process is.

We hope this new EFSA hurdle will not take long to overcome for both the industry and businesses like ourselves – but also for the benefit of the consumer and patient.

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