Ms Emily Miles
CEO, Food Standards Authority
Floors 6 and 7, Clive House
70 Petty France
London SW1H 9EX

10 April 2024

Dear Ms Miles

Assessment of novel foods by the FSA

I am writing on behalf of members of the Association for the Cannabinoid Industry (ACI) to express our serious concern regarding the delays in progressing novel food applications submitted to the Food Standards Agency (FSA) in 2021. These extreme delays are in breach of the Novel Food Regulations, they are unexplained, and our members have received little if any update on progress and anticipated timelines from the FSA and Food Standards Scotland (FSS).

Timelines under the Novel Food Regulations and applicable Guidelines

The procedure for authorisation of novel foods in Great Britain is provided by Regulation (EU) 2015/2283 of the European Parliament and of the Council as retained in UK law ("the Regulation"), which also specify the timelines which are to apply to such procedures. In this respect, the Regulations state:

- Article 11(1): "*Where the appropriate authority requests an opinion from the Food Safety Authority, it must forward the valid application to the Food Safety Authority without delay, and not later than one month after having verified its validity. The Food Safety Authority must adopt its opinion within nine months from the date of receipt of a valid application"*.
- Article 12:
  "(1) Within seven months from the date of publication of the Food Safety Authority's opinion, the appropriate authority must, by prescribing an update of the list, authorise the placing on the market within Great Britain of a novel food, taking into account the following—
  (a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;
  (b) any relevant provision of retained direct EU legislation, including the precautionary principle as referred to in Article 7 of Regulation (EC) No. 178/2002;
  (c) the Food Safety Authority's opinion;
  (d)any other legitimate factors relevant to the application under consideration.
  2.Where the appropriate authority has not requested an opinion from the Food Safety Authority in accordance with Article 10(3), the seven month period provided for in paragraph 1 of this Article starts from the date on which the valid application is received by the appropriate authority in accordance with Article 10(1)".

- Article 22: "*In exceptional circumstances, the appropriate authority may extend the time periods provided for in Articles 11(1), ….. on its own initiative or, where applicable, at the*

Food Safety Authority's request, where the nature of the matter in question justifies an appropriate extension".

Guidance issued by the FSA under the heading "How long will my application take?" states:

> *"The law includes deadlines for key steps in the process. In a full novel food application made under Article 10, one month is allowed for the validation process, then up to nine months (on a start stop the clock basis if further information is needed) for the risk assessment element, with up to a further seven months for any subsequent risk management considerations and authorisation decision. These add up to a total of seventeen months as the overall legislative timeline for authorisation, noting this can be extended if the clock is stopped and re-started".*

There are no other statements published by the FSA which refer to "exceptional circumstances" or otherwise modify the timelines issued under Article 11(1) or the advice.

The experience of Association Members

Three years have passed since ACI member companies started to submit applications to the FSA for authorisation of foods containing cannabidiol (CBD) as novel foods. However, only half (6,431) of the products on the public list have had their statuses updated to 'validated', with the remainder of the 12,115 products currently described as 'awaiting evidence'.

The ACI is aware of several companies which have received letters of validation for products which are not described on the public list as 'validated'. However, the majority of our own members who are engaging with the novel foods process have only been told by the FSA that no further evidence is required from them at the present time.

The ACI is also aware of no extension of the time limits required under the Regulations, and no such extension has been notified to ACI member companies or published on FSA's website.

These experiences demonstrate that the FSA has wholly failed to comply with the requirement to validate applications within a month and then to complete risk assessment within nine months.

While it is now some three years since most of ACI's member companies submitted their novel food applications, members have received little if any communications from the FSA advising on the progress of their applications and no indication as to when the FSA intends to comply with the requirements of the Regulations. This not only breaches the FSA's legal obligations, it is procedurally unfair and inconsistent with good administration.

Conclusion

You will appreciate that the extreme delays in processing novel food applications is highly prejudicial to ACI members' business interests. The Government has promised that, post Brexit, rules and regulation for British businesses will be proportionate and will take into wider impacts on consumers, innovation and competition. However the approach of the FSA to the CBD industry in the UK wholly fails to meet these aims.

In these circumstances would you please:

i. Provide cogent reasons for the failure of the FSA to comply with its regulatory obligations in terms of validating and assessing applications for novel food authorisations for food products containing CBD;
ii. Set out immediate corrective measures with timelines for addressing the backlog of applications and processing these;

iii. Confirm that each applicant company will be sent a letter updating it as to the status of its application(s) and the timeframe going forward.

We look forward to hearing from you as a matter of urgency.

Yours sincerely,

Steve Moore, Director

Dr Parveen Bhatarah, Regulatory and Compliance Associate

Dr Paul Duffy, Toxicology Associate

Greer Deal, Regulatory and Compliance Associate

Paul Birch, Founder