Information on invalidated CBD applications

Information for applicants who submitted novel food authorisation applications for existing CBD products before 31 March 2021 and whose applications have been invalidated.

Why your application has been invalidated

Your application has been invalidated because the submission was missing the information needed to assess if it meets the requirement under the novel food regulations. A novel food authorisation application for a CBD product cannot be taken forward in the authorisation process if this is the case.

To be validated, applications should have been submitted with a full set of data and with all relevant studies.

Withdrawing your products from the market

CBD products or ingredients linked to invalidated applications should be removed from the market as they are not linked to progressing applications.

We expect such products to be voluntarily withdrawn from the market. The decision on enforcement lies with enforcement authorities.

Reapplying for authorisation

You can re-submit your application to us with a revised dossier including any information highlighted to you as missing in the original assessment. We expect any future applications to be submitted as a standalone dossier which integrates the missing data, and not presented as additions to the original application.

Toxicological testing

Following the additional data provided to support novel food authorisations, further animal study data should only be generated for CBD ingredients with greater than 98% CBD. We are unable to accept literature information alone for the toxicological aspects of the application. In addition, we cannot use information from one novel food application to benefit another applicant without the permission of the data owner. To minimise the use of animals we encourage applicants to access, where relevant, the existing data sets that have been generated.

Data generated to support novel food applications should be on a relevant test material that reflects the composition of the novel food seeking authorisation. It should be also undertaken in line with internationally recognised toxicological methods such as OECD TC 408 protocol.

The statement from the ACNFP and COT outlines several areas where additional data could be generated and how this information could inform the knowledge of the safety of CBD. We

encourage applicants looking to generate data to consider these data gaps and where possible use standardised methods. Where new data is being generated, we encourage applicants to work collaboratively to maximise the information generated.

Appealing decision to invalidate application

There is no appeal process for the decisions made on whether a dossier is valid and can progress through the assessment process. There is a core set of information needed to review a dossier and assess if it meets the requirement under the regulation, as outlined in the guidance for applicants. For the dossiers considered invalid it has been identified that there is insufficient information for the assessment. We have provided detailed feedback, so that if applicants would like to reapply it is clear what additional information is needed to pass validation.