Meeting

Calcidiol Draft Committee Advice Document for Review

Committee Paper for Discussion - ACNFP/164/02

Advisory Committee for Novel Foods and Processes

Application for Authorisation of Calcidiol as a Novel Food - Draft committee advice document for review.

Application number RP35

Issue

This Calcidiol dossier has been discussed at six meetings. The Secretariat were asked to prepare a Committee Advice Document (CAD) summarising the assessment to date, this was developed and reviewed at the April 2023 meeting. The Committee requested the Secretariat to revise this draft further in light of the comments received. The revised draft is presented for further comment and input with a view to finalising the document.

Background

1. On the 12th of January 2021, the FSA (Food Standards Agency) received the submission for “Calcidiol” from DSM Nutritional Products Ltd (Switzerland). Calcidiol is a new form of Vitamin D for use as a food supplement targeted at a generally healthy population including pregnant and lactating women, except children under 3 years. It is a vitamer of vitamin D3 (cholecalciferol) and is directly absorbed by the human body.

2. The application has been subject to review by the Committee at 6 meetings. In April, the Secretariat was asked to prepare the CAD for Committee review. Following comments in June the document has been subject to significant revision and is provided in Annex A for review and comment.

3. In preparing the CAD there were some aspects of the assessment the Secretariat would like to ensure are captured appropriately. These are:

- Whether a conversion factor of 5 times the bioavailability of vitamin D and the committee’s discussion on this issue has been appropriately captured. In considering this question the Secretariat has provided the latest EFSA opinion on the bioavailablility of calcidiol monohydrate (Annex B) which sets a conversion factor of 2.5.
- From the 90-day study a NOAEL of 180µg 25 hydroxy vitamin D3/kg body weight was identified by the authors. However, in an approach consistent with EFSA this was not considered a point of departure. Is this assessment appropriately described.
- In the absence of a toxicological point of departure are members content with the margin of safety approach used to put the consumption of the novel food in the context of wider vitamin D exposure from oral consumption in order to set the 10µg maximum intake level.
- Consideration of the applicants proposed maximum intake for those under 11yrs (5 µg per day for children 3-10 years) and whether the evidence for a lack of hypercalcaemia at higher doses is sufficient to allow this use for this age group. To note EFSA did not conclude on this age group in their original opinion for the application but have in the 2024 updated opinion.

Committee Action Required

- The Committee is asked to review and comment on the draft Committee Advice for this novel food.

ACNFP Secretariat

January 2024

Annexes

Annex A – Draft Committee Advice Document.

Annex B – EFSA opinion on the bioavailability of calcidiol monohydrate.