Meeting

Calcidiol Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/157/04

Advisory Committee for Novel Foods and Processes

Application for Authorisation of Calcidiol as a Novel Food. Additional information from applicant - Reference number RP35

Issue

This paper has been reviewed three times with the Committee requesting further information most recently at the meeting in June 2022, so as to proceed with their assessment. Members are invited to consider the response from the applicant and comment on whether it addresses the outstanding question for this dossier .

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. During the review in the last meeting, the Committee raised several areas where further information was required to assess the safety of the novel food and its proposed use. Information was requested in the following areas:

- Identity
- Production process
- Proposed use and intake

The Secretariat requested further information in Annex A which is included with the applicant’s response in Annex B and associated appendices Annex C (contains confidential information).

Applicants’ response to request for further information Identity

3. Further information was sought on the methodology and results so as to support the full characterisation of the novel food in terms of composition and structure. The applicant was requested to provide documentation concerning certification of the reference standard. Further explanation was sought to put the information provided on the reference standard in the context of the Ullman Encyclopaedia information and whether this provides structural and quantification information for Calcidiol. Additionally, it was suggested additional spectral analysis would be helpful especially in understanding the properties of the molecule and whether it is the same as the calcidiol formed in the metabolism of vitamin D.

4. The applicant has responded by providing the Ph. Eur. Monograph which outlines the analytical methods for calcidiol, evidence that infrared absorption spectrometry is used for calcidiol identification and according to the USP [Annex C (annex I, II and III**)**].

5. They have also provided the COA for the reference standard used to confirm the identity of calcidiol [Annex C (annex IV)]. They highlight in their internal report [Annex C (Annex V)] regarding additional elements in the structure of calcidiol, that NMR is not the analytical choice in 25-hydroxy-vitamin D3 due to interferences related to scratches used for formulation. They further explain this in detail in their response (Annex B).

Production Process

6. The Committee once again advised the applicant to provide a HACCP plan that addressed risks within or introduced by the production process and the steps taken to manage the identified risks so as to give reassurance on product safety.

7. The applicant has responded by drawing attention back to the HACCP previously provided [Annex C (HACCP-Confidential) with particular mention of part 1 (fermentation), part 2 (photoconversion into HD3 crystals) and part 3 (production of calcidiol crystals) stating that this HACCP plan covers all risks

which may be introduced during the production process. They also clarify the specific mention of metal (and of it’s detection) is purely because it’s a standard requirement, not because it is a specific concern for the novel food.

Proposed use and intake

8. In consideration to the applicants suggested use levels and that Calcidiol is 3 times as bioavailable as vitamin D, the Committee suggested that this should be considered as 5 times bioavailable and appreciated that the applicant was willing to state that for the product. However, they raised concern on how the applicant proposes to cater to individuals who might want to take the daily dose of 10µg/day and how they will mitigate potential of foreseeable misuse by consumers.

9. The applicant re-emphasises they are an ingredient producer and as such, their customers (brand owners and food supplement manufacturers) decide on the levels of calcidiol they want to promote which could be anything up to the maximum of 10µg/day above 11yrs of population and up to 5µg/day for children 3-10years.

10. They further clarify the inclusion level is a decision to be made by the food supplement companies, and that decision depends on how the product is promoted which might correspond with the national/regional recommended level for vitamin D. They state consumers will be informed on the safety profile of the consumer with a good source of reference being EFSAs opinion on calcidiol. Also, proper labelling is advised including warning not to exceed recommended dose.

11. A detailed discussion has been provided on proposed use levels for children 3-10 years in reference to EFSAs 2021 opinion on safety of cacidiol (Annex C), with a conclusion that a total vitamin D intake of 49.4µg/day is safe as estimated by EFSA since it is below the upper limit with sufficient safety margin included, hence, a maximum use level of 5µg/day is safe for this age group.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to complete the risk assessment.
- If not, the Committee is asked to indicate what additional information would be required.

ACNFP Secretariat

January 2023

Annexes

Annex A– Request for further information

Annex B – The applicants response

Annex C – Response Annexes