

Safety assessment: Calcidiol (25-hydroxycholecalciferol monohydrate) as a novel food for use in food supplements

Area of research interest: [Research projects](#)

Project status: Completed

Project code: RP35

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Executive summary

An application was submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) in January 2021 from DSM Nutritional Products Ltd (“the applicant”) for the authorisation of Calcidiol, 25-hydroxycholecalciferol monohydrate as a novel food.

The novel food is a new source of vitamin D3 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 in the human gut. To support the FSA and FSS in their evaluation of the application, the Advisory Committee on Novel Foods and Processes (ACNFP) were asked to review the safety dossier and supplementary information provided by the applicant. Please note the Committee did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe, and not putting consumers at a nutritional disadvantage.

The FSA and FSS concluded that the applicant had provided sufficient information to assure the novel food, Calcidiol, was safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food supplements was not considered to be nutritionally disadvantageous.

The views of the ACNFP have been taken into account in the regulatory assessment which represents the opinion of the FSA and FSS.

Safety assessment

PDF

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