COMMITTEE PAPER FOR DISCUSSION **ACNFP/148/01**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

CALCIDIOL- NOVEL FOOD NOTIFICATION- RP35

Issue

An application for "Calcidiol" as a nutrient source in food supplements, has been received under Regulation 2015/2283. The Committee is asked to advise on whether the available data provides an adequate basis for a risk assessment, and if it recommends authorisation of this novel ingredient.

Background

1. On the 12th January 2021, the FSA received a notification from DSM Nutritional Products Ltd for authorisation of Calcidiol, 25-hydroxycholecalciferol as a new source of vitamin D3. The applicant intends to use the product within the category food supplements and does not have an anticipated food or beverage use.

2. The application has been submitted under the EU process and reviewed by EFSA - EFSA-Q-2018-00514, and the applicant has responded to five rounds of questions. A risk assessment has not yet been produced. The further information submitted to EFSA can be found in the relevant dossier sections.

Identity of the novel food

3. The applicant describes the product as a novel form of vitamin D3 for use in food supplements, suitable for the general population including pregnant and lactating women and children over 3 years of age. They suggest Calcidiol is a vitamer of vitamin D3 (cholecalciferol), with higher biological activity than cholecalciferol.

Production process

4. The production process of calcidiol starts with a yeast fermentation which results in a mixture of sterols. Several chemical conversions (saponification and extraction, hydroxylation and isomerization by photoconversion) deliver after crystallization and isolation a crude calcidiol. This product is recrystallized to deliver after isolation and drying calcidiol.

Compositional data

5. Compositional testing is provided for four representative batches. Stability testing is provided for 3 representative batches. The applicant estimates the shelf life of the 0.25% product to be 36 months.

Specifications

6. Specifications were provided for both the concentrated and 0.25% preparation.

History of use of the novel food ingredient and/ or of its source

7. Calcidiol is produced via chemical synthesis. However, calcidiol is a metabolite of vitamin D3 which is an essential micronutrient of humans and some animals. Humans produce vitamin D3 in response to the UV in sunlight. Calcidiol, or 25(OH)D3, is a metabolite of vitamin D3 formed in the liver and circulating in the blood. Both, vitamin D3 and calcidiol are precursors of the active compound 1,25- dihydroxyvitamin D3 (calcitriol). Calcidiol can be detected in the tissues of animals used as food.

8. Calcidiol (25-hydroxycholecalciferol) has been introduced in the European Union as a feed additive after the approval by the European Commission in Commission Regulation 1443/2006 on its use as vitamin for poultry (chickens for fattening, laying hens and turkeys).

Proposed uses and use levels

9. The applicant states that calcidiol will be used as a new source of vitamin D3 as a food supplement and as an alternative form of vitamin D3 in some supplements.

10. The dossier gives an upper limit for adults and children aged 11-17 years as 100µg/day. For children aged 1-10years the upper limit is 50µg/ day. The proposed use for adults and children ≥11 years is 10µg/ day including pregnant and lactating women. For children aged 3-10 years the daily dose is 5µg/day.

11. Calcidiol is not intended for use by children under the age of 3 years.

Absorption, distribution, metabolism and excretion

10. The applicant discusses that calcidiol is a primary metabolite of cholecalciferol and is the major circulating from of vitamin D. The data in this section then focusses on the comparison of the two forms of vitamin D.

Nutritional information

11. The applicant describes calcidiol as nutritionally equivalent to cholecaliferol (when taking into account the conversion factor of 3).

Toxicological information

12. The applicants commissioned mutagenicity and genotoxicity studies. The results of which showed no potential for mutagenicity and no indication of clastogenicity or aneugenicity.
13. The subchronic toxicity and human toxicity sections comprise of existing literature supplemented by studies commissioned by the applicant.
14. Chronic toxicity and carcinogenicity testing was not carried out following the results from the other toxicity testing which showed no indications of neurotoxic, immunotoxic, or pre-neoplasia.

Allergenicity

15. The application states that allergenicity is not applicable for this product.

Committee action required

- Members are asked whether there are safety concerns with this novel food and/or if additional information is required to assess it.
- The Committee's advice will form the basis for the UK's formal risk assessment for the novel food.

Secretariat

May 2021