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Safety for the environment of vitamin D₃ for salmonids

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Abstract

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) of EFSA assessed the safety for the target species and the consumer of the use of a maximum total level of 1.5 mg vitamin D₃/kg feed in fish nutrition (2017). The assessment was based on data that had been provided by the Norwegian Food Safety Authority (NFSA). Since the data set provided by the NFSA did not include any new information concerning the safety for the user and the environment, the 2017 opinion did not address the potential effects of the proposed increase in the maximum authorised levels of vitamin D₃ on the safety for the user and the environment. The NFSA has submitted additional data and the European Commission has requested EFSA to deliver a new opinion on the safety for the environment of vitamin D₃ as a nutritional additive for salmonids. Planktonic microalgae, inhabiting the sea, are a large group of photosynthetic organisms that contain both vitamin D₃ and provitamin D₃. Marine phytoplankton is distributed throughout the sea serving as the basis for all marine food webs. Therefore, since it is produced by phytoplankton, vitamin D₃ may also be considered as being ubiquitous in the aquatic environment. Considering the different sources of vitamin D₃ already present in the marine environment, the FEEDAP Panel considers that an increase in concentration of vitamin D₃ when used as a feed additive in compound feed for salmonids up to a maximum of 1.5 mg/kg is not expected to pose a risk for the environment.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

Table 1: Description of the substances

Category of additive	Nutritional additive
Functional group of additive	Vitamins, provitamins and chemically well-defined substances having a similar effect
Description	DSM – Cholecalciferol + precholecalciferol (62.7%) Fermenta Biotech Ltd – Vitamin D ₃ 40 MIU/g powder and Vitamin D ₃ resin MIU/g Lohmann Animal Health GmbH – Vitamin D ₃ 84%
Target animal category	Fish 60,000 IU maximum content equivalent to 1.5 mg/kg
Applicant	DSM, Lohmann Animal Health GmbH and Fermenta Biotech Ltd
Type of request	New opinion

On 25 January 2017, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ('Authority'), in its opinion on the Safety of vitamin D₃ addition to feedingstuffs for fish, could not conclude on the safety for the aquatic compartment if the level of vitamin D₃ in fish feed is increased as proposed by the Norwegian Food Safety Authority (NFSA). After the discussion with the Member States at the Standing Committee held on 17 – 19 July 2017, it was agreed to request further information to the Norwegian Food Safety Authority in order to demonstrate the safety for the environment. This will allow EFSA to assess the impact on the environment of the maximum limit of 1.5 mg vitamin D₃/kg compound feed for salmonids.

The Commission gave the possibility to the Norwegian Food Safety Authority to submit complementary information in order to complete the assessment and to allow a revision of Authority's opinion.

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety for the environment of vitamin D₃ as nutritional additive for salmonids based on the additional data submitted by the Norwegian Food Safety Authority.¹

1.2. Additional information

In 2012, 2013 and 2014, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued three opinions on the safety and efficacy of vitamin D₃ (cholecalciferol and precholecalciferol) as an additive to feed and water for drinking for all animal species (EFSA FEEDAP Panel, 2012a, 2013, 2014). The FEEDAP Panel Concluded that no safety concern was identified for the use of vitamin D₃ for fish at the maximum authorised content of 0.075 mg/kg feed for the target species, the consumer and the environment.

As per request of the European Commission, the EFSA FEEDAP Panel (2017) assessed the safety for the target species and the consumer of the use of a maximum total level of 1.5 mg vitamin D₃/kg feed in fish nutrition. The assessment was based on data provided by the NFSA. The FEEDAP Panel concluded that a total level of 1.5 mg vitamin D₃/kg compound feed is safe for salmonids with a margin of safety of at least 10. For other fish, insufficient data were available to conclude on the safety of a total level of 1.5 mg vitamin D₃/kg feed. Although the assessment of safety for the consumer was impaired by uncertainties concerning the transfer of vitamin D₃ from feed to fish flesh, it was concluded that an increase of total vitamin D content in fish feeds up to 1.5 mg/kg feed would not lead the tolerable upper intake level to be exceeded even in high consumers. Since the data set provided by the NFSA did not include any new information concerning the safety for the user and the environment, that opinion did not address the potential effects of the proposed increase in the maximum authorised levels of vitamin D₃ on the safety for the user and the environment.

¹ The European Commission was contacted for clarification on the terms of reference. It was indicated that more specifically, the opinion should assess the impact on the environment of the maximum limit of 1.5 mg vitamin D₃/kg compound feed for salmonids.

The NFSA has provided data to support the safety for the environment of using in salmonids feed 1.5 mg vitamin D₃/kg, which is the object of the present assessment.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the NFSA² in support of the authorisation request for the use of vitamin D₃ as a feed additive. Particularly to estimate if there is any impact for the environment when the maximum level of vitamin D₃ in feed for salmonids is increased up to 1.5 mg/kg feed.

The FEEDAP Panel used the data provided by the NFSA together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output. The data set from the NFA consisted on a Phase I environmental risk assessment performed by the Norwegian Institute for Water Research; a report on factors affecting the concentration of fish feed additives in sediment issued by the Norwegian Institute of Marine Research; 10 scientific papers, and information describing a typical fish farm.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of vitamin D₃ for the environment is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on nutritional additives (EFSA FEEDAP Panel, 2012a,b) and Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008).

3. Assessment

The object of this assessment is vitamin D₃ when used in salmonids nutrition as a nutritional additive, under functional group 'vitamins, pro-vitamins and chemically well-defined substances having a similar effect'.

More specifically, the aim of the present assessment is to evaluate the consequences for the environment of the use of a maximum total concentration of 1.5 mg vitamin D₃/kg feed in salmonids nutrition. To this purpose, data on vitamin D₃ when used in feed and its potential impact on the environment were submitted by the NFSA.

The additives were characterised in previous EFSA opinions (EFSA FEEDAP Panel, 2012a, 2013, 2014).

3.1. Safety

The safety of the additive at a use level up to 0.075 mg vitamin D₃/kg feed for the target species, the consumer, the user and the environment were addressed in previous opinions (EFSA FEEDAP Panel 2012a, 2013, 2014). In those opinions, the FEEDAP Panel concluded that 'vitamin D is widely distributed in plants and animals as a result of endogenous synthesis. It is susceptible to oxidation by light and oxygen. The use of vitamin D₃ in animal nutrition is not expected to substantially increase the concentration in the environment. Therefore, no risk to the environment resulting from the use of cholecalciferol in animal nutrition is expected'.

The current assessment evaluates the environmental impact of the maximum limit of 1.5 mg vitamin D₃/kg compound feed for salmonids.

3.1.1. Safety for the environment

Vitamin D₃ is a natural substance and is a nutrient for a lot of organisms, including the aquatic ones.

Fish have the highest natural content of vitamin D but cannot synthesise either vitamin D or provitamin D (Bjorn and Wang, 2000). Although it is recognised that trout may synthesise vitamin D₃ in the skin when exposed to blue light (Pierens and Fraser, 2015), in general fish and other aquatic organisms need to derive vitamin D via the food chain originating from microalgae (Jäpelt and

² FEED dossier reference: FAD-2018-0036.

Jakobsen, 2013): fish produce vitamin D from its precursor provitamin D₂, obtained via the diet of zooplankton (Dobrevá, 2014).

Sunita Rao and Raghuramulu (1996) reported that the origin of vitamin D in fish may be explained as follows: phytoplankton, which are at the base of the aquatic community, contain high amounts of provitamins D which, upon UV irradiation, could convert to vitamins D. Furthermore, zooplankton may derive their high amount of vitamin D from phytoplankton, apart from endogenous formation. Plankton constitutes the chief dietary source of the little fish, and the bigger fish feed on them. It, thus, appears that vitamin D in fish may mainly be derived from the food chain, starting from plankton.

Planktonic microalgae, inhabiting the sea, are a large group of photosynthetic organisms that contain both vitamin D₃ and provitamin D₃ (Kenny et al., 2004). Marine phytoplankton account for a quarter of the total global primary production (Ott, 1996) and are distributed throughout the sea serving as the basis for all marine food webs. Therefore, since it is produced by phytoplankton, vitamin D₃ may also be considered as being ubiquitous in the aquatic environment. Levels of vitamin D₂ (1.9–4.3 µg/100 g), vitamin D₃ (5.0–15 µg/100 g) and their provitamins (260–1,450 µg/100 g) have been measured in microalgae (Atsuko et al., 1991).

Vitamin D₃ is strongly adsorbed to particulate matter: the estimated K_{oc} value (structure estimation method based on molecular connectivity indices) is about 1.5×10^6 . This very high value suggests that vitamin D₃ will not only be adsorb to sediment, but also be adsorb to dissolved organic matter present in marine water, and therefore, transported by currents. No information on the natural background concentration of vitamin D₃ in sediment was found in literature; nevertheless, considering that vitamin D is a nutrient not just for fish in cages but also for other organisms living around the cages themselves, considering the different sources of vitamin D₃ already present in the marine environment, the increase in the levels of vitamin D₃ as a feed additive in compound feed for salmonids to a maximum concentration of 1.5 mg vitamin D₃/kg is not expected to result in a significant impact on the environment.

3.1.1.1. Conclusions on safety for the environment

Considering the different sources of vitamin D₃ already present in the marine environment, an increase in the levels of vitamin D₃ as a feed additive in compound feed for salmonids to a maximum concentration of 1.5 mg vitamin D₃/kg is not expected to result in a significant impact on the environment.

4. Conclusions

The FEEDAP Panel considers that an increase in concentration of vitamin D₃ when used as a feed additive in compound feed for salmonids up to a maximum of 1.5 mg/kg is not expected to pose a risk for the environment.

Documentation provided to EFSA

- 1) Safety for the environment of vitamin D₃ as feed additive for salmonids. July 2018. Submitted by Norwegian Food Safety Agency.

Chronology

Date	Event
8/6/2018	Dossier received by EFSA
21/6/2018	Reception mandate from the European Commission
28/6/2018	Application validated by EFSA – Start of the scientific assessment
29/11/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
K _{oc}	Organic carbon/water partitioning coefficient
NFSA	Norwegian Food Safety Authority
UV	ultraviolet light