SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of vitamin D_3 (cholecalciferol) as a feed additive for all animal species or categories based on a dossier submitted by Lohmann Animal Health GmbH[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

ABSTRACT

The principal physiological role of vitamin D in all vertebrates is in calcium and phosphorus homeostasis. The classic clinical deficiency syndrome is rickets. The FEEDAP Panel notes that for turkeys for fattening, equines, bovines, ovines and pigs the maximum authorised content of vitamin D_3 in feed does not provide any margin of safety, and that, except for pigs and fish, the maximum content is above the upper safe level, according to National Research Council data when animals were fed a supplemented diet for more than 60 days. The FEEDAP Panel is not in a position to draw final conclusions on the safety of vitamin D for target animals but considers the current maximum contents temporarily acceptable pending a review of the recent scientific literature. The two vitamin sources under application are considered safe for the target animals provided the current maximum contents in feed are respected. Any administration of vitamin D_3 via water for drinking could exceed the safe amounts of vitamin D and therefore represents a safety concern. Current nutritional surveys in 14 European countries showed that vitamin D intake is below the upper safe limit. The FEEDAP Panel assumes that foodstuffs of animal origin were produced following current production practices, including vitamin D_3 supplementation of feed, and concludes that the use of vitamin D in animal nutrition at the currently authorised maximum dietary content has not and will not cause the tolerable upper intake level to be exceeded. Vitamin D_3 should be considered as irritant to skin and eyes, and as a dermal sensitiser. Inhaled vitamin D_3 is highly toxic; exposure to dust is harmful. No environmental risk resulting from the use of vitamin D_3 in animal nutrition is expected. The vitamin D_3 under application is regarded as an effective dietary source of the vitamin in animal nutrition.

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KEY WORDS

nutritional additive, vitamins and pro-vitamins, vitamin D_3, cholecalciferol, safety

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[1] On request from European Commission, Question No EFSA-Q-2011-00952, adopted on 30 January 2014.

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SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of vitamin D_3 (cholecalciferol) as an additive to feed and water for drinking for all animal species.

The principal physiological role of vitamin D in all vertebrates including humans is in calcium and phosphorus homeostasis. The classic clinical deficiency syndrome is rickets.

Despite the long history of supplementing compound feed with vitamin D up to the maximum authorised content and the absence of publicly reported intolerances, the FEEDAP Panel is not in a position to draw final conclusions on the safety of vitamin D in animal nutrition based on the National Research Council (NRC) data collection. Compared with the upper safe levels for long-term use published by the NRC, the currently authorised maximum contents of vitamin D_3 in feeds for turkeys for fattening, equines, bovines, ovines and pigs do not provide any margin of safety and are often above the upper safe levels. The FEEDAP Panel considers the currently authorised maximum contents to be temporarily acceptable for the target animals. In the view of the FEEDAP Panel, a complete review of the more recent literature is necessary to maintain or to revise the current maximum contents.

The two vitamin sources under application are considered safe for the target animals provided the currently authorised maximum contents in feed are respected. Any administration of vitamin D_3 via water for drinking could exceed the safe amounts of vitamin D and therefore represents a safety concern.

Current nutritional surveys in 14 European countries have shown that vitamin D intake by consumers of large amounts (95th percentile) is below the tolerable upper intake level (UL). The FEEDAP Panel assumes that foodstuffs of animal origin monitored in these studies were produced following current production practices, including vitamin D_3 supplementation of feed. It is concluded that the use of vitamin D in animal nutrition at the currently authorised maximum dietary content has not and will not cause the UL set by EFSA NDA Panel to be exceeded.

The FEEDAP Panel considers it prudent to treat the vitamin D_3 under assessment as irritant to skin and eyes, and as a dermal sensitiser. In the case of solid formulations of vitamin D_3, there is a potential for workers to be exposed to high levels of vitamin D by inhalation. Inhaled vitamin D_3 is highly toxic; exposure to dust is harmful.

Vitamin D is widely distributed in plants and animals, as a result of endogenous synthesis. It is susceptible to oxidation by light and air. No risk to the environment resulting from the use of vitamin D_3 in animal nutrition is expected.

The vitamin D_3 under application is regarded as an effective dietary source of the vitamin in animal nutrition.

The FEEDAP Panel made recommendations concerning (i) the specification of the product under application, (ii) labelling of the additive and (iii) the route of incorporation in complete and complementary feedingstuffs.