# Commission Implementing Regulation (EU) 2019/849 of 24 May 2019 amending Implementing Regulation (EU) 2017/1492 as regards the maximum content of cholecalciferol (vitamin D3) in feed for salmonids (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2019/849

## of 24 May 2019

## amending Implementing Regulation (EU) 2017/1492 as regards the maximum content of cholecalciferol (vitamin D3) in feed for salmonids

## (Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 13(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2017/1492[(2)] authorises cholecalciferol (vitamin $D_3$) as nutritional additive for all animal species. In that Regulation, the maximum authorised content of vitamin $D_3$ for fish is 3 000 IU/kg of complete feedingstuff.

(2) The Norwegian Food Safety Authority (NFSA) submitted studies on the safety of vitamin $D_3$ for fish and consumers at substantially higher levels (60 000 IU/kg of complete feedingstuff) than the maximum authorised content.

(3) For control purposes the results of calculation of tolerance levels can lead to a discrepancy in values between the two units (mg or IU). For this reason, the levels in the authorisation should be established only in International Units.

(4) On the basis of the data submitted by the NFSA, the European Food Safety Authority concluded in its opinions of 25 January 2017[(3)] and 29 November 2018[(4)] that a total level of 60 000 IU of vitamin $D_3$ per kg of complete feedingstuff is safe for consumers and the environment. The European Food Safety Authority also concluded that the levels proposed were safe for salmonids. For other fish, no sufficient data were available to conclude on the safety for a total level of 60 000 IU vitamin $D_3$/kg of complete feedingstuff. Consequently, the authorisation should be restricted to salmonids. It also concluded in the opinion of 13 November 2012[(5)] that vitamin $D_3$ is not an irritant to skin and eyes and is not a skin sensitiser. For some formulations of vitamin $D_3$ there is a potential for workers to be exposed to high levels of vitamin $D_3$ by inhalation. Inhaled vitamin $D_3$ is highly toxic. Exposure to dust is harmful to persons handling the additive. As the levels of vitamin $D_3$ have been increased this may have implications for user safety, therefore, the Commission considers that appropriate protective measures

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/849. (See end of Document for details)*

should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(5) The Annex to Implementing Regulation (EU) 2017/1492 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) 2017/1492 is replaced by the text set out in the Annex to this Regulation.

*Article 2*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 May 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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ANNEX

| Identification number of the additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | IU of cholecalciferol[a]/kg of complete feedingstuff with a moisture content of 12 %. | | | |
| Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect. | | | | | | | | | |
| 3a671 | — | ‘Cholecalciferol’ or ‘Vitamin $D_3$’ | *Additive composition* Cholecalciferol. *Characterisation of the active substance* Cholecalciferol $C_{27}H_{44}O$ CAS number: 67-97-0 Cholecalciferol solid and resin form, produced by chemical synthesis. Purity criteria: Min. 80 % (cholecalciferol and precholecalciferol) and max. 7 % tachysterol | Pigs | — | — | 2 000 IU | 1. Vitamin $D_3$ may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixtures, the storage | 11 September 2027 |
| | | | | Milk replacers for piglets | — | — | 10 000 IU | | |
| | | | | Bovines | — | — | 4 000 IU | | |
| | | | | Milk replacers for calves | — | — | 10 000 IU | | |
| | | | | Ovines | — | — | 4 000 IU | | |
| | | | | Chickens for fattening | — | — | 5 000 IU | | |
| | | | | Turkeys | — | — | 5 000 IU | | |
| | | | | Other poultry | — | — | 3 200 IU | | |
| | | | | Equines | — | — | 4 000 IU | | |
| | | | | Salmonids | — | — | 60 000 IU | | |
| | | | | Other fish species | — | — | 3 000 IU | | |

**a** 40 IU cholecalciferol = 0,001 mg cholecalciferol

**b** Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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|---|---|---|---|---|---|---|---|---|---|
| | | | *Method of analysis*[b] — | Other animal species For the determination of Vitamin $D_3$ in the feed additive: High Performance Liquid Chromatography coupled to UV detection (HPLC-UV, 254 nm) - European Pharmacopoeia method 01/2008:0574,0575,0598. — For the determination of Vitamin $D_3$ in premixtures: High Performance Liquid Chromatography coupled to UV detection at 265 nm (HPLC- | — | — | 2 000 IU | and stability conditions shall be indicated. | |
| | | | | | | | | 4. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol per kg of complete feedingstuff: — ≤ 5 000 IU of vitamin $D_3$ for chickens for fattening and turkeys for fattening, — ≤ 3 200 IU for other poultry, — ≤ 2 000 IU for pigs. | |

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