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**COMMISSION REGULATION (EU) .../...**

**of XXX**

**amending Annex III to Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed**

(Text with EEA relevance)

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# COMMISSION REGULATION (EU) .../...

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**amending Annex III to Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed**

(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 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, and in particular Article 6(2) thereof,

Whereas:

- (1) Regulation (EC) No 767/2009 lays down general safety and marketing requirements for feed. In particular, it contains a list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited.
- (2) The European Food Safety Authority ('the Authority') adopted in 2011 a scientific opinion on the safety of hemp (*Cannabis* sp.) for use as animal feed<sup>1</sup>. In its opinion, the Authority concluded that the use of whole hemp plant-derived feed materials in animal nutrition is not safe for the consumer and recommended that the placing on the market and use for animal nutrition of hemp-derived feed materials, other than hemp seed-derived feed materials, should be restricted or prohibited. The EFSA assessment on the safety of hemp was performed taking into consideration that hemp for use in animal feed was only originating from varieties that did not exceed 0.2 % of tetrahydrocannabinol (THC).
- (3) In 2015, the Authority adopted a scientific opinion on the risks to human health related to the presence of tetrahydrocannabinol in milk and other food of animal origin<sup>2</sup>, where it concluded that THC, more precisely  $\Delta^9$ -THC, is the most relevant constituent derived from the hemp plant *Cannabis sativa*. The Authority established an acute reference dose (ARfD) of 1  $\mu\text{g}$   $\Delta^9$ -THC/kg body weight (bw). A study performed by the German Federal Institute for Risk Assessment and published in 2022<sup>3</sup> demonstrated that the

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<sup>1</sup> EFSA **Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)**; Scientific Opinion on the safety of hemp (*Cannabis* genus) for use as animal feed. EFSA Journal 2011;9(3):2011. [41 pp.] doi:10.2903/j.efsa.2011.2011.

<sup>2</sup> EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA Journal 2015;13(6):4141, 125 pp. doi:10.2903/j.efsa.2015.4141.

<sup>3</sup> Wagner, B., Gerletti, P., Fürst, P. et al. Transfer of cannabinoids into the milk of dairy cows fed with industrial hemp could lead to  $\Delta^9$ -THC exposure that exceeds acute reference dose. Nat Food 3, 921–932 (2022). <https://doi.org/10.1038/s43016-022-00623-7>.

established ARfD for humans was exceeded in several consumer groups in exposure scenarios for milk and dairy product consumption, when using hemp silage to feed dairy cows made from whole hemp plants from varieties of *Cannabis* sp. with a tetrahydrocannabinol content  $\leq 0,3\%$ . In that same study, also adverse animal health effects due to the feeding with certain hemp-derived feed materials were observed.

- (4) In accordance with Article 24 of Regulation (EC) No 767/2009, a Catalogue of feed materials was established by Commission Regulation (EU) No 68/2013<sup>4</sup>. Pursuant to that Regulation, the name of a feed material listed in the Catalogue may be used only for a feed material complying with the requirements of the entry concerned. However, the use of the Catalogue by feed business operators is voluntary and the use of feed materials that are not listed in the Catalogue is not prohibited or restricted.
- (5) In the Catalogue of feed materials, only feed materials from hemp varieties containing less than 0,2% of tetrahydrocannabinol, quantified in accordance with Commission Delegated Regulation (EU) No 639/2014<sup>5</sup>, and feed materials derived from seeds and stems of hemp are listed, because the other parts of this plant (leaves and flowering tops, in particular) naturally contain unacceptably high levels of tetrahydrocannabinol. In the meantime, in accordance with Regulation (EU) 2021/2115 of the European Parliament and of the Council<sup>6</sup>, a maximum content of tetrahydrocannabinol of 0,3%, has become applicable. For the feed materials listed in the Catalogue of feed materials, maximum levels for tetrahydrocannabinol are foreseen to be established in accordance with Directive 2002/32/EC of the European Parliament and of the Council<sup>7</sup>.
- (6) Moreover, based on Regulation (EU) 2021/2115, producing hemp with a 0,3% limit of tetrahydrocannabinol has become common practice for the growing of hemp for industrial purposes. As a result, it would be difficult to differentiate between the hemp used in feed from the rest of the production for other industrial purposes. Consequently, the limit of 0.2% tetrahydrocannabinol seems no longer fitting with market practices.
- (7) It must be added that, considering the risk identified in dairy cows and that there is no differentiation between animal species in the scope of feed materials, this maximum limit of 0,3 % of tetrahydrocannabinol must be applied to hemp varieties used for animal nutrition in all species.
- (8) It is therefore appropriate to prohibit the use of feed materials derived from hemp varieties containing more than 0,3 % of tetrahydrocannabinol and to restrict the use of feed materials derived from parts of the hemp plants other than seeds and stems .

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<sup>4</sup> Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/68/oj>).

<sup>5</sup> Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014 supplementing Regulation (EU) No 1307/2013 of the European Parliament and of the Council establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and amending Annex X to that Regulation (OJ L 181, 20.6.2014, p. 1, ELI: [http://data.europa.eu/eli/reg\\_del/2014/639/oj](http://data.europa.eu/eli/reg_del/2014/639/oj)).

<sup>6</sup> Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1; ELI: <http://data.europa.eu/eli/reg/2021/2115/oj>).

<sup>7</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10, ELI: <http://data.europa.eu/eli/dir/2002/32/oj>).

- (9) For use in feed, cannabidiol (CBD) in order to be put on the market needs to be authorised as a feed additive in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council<sup>8</sup>. However, cannabidiol occurs naturally in the different parts of the hemp plant, at varying concentrations. In order to avoid that cannabidiol-enriched hemp oils or other cannabidiol-enriched hemp products, that would require authorisation as feed additives, are placed on the market as feed materials, it is appropriate to establish a maximum content of cannabidiol which reflects the natural content of cannabidiol in feed materials derived from hemp.
- (10) In 2024, the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) published an opinion on the residual content of cannabidiol present in hemp-based foodstuff having a history of consumption. This opinion concludes that the highest level of natural presence of cannabidiol in feed materials derived from hemp identified in literature is 83 ppm, which equals to 0,0083%. It is therefore appropriate to prohibit the use of feed materials with a CBD content of > 0,0083%, as a higher concentration of cannabidiol can only derive from a voluntary addition of cannabidiol and not from its natural content in feed materials derived from hemp.
- (11) Regulation (EC) No 767/2009 should therefore be amended accordingly.
- (12) 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*

#### **Amendments to Regulation (EC) No 767/2009**

Annex III to Regulation (EC) No 767/2009 is amended as follows:

1. In Chapter 1, the following point 9 is added:
  - ‘9. The following feed materials:
    - a) Feed materials with a cannabidiol content of > 0,0083%;
    - b) Feed materials derived from varieties of *Cannabis* sp. with a tetrahydrocannabinol content > 0,3%.’
2. In Chapter 2, the following point 1 is added:
  - ‘1. Varieties of *Cannabis* sp. with a tetrahydrocannabinol content  $\leq$  0,3%:
    - (a) parts of the plant other than seeds and stems: use restricted to the manufacturing of feed additives.’
    - (b) products derived from hemp other than feed materials listed in Regulation (EU) No. 68/2013: use restricted to the manufacturing of feed additives.’

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<sup>8</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>).

*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,

*For the Commission*  
*The President*  
Ursula VON DER LEYEN