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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)

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. At present, there is no explicit limitation of the use of various parts of the hemp plant (*Cannabis* sp.) for the production of feed materials for animal nutrition, including seeds, stems, leaves and flowers. However, the content of tetrahydrocannabinol (THC) differs depending on the variety of *Cannabis sativa* L. and also on the part of the plant that is considered, which might entail distinct conclusions in terms of fitness for feeding of animals.
3. In 2011, the European Food Safety Authority (‘the Authority’) adopted a scientific opinion on the safety of hemp for use as animal feed[[1]](#footnote-1). 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 of milk produced by animals fed with those feed materials. Indeed, the Authority noted that in all scenarios calculated with the feeding of dairy cows with whole hemp plant-derived feed material containing 0.2 % THC, the exposure to THC of the consumers of the milk was considerably above the provisional maximum tolerable daily intake (4 to 25 times higher in adults, 13 to 90 times higher in children). In addition to that, the Authority mentioned a likely transfer of THC and its lipophilic metabolites to animal tissues and eggs following repeated administration, which means that meat and eggs produced by animals fed with whole hemp plant-derided feed materials would be a likely additional source of THC exposure for the consumers. the Authority therefore concluded that the safety concerns related to milk consumption would therefore in principle apply also to the consumption of meat or eggs of animals fed with whole hemp plant-derived feed materials. As a consequence, the Authority did not see any option for the use of whole hemp plant-derived feed materials in animal nutrition and the EFSA opinion recommends that the placing on the market and use for animal nutrition of hemp-derived feed materials (whole hemp plant, hemp hurds, hemp flour (ground dried hemp leaves)) be restricted or prohibited.
4. Following this opinion from the Authority, it was appropriate to consider the need to establish possible maximum levels for THC in milk and other food of animal origin. For that purpose a detailed risk assessment as regards the risks for human health in relation to the presence of THC in milk and other food of animal origin was requested from the Authority[[2]](#footnote-2) In 2015, the Authority adopted the scientific opinion on the risks to human health from the presence of THC in milk and other food of animal origin[[3]](#footnote-3). It concluded that THC, more precisely Δ9-THC, is the most relevant constituent derived from the hemp plant *Cannabis sativa*. The Authority established an acute reference dose (ARfD) of 1 μg Δ9-THC/kg body weight (bw). However, according to the opinion, a risk assessment of the actual dietary exposure to Δ9-THC via milk and dairy products resulting from the use of whole-hemp-plant derived feed materials was not possible because of the lack of representative occurrence data for Δ9-THC in whole hemp plant-derived feed materials. In addition, due to the lack of data on the potential transfer and fate of ∆9-THC in animal tissues and eggs, scenarios considering the exposure via other food of animal origin resulting from the use of hemp-derived feed materials could also not be performed. Consequently, the Authority could neither establish nor exclude a risk related to the consumption of food of animal origin originating from animals fed with whole hemp plant-derived feed material. Additionally, the Authority highlighted the need of the following: more data on the presence of Δ9-THC and its precursors in hemp-derived feed materials for food producing livestock; further studies on the transfer rate of Δ9-THC and its metabolites into animal products intended for human consumption; more information on the fate of Δ9-THC and its precursor acids in food-producing animals, especially ruminants, and in food processing.
5. In 2016, Commission Recommendation (EU) 2016/2115[[4]](#footnote-4) was adopted to obtain, among other, more data on the presence of Δ9-THC in food of animal origin, of which evidence is available that the food of animal origin is produced by animals being fed with feed containing hemp or hemp derived feed materials. In 2019, the Authority adopted a scientific report on the acute human exposure assessment to tetrahydrocannabinol (Δ9-THC)[[5]](#footnote-5) once again calling for studies to investigate the carry-over of Δ9-THC in the food chain and especially in food of animal origin, when the animals are fed with hemp and hemp-derived products, and encouraging Member States to collect and submit to EFSA more data on the presence of Δ9-THC in food, especially food of animal origin, including dairy products, eggs and meat of animals fed with hemp and hemp-derived products .
6. In 2022, a study performed by the German Federal Institute for Risk Assessment[[6]](#footnote-6) demonstrated that the established ARfD for humans was exceeded in several consumer groups in exposure scenarios for milk and dairy product consumption, when using hemp silage from whole hemp plants to feed dairy cows. In the same study, adverse animal health effects due to the feeding with hemp silage made from leaves and flowers in particular were also observed.
7. Given the risks for human health from the possibility of exceeding the ARfD for Δ9-THC in humans through the consumption of milk and dairy products from animals fed with feed materials derived from whole-hemp-plant and parts of the hemp plant other than seeds and stems , and the risks for animal health from the presence of THC in animal feed, it is necessary to take action to safeguard human and animal health.. While there is currently scientific uncertainty, due to the limited data available in animal species other than cattle and animal-derived food products other than milk, the reported effects in dairy cows fed with hemp-derived materials and their milk indicate a risk for animal and human and health that may extend to other animal species. Recognizing the current scientific uncertainty, it is evident that there is a risk for animal and public health related to the feeding of whole hemp feed materials but it is important that research and risk assessments in this area continue to enable a more accurate estimate of the risk. Any future regulatory adjustments will be informed by evolving scientific evidence.
8. Regulation (EC) 767/2009 and Commission Regulation (EU) 68/2013 do not make any distinction between animal species and, therefore, feed materials are marketed for use in animal nutrition without specifying the animal species for which they are intended. Moreover, feed materials containing hemp or its derivatives are currently used in various livestock production systems. An effective enforcement of the restriction to the feeding of hemp-derived feed materials to only some animal species or even some categories of animals within a same species (e.g. dairy cows vs. beef cattle) would therefore be impossible or excessively difficult. ,.
9. Various parts of the plant of hemp (*Cannabis* sp.) may be considered for the production of feed materials for animal nutrition, mainly the seeds, stems, leaves and flowers, however the content of tetrahydrocannabinol (THC) differs depending on the part of the plant that is considered. Only the parts which naturally contain a quantity of THC which has been proved to be safe should be considered fit for the feeding of animals.
10. The 2011 opinion from the Authority acknowledges feed materials derived from hemp seed as safe. There are studies[[7]](#footnote-7) demonstrating that the cannabinoid content, including THC and cannabidiol, in the hemp stems is in the same range as in the hemp seeds. Therefore, the conclusion as regards the safety of the hemp seed derived feed materials is also applicable to hemp stem derived feed materials Therefore, seeds, stems and other feed materials derived from these parts only of the hemp plant can be considered safe for use in animal nutrition.
11. 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[[8]](#footnote-8). Pursuant to that Regulation, the use of the Catalogue by feed business operators is voluntary, however 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. The only hemp derived feed materials currently listed in the Catalogue of feed materials are hemp seed, hemp expeller, hemp seed oil, hemp flour and hemp fibre, which are derived from hemp seeds and stems and therefore considered safe for use in animal nutrition.
12. There are several notifications in the Rapid Alert System for Food and Feed (RASFF) related to the high levels of cannabidiol (CBD) in feed. The use of CBD in feed requires a pre-market authorisation of CBD as feed additive and currently CBD is not authorised as feed additive. These high levels of CBD relate to the illegal use of CBD as a non-authorised feed additive. CBD occurs naturally in the different parts of the hemp plant, at varying concentrations. In order to avoid that cannabidiol-enriched feed materials derived from hemp related to the illegal use of CBD are placed on the market, it is appropriate for enforcment purposes to establish a maximum content of CBD which reflects the natural content of CBD in the feed materials derived from hemp, listed in Regulation (EU) No 68/2013.

In 2024, the Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail (ANSES) published an opinion[[9]](#footnote-9) on the residual content of CBD present in hemp seed-based food having a history of consumption in Europe. This opinion concludes that the highest level of unavoidable presence of CBD in hemp seeds identified in literature is 83 ppm. Considering a CBD concentration factor of approximately 2,5 when pressing hemp seeds to produce hemp seed oil, it is appropriate to prohibit the use of hemp seed oil with a CBD content of > 210 ppm and of other feed materials derived from hemp with a CBD content of > 83 ppm, as higher levels can only derive from a voluntary addition of CBD and not from its presence due to unavoidable presence following contamination with other parts of the plant during harvesting. As stems are produced during the same harvesting process and are contaminated with other parts of the hemp plant in the same way as hemp seeds, this level of unavoidable presence of CBD should also be applicable to hemp feed materials derived from stems.

1. Regulation (EC) No 767/2009 should therefore be amended accordingly.
2. 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**

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

In Chapter 1, the following point 9 is added:

‘9. Any feed material derived from *Cannabis* sp, other than the following feed materials, as defined in Regulation (EU) No 68/2013:

* - hemp seed
* - hemp expeller
* - hemp seed oil
* - hemp flour
* - hemp fibre

10. Hemp seed oil with a cannabidiol content > 210 ppm, and any other feed material derived from Cannabis sp, listed in Regulation (EU) No 68/2013, with a cannabidiol content > 83 ppm.’

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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

1. [↑](#footnote-ref-1)
2. 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. https://open.efsa.europa.eu/question/EFSA-Q-2013-00787 [↑](#footnote-ref-2)
3. 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. [↑](#footnote-ref-3)
4. Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food *OJ L 327, 2.12.2016, p. 103* ELI: <http://data.europa.eu/eli/reco/2016/2115/oj> [↑](#footnote-ref-4)
5. EFSA Journal 2020;18(1):5953. doi: 10.2903/j.efsa.2020.5953. [↑](#footnote-ref-5)
6. Wagner, B., Gerletti, P., Fürst, P. et al. Transfer of cannabinoids into the milk of dairy cows fed with industrial hemp could lead to Δ9-THC exposure that exceeds acute reference dose. Nat Food 3, 921–932 (2022). https://doi.org/10.1038/s43016-022-00623-7. [↑](#footnote-ref-6)
7. For example, the study Nutrient concentrations, digestibility, and cannabinoid concentrations of industrial hemp plant components, published in Applied Animal Science (2020) 36:489–494. Available at: <https://doi.org/10.15232/aas.2020-02018> [↑](#footnote-ref-7)
8. 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>). [↑](#footnote-ref-8)
9. Anses. (2024). Avis relatif à la teneur résiduelle en cannabidiol présente dans les denrées alimentaires à base de chanvre bénéficiant d'un historique de consommation. (saisine 2024- SA-0040) – Partie 1 : les graines et produits dérivés, <https://www.anses.fr/sites/default/files/NUT2024SA0040.pdf>; Partie 2 : les feuilles pour infusion aqueuse. Maisons-Alfort : Anses, 10 p. https://www.anses.fr/fr/system/files/NUT2024SA0040-2.pdf [↑](#footnote-ref-9)