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[...] (2023) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for arsenic, cadmium, lead, nickel, rye ergot, delta-9-tetrahydrocannabinol, endosulfan, heptachlor, hexachlorbenzene, hexachlorohexane, dioxins and PCBs, *Datura* sp., certain coccidiostats and histomonostats and p-phenetidine in animal feed

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Directive 2002/32/EC of the European Parliament and of the Council¹ establishes maximum levels and action thresholds for undesirable substances in feed to ensure a high level of human health, animal health and protection of the environment and to not adversely affect livestock production. Products intended for animal feed may enter the Union, be put into circulation and/or used in the Union only if they are sound, genuine and of merchantable quality and therefore when correctly used do not represent any danger to human health, animal health or to the environment or do not adversely affect livestock production. In particular products intended for animal feed are deemed not to be in conformity if the level of undesirable substances does not comply with the maximum levels established by the Directive.

Taking into account the experience in implementation of the Directive and the outcome of scientific opinions from the European Food Safety Authority (EFSA) an update of the Annexes to Directive 2002/32/EC is needed.

The changes to the Annexes to the Directive relates to

- the establishment of maximum levels for nickel, Δ 9-tetrahydrocannabinol (Δ 9-THC) and p-phenetidine;
- changes to certain maximum levels for arsenic, cadmium, lead, rye ergot, endosulfan, heptachlor, hexachlorobenzene, hexachlorocyclohexane, dioxins and dioxin-like PCBs, *Datura* seeds;
- changes to the section on authorised feed additives in feed for non-target animal species following unavoidable carry-over following changes in the conditions of authorisation of certain feed additives;
- changes to certain action levels for dioxins and PCBs.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft Delegated Regulation has been discussed during meetings of the Commission Expert Group on Animal Nutrition (E03698), representing the competent authorities of all Member States and private stakeholders, the last one on 4 October 2023, and is largely supported by those experts.

Before adopting this Delegated Regulation, the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making².

3. LEGAL ELEMENTS OF THE DELEGATED ACT

In accordance with Article 8(1) of Directive 2002/32/EC, the Commission is empowered to adopt delegated acts to adapt Annexes I and II to Directive 2002/32/EC to the scientific and technical developments.

¹ 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)

² OJ L 123, 12.5.2016, p. 1.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed³, and in particular Article 8(1) thereof,

Whereas:

- (1) Directive 2002/32/EC establishes maximum levels and action thresholds in Annex I and Annex II, respectively, for undesirable substances in feed, in order to ensure a high level of human health, animal health and protection of the environment and to not adversely affect livestock production. The Annexes to that Directive should be updated, taking into account scientific and technical developments.
- (2) According to scientific data from competent authorities and feed business operators concerned, the current maximum level for total arsenic in fish, other aquatic animals and products derived thereof and in complementary feed for fish (including *Crustacea*) is not achievable in all production conditions despite applying good practices to reduce the presence of arsenic in these feeds. Varying levels of arsenic are observed in the marine environment, resulting in different levels of contamination of marine organisms used for the production of feed materials. It is therefore appropriate to increase the maximum level for total arsenic in these feeds to a level that is assessed to be as low as reasonably achievable, taking into account the available scientific data. Such increase of the maximum level does not adversely affect human health, animal health or the protection of the environment, as the maximum level for total arsenic in complete feed and the maximum level for inorganic arsenic, the toxic form of arsenic, in the concerned feeds remain unchanged.
- (3) Scientific information shows that certain seaweed species not yet provided for in Directive 2002/32/EC contain high levels of inorganic arsenic. Those species should therefore be subject to control for the level of inorganic arsenic.
- (4) The name of certain trace elements, i.e. cupric sulphate pentahydrate, cupric carbonate, ferrous carbonate, cupric oxide, manganous oxide and ferrous carbonate has changed and it is appropriate to update these.

³ OJ L 140, 30.5.2002, p.10

- (5) According to scientific data from concerned feed business operators, the general maximum level of 10 mg/kg for cadmium in feed additives belonging to the functional group of compounds of trace elements is not consistently achievable for the trace element copper (I) oxide in all production conditions despite applying good practices to reduce the presence of cadmium in copper (I) oxide. It is therefore appropriate to increase the maximum level for cadmium in copper (I) oxide to a level that is assessed to be as low as reasonably achievable, taking into account the available scientific data. [Such increase of the maximum level does not adversely affect the human health, animal health or the protection of the environment, as the maximum level laid down for cadmium in complete feed remains unchanged.
- (6) According to scientific data from competent authorities, the current maximum level for lead in game meat for use in pet food is not consistently achievable in all production conditions despite applying good practices. It is therefore appropriate to increase the maximum level for lead in game meat for use in pet food to a level that is assessed to be as low as reasonably achievable, taking into account the available scientific data. Such increase of the maximum level does not adversely affect the animal health as the maximum level laid down for lead in complete feed for pet animals remains unchanged.
- (7) On 31 March 2015, the European Food Safety Authority ('the Authority') adopted a scientific opinion as regards the presence of nickel in feed⁴. It concluded that any adverse impact on animal health of nickel via feed is unlikely, but that the contribution of food of animal origin to human dietary exposure to nickel should not be underestimated. Following Commission Recommendation (EU) 2016/1110⁵, the Authority assessed in May 2019 the occurrence data of nickel in feed and on animal exposure⁶. In the framework of that assessment, certain feed materials were identified to contain significant levels of nickel as the consequence of the use of nickel as catalyst in hydrogenation processes. As low levels of nickel can be ensured by applying good practices, it is appropriate to establish a maximum level of nickel for these feed materials to a level that is assessed to be as low as reasonably achievable, taking into account the application of good practices.
- (8) According to the Authority, the presence of ergot alkaloids in feed might be of animal health concern⁷. It is possible by applying good practices, including sorting techniques, to lower the level of rye ergot in unground cereals. Therefore, it is appropriate to lower the maximum levels of rye ergot in feed materials and compound feed containing unground cereals to the level that is assessed to be as low as reasonably achievable by the application of good practices.

⁴ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks to animal and public health and the environment related to the presence of nickel in feed. EFSA Journal 2015;13(4):4074, 76 pp. <https://doi.org/10.2903/j.efsa.2015.4074>

⁵ Commission Recommendation (EU) 2016/1110 of 28 June 2016 on the monitoring of the presence of nickel in feed (OJ L 183, 8.7.2016, p. 68)

⁶ EFSA (European Food Safety Authority), Arcella D, Gergelova P, Innocenti ML, Lopez-Gálvez G and Steinkellner H, 2019. Occurrence data of nickel in feed and animal exposure assessment. EFSA Journal 2019;17(6):5754, 34 pp. <https://doi.org/10.2903/j.efsa.2019.5754>

⁷ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Ergot alkaloids in food and feed. EFSA Journal 2012;10(7):2798. (158 pp.) <https://doi.org/10.2903/j.efsa.2012.2798>

- (9) Certain feed materials derived from hemp are listed in the catalogue of feed materials⁸. Already in 2011, the Authority concluded that the use in feed of hemp-derived feed materials should be restricted or prohibited due to the presence of Δ 9-tetrahydrocannabinol (Δ 9-THC)⁹ to ensure a high level of human health protection. Maximum levels for Δ 9-THC for certain hemp-derived products intended for human consumption are established by Commission Regulation (EU) 2023/915¹⁰. As these maximum levels are achievable by applying good practices regardless of whether these hemp-derived products are destined for food or feed, it is appropriate to establish corresponding maximum levels for relevant feed materials and complete feed.
- (10) Taking into account the conclusions in opinions of the Authority, the presence of endosulfan¹¹, heptachlor¹², hexachlorobenzene¹³ and gamma-hexachlorocyclohexane¹⁴ in feed is of possible health concern and the presence of these substances should be as low as reasonably achievable. Recent data on occurrence of these substances in feed provides evidence that lower levels than the current maximum levels are reasonably achievable. Therefore, it is appropriate to lower certain maximum levels for these substances and to align them with the maximum residue levels established by Regulation (EC) No 396/2005 of the European Parliament and of the Council¹⁵.
- (11) According to the Authority, the presence of dioxins and dioxin-like PCBs in feed and food is of health concern¹⁶. Maximum levels of those substances are expressed as Toxic Equivalent Quantities (TEQ). The Authority concluded that the current WHO₂₀₀₅-Toxic Equivalent Factors (TEFs) used for the calculation of the TEQ values should be re-evaluated to take into account new toxicity data. The World Health Organisation has re-evaluated the TEFs in 2022 and the publication of new TEF values is envisaged in 2023 and should be the basis for a comprehensive review of the maximum and action levels for dioxins and dioxin-like PCBs in feed. Pending this comprehensive review, taking into account the health concern and scientific data from recent years available in the EFSA database on the occurrence of dioxins and dioxin-

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)

⁹ 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. 41pp. <https://doi.org/10.2903/j.efsa.2011.2011>

¹⁰ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103).

¹¹ Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to endosulfan as undesirable substance in animal feed. The EFSA Journal (2005) 234, 1-31. <https://doi.org/10.2903/j.efsa.2005.234>

¹² Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to heptachlor as undesirable substance in animal feed. The EFSA Journal (2007) 478, 1-48. <https://doi.org/10.2903/j.efsa.2007.478>

¹³ Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to hexachlorobenzene as undesirable substance in animal feed. The EFSA Journal (2006) 402, 1-49. <https://doi.org/10.2903/j.efsa.2006.402>

¹⁴ Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to gamma-hexachlorocyclohexane (γ -HCH) and other hexachlorocyclohexanes as undesirable substance in animal feed. The EFSA Journal (2005) 250, 1-39. <https://doi.org/10.2903/j.efsa.2005.250>

¹⁵ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)

¹⁶ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Scientific Opinion on the risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food. EFSA Journal 2018;16(11):5333, 331 pp. <https://doi.org/10.2903/j.efsa.2018.5333>

like PCBs in certain feeds which provide evidence that lower levels than the current maximum levels are reasonably achievable by applying good practices. Therefore, it is appropriate to lower the maximum and action levels in these feeds to the levels assessed to be as low as reasonably achievable by good practices.

- (12) As the harmful botanical impurities have generally the same moisture content as the feed in which they are present, it is appropriate for the harmful botanical impurities to express the maximum level relative to the feed without correction for moisture content.
- (13) In an opinion on tropane alkaloids (from *Datura* sp.) in animal feed¹⁷, the Authority indicated that it cannot be excluded that feed contamination with *Datura* sp. at the current maximum level would cause adverse health effects in pigs. By applying good agricultural practices and, if necessary, cleaning the harvested cereals whereby the *Datura* sp. seeds are sorted out before processing, lower levels than the current maximum levels are achievable. It is therefore appropriate to lower the maximum level of *Datura* sp. as a harmful botanical impurity in feed to a level that is reasonably achievable by applying good agricultural practices and if necessary sorting that ensures that feed containing a quantity of *Datura* sp. at the maximum level does not result in adverse health effects in pigs
- (14) As regards coccidiostats and histomonostats, transfer from one production lot to another may occur when such substances are used as authorised feed additives. Such transfer may result in the contamination of feed subsequently produced by the presence of technically unavoidable traces of such substances, referred to as unavoidable carry-over or cross-contamination, in feed for non-target animal species. Taking into account the application of good manufacturing practices, maximum levels of unavoidable carry-over of coccidiostats or histomonostats in feed for non-target animal species are established following the as low as reasonably achievable principle. For the purpose of enabling the feed manufacturer to manage unavoidable carry-over, a carry-over rate of 3 % of the authorised maximum content is considered acceptable as regards feed for less sensitive non-target animal species while a carry-over rate of 1 % of the authorised maximum content is considered acceptable for feed intended to sensitive non-target animal species and feed used for the period before slaughter. The carry-over rate of 1 % is also considered acceptable for cross-contamination of other feed for target species to which no coccidiostats or histomonostats are added, and as regards feed for non-target animal species for ‘continuous food-producing animals’, such as dairy cows or laying hens, where there is evidence of transfer from feed to food of animal origin. As the conditions of authorisation of the feed additives diclazuril, lasalocid sodium, nicarbazin, robenidine hydrochloride and salinomycin sodium, these changes should be reflected in the provisions related to maximum levels of unavoidable carry-over of authorised feed additives in feed for non-target animal species in accordance with the proposed carry-over rates.
- (15) Given that maduramicin ammonium alpha is no longer authorised as feed additive in the Union, the entry related to that feed additive should be deleted from Annex I to Directive 2002/32/EC.

¹⁷ Scientific Opinion of the Panel on Contaminants in the Food Chain on tropane alkaloids (from *Datura* sp.) as undesirable substance in animal feed. The EFSA Journal (2008) 691, 1-55. <https://doi.org/10.2903/j.efsa.2008.691>

- (16) In its opinion of 27 January 2022 on ethoxyquin¹⁸, the Authority could not conclude on the safety of that additive at any level, considering that the additive contains p-phenetidine, a recognised possible mutagen which remains as an impurity in the additive. Commission Implementing Regulation (EU) 2022/1375¹⁹ denied the authorisation of ethoxyquin (E324) as a feed additive. Therefore, the use of ethoxyquin in feed is no longer allowed in the Union, including in feed entering the Union from third countries. Given that ethoxyquin with significant levels of p-phenetidine as impurity is still authorised and used in certain third countries, and cross contamination cannot be excluded, a maximum level of p-phenetidine at the limit of quantification should be established for all feed to ensure a high level of animal and public health protection.
- (17) To enable feed business operators to prepare for the new rules introduced by this Regulation, it is appropriate to provide for transitional measures.
- (18) Directive 2002/32/EC should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Directive 2002/32/EC

Annexes I and II to Directive 2002/32/EC are amended, respectively, in accordance with Annexes I and II to this Regulation.

Article 2

Transitional measures

Feed containing Arsenic, cadmium, lead, nickel, rye ergot, delta-9-tetrahydrocannabinol, endosulfan, heptachlor, hexachlorbenzene, hexachlorohexane, dioxins and PCBs, *Datura* sp., p-phenetidine, diclazuril, lasalocid sodium, nicarbazin, robenidine hydrochloride and salinomycin sodium listed in the Annex to this Regulation, lawfully produced before [*OP please insert the date of entry into force*], may continue to be placed on the market until [*3 months after the date of entry into force*] and may be used until [*6 months after the date of entry into force*]

¹⁸ EFSA FEEDAP Panel (EFSA Panel on Additives, Products or Substances used in Animal Feed), Scientific Opinion on the safety and efficacy of a feed additive consisting of ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) for all animal species (FEFANA asbl). EFSA Journal 2022;20(3):7166. 44 pp. <https://doi.org/10.2903/j.efsa.2022.7166>

¹⁹ Commission Implementing Regulation (EU) 2022/1375 of 5 August 2022 concerning the denial of authorisation of ethoxyquin as a feed additive belonging to the functional group of antioxidants and repealing Implementing Regulation (EU) 2017/962 (OJ L 206, 8.8.2022, p. 39)

By way of derogation from the first paragraph, point (10) of Annex I shall apply as from 1 July 2025.

Article 3
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