



Brussels, XXX
[...]
[...] (2024) XXX draft

COMMISSION RECOMMENDATION

of XXX

on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 toxins and fumonisins in feed

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on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 toxins and fumonisins in feed

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Commission Recommendation 2006/576/EC¹ recommended Member States with the active involvement of feed business operators to increase the monitoring of the mycotoxins deoxynivalenol, zearalenone, ochratoxin A, fumonisin B₁ + B₂ and T-2 and HT-2 toxin in cereals and cereal products intended for animal feeding and compound feed. In addition, guidance levels were established for judging the acceptability of compound feed and cereal and cereal products for animal feeding.
- (2) The guidance levels for cereal and cereal products were established taking into account the then available occurrence data of these mycotoxins. The guidance levels for compound feed were established on the basis of the outcome of the scientific opinions of the European Food Safety Authority (EFSA) on deoxynivalenol on 2 June 2004², zearalenone on 28 July 2004³, ochratoxin A on 22 September 2004⁴ and fumonisins on 22 June 2005⁵.
- (3) EFSA adopted in 2011 a scientific opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed⁶. On the basis of this opinion, Commission Recommendation 2013/165/EU⁷ recommended Member States with the active involvement of feed business operators to perform monitoring for the presence of T-2 and HT-2 toxin in cereals and cereal products. Indicative levels were established for cereals, cereal products for feed and compound feed with the exception of feed for cats. Given that cats are amongst the most sensitive animal species, a

¹ Commission Recommendation of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding. OJ L 229, 23.8.2006, p. 7 ELI: <http://data.europa.eu/eli/reco/2006/576/oj>

² Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to deoxynivalenol (DON) as undesirable substance in animal feed. Available at: <https://doi.org/10.2903/j.efsa.2004.73>

³ Opinion of the Scientific Panel on contaminants in the food chain (CONTAM) related to zearalenone as undesirable substance in animal feed. Available at: <https://doi.org/10.2903/j.efsa.2004.89>

⁴ Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to ochratoxin A (OTA) as undesirable substance in animal feed Available at: <https://doi.org/10.2903/j.efsa.2004.101>

⁵ Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to fumonisins as undesirable substances in animal feed. Available at: <https://doi.org/10.2903/j.efsa.2005.235>

⁶ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011; 9(12):2481. 187 pp. Available at : <https://doi.org/10.2903/j.efsa.2011.2481>

⁷ Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products OJ L 91, 3.4.2013, p. 12, ELI: <http://data.europa.eu/eli/reco/2013/165/oj>

guidance level was established in Commission Recommendation 2006/576/EC by Commission Recommendation 2013/637/EU⁸.

- (4) On deoxynivalenol, in 2013 a scientific report of EFSA was published on the occurrence and exposure⁹ and EFSA adopted in 2017 an opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed¹⁰. The Panel on Contaminants in the Food Chain (CONTAM Panel) identified reduced feed intake, and reduced body weight and body weight gain as critical chronic adverse effects for farm and companion animals and identified reference points for adverse animal health effects (no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs)) for these effects. In 2022, EFSA adopted an opinion on the assessment of information as regards the toxicity of deoxynivalenol for horses and poultry¹¹. The reference points for adverse animal health effects were lowered for horses, broiler chickens and turkeys.
- (5) On zearalenone, EFSA adopted in 2017 an opinion on the risks for animal health related to the presence of zearalenone and its modified forms in feed¹². Reference points for adverse animal health effects were identified for farm and companion animals.
- (6) On ochratoxin A, EFSA adopted in 2023 an opinion on the risks for animal health related to the presence of ochratoxin A (OTA) in feed¹³. Reference points for adverse animal health effects were identified for pigs, chickens for fattening, hens, rabbits and herbivore fish.
- (7) On fumonisins, EFSA adopted in 2018 an opinion on the risks for animal health related to the presence of fumonisins, their modified forms and hidden forms in feed¹⁴. The EFSA CONTAM Panel identified NOAELs for cattle, pig, poultry (chicken, ducks and turkeys), horses, and LOAELs for fish (extrapolated from carp) and rabbits. No reference points could be identified for sheep, goats, dogs, cats and mink. In 2022, EFSA adopted an opinion on the assessment of information as regards the toxicity of

⁸ Commission Recommendation 2013/637/EU of 4 November 2013 amending Recommendation 2006/576/EC as regards T-2 and HT-2 toxin in compound feed for cats. OJ L 294, 6.11.2013, p. 44. ELI: <http://data.europa.eu/eli/reco/2013/637/oj>

⁹ European Food Safety Authority, 2013. Deoxynivalenol in food and feed: occurrence and exposure. EFSA Journal 2013;11(10):3379, 56 pp. Available at: <https://doi.org/10.2903/j.efsa.2013.3379>

¹⁰ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain) 2017. Scientific Opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed. EFSA Journal 2017;15(9):4718, 345 pp. Available at: <https://doi.org/10.2903/j.efsa.2017.4718>

¹¹ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2023. Scientific Opinion on the assessment of information as regards the toxicity of deoxynivalenol for horses and poultry. EFSA Journal 2023;21(2):7806, 30 pp. Available at: <https://doi.org/10.2903/j.efsa.2023.7806>

¹² EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2017. Scientific opinion on the risks for animal health related to the presence of zearalenone and its modified forms in feed. EFSA Journal 2017;15(7):4851, 123 pp. Available at: <https://doi.org/10.2903/j.efsa.2017.4851>

¹³ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2023. Risks for animal health related to the presence of ochratoxin A (OTA) in feed. EFSA Journal,21(11), 1–89. Available at: <https://doi.org/10.2903/j.efsa.2023.8375>

¹⁴ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2018. Scientific opinion on the risks for animal health related to the presence of fumonisins, their modified forms and hidden forms in feed. EFSA Journal 2018;16(5):5242, 144 pp. Available at <https://doi.org/10.2903/j.efsa.2018.5242>

fumonisin for pigs, poultry and horses¹⁵. The reference points for adverse animal health effects were lowered for poultry and horses.

- (8) On T-2 and HT-2 toxin, EFSA adopted a scientific report on the human and animal dietary exposure to T-2 and HT-2 toxin¹⁶ and an opinion on the assessment of information as regards the toxicity of T-2 and HT-2 toxin for ruminants¹⁷. The reference points for adverse animal health effects were lowered for sheep and cows.
- (9) Taking into account the more recent occurrence data and the outcome of the more recent scientific opinions, the existing guidance levels need to be updated to ensure a high level of animal health protection.
- (10) The guidance levels for feed materials are established taking into account the occurrence data thereby acknowledging the regional and high year-to-year variation.
- (11) The guidance levels for complete feed are established based on the reference points for adverse animal health risks. Exceedance of these guidance levels in complete feed or complementary feed, taking into account the proportion prescribed for their use in daily ration, might result in adverse animal health effects. It is therefore of importance that these guidance levels should be complied with.
- (12) Given the substantial changes it is appropriate to establish a new Recommendation. Recommendation 2006/576/EC and 2013/165/EU should therefore be repealed.

HAS ADOPTED THIS RECOMMENDATION:

- (1) Member States with the active involvement of all feed business operators should monitor the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 toxins and fumonisins B₁ + B₂ in feed.
- (2) Member States and feed business operators should ensure that samples are simultaneously analysed for the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 toxin and fumonisins B₁ + B₂ to allow the extent of co-occurrence to be assessed.
- (3) Member States should ensure that all feed business operators and farmers apply the guidance values, as set out in the Annex, for judging the acceptability of feed materials and compound feed for animal feeding. Feed business operators should use in their Hazard Analysis and Critical Control Points (HACCP) system¹⁸, the guidance values referred to in the Annex to determine the critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards. Guidance levels are established for certain feed materials and complete feed.

¹⁵ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2022. Scientific Opinion on the assessment of information as regards the toxicity of fumonisins for pigs, poultry and horses. EFSA Journal 2022;20(8):7534, 26 pp. <https://doi.org/10.2903/j.efsa.2022.7534>

¹⁶ EFSA (European Food Safety Authority), Arcella D, Gergelova P, Innocenti ML and Steinkellner H, 2017. Scientific report on human and animal dietary exposure to T-2 and HT-2 toxin. EFSA Journal 2017;15(8):4972, 57 pp. <https://doi.org/10.2903/j.efsa.2017.4972>

¹⁷ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2022. Scientific Opinion on the assessment of information as regards the toxicity of T-2 and HT-2 toxin for ruminants. EFSA Journal 2022;20(9):7564, 17 pp. <https://doi.org/10.2903/j.efsa.2022.7564>

¹⁸ Regulation (EC) No 1831/2003 of the European Parliament and of the Council, OJ L 35, 8.2.2003, P. 1, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>

- (4) For complementary feed, the guidance levels for complete feed should be applied, taking into account the proportion prescribed for their use in a daily ration. However, the guidance level for complementary feed should in any case not be higher than the level calculated taking into account the guidance level established for the feed materials and the relative proportion of the feed materials in the complementary feed.
- (5) To ensure a high level of animal health protection, Member States with the active involvement of all feed business operators and farmers should ensure that feed exceeding the guidance levels is not used for animal feeding without precautionary measures aimed at protection of animal health.

In particular, feed materials intended for placing on the market and complete and complementary feed intended for placing on the market exceeding their guidance value should be considered as not “sound, genuine, unadulterated, fit for its purpose and of merchantable quality”, as provided for in Article 4 (2) (a) of Regulation (EC) No 767/2009¹⁹ unless appropriate measures are taken including providing to the buyer clear information about the mycotoxin content. In addition, when the guidance level for complete feed, as well as for complementary feed and for feed materials intended to be fed directly to the animals, is exceeded, a risk assessment should be performed to ensure that the feed safety requirement, as provided for in Article 15 of the Regulation (EC) 178/2002²⁰ and Article 4 (1) of Regulation (EC) No 767/2009 is complied with.

In order to enable the compound feed manufacturer to produce safe feed, in particular for the more sensitive animal species thereby ensuring a high level of animal health protection, Member States should ensure that sufficient information about the mycotoxin content of feed materials is provided to compound feed manufacturers.

- (6) Member States and feed business operators should provide to EFSA, by 30 June of each year, the data for the previous year for compilation into one database in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed and EFSA's additional specific reporting requirements²¹.
- (7) Commission Recommendations 2006/576/EC and 2013/165/EU are repealed.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

¹⁹ 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 OJ L 229, 1.9.2009, p. 1. ELI: <http://data.europa.eu/eli/reg/2009/767/oj>

²⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 31, 1.2.2002, p. 1. ELI: <http://data.europa.eu/eli/reg/2002/178/oj>

²¹ <https://www.efsa.europa.eu/en/call/call-continuous-collection-chemical-contaminants-occurrence-data-0>

ANNEX

GUIDANCE VALUES

Deoxynivalenol	Guidance level in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12%
Feed materials ⁽¹⁾	
Cereals and products derived thereof ⁽²⁾ with the exception of maize and maize products	4.0
Maize and maize products ⁽³⁾	8.0
Sugar beet products	4.0
Soybean and products derived thereof	2.5
Oil seeds, oil fruits, and products derived thereof with the exception of soybean and products derived thereof	0.5
Complete feed	
Complete feed with the exception of	5.0
- complete feed for <i>Suidae</i>	0.7
- complete feed for calves (< 4 months), lambs, kids and dogs	2.0
- complete feed for <i>Equidae</i>	3.5
- complete feed for chickens for fattening and turkeys	1.0
- complete feed for rabbits	4.0
- complete feed for fur animals	1.0
- complete feed for aquatic animals	0.5

T-2 and HT-2 toxin	Guidance level in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12%
Feed materials ⁽¹⁾ ⁽²⁾	
Oats (with husk)	1.5
Cereals, other than oats with husk	0.2
Oat milling products (including husk), including oat pulp	3.0
Products derived from cereal grains other than oat milling products	0.5
Complete feed	
Complete feed with the exception of	0.2
- complete feed for laying hens and aquatic animals	0.5
- complete feed for sheep	0.05
- complete feed for poultry other than laying hens	0.1
- complete feed for cats	0.05

Zearalenone	Guidance level in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12%
Feed materials ⁽¹⁾	
Cereals and products derived thereof ⁽²⁾ with the exception of maize and maize products	1.0
Maize and maize products ⁽³⁾	2.0
Sugar beet products	2.0
Oil seeds, oil fruits, and products derived thereof except soya hulls	0.5
Soya hulls	1.0 (subject to specific occurrence data provided by COCERAL)
Green silage ⁽⁴⁾ , forage meal ⁽⁴⁾ , hay and lucerne (products)	1.0
Complete feed	
Complete feed with the exception of	2.0
- piglets, gilts (young sows), puppies, kittens, adult dogs and cats for reproduction	0.1 (0.2 for piglets and gilts?)
- sows and pigs for fattening	0.25 (0.5?)
- adult dogs and cats other than for reproduction	0.2
- aquatic animals	0.3
- dairy cattle (including calves), sheep (including lambs), goats (including kids)	0.5
- <i>Equidae</i> and cattle for fattening	1.0

Fumonisin B1 + B2	Guidance level in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12%
Feed materials ⁽¹⁾	
Maize and maize products ⁽³⁾	10
Cereals and products derived thereof ⁽²⁾ with the exception of maize and maize products	2.5
Soybean and products derived thereof	1.0
Complete feed	
Complete feed with the exception of:	5.0
- adult ruminants and fur animals	10
- calves (< 4 months), lambs and kids	10
- poultry except turkeys and ducks	2.0
- turkeys	10

- <i>Equidae</i>	1.0
- rabbits	1.0
- <i>Suidae</i>	1.0
Ochratoxin A	Guidance level in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12%
Feed materials ⁽¹⁾	
Cereals and products derived thereof ⁽²⁾	0.05
Oil seeds, oil fruits, and products derived thereof	0.05
Horse bean and products derived thereof	0.05
Lucerne (products)	0.05
Complete feed	
Complete feed with the exception of	0.02
- <i>Suidae</i>	0.01
- poultry	0.03
- cats and dogs	0.01
- rabbits	0.01
- aquatic animals	0.05

(¹) Particular attention has to be paid to feed materials intended to be fed directly to the animals to ensure that their use in a daily ration should not lead to the animal being exposed to a higher level of these mycotoxins than the corresponding levels of exposure where only complete feed are used in a daily ration.

(²) The reference to cereals, oats and products derived thereof includes not only the feed materials listed under heading 1 ‘Cereal grains and products derived thereof’ of the list of feed materials referred to in part C of the Annex to Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p.1) but also other feed materials derived from cereals in particular cereal straw and other cereal forages and roughages and includes also pseudocereals (such buckwheat and quinoa) and products derived thereof.

(³) The term ‘Maize and maize products’ includes not only the feed materials listed under heading 1 ‘Cereal grains and products derived thereof’ of the list of feed materials referred to in part C of the Annex to Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p.1) but also other feed materials derived from maize in particular maize silage and other maize forages and roughages.

(⁴) The term ‘green silage’ refers to the ensiled biomass from arable land and grassland consisting of any grass, legume plants or herbs and the term ‘forage meal’ to the product obtained by drying and milling and in some cases compacting forage plants (list of feed materials referred to in part C of the Annex to Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p.1)).