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Ensuring European feed and food safety: update on European regulations

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EUROPEAN FISHMEAL AND FISH OIL PRODUCERS

EMFAF PROGRAMME 2021-2027

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Directorate-General for
Health & Food Safety

Ensuring European feed and food safety – update on EU Regulations and outlook

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Health and Food Safety

European Commission

This presentation relates to updates on EU Regulations for feed (and food) on contaminants/undesirable substances in feed and food of relevance for EFFOP.

Presentation consists of three parts

- Recent – ongoing (under finalisation) developments in feed legislation
- Outlook feed
- Other recent – ongoing developments in food legislation

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RECENT – ONGOING (under finalisation) DEVELOPMENTS IN FEED LEGISLATION

Health and Food Safety

Amendment to Directive 2002/32/EC - Status

- published for feedback January 2024
- examination of comments received
- finalisaiton at expert group Animal nutriton meeting early July
- adoption by Commission *August 2024*
- transmission to European Parliament and Council for scrutiny *August 2024*
- Publication in the Offcial Journal *October/November 2024*

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Relevant (for EFFOP) provisions in amendment 2002/32/EC

- arsenic in fish meal from 25 to 40 mg/kg (*with a stronger provision as regards compliance with the maximum level of 2 mg/kg for inorganic arsenic*
- cadmium in copper (I) oxide, 10 ppm → 15 ppm
- nickel in certain feed materials

Relevant provisions in amendment 2002/32/EC – footnote arsenic

New footnote (2)

(2) The maximum level is for total arsenic. The maximum level of inorganic arsenic shall be lower than 2.0 mg/kg. Upon request of the competent authorities, the responsible operator shall perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 mg/kg.

This analysis is of particular importance for the seaweed species macro algae species *Asparagopsis* spp., *Sargassum/Hizikia* spp., *Halidrys* spp., *Laminaria* spp., *Alaria* spp. and for fish, other aquatic animals and products derived thereof.

Relevant provisions in amendment 2002/32/EC – Nickel

- → Setting of an ML for nickel of 20 ppm for fatty acids esterified with glycerol, mono di and triglycerides of fatty acids, salts of fatty acids, crude fatty acids, salt of lactylates of fatty acids, pure distilled fatty acids, crude glycerine and glycerine
- → mineral and products derived thereof (feed materials), feed additives belonging to the functional group of compounds of trace elements and feed additives belonging to the functional groups of binders and anticaking agents (including mycotoxin binders and radionuclide binders): considered not to set maximum levels for nickel (although sometimes very high levels of nickel are found) (certain feed materials do have a specification on nickel content).
- → No discussion on possible ML for nickel in algae/seaweed and algae/seaweed products

Relevant provisions in amendment 2002/32/EC – dioxins and PCBs

Lowering of maximum levels for following feed materials

- Animal fat, including milk fat and egg fat: from 1,50 to **1,0 ng/kg** for dioxins and no change for ML on sum of dioxins and dioxin-like PCBs (2,0 ng/kg)
- Fish oil: from 5,0 to **3,5 ng/kg** for dioxins and from 20 ng/kg to **12,0 ng/kg** for sum of dioxins and dioxin-like PCBs
- Fish meal: no change in ML for dioxins (1,25 ng/kg) and from 4,0 to **3,0 ng/kg** for sum of dioxins and dioxin-like PCBs
- Fish protein > 20% fat, crustacea meal: **no change in ML for dioxins and** from 9,0 ng/kg to **6,0 ng/kg** for sum of dioxins and dioxin-like PCBs

Relevant provisions in amendment 2002/32/EC – dioxins and PCBs

Lowering of maximum levels for following compound feed

- Compound feed for fish: from 1,75 to **1,0 ng/kg** for dioxins and from 5,5 to **2,0 ng/kg** for the sum of dioxins and dioxin-like PCBs

Relevant provisions in amendment 2002/32/EC – dioxins and PCBs

Lowering of action levels for following feed materials

- Animal fat, including milk fat and egg fat: from 0,75 to **0,5 ng/kg** for dioxins and no change for AL for sum of dioxins and dioxin-like PCBs (2,0 ng/kg)
- Fish oil: from 4,0 to **2,5 ng/kg** for dioxins and from 11 ng/kg to **8,0 ng/kg** for sum of dioxins and dioxin-like PCBs
- Fish meal: no change in AL for dioxins (0,75 ng/kg) and from 2,0 to **1,5 ng/kg** for sum of dioxins and dioxin-like PCBs
- Fish protein > 20% fat, crustacea meal: **no change in action level for dioxins and** from 5,0 ng/kg to **4,0 ng/kg** for sum of dioxins and dioxin-like PCBs

Relevant provisions in amendment 2002/32/EC – dioxins and PCBs

Lowering of action levels for following compound feed

- Compound feed for fish: from 1,25 to **0,75 ng/kg** for dioxins and from 2,5 to **1,25 ng/kg** for the sum of dioxins and dioxin-like PCBs

Recommendation- inorganic arsenic

- **Commission Recommendation of 20 May 2022 on monitoring the presence of inorganic arsenic in feed (2022/C 206/01).**

- Member States should, with the active involvement of feed business operators, perform monitoring for the presence of inorganic arsenic in feed. It is recommended to determine in the same samples the total arsenic content in view of determining the ratio between the presence of inorganic arsenic compared to total arsenic.

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Recommendation - inorganic arsenic

- In particular samples of following feed materials and compound feed should be taken
  - meal made from grass, from dried lucerne and from dried clover;
  - dried (sugar) beet pulp and dried (sugar) beet pulp (molassed);
  - palm kernel expeller;
  - **fish, other aquatic animals and products derived thereof;**
  - **seaweed meal and feed materials derived from seaweed;**
  - compound feed containing fish, other aquatic animals and products derived thereof and/or seaweed meals and feed materials derived from seaweed.

- In that context, the information provided by Norway of high levels of inorganic arsenic in certain algae/seaweed species was highlighted (was already integrated in the amendment to 2002/32/EC)

PFAS: Regulatory follow-up to the 2020 EFSA opinion - food

- Commission Regulation (EU) 2022/2388 of 7 December 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs
- Commission Recommendation (EU) 2022/1431 of 24 August 2022 on the monitoring of perfluoroalkyl substances in food
- Commission Implementing Regulation (EU) 2022/1428 of 24 August 2022 laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs

PFAS in feed

- The analytical capability for feed was limited: EURL work is ongoing.
- A monitoring Recommendation for feed is under finalisation.

PFAS in feed

- Awaiting formal adoption of the feed Recommendation, the food Recommendation already contains some provisions on feed:
  - Those Member States, which have the analytical capability to analyse PFAS in feed, are recommended to also monitor PFAS in feed.
  - Presence of PFAs in food of animal origin: investigations to be performed on source of contamination : feed, drinking water, soil, …
  - In those Member States, which don’t have the required analytical capability yet, the laboratories are encouraged to validate methods for PFAS in feed.

PFAS in feed – Elements of the Recommendation under finalisation

- Monitoring 2024-2026
- Member States should test for the presence in food of the following PFASs:
  - (a) Perfluorooctane sulfonic acid (PFOS);
  - (b) Perfluorooctanoic acid (PFOA);
  - (c) Perfluorononanoic acid (PFNA);
  - (d) Perfluorohexane sulfonic acid (PFHxS).
- Member States should, if possible, test also for the presence of other PFAS compounds with relevant occurrence in food, drinking water and/ or human serum such as those mentioned in Recommendation (EU) 2022/1431.

PFAS in feed – Elements of the Recommendation under finalistion

The monitoring should include a wide variety of feed, in particular

(a) **fish, other aquatic animals and products derived thereof;**

(b) seaweed meal and feed materials derived from seaweed;

(c) feed of mineral origin

(d) forage, silage, hay and fresh grass

(e) compound feed containing fish, other aquatic animals and products derived thereof and/or seaweed meals and feed materials derived from seaweed.

PFASs should also be analysed in the soil on which food producing animals forage and in their drinking water and feed contact materialds.

Data should be collected for feed produced in non-polluted regions, but also data from feed from polluted regions may be reported, provided that this is clearly indicated.

PFAS in feed – Elements of the Recommendation under finalisation

In order to ensure that the samples are representative of the sampled lot, sampling procedure laid down in Commission Regulation (EC) No 152/2009 should be followed

The analyses should be carried out in accordance with article 34 of Regulation (EU) 2017/625 of the European Parliament and the Council using a method of analysis that has been proven to generate reliable results. The limits of quantification of the analytical methods should be below or at 0,1 µg/kg for each individual PFAS in feed

Analytical results are to be provided on a regular basis to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD2) for Food and Feed and the additional EFSA's specific reporting requirements.

PFAS in feed – possible maximum levels

- The data on occurrence in feed will be used to allow a discussion on the possible need to establish maximum levels for PFAS in feed.
- When establishing maximum levels consideration of
  - of possible adverse animal health effects
  - transfer from feed to food of animal origin
- Possible maximum levels in feed to be established in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed
- In the meantime, indicative levels for PFOS/PFOA in feed related to maximum levels in food ?

Nitrates and nitrites

- - Follow-up to the EFSA's risk assessment on nitrite and nitrate in feed under discussion:

- 1) Keep current provisions nitrites in Directive 2002/32/EC (including the exemptions) (including ML for nitrites in fishmeal of 30 mg/kg)
- 2) Recommendation
  - Good practices to reduce nitrates/nitrites
  - Guidance level for nitrites in products and by-products from sugar beet and sugarcane and from starch and alcoholic drink production and silage

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OUTLOOK FEED

Health and Food Safety

Dioxins and PCBs
Update on review TEFs – follow-up

- WHO expert consultation on updating the 2005 toxic equivalency factors for dioxin like compounds, including some polychlorinated biphenyls - 17 to 21 October 2022.

- **Publication of TEF values with scientific justification**

Available Online 14 November 2023

- https://www.sciencedirect.com/journal/regulatory-toxicology-and-pharmacology/special-issue/1015NJNC6Q6

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New TEF values – PCDD/F

Congener	TEF value 2005	TEF value 2022
Dioxins		
Dibenzo-p-dioxins ("PCDDs")		
2,3,7,8-TCDD	1	**1**
1,2,3,7,8-PeCDD	1	**0.4**
1,2,3,4,7,8-HxCDD	0,1	**0.09**
1,2,3,6,7,8-HxCDD	0,1	**0.07**
1,2,3,7,8,9-HxCDD	0,1	**0.05**
1,2,3,4,6,7,8-HpCDD	0,01	**0.05**
OCDD	0,0003	**0.001**
2,3,7,8-TCDF	0,1	**0.07**
1,2,3,7,8-PeCDF	0,03	**0.01**
2,3,4,7,8-PeCDF	0,3	**0.1**
1,2,3,4,7,8-HxCDF	0,1	**0.3**
1,2,3,6,7,8-HxCDF	0,1	**0.09**
1,2,3,7,8,9-HxCDF	0,1	**0.2**
2,3,4,6,7,8-HxCDF	0,1	**0.1**
1,2,3,4,6,7,8-HpCDF	0,01	**0.02**
1,2,3,4,7,8,9-HpCDF	0,01	**0.1**
OCDF	0,0003	**0.002**

New TEF values – DL-PCBs

Congener	TEF value 2005	TEF value 2022
'Dioxin-like' PCBs		
Non-ortho–substituted PCBs		
PCB 77	0,0001	0.0003
PCB 81	0,0003	0.006
PCB 126	0,1	0.05
PCB 169	0,03	0.005
Mono-ortho–substituted PCBs		
PCB 105	0,00003	0,00003
PCB 114	0,00003	0,00003
PCB 118	0,00003	0,00003
PCB 123	0,00003	0,00003
PCB 156	0,00003	0,00003
PCB 157	0,00003	0,00003
PCB 167	0,00003	0,00003
PCB 189	0,00003	0,00003

Dioxins and PCBs
Update on review TEFs – follow-up

- Next steps – mandate to EFSA
  - Conversion of existing congener-specific occurrence data in the EFSA database into the new TEF values
  - Update occurrence data and human and animal exposure. (data from the last 10 years – sampling years 2014-2023)
    - main changes following the use of the 2022 WHO TEF values compared to the use of the 2005 WHO TEF values in occurrence and relative contribution of the dioxin-like PCBs to the total TEQ level for the different feed and food categories as well the main changes in contributors to the exposure of animals and humans. A detailed overview of the occurrence data of dioxins and dioxin-like PCBs in feed and food in toxic equivalent values (TEQ) on the basis of the new 2022 WHO TEF values with information on the main changes compared to the occurrence data based on the 2005 WHO TEF values should be available by 31/01/2025

Dioxins and PCBs
Update on review TEFs – follow-up

- Next steps:
  - Update of the risk characterisation part and other parts of the EFSA 2018 opinion (30/04/2026)
  - Comprehensive review of EU legislation/of EU MLs.

Iodine - Bromine /bromide in algae and seaweed

- Concerns related to the presence of high levels of iodine and bromine in algae and seaweed
- Iodine is authorized as feed additive (trace element).
- Iodine content in algae, and seaweed and products derived thereof placed on the market as feed material to be declared in case it exceeds 100 ppm. (Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials)
- Regulation of bromine/bromide content falls under Regulation 2002/32/EC on undesirable substances in feed
- Initially, a request for scientific opinion on the risks for animal health and transfer from feed to food of animal origin related to the presence of bromine in feed, in particular in algae and seaweed and derived product was requested to EFSA on 26 October 2021 (available at: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00698) and this request was accepted by EFSA with a deadline for delivery of the opinion by 31 December 2023.

Bromine /bromide

- As there was simultaneously an intention to request to EFSA to assess the health risks related to the presence of the bromide ion as a pesticide residue in food, following discussions internally in the Commission and with EFSA, a comprehensive mandate was sent to EFSA on 28 April 2022 to assess the risks for human health related to the presence of bromide ion/bromine in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion/bromine in feed, in particular in algae and seaweed and derived products with a deadline for the scientific opinion by 30 June 2024
- (Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2022-00329)
- Deadline extended: opinion expected to be available early 2025 (in the meantime draft will be published for public consultation)

Metals in algae and seaweed for feed

- EFSA report on "Dietary exposure to metals and iodine via consumption of seaweed and halophytes in the European population" (published January 2023) - Occurrence data of contaminants in seaweed

- Analytical results on arsenic, mercury, cadmium, lead and iodine in seaweed, halophytes and products based or containing seaweed (sampling years 2011-2021, food and feed) – see next slide

Metals in algae and seeweed for feed

	Number of analytical results	
	Food	**Feed**
Cadmium	2,093	55
Lead	1,988	54
Total Arsenic (tAs)	1,934	67
Inorganic Arsenic (iAs)	920	7
Methylarsonic acid (MA)	12	-
Dimethylarsinic acid (DMA)	125	-
Arsenate - As(V)	29	-
Arsenite - As(III)	29	-
Arsenobetaine	25	-
Total mercury (tHg)	1,499	67
Methylmercury	54	4
Inorganic mercury	5	-
Iodine	1,002	-

Chlorinated paraffins

- An approach for analysis of chlorinated paraffins in food and feed was agreed.
- The sum of polychlorinated alkanes (PCAs) C10-17 to be analysed as semi-quantitative screening against a threshold. If threshold is exceeded, more specific analysis is recommended.
- A monitoring recommendation will be prepared on this basis

Polychlorinated naphthalenes (PCNs)

- EFSA opinion adopted 31 Janaury 2024 – published 12 march 2024: Risks for animal and human health related to the presence of polychlorinated naphthalenes (PCNs) in feed and food
- The assessment focused on hexaCNs due to very limited data on other PCN con-geners.
- A risk characterisation for the risks related to the presence of PCNs (hexaCNs) in feed could not be performed because none of the toxicological studies allowed identification of reference points.

Polychlorinated naphthalenes (PCNs)

- As regards the risks for human health related to the presence of PCNs in food : Taking account of the uncertainties affecting the assessment, the Panel concluded with at least 99% certainty that dietary exposure to hexaCNs does not raise a health concern for any of the population groups considered. Due to major limitations in the available data, no assessment was possible for genotoxic effects or for health risks of PCNs other than hexaCNs.
- Follow-up to the opinion still to be discussed

Brominated flame retardants (BFRs) – EFSA updated risk assessments

- HBCDDs: March 2021 updated risk assessment published
  - The **current dietary exposure** to HBCDDs **does not raise a health concern**.
  - An **exception** are breastfed infants with high milk consumption, for which the lowest MOE values may raise a health concern.
  - No intention for the time being to establish an ML in food
  - No follow up for feed

Brominated flame retardants (BFRs) – EFSA updated risk assessments

PBDE's : EFSA opinion adopted November 2023, published January 2024

The most important contributors to the chronic dietary Lower Bound exposure to PBDEs were meat and meat products and fish and seafood. Taking into account the uncertainties affecting the assessment, the Panel concluded that it is likely that current dietary exposure to PBDEs in the European population raises a health concern.

- follow-up food
- follow-up feed ?

Brominated flame retardants (BFRs) EFSA updated risk assessments

- TBBPA: scientific opinion published for public consultation 26/03/2024-07/05/2024 https://open.efsa.europa.eu/consultations/a0cTk000000YVzPIAW
- The current dietary exposure to TBBPA does not raise a health concern for any of the population groups considered.

  Opinion expected to be adopted June 2024

  - follow-up food ?
  - no follow-up feed

Brominated flame retardants (BFRs) EFSA updated risk assessments

- Brominated phenols: opinion expected September 2024
- EFSA opinion emerging and novel BFRs in food: opinion expected November 2024
- Possible opinion on the combined exposure to the different groups of BFRs expected in May 2025

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OTHER RECENT – ONGOING DEVELOPMENTS OF RELEVANCE IN FOOD LEGISLATION

Health and Food Safety

Replacement of Reg. (EC) 1881/2006 → by Regulation (EU) 2023/915

- Regulation (EC) 1881/2006 has been already more than 45 times been amended
- Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 includes all amendments
- Harmonised terminology
- Footnotes in most cases replaced by comments in an additional comment box (similar format as provided for in the Codex General Standard for Contaminants and Toxins in food and Feed CXS 193-1995)

Nickel

- ML for nickel established for seaweed.
- Regulation (amendment to Regulation (EU) 2023/915) expected to be adopted and published end of June.
- Maximum level apply as from 1 July 2025

Seaweed	mg/kg	For dry seaweed the maximum level applies to the product as placed on the market. For fresh seaweed the maximum level applies after washing and separating the edible part. For fresh seaweed the maximum level applies on a dry matter basis.(*)
Seaweed except wakame	30	
Wakame	40	

Nickel

- Commission Recommendation (EU) 2024/907 of 22 March 2024 on the monitoring of nickel in food
  - It is recommended to monitor in 2025, 2026 and 2027 nickel in food:
    - Food supplements, chocolate, cocoa beans and chocolate spreads, nut spreads, cereal based products, ready to eat soups, coffee, tea, vegetables, **seaweed**, oilseeds and soy-based products, pulses, nuts, **fish and other seafood**
  - For seaweed, the species, including its Latin name, should be reported and whether the data concern fresh or dry seaweed.

Other topics in food

- Discussion on MLs for inorganic arsenic (sum of As(III) and As(V)) in fish and other seafood.
- Discussion on maximum levels for inorganic arsenic, cadmium, lead, mercury and iodine in algae as currenty MLs are established only for food supplements consisting exclusively or mainly of seaweed or products derived from seaweed.
- Brominated flame retardants (EFSA opinions – regulatory follow-up)

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Thank you for your attention !

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