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Directorate-General for
Health & Food Safety

EU policy on certain contaminants
Recent developments and outlook

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Health and Food Safety

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Review MLs for deoxynivalenol (DON)

Commission Regulation (EU) 2024/1022 of 8 April 2024

- The maximum levels apply from 1 July 2024

- The maximum level for deoxynivalenol in wheat bran not placed on the market for the final consumer is under discussion (see next slide).

- Review of the maximum levels was for the parent compound only, on the basis of the ALARA principle taking into account recent occurrence data given that it was considered premature to establish maximum levels based on the sum of the DON and modified forms.

However, in accordance with the outcome of the EFSA opinion, it is important to continue gathering information on the presence of modified forms, in view of a possible future setting of maximum levels for the sum of DON and modified forms.

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Deoxynivalenol in wheat bran

Reconsideration of the ML of 600 µg/kg applicable as from 1 July 2024 for deoxynivalenol in wheat bran, not placed on the market for the final consumer.

Any possible change of the current ML, will have no consequences for the ML of 400 µg/kg established for bakery wares, cereal snacks and breakfast cereals.

The ML for deoxynivalenol of 600 µg/kg in wheat bran placed on the market for the final consumer is not under discussion.

For further discussion : 750 µg/kg for wheat bran B2B?

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Establishment MLs for T-2 and HT-2 toxin

Commission Regulation (EU) 2024/1038 of 9 April 2024

- Establishment of maximum levels - applicable from 1 July 2024
- Member States and interested parties shall communicate by 1 January 2028 to the Commission the results of investigations undertaken and progress made with regard to the application of prevention measures to reduce contamination by T-2 and HT-2 toxins in oats and oat products.
- Member States and interested parties shall report on a regular basis to the Authority the occurrence data on T-2 and HT-2 toxins in oats and oat products

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MLs Ergot alkaloids

- Following a detailed examination of the information provided by the stakeholders at the ergot alkaloid forum on 13 October 2023 → the lower maximum levels foreseen to become applicable as from 1 July 2024 are not yet achievable for

  - ergot sclerotia in unprocessed rye grains and for
  - ergot alkaloids in milling products of wheat (with an ash content lower than 900 mg/100 g dry matter), rye milling products and rye placed on the market for the final consumer

  because of an increase in the prevalence of ergot sclerotia and ergot alkaloids in cereals due to climatic conditions.

MLs Ergot alkaloids

- It has therefore decided to defer the application of the lower maximum levels
  - for ergot sclerotia in unprocessed rye grains for 1 year and
  - for ergot alkaloids in milling products of wheat (with an ash content lower than 900 mg/100 g dry matter), rye milling products and rye placed on the market for the final consumer for 4 years.

- Commission Regulation (EU) 2024/1808 of 1 July 2024 amending Regulation (EU) 2023/915 as regards the application date of lower maximum levels for ergot sclerotia and ergot alkaloids in food

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Aflatoxins in tiger nuts

Based on P95 of the available occurrence data the following maximum levels for tigernut were concluded at the WG 14/02/2024:

- Aflatoxin B1: 5 µg/kg
- Aflatoxins total: 10 µg/kg

Alternaria toxins

- Commission Recommendation (EU) 2022/553 of 5 April 2022 on monitoring the presence of Alternaria toxins in food, including setting of indicative levels for alternariol (AOH) alternariol monomethyl ether (AME) and tenuazonic acid (TeA) in certain foods
- Indicative levels established for Alternariol (AOH) , alternariol monomethyl ether (AME) and tenuazonic acid (TeA) in certain foods based on the available data in the EFSA database above which investigations should be performed, certainly in case of repetitive findings on the factors leading to the presence of Alternaria toxins or on the effect of food processing. The indicative levels are not food safety levels.

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Alternaria toxins - indicative levels -food

Food	Alternariol (AOH) (µg/kg)	Alternariol monomethyl ether (AME) (µg/kg)	Tenuazonic acid (TeA) (µg/kg)
Processed tomato products	10	5	500
Paprika powder	-	-	10000
Sesame seeds	30	30	100
Sunflower seeds	30	30	1000
Sunflower oil	10	10	100
Tree nuts	-	-	100
Dried figs	-	-	1000
Cereal based foods for infants and young children	2	2	500

Alternaria toxins

- Given the increased presence of Alternaria toxins in feed and food, it is appropriate that the scientific opinion of 2012 is updated, taking into account new information that might have become available on toxicity and occurrence since 2012
- Mandate to EFSA – deadline September 2026.

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Evolving dietary patterns
New contaminant challenges

- More plant-based food (meat-replacers)
- Alternative sources of proteins (lupins)
- Algae (heavy metals, iodine)
- Insects

- New hazards (quinolizidine alkaloids in lupins)
- Risk assessments needs to be updated (exposure)
- Mycotoxins and plant toxins affect food of which the consumption increases related to the shift to plant-based diet

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Climate change and mycotoxins/plant toxins

- More insects, more damage to the plants, more risks of contamination by mycotoxins
- Alternance extreme droughts and (extreme) rainfalls impact occurrence of mycotoxins (e.g. aflatoxins)
- Increased contamination of cereals with seeds of invasive *Datura* species
- …

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Concrete example - mycotoxins in plant-based drinks

- Mycotoxins in plant drinks – almond, soy, oat drinks
- Study of the Max Rubner-Institute (MRI) and assessment of the Bundesinstitut für Risikobewertung (BfR) on mycotoxins in plant drinks – conclusions :
  - Mycotoxins in plant drinks: more data needed
  - Regular consumption of almond drink containing identified levels of aflatoxins may lead to health impairments with an average probability of occurrence in children in the 0.5 to < 6 age group.

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Other mycotoxin/plant toxins in food – topics under discussion

- Ochratoxin A in ham and cheese
- ML for rice subject to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food
- ML for DON in breadcrumbs
- ML for ochratoxin A in dried apricots (in particular for the non-sulphured apricots) and dried mulberries to be reconsidered

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Other mycotoxin/plant toxins in food - topics under discussion

- Tropane alkaloids (food poisonings)
- Pyrrolizidine alkaloids in tea, herbal infusions and herbs
- ML HCN in organic wheat flour (contamination with *Vicia sativa*)
- Quinolizidine alkaloids (monitoring recommendation)
- ML for hydrocyanic acid in apricot kernels to be reconsidered
- Guidance document on aflatoxin control to update
- …

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Outlook mycotoxins – plant toxins

- beauvericin – EFSA mandate - new mandate
- enniatins – EFSA mandate
- phomopsins – EFSA mandate
- thebaine (opium alkaloid) (EFSA mandate)
- delta-8-THC (EFSA mandate)
- quinolizidine alkaloids (MLs in addition to monitoring recommendation)
- lectins (EFSA mandate)
- sterigmatocystin
- modified forms of DON
- …

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Sampling and analysis mycotoxins food

- Commission Regulation (EU) 2023/2782: methods of sampling and analysis for the control of the levels of mycotoxins in food as amended by Commission Regulation (EU) 2024/885 (method of sampling for dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices).

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Sampling and analysis mycotoxins and plant toxins –auto-controls

- **Why ?** – ensuring representativeness of sampling and reliability of analytical results for the controls for mycotoxins and plant toxins by food business operators

- Legal basis: Article 4(4) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

- Targeted stakeholder consultation – Comments received – still to be discussed

- Elaboration of Commission Regulation establishing (basic) requirements for sampling and methods of analysis used for autocontrols for the presence of mycotoxins and plant toxins

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Sampling and analysis mycotoxins and plant toxins – autocontrols

Samples taken have to be representative for the sampled batch. The representativeness can be ensured by taking

- Sufficient incremental samples and
- Sufficient large samples

In order to assess the representativity of a sample for the sample batch, the rules as established in Commission Regulation (EU) 2023/2782 as well relevant international standards, such as EN ISO 24333:2009 or GAFTA Sampling Rules 124, have to be considered.

The application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation are considered to be equivalent as regards representativity to the sampling rules set out in Commission Regulation (EU) 2023/2872.

PAH in freekeh – roasted durum wheat

- Technical discussion on maximum levels of PAH finalised:

ML of PAH in freekeh (roasted durum wheat) – **reflecting P80** !

- Benzo(a)pyrene: 15 µg/kg
- PAH 4: 80 µg/kg

Percentile (96 samples)	B(a)P (µg/kg)	PAH4 (µg/kg)
P50	8.3	33.7
P75	13.3	55.5
P80	15.8	61.4
P85	34.6	145.4
P90	53.3	198.3
P95	73.6	282.4

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3-MCPD esters and glycidyl esters in foods for infants and young children (under discussion)

Food	Suggested ML for glycidyl esters (µg/kg)	Suggested ML for sum of 3-MCPD and 3-MCPD esters (expressed as 3-MCPD) (µg/kg)
Cereal based foods for infants and young children (including biscuits and rusks) – MLs apply to food as placed on the market	25 µg/kg	50 µg/kg
Baby food (Ready-to-eat meals for infants and young children) – MLs apply to food as placed on the market	25 µg/kg	50 µg/kg

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Glycidyl esters – 3 MCPD esters in other foods

- Several RASFF notifications indicating very high levels in certain foods such as biscuits
- Regulation of ingredients not protective enough as regards compound foods (?)
- Discussion on the need to regulate the presence of glycidyl esters and 3-MCPD esters in certain foods have been initiated

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Glycidyl esters – 3 MCPD esters in other foods

Regulatory approaches considered (see next slides)

- MLs for specific compounds foods
- Guided application of Article 3
- ML applicable to the for analysis extracted “fat” (extraction procedure to be specified)

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Glycidyl esters – 3 MCPD esters – Ongoing discussions

- Possible maximum levels are complementary to the maximum levels established by Commission Regulation (EU) 2020/1322 of 23 September 2020
- Possible maximum levels for compound food considered are on a whole weight basis.
- When setting maximum levels, besides occurrence data available in EFSA database, also other considerations to be taken into account (typical vegetable oil content, typical emulsifier content if known). Food categories for which maximum levels are set needs to be well described

Glycidyl esters – 3 MCPD esters – Ongoing discussions

- For foods for which no ML has been set – guidance for application of article 3 of Regulation (EU) 2023/915 to ensure an as much as possible uniform application of article 3 across the EU and to ensure an effective enforcement of legislation
- ML applicable to the for analysis extracted fat: advantages – disadvantages

- Technical discussion to be finalised first half of 2025

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Acrylamide
Regulation (EU) 2017/2158

COMMISSION REGULATION (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food

Entry into force : 11 December 2017

Entry into application: 11 April 2018

Survey on the application of Regulation 2017/2158

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Ongoing discussions – outlook

- **The review of existing benchmark levels** established by Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.
- **Update of the mitigation measures needed/strengthened** ?
- The **establishment of new benchmark levels**, in particular for certain foods mentioned in Commission Recommendation (EU) 2019/1888 of 7 November 2019 on the monitoring of the presence of acrylamide in certain foods
- The **establishment of maximum levels** in certain foods (i.e. in more foods than foods for infants and young children).

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Ongoing discussions – outlook

- Targeted stakeholder consultation has taken place been with a stakeholder forum (January/February 2022)
- Continuation of technical discussions taking into account
  - the comments received during targeted stakeholder consultation
  - outcome questionnaire Member States
  - the most recent available occurrence data
- Challenges/difficulties encountered
- Technical discussions expected to be finalised first half of 2025

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Data analysis for benchmark and maximum levels

- Challenges/difficulties encountered with data analysis

- Only occurrence data from sampling year 2016 onwards to be considered;
- The occurrence data will be split into two sets:
  - Sampling years 2016-2017-2018 (ante Regulation (EU) 2017/2158) and sampling years 2019-2020-2021-2022-2023 (Post Regulation (EU) 2017/2158)
- The benchmark levels and maximum levels will be based on the occurrence data 2019-2020-2021-2022-2023. The data set 2016-2017-2018 will be considered only in case of need (in case of limited data available).

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Benchmark and maximum levels

- Within a certain food category there a wide variation of products with a wide variation of acrylamide levels due to different recipes and processing conditions. Therefore, the food categories for the **benchmark levels** can be sufficient detailed with benchmark levels set tailored to the detailed food subcategory to serve as driver for applying mitigation measures and a “misclassification” of a product does not necessarily have serious negative consequences because of unjustified withdrawal/recall.

- Maximum levels should be set for rather broad categories to **minimize the risk of misclassification** (with possible significant risk of serious negative consequences because of unjustified withdrawal/recall). However this means that the maximum level has to be set taking into account the food subcategory with the highest acrylamide levels (i.e. higher maximum levels). The difference between the benchmark level and the maximum level might be for certain food subcategories large.

Establishment of maximum levels Some principles/criteria

- Maximum levels to be set only for products as placed on the market (i.e. no preparation to be done in the laboratory). Very difficult to standardise the frying/cooking procedure in the laboratory and therefore even in case of small deviations in preparation procedure (e.g. frying a bit longer than recommended) could result in unjustified withdrawal-recall.

  (*On the other hand, benchmark levels can be (continued to be) set for products ready to eat – i.e. preparation in the laboratory according to instructions on the label as small deviations in preparation procedure will not result in unjustified withdrawal-recall)*

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Establishment of maximum levels Some principles/criteria

- If maximum levels are set for bread, it is not foreseen to include specialty bread (bread with added fruits, nuts, vegetables, banana bread, potato bread, etc…
- Breakfast cereals: cf discussion broad food categories versus detailed food subcategories. Only heat-treated breakfast cereals to be covered by benchmark level and maximum level

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Establishment of maximum levels Some principles/criteria

- Processed cereal based foods, biscuits and rusks marketed for infants and young children (not falling in the scope of Regulation (EU) No 609/2013.
- Maximum levels only to be considered for foods currently subject to benchmark level (unless there would be for a certain food an extensive amount of data enabling to set on a solid basis a maximum level).
- …

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Review and establishment of new benchmark levels

- Review of existing benchmark levels
- New benchmark levels
  - for Rösti (800 µg/kg), other potato-based (heated in oven or frying) (300 µg/kg) , root and tuber vegetable fries (500 µg/kg), oxidized black olives 850 µg/kg), fruit crisps and chips (250 µg/kg), vegetable crisps other than potato and cereal crisps (700 µg/kg), onion processed (700 µg/kg) cocoa powder (450 µg/kg) -

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Review and establishment of new benchmark levels

- Benchmark levels for new food categories: in certain case not to be linked to existing mitigation measures.
- Additional benchmark levels to be considered for liquorice, sweets, RTE coffee drink, chocolate, instant noodles, instant soups, roasted nuts, dried fruit, panela.

MOH (MOSH and MOAH)

- 2023 EFSA opinion on an update of the risk assessment of MOHs in food
  - The present dietary exposure to **MOSH** does not raise concern for human health for all age classes.
    - The margin for safe exposure is limited, so those conclusions might change if the mitigation measures would be dropped.
  - Genotoxicity and carcinogenicity are associated with MOAH with three or more aromatic rings.
  - For 1-2 ring MOAH some studies point towards adverse effects, but insufficient toxicological information is available for a conclusive risk assessment.
  - Based on two scenarios on three or more ring MOAH contents in the diet and lacking toxicological information on effects of 1 and 2 ring MOAH, a possible concern for human health was raised in relation to the presence of **MOAH** in food.

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MOH (MOSH and MOAH)

Regulatory measures under discussion

- Maximum levels for MOAH in a wide range of foodstuffs under discussion (including in tree nuts, cereals)
- Monitoring recommendation with
  - Indicative levels for MOSH
  - Indicative levels for MOAH (for foods for which no ML is foreseen to be established)

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Metals in algae and seaweed

- Given the change in dietary pattern (higher consumption of algae and seaweed in diet) presence of metals in algae and seaweed of increasing importance for exposure and human health.

- 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

- Discussion on maximum levels for inorganic arsenic, cadmium, lead, mercury and iodine in algae as currently MLs are established only for food supplements (consisting exclusively or mainly of seaweed or products derived from seaweed).

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Thank you for your attention !

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