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Directorate-General for
Health & Food Safety

Contaminants update
Dried fruits and nuts

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Selected topics

- Ochratoxin A
- Alternaria toxins
- Aflatoxins
- Hydrocyanic acid
- Replacement of Regulation (EC) 401/2006
- Acrylamide
- PFAS
- Mineral oil hydrocarbons
- Replacement of Regulation (EC) 1881/2006

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Ochratoxin A – EFSA opinion

- EFSA opinion 31/03/2020

- The EFSA's Panel on Contaminants in the Food Chain considered that it was not appropriate to establish a health based guidance value for OTA and that the Tolerable Weekly Intake of 120 ng/kg body weight (bw) as established by EFSA in 2006 is consequently no longer valid.

- In the absence of elucidated mode of action for the genotoxicity/ carcinogenicity of OTA, the Panel concluded that an Margin of Exposure (MOE) of 10,000 needs to be applied to the BMDL10 of 14.5 µg/kg bw per day for neoplastic effects (kidney tumours) in the rat.

- The Panel further concluded that the calculated margins of exposure for carcinogenic effects of ochratoxin A indicate a possible health concern for certain consumer groups.

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

- As follow up to EFSA opinion, changes to current legislation were discussed in order to ensure a high level of human health protection → MLs for foodstuffs not yet covered // review of existing MLs
  - Establishment of maximum levels for OTA in **dried fruit other than dried vine fruit,** certain liquorice products, dried herbs, certain ingredients for herbal infusions, certain oilseeds, **pistachio nuts**, and cocoa powder and
  - Lowering of existing maximum level in bakery products, cereal snacks, breakfast cereals, **dried vine fruit,** roasted coffee and soluble coffee

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Bakery wares, cereal snacks and breakfast cereals - products not containing oilseeds, nuts or dried fruit	2.0 µg/kg
- products containing at least 20 % dried vine fruit and/or dried figs	4.0 µg/kg
- other products containing oilseeds, nuts and/or dried fruit	3.0 µg/kg

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Dried fruit - dried vine fruit (currants, raisins and sultanas) and dried figs - other dried fruit	 8.0 µg/kg 2.0 µg/kg
Date syrup	15 µg/kg

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Roasted coffee - roasted coffee beans and ground roasted coffee, excluding soluble coffee - soluble coffee (instant coffee)	3.0 µg/kg 5.0 µg/kg
Cocoa powder	3.0 µg/kg

Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Liquorice (*Glycyrrhiza glabra*, *Glycyrrhiza inflate* and other species)	
- liquorice root, including as an ingredient in herbal infusions	20 µg/kg
- liquorice extract ([42]) for use in food in particular beverages and confectionary	80 µg/kg
- liquorice confectionary containing ≥ 97% liquorice extract on dry basis	50 µg/kg
- other liquorice confectionary	10.0 µg/kg

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Dried herbs	10.0 µg/kg
Ginger roots for use in herbal infusions	15 µg/kg
Marshmallow roots, dandelion roots and orange blossoms for use in herbal infusions or in coffee substitutes	20 µg/kg

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Commission Regulation (EU) 2022/1370 of 5 August 2022: maximum levels of OTA

Sunflower seeds, pumpkin seeds, (water) melon seeds hempseeds, soybeans	5.0 µg/kg
Pistachios to be subjected to sorting, or other physical treatment, before placing on the market for final consumer or use as ingredient in food	10.0 µg/kg
Pistachios placed on the market for final consumer or use as ingredient in foodstuffs	5.0 µg/kg

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Alternaria toxins – food

Following EFSA's "Scientific Opinion on the risks for animal and public health related to the presence of *Alternaria* toxins in feed and food" (2011) and the EFSA report on " Dietary exposure assessment to *Alternaria* toxins in the European population" (2016), the estimated chronic dietary exposure to **alternariol (AOH) and alternariol monomethyl ether (AME) and tenuozonic acid (TeA) exceeded the relevant Threshold of Toxicological Concern (TTC)** value indicating **a need for additional compound-specific toxicity data.** The estimated chronic dietary exposure to tentoxin (TEN) are lower than the relevant TTC value and is therefore considered unlikely to be a human health concern.

Alternaria toxins - food

- 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

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Aflatoxins

- EFSA opinion 30/01/2020
- MOE values for AFB1 exposure ranged from 5,000 to 29 and for AFM1 from 100,000 to 508. The calculated MOEs are below 10,000 for AFB1 and also for AFM1 where some surveys, particularly for the younger age groups, have an MOE below 10,000.
- This raises a health concern. The estimated cancer risks in humans following exposure to AFB1 and AFM1 are in-line with the conclusion drawn from the MOEs. The conclusions also apply to the combined exposure to all five aflatoxins.
- As follow up to EFSA opinion, possible changes to current legislation under consideration

Points raised for possible consideration of review/setting maximum levels : herbs, spices, cocoa, almonds , ices/desserts, gluten

Hydrocyanic acid – Commission Regulation (EU) 2022/1364 of 4 August 2022: maximum levels of hydrocyanic acid

Hydrocyanic acid, including hydrocyanic acid bound in cyanogenic glycosides	mg/kg
Unprocessed whole, ground, milled, cracked, chopped linseed not placed on the market for the final consumer	250
Unprocessed whole, ground, milled, cracked, chopped linseed placed on the market for the final consumer	150
Unprocessed whole, ground, milled, cracked, chopped almonds placed on the market for the final consumer	35
Unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer	20
Cassava root (fresh, peeled)	50
Cassava flour and tapioca flour	10

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Replacement (EC) 2006/401 Sampling

- Sampling rules: generally unchanged but generalised (also applicable to sample for plant toxins)

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

Recovery: the average recovery should be between 70 and 120%.

- Here the average recovery is the average value from replicates obtained during validation when determining the precision parameters RSDr and RSDwR. The criterion applies to all concentrations and all individual toxins, with the exception of ergot alkaloids.
- For ergot alkaloids the criterion applies to the sum of each epimer-pair.
- In exceptional cases, average recoveries outside the above range can be acceptable but shall lie within 50-130%, and only when the precision criteria for RSDr and RSDwR are met.

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

Precision

- RSDr shall be ≤ 20%.
- RSDwR shall be ≤ 20%.
- RSDR should be ≤ 25%.
- These criteria apply to all concentrations.
- In case the maximum level applies to a sum of toxins, then the criteria for precision apply to both the sum and the individual toxins. For ergot alkaloids, the criteria for individual toxins applies to the sum of each epimer pair.

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

Limit of quantification

- When a specific requirement for the LOQ of a toxin has been set in the table below, the method shall have an LOQ at or below this value.
- Table LOQ requirements for certain mycotoxins

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

Mycotoxin	LOQ requirement (µg/kg)
Aflatoxins	
Processed cereal based foods for infants and young children, baby foods and dietary foods for special medical purposes intended specifically for infants: B1	≤ 0.1
For all other foods : B1, B2, G1, G2, each of the aflatoxins	≤ 1
Ergot alkaloids (each of 12 epimers included in sum definition of ML)	
Cereals and cereal-based foods	≤ 4
Cereal-based food for infants and young children	≤ 2

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

Ochratoxin A	
Liquorice confectionary containing < 97%	
Liquorice extract on dry basis	≤ 10.0
Cocoa powder	≤ 3.0

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Replacement (EC) 2006/401
Performance criteria confirmatory methods

In all other cases, the following applies:

- LOQ: shall be ≤ 0.5*ML, and should preferably be lower (≤0.2*ML).
- In case the maximum level applies to a sum of toxins, then the LOQ of the individual toxins shall be ≤ 0.5*ML/n, with n being the number of toxins included in the ML definition.

Acrylamide - Recommendation 2019/1888 on the monitoring of the presence of acrylamide in certain food

- insufficient data available on the presence of acrylamide in certain foods covered by Regulation (EU) 2158/2017 and in foods not covered by Regulation (EU) 2158/2017 but which might contain significant of acrylamide and/or could be relevant contributors to the dietary exposure to acrylamide
- appropriate that competent authorities and food business operators monitor the presence of acrylamide in such food in view of possible further risk management measures

Acrylamide - Recommendation 2019/1888 on the monitoring of the presence of acrylamide in certain food

Potato products

- Rösti, coquettes, pommes duchesse, pommes noisettes, potato casserole (and vegetable casserole), potato and meat meal, potato and cheese meal

Bakery products

- Rolls (hamburger rolls, whole wheat rolls, milk rolls, …), pita bread, Mexican tortillas, croissants, doughnuts, speciality bread (such as pumpernickel bread, ciabatta with olives, onion bread, ….), pancakes, crisp cookies from thin strip of dough and deep fried, churros

Cereal products

- Rice crackers, maize crackers, cereal snacks (such as extruded maize and/or wheat products), honey roasted muesli

Other

- Vegetable crisps/fries, **roasted nuts,** roasted oilseeds**, dried fruits**, roasted cocoa beans and derived cocoa products**,** olives in brine, coffee substitutes not based on cichory or cereals, fudge, caramel, nougat, …

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Draft Regulation on perfluoro-alkylsubstances (PFAS) in food

- 2020 EFSA opinion on the risk to human health related to the presence of perfluoroalkyl substances in food
  - **TWI 4.4 ng/kg bw** per week for the sum of PFOS, PFOA, PFNA and PFHxS on the basis of the effects on the immune system
    - PFOS: Perfluorooctane sulfonic acid
    - PFOA: Perfluorooctanoic acid
    - PFNA: Perfluorononanoic acid
    - PFHxS: Perfluorohexane sulfonic acid
  - The **exposure** of parts of the European population **exceeds the TWI**, which is of concern

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Draft Regulation on perfluoro-alkylsubstances (PFAS) in food

Maximum Levels (MLs) for PFAS in food

- Separate MLs for PFOS, PFOA, PFNA, PFHxS and the sum of the 4 PFAS.
- MLs for commodities, which are relevant contributors to the exposure, for which sufficient occurrence data are available and for which there is sufficient analytical capability among the laboratories.
- The ML applies to the sum of linear and branched stereoisomers, whether they are chromatographically separated or not.

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Draft Regulation on perfluoro-alkylsubstances (PFAS) in food

Maximum Levels (MLs) for PFAS in food

- For the sum of PFOS, PFOA, PFNA and PFHxS lower bound concentrations are calculated on the assumption that all the values below the limit of quantification are zero.
- MLs are established for eggs, fish meat, crustaceans and bivalve molluscs and meat and edible offal of terrestrial animals.

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PFAS Recommendation(EU) 2022/1431

- Previous Recommendation 2010/161/EU on PFAS in various foods
- New Commission Recommendation (EU) 2022/1431 of 24 August 2022 on the monitoring of perfluoroalkyl substances in food
  - Currently **for some commodities data are lacking** for the establishment of MLs: e.g. foods for infants and young children.
  - Many **laboratories are not able to analyse the low concentrations** in which PFAS occur in certain commodities: e.g. milk, fruits, vegetables, foods for infants and young children.
  - Occurrence **data are lacking for PFAS other than PFOS, PFOA, PFNA and PFHxS** → needed for a possible future risk assessment for other PFAS

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PFAS Recommendation(EU) 2022/1431

- It is recommended to monitor PFAS in food from 2022-2025 in a wide range of foodstuffs .
- Commodities: **fruits**, vegetables, starchy roots and tubers, cereals, **nuts**, food for infants and young children, food of animal origin, non-alcoholic drinks, wine and beer.
  - Different production types
  - Include hunted or wild caught animals and products
- Analysis of raw and processed products to determine processing factors.

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PFAS Recommendation(EU) 2022/1431

- All PFAS
  - Including PFOS, PFOA, PFNA, PFHxS, PFBA, PFPeA, PFHxA, PFHpA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFBS, PFPS, PFHpS, PFNS, PFDS, PFUnDS, PFDoD, PFTrDS, FOSA)
  - For consideration emerging PFAS:, acid form of F53B, aciod form of GenX, acid form of ADONA, Capstone A and B

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PFAS Recommendation(EU) 2022/1431

- Target LOQs
  - **0.002 µg/kg for PFOS, 0.001 µg/kg for PFOA, 0.001 µg/kg for PFNA and 0.004 µg/kg for PFHxS in fruits, vegetables, starchy roots and tubers and food for infants and young children**
  - 0.010 µg/kg for PFOS, 0.010 µg/kg for PFOA, 0.020 µg/kg for PFNA and 0.040 µg/kg for PFHxS in milk
  - 0.50 µg/kg for PFOS, PFOA, PFNA and PFHxS in fish oil and in edible offal of terrestrial animals
  - 0.10 µg/kg for PFOS, PFOA, PFNA and PFHxS in fish meat and meat of terrestrial animals
  - 0.30 µg/kg for PFOS, PFOA, PFNA and PFHxS in eggs, crustaceans and molluscs.

PFAS Recommendation(EU) 2022/1431

- Indicative levels
  - **0.010 µg/kg for PFOS, 0.010 µg/kg for PFOA, 0.005 µg/kg for PFNA and 0.015 µg/kg for PFHxS in fruits, vegetables (except wild fungi) , starchy roots and tubers**
  - 1,5 µg/kg for PFOS, 0.010 µg/kg for PFOA, 0.005 µg/kg for PFNA and 0.015 µg/kg for PFHxS in wild fungi
  - 0,020 µg/kg for PFOS, 0.010 µg/kg for PFOA, 0.050 µg/kg for PFNA and 0.060 µg/kg for PFHxS in milk
  - 0,050 µg/kg for PFOS, 0.050 µg/kg for PFOA, 0.050 µg/kg for PFNA and 0.050 µg/kg for PFHxS in baby food

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PFAS Recommendation(EU) 2022/1431

- Awaiting the achievement of the limits of quantification by their laboratories, Member States may also submit results, which were obtained with methods with higher limits of quantification.
- An exceedance of the indicative level should trigger an investigation towards the cause of the contamination.

Sampling and analysis of PFAS

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

- **Sampling**: similar provisions to those of dioxins and PCBs with additional requirements to avoid contamination of the sample.

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Sampling and analysis of PFAS

- **Analysis**:
  - Specific sample preparation procedures and precautions
  - Within-laboratory reproducibility (intermediate precision) (RSDR) ≤ 20 %
  - Trueness: ± 20 %
  - LOQ: The LOQ for PFOS, PFOA, PFNA and PFHxS each ≤ the ML for the respective individual PFAS substance. Compliance with this requirement entails that no LOQ should be derived for the concentration of the sum of PFOS, PFOA, PFNA and PFHxS, which is calculated by summing up only the concentrations of PFOS, PFOA, PFNA and PFHxS, which were quantified at or above their respective LOQ.
- **Reporting and interpretation of results**

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Mineral Oil Hydrocarbons (MOHs) EFSA opinion 2012

- MOHs:
  - » MOSH: mineral oil saturated hydrocarbons
  - » MOAH: mineral oil aromatic hydrocarbons
- MOHs can be present in food through environmental contamination, lubricants for machinery used during harvesting and food production or contamination of food contact materials.
- Exposure to MOHs in food is of potential concern.
  - » MOSH can accumulate in human tissue and may cause adverse effects in the liver.
  - » MOAH may be mutagenic and carcinogenic

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Mineral Oil Hydrocarbons (MOHs) EFSA opinion 2012

- Only limited occurrence data were available in food.
- No health based guidance values could be established.
- EFSA made recommendations
  - » To gather data on the occurrence and sources of MOHs in food
  - » To develop a common harmonised approach for the measurement of MOHs

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Mineral Oil Hydrocarbons (MOHs) Commission Recommendation (EU) 2017/84

- Monitor the presence of MOHs in food and food contact materials.
  - Animal fat, bread and rolls, fine bakery ware, breakfast cereals, confectionery (including chocolate) and cocoa, fish meat, fish products (canned fish), grains for human consumption, ices and desserts, oilseeds, pasta, products derived from cereals, pulses, sausages, **tree nuts**, vegetable oils, as well as food contact materials.
  - For pre-packaged food, the level of mineral oil hydrocarbons should be determined both in the food and in the food contact material if that is the suspected source of detected MOH

Mineral Oil Hydrocarbons (MOHs) Commission Recommendation (EU) 2017/84

- Food business operators are advised to monitor their processes and products, to identify potential sources of MOHs, and especially MOAH, in their products, and take action to minimise the presence of these substances in the food they put on the market.
  - Verification of lubricants and anti-dusting agents.
  - Control of ingredients and food additives.

Mineral Oil Hydrocarbons (MOHs)

- EFSA mandate for an updated risk assessment
  - Public consultation: mid 2022
  - Publication: end 2022
  - → Then discussions on a possible regulatory follow-up can be started (MLs for MOSH/ MOAH in food).
- In the meanwhile Competent Authorities in the Member States may take enforcement action against MOHs in food on the basis of Article 14 of the General Food Law (Regulation (EC) No 178/2002), whenever a food is not considered safe.

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Mineral Oil Hydrocarbons (MOHs) Statement SCoPAFF 21/04/2022

- If the quantified presence of MOAH, which are possible genotoxic carcinogens, in food including food for infants and young children is confirmed by an official control, the products concerned should be withdrawn and, if necessary, recalled from the market on the basis of Article 14 of the General Food Law (Regulation (EC) No 178/2002), to ensure a high level of human health protection. In this regard the Member States also stress the responsibilities of food business operators in accordance with Article 19 of the General Food Law.

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Mineral Oil Hydrocarbons (MOHs) Statement SCoPAFF 21/04/2022

- In order to ensure a uniform enforcement approach throughout the EU, the Member States agreed to withdraw and, if necessary, to recall products from the market, when the sum of the concentrations of MOAH in food are at or above the following maximum LOQs:
- 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)
- 1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil)
- 2 mg/kg for fats/ oils

Analysis and sampling should be done according to the provisions of Regulation (EC) No 333/2007.

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Replacement of Reg (EC) 1881/2006

- More than 40 amendments
- Consistent terminology
- New structure (instead of endnotes/footnotes → additional column with comments)
- Improve readability

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Thank you for your attention !

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