

Directorate-General for Health & Food Safety

CONTAMINANTS

Update on recent developments with focus on nuts and dried fruits

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MYCOTOXINS

- Ochratoxin A
- Aflatoxins
- Alternaria toxins





Ochratoxin A

- EFSA opinion 31/03/2020
- In the absence of elucidated MoAs for the genotoxicity/ carcinogenicity of OTA, the Panel concluded that an MOE of 10,000 needs to be applied to the BMDL10 of 14.5 μ g/kg bw per day for neoplastic effects (kidney tumours) in the rat.
- The calculated MOEs for neoplastic effects in most of the surveys, in particular those for high consumers and for breastfed infants in all scenarios were below 10,000 and thus indicate a possible health concern for these consumer groups. current exposure raises a health concern
- As follow up to EFSA opinion, changes to current legislation foreseen \rightarrow MLs for foodstuffs not yet covered // review of existing MLs
- Monitoring OTA in cheese and ham (sampling!)
- Timing



Ochratoxin A – possible changes nuts/dried fruit under discussion

Foodstuffs	Maximum level under discussion (μg/kg)
Current entry "2.2.2" to be replaced by	
2.2.2.a : All products, derived from unprocessed cereals, including processed cereal products, malt and cereals intended for direct human consumption with the exception of foodstuffs listed in 2.2.9., 2.2.10, 2.2.13, 2.2.2.b	3.0
2.2.2.b : bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals	
 products not containing oilseeds, nuts, dried fruit 	2.0
 products containing oilseeds, nuts, dried fruit 	3.0
2.2.2.c: beer-like non-alcoholic beverages (malt drinks) (*)	3.0 (*)
(*) to be reviewed within 2-years time based on more data and information on the relation between the level increases and the malt drink.	



Ochratoxin A – possible changes – nuts/dried fruit under discussion

Foodstuffs	Maximum level under
	discussion (µg/kg)
Current entry "2.2.3 Dried vine fruit (currants, raisins and	
sultanas)" to be replaced by :	
Dried vine fruit (currants, raisins and sultanas) and dried figs	8.0
Other dried fruit	2.0
(date juice \rightarrow September 2021)	

New entry	
Sunflower seeds, pumpkin seeds, (water) melon seeds	5.0
hempseeds, soybeans	





Ochratoxin A – possible changes – nuts/dried fruit under discussion

Foodstuffs	Maximum level under discussion (μg/kg)
<i>New entry</i> Pistachios placed on the market for final consumer or use ingredient in foodstuffs	5.0
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





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
- Consideration of review/setting maximum levels ongoing for herbs, spices, cocoa, almonds, ices/desserts, gluten
- Timing



Alternaria toxins

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

- Monitoring recommendation, 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.





Alternaria toxins - indicative levels

Food	Alternariol	Alternariol	Tenuazonic acid
	(AOH)	monomethyl ether	(TeA)
	(µg/kg)	(AME) ($\mu g/kg$)	(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	2	2	500
and young children			
	Health and		

Food Safety



PLANT TOXINS

- Hydrocyanic acid
- Opium alkaloids
- THC





Cyanogenic glycosides in other foodstuffs

- Scientific Opinion on evaluation of the health risks related to the presence of cyanogenic glycosides in foods other than raw apricot kernels –
- Existing maximum levels for hydrocyanic acid in nougat, marzipan or its substitutes or similar products (50 mg/kg) canned stone fruits (5 mg/kg) and alcoholic beverages (35 mg/kg) established by Regulation (EC) No 1334/2008 and 7 grams of hydrocyanic acid per hectolitre of 100 % vol. alcohol in stone fruit spirits and fruit marc spirit, established by Regulation (EC) No 110/2008
- Setting of maximum levels in foodstuffs other than apricot kernels are considered : almonds, linseed and linseed products, cassava and cassava products
- Provisions on sampling and analysis under discussion





Hydrocyanic acid in food other than apricot kernels- possible maximum levels – under discussion

Food	Possible Maximum level for
	hydrocyanic acid in
	mg/kg
Whole linseed	250
Ground, milled, cracked, chopped linseed	150
Whole, ground ,milled, cracked, chopped	35
almonds placed on the market for the final	
consumer	
Cassava (fresh, peeled)	50
Cassava flour	10.0





Opium alkaloids – maximum levels

- Following the outcome of the EFSA opinion, maximum levels in poppy seeds for morphine equivalents (morphine + 0.2 codeine) are considered.
- For the time being no maximum levels for thebaine proposed.
- Provisions on sampling and analysis under discussion
 - LOQ for poppy seeds: 2 mg/kg
 - LOQ for bakery products: 0.5 mg/kg





Opium alkaloids – maximum levels

Food	Maximum level for morphine equivalents (*) mg/kg
Whole, ground, milled poppy seeds placed on the market for the final consumer	20
Bakery products (**) containing poppy seeds and/or derived products thereof (***)	1.5





Opium alkaloids – maximum levels under discussion

(*) morphine equivalents = morphine + 0.2 codeine
(**) bakery products include also flour-based ready to eat savouries and snacks.

(***) The food business operator supplying the poppy seeds to the food business operator manufacturing the bakery products shall provide all the necessary information, including analytical data, where appropriate, to enable the manufacturer of the bakery products to place products on market compliant with the maximum level





Tetrahydrocannabinol (THC)

- The CONTAM Panel derived an acute reference dose (ARfD) of 1 μ g Δ ⁹-THC/kg b.w.
- The exposure estimates are at most 3 % and 13 % the ARfD, in adults and toddlers, respectively.
- Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food (food of animal origin/hemp derived food)
- → EFSA report on exposure published in January 2020





Tetrahydrocannabinol (THC) –possible maximum levels – under discussion

Food	Possible Maximum level for THC (*) mg/kg
Hemp seeds	3.0
Ground hemp seeds, hemp seed powder, (partially) defatted hemp seed (press cake) hemp seed flour, hemp seed bran	3.0
Hemp seed oil	7.5

(*) the maximum level refers to the sum of Δ 9-tetrahydrocannabinol (Δ 9-THC) and Δ 9-tetrahydrocannabinolic acid (Δ 9-THCA





OTHER CONTAMINANTS

- Acrylamide
- Cadmium
- Lead
- Nickel





ACRYLAMIDE – ONGOING DISCUSSIONS

- 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.
- 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





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
- Foods targeted for monitoring (inter alia):
 - Roasted nuts, roasted oilseeds, dried fruits





Acrylamide – Benchmark levels under discussion

- No benchmark or maximum levels under discussion for roasted nuts, roasted oilseeds, dried fruits
 - new benchmark levels under discussion for fruits crisps/chips





Cadmium: revision/lowering of MLs

Lowering of the ML for

- Several fruits
 - citrus fruits, stone fruits, olives, kiwifruits, bananas, mangoes, papaya and pineapples 0,050 mg/kg → 0,020 mg/kg
 - berries and small fruits 0,050 mg/kg \rightarrow 0,030 mg/kg
 - Raspberries : 0,050 \rightarrow 0,040 mg/kg
- Tropical roots and tubers, parsley roots, turnips, beetroots, celeriacs, radishes
- Bulb vegetables except garlic
- Fruiting vegetables
- Brassica vegetables





Cadmium: revision/lowering of MLs

Lowering of the ML for

- Legume vegetables
- Stem vegetables, including celeries
- Common mushroom, Shiitake and Oyster mushroom, other cultivated fungi, wild fungi
- Rye and barley, wheat (except durum wheat), rice





Cadmium: revision/lowering of MLs

Setting of an ML for

- Pulses
- Oilseeds
 - Oilseeds : 0,10 mg/kg except
 - Rape seeds: 0,15 mg/kg
 - Peanuts and soybeans: 0,20 mg/kg
 - Mustard seeds: 0,30 mg/kg
 - Linseed and sunflower seed: 0,50 mg/kg
 - Poppy seed: 1,20 mg/kg
- tree nuts
 - tree nuts except pine nuts: 0,20 mg/kg
 - Pine nuts : 0,30 mg/kg
- salt



Lead – revision/lowering of MLs

Lowering of the ML

- foods for infants and young children

Alignment with Codex levels

- edible offal
- wine/liqueur wine
- salt

Setting of an ML

- wild fungi, fresh curcuma and fresh ginger
- dried spices with different levels for fruit spices seed spices bud spices root spices and spices

Nuts and dried fruit not affected by this review.





Nickel

- EFSA Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water
- Discussion with MSs → monitoring Recommendation (EU) 2016/1111
- Time frame 2016 2018





Nickel – monitoring recommendation Foods targeted

- Cereals & cereal-based products
- Infant formula, follow-on formula, processed cereal-based food for infants and young children, baby food, food for special medical purposes intended specifically for infants and young children
- Food supplements
- Legumes
- Nuts and oil seeds
- Milk and dairy products
- Alcoholic and non-alcoholic beverages
- Sugar and confectionery (including cocoa and chocolate)
- Fruits, vegetables and vegetable products (including fungi)
- Dry tea leaves, dry parts of other plants used for herbal infusions
- Bivalve molluscs





Nickel – Updated EFSA opinion -Follow-up

- EFSA updated on request by the Commission the scientific opinion on the risks to public health related to the presence of nickel in food and drinking water taking into account the new occurrence data, the updated BMD Guidance and any newly available scientific information
- Updated risk assessment published <u>https://www.efsa.europa.eu/en/efsajournal/pub/6268</u>
- The chronic exposure estimates may raise a health concern in toddlers and in other children, as well as in infants The acute dietary exposure estimates raises a health concern for nickel-sensitised individuals.
- \rightarrow As a follow-up risk management measures will be discussed





OTHER ISSUES

- Control plan contaminants
- Replacement of Regulation (EC) 1881/2006





Commission

Thank you for your attention !