



Directorate-General for Health & Food Safety

Update on legislation and emerging
issues in the field of mycotoxins and
plant toxins

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MYCOTOXINS

Citrinin

- It was agreed that the data contained in the EFSA report on the presence of citrinin in cereals and cereal based foods do not require an immediate follow-up as regards risk management as regards cereal based foods as the findings of citrinin in cereal based food do not raise a particular health concern.

Citrinin

- Current maximum level (established in 2014) of citrinin in food supplements based on rice fermented with red yeast « *Monascus purpureus* » to be lowered from 2000 µg/kg to 100 µg/kg (on the basis of recent data)
- Performance criteria – food supplements homogenisation

Ergot alkaloids - Under discussion

- Discussion on possible maximum levels for ergot alkaloids on the sum of the following 12 ergot alkaloids : ergometrine, ergosine, ergocornine, ergotamine, ergocristine , ergocryptine (α - and β -form) and their respective -inine forms.
- Lowerbound – LOQ for cereal milling products: 4 $\mu\text{g}/\text{kg}$ for the individual epimers / for final cereal based consumer products, 2 $\mu\text{g}/\text{kg}$ for the individual epimers.

Ergot alkaloids –Under discussion

- Possible lowering of the maximum level for **ergot sclerotia** in unprocessed cereals, with the exception of corn and rice
 - Rye: 0,5 g/kg → 0,5/0,2 g/kg (1/7/2022)
 - Other cereals: 0.5 g/kg -> 0.2 g/kg
- Maximum levels for **ergot alkaloids** are discussed for
 - rye milling products: 500 → 250 µg/kg (1/7/2022)
 - barley, wheat, spelt and oats milling products: 150 µg/kg with ash content ≥ 900 mg/100 g;
 - 100 → 50 µg/kg (1/7/2022) with ash content < 900 mg/100 g)
 - processed cereal based food for infants and young children: 20 µg/kg.

Ergot alkaloids –Under discussion

- Date of application
- Reliability and speed of screening methods for the presence of ergot alkaloids.
- Other foodstuffs such as bread (including small bakery wares), pastries, biscuits, cereal snacks, breakfast cereals: no maximum levels **yet** discussed (analytical issues)

Alternaria toxins - under discussion

- Discussion on a monitoring recommendation, including setting of guidance levels for alternariol (AOH) alternariol monomethyl ether (AME) and tenuazonic acid (TeA) in certain foods
- Foods considered for guidance levels ($\mu\text{g}/\text{kg}$) for
 - AOH, AME and TeA: processed tomato products except tomato juice), sesame seeds, sunflower seeds, sunflower oil, cereal based foods for infants and young children
 - TeA: tomato juice, paprika powder, millet grains, dried figs and (certain) tree nuts

Deoxynivalenol

Deoxynivalenol: updated risk assessment from EFSA available : feed and food, acetylated derivatives, DON-3-glucoside: potential health risk (food and feed)

Review maximum levels DON

- o Sum of DON, 3-AcDON, 15-AcDON and DON-3-glucoside
- o Consideration of recent occurrence data
- o Year to year variation

In combination with prevention measures, approaches to deal with the large year to year variation, mitigation measures, agricultural practices,...

T-2 and HT-2 toxin

Follow-up Recommendation 2013/165/EU on T-2 and HT-2 toxin (lower TDI, exposure > TDI)

Setting maximum levels T-2 and HT-2

- o Sum of T-2 and HT-2
- o (Modified forms → not foreseen to be considered for regulation for the time being)
- o Consideration of recent occurrence data
- o Year to year variation

In combination with prevention measures, approaches to deal with the large year to year variation, mitigation measures, agricultural practices, ...

Ochratoxin A

- Discussion on maximum levels for foodstuffs (e.g. dried figs, sunflower seeds, cocoa powder, ...) not yet covered by EU legislation initiated
- Discussion suspended for the time being until availability of EFSA opinion:
 - Update exposure assessment
 - Update hazard identification and characterisation

Mycotoxins – feed

- Maximum levels; aflatoxin B1, ergot
- Guidance values : DON, zearalenone, fumonisins, ochratoxin A, T-2/HT-2 toxin
- Indicative values : T-2/HT-2 toxin

- Detoxification
- Mycotoxin binders

- Update regulatory measures – DON / T-2 HT-2 toxin → reference to food discussions – **animal health**

Mycotoxins – other

- Zearalenone – modified forms – relative potency factors – feed (animal health - transfer feed to food of animal origin). Modified forms → not foreseen to be considered for regulation for the time being
- Fumonisin : modified forms → not foreseen to be considered for regulation for the time being
- **Enniatins**
- Aflatoxins: update comprehensive risk assessment aflatoxins → in support of upcoming Codex discussions !



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PLANT TOXINS

Erucic acid

	g/kg
Vegetable oils and fats with the exception of camelina oil, mustard oil, borage oil	20.0 product
Camelina oil, mustard oil and borage oil	50.0 product
Mustard (condiment)	35.0 product
Infant formulae and follow-on formulae	4.0 on fat content

Pyrrolizidine alkaloids: EFSA statement July 2017

- The EC requested an updated risk assessment, which takes account of exposure estimates using more recent data on the levels of these toxins in honey, tea, herbal infusions and food supplements → Statement of EFSA as regards the risks for public health in July 2017
- The CONTAM Panel established a new Reference Point of 237 µg/kg body weight per day to assess the carcinogenic risks of PAs, and concluded that there is a possible concern for human health related to the exposure to PAs, in particular for frequent and high consumers of tea and herbal infusions. The Panel noted that consumption of food supplements based on PA-producing plants could result in exposure levels causing acute/short-term toxicity

Pyrrolizidine alkaloids – under discussion

Possible maximum levels refer to the sum of 21 individual PAs

- intermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide,
- senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide,
- seneci(o)phylline, seneciphylline-N-oxide,
- retrorsine, retrorsine-N-oxide,
- Echimidine, echimidine-N-oxide,
- lasiocarpine, lasiocarpine-N-oxide,
- Senkirikine
- europine, europine-N-oxide,
- heliotrine and heliotrine-N-oxide.

Pyrrolizidine alkaloids – under discussion

Issue of co-elution

- Indicine (possible co-elution with lycopsamine/intermediate)
- Indicine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermediate-N-oxide)
- Echinatine (possible co-elution with indicine)
- Echinatine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermediate-N-oxide)
- Rinderine (possible co-elution with indicine)
- Rinderine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermediate-N-oxide)
- Integerrimine (possible co-elution with senecivernine)
- Integerrimine-N-oxide (possible co-elution with senecivernine-N-oxide)
- Heliosupine (possible co-elution with echimidine)
- Heliosupine-N-oxide (possible co-elution with echimidine-N-oxide)
- Spartioidine (possible co-elution with seneciphylline)
- Spartioidine-N-oxide (possible co-elution with seneciphylline-N-oxide).

Pyrrolizidine alkaloids – under discussion

- Co-elution: questions addressed to EURL
- LOQ (10 µg/kg)
- Maximum levels under discussion
- Food supplements
- Transition period

Pyrrrolizidine alkaloids – under discussion

Herbal infusions – Rooibos, Anise; Lemon balm, Chamomile, thyme, peppermint, mon verberna (dried product)

Other herbal infusions (dried product)

Tea (*Camellia sinensis*) and flavoured tea (*Camellia sinensis*) (dried product)

Tea (*Camellia sinensis*) and herbal infusions for infants and young children (dried product)

Tea (*Camellia sinensis*) and herbal infusions for infants and young children (liquid)

Food supplements containing herbal ingredients

Pollen based food supplements

Pollen and pollen products

Dried herbs *except*

– lovage, borage, marjoram and oregano (dried)

-- borage (fresh, frozen)

Cumin seeds (seed spice)

Tropane alkaloids

Commission Regulation (EU) 2016/239 of 19/02/2016 setting maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children

- Processed cereal-based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat or their derived products
 - * atropine 1.0 µg/kg
 - * scopolamine 1.0 µg/kg

Tropane alkaloids – under discussion

- The maximum level for atropine and scopolamine in processed cereal –based foods for infants and young children, containing millet, sorghum, buckwheat or their derived products is foreseen, to be extended to processed cereal foods and baby foods for infant and young children **containing corn**

Tropane alkaloids under discussion

- Maximum levels for the sum of atropine and scopolamine under discussion

Unprocessed grains of millet and sorghum

Maize for popping

Maize placed on the market for the final consumer

Unprocessed grains of maize with the exception of unprocessed maize intended to be processed by wet milling

Milling products of maize, millet and sorghum

Unprocessed grains of buckwheat and milling products of buckwheat

Herbal infusions (dried product) with the exception of foodstuffs

Herbal infusions (liquid) with the exception of foodstuffs

Herbal infusions for infants and young children (dried product)

Herbal infusions for infants and young children (liquid product)

Opium alkaloids – under discussion

- Following the outcome of the EFSA opinion, maximum levels in poppy seeds for morphine equivalents (morphine + 0.2 codeine) and thebaine are considered – status of the discussions
- Poppy seeds placed on the market for the final consumer
- Bakery products containing poppy seeds placed on the market for the final consumer
 - **Bread and similar**
 - **Biscuits rusks and crackers**
- For the time being no maximum levels for thebaine under discussion

Cyanogenic glycosides in apricot kernels

- EFSA opinion on "Acute health risks related to the presence of cyanogenic glycosides in raw apricot kernels and products derived from raw apricot kernels"
- ARfD for cyanide = 20 $\mu\text{g}/\text{kg}$ bw

Cyanogenic glycosides in apricot kernels

Commission Regulation (EU) 2017/1237 of 7 July 2017 amending Regulation (EC) No 1881/2006 as regards a maximum level of hydrocyanic acid in unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer

setting of a strict maximum level (**20mg/kg**) for cyanide in in unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer

Cyanogenic glycosides in apricot kernels

Possible need to set levels for foodstuffs such as cassava, linseed, ... and to revise current 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 → to be considered at following an EFSA opinion

EFSA opinion March 2019

TETRAHYDROCANNABINOL (THC)

- EFSA was asked to deliver a scientific opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin.
- Opinion adopted on 5 June 2015
- THC, more precisely delta-9-tetrahydrocannabinol (Δ^9 -THC) is derived from the hemp plant *Cannabis sativa*. In fresh plant material, up to 90 % of total Δ^9 -THC is present as the non-psychoactive precursor Δ^9 -THC acid.

TETRAHYDROCANNABINOL (THC)

- The CONTAM Panel derived an acute reference dose (ARfD) of 1 μg Δ^9 -THC/kg b.w.
- The exposure estimates are at most 3 % and 13 % the ARfD, in adults and toddlers, respectively.

TETRAHYDROCANNABINOL (THC)

Follow-up discussions feed and food:

FEED:

- No immediate action as regards use of hemp derived feed materials in feed (only hemp with less than 0.2 % THC can be used)

→ corresponding levels of THC for the different hemp derived feed materials to be defined.

TETRAHYDROCANNABINOL (THC)

- Follow-up discussions feed and food:

FOOD :

Monitor the presence of Δ^9 -THC in food of animal origin and hemp derived foods

Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ^9 -tetrahydrocannabinol, its precursors and other cannabinoids in food

→ **EFSA report on exposure**

Further outlook plant toxins

- EFSA has been requested for a scientific opinion on:
 - glyco-alkaloids (solanine, chaconine etc)
 - quinolizidine alkaloids: **public consultation**
- EFSA shall be requested for an opinion/report
 - grayanotoxins in honey
- ...

Feed – plant toxins

- Regulatory discussions → follow-up to discussions on food + **animal health aspects** – (public health aspects – transfer feed → food in most cases not that relevant)
- Review Regulation 152/2009 → method for the determination of free and total gossypol to be deleted.



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**Thank you for
your
attention !**