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Directorate-General for
Health & Food Safety

Control of chemical hazards in the food chain: challenges for the risk manager

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Preliminary remark

Presentation is focused on the presence of contamiants in feed and food → therefore the challenges identified are related to the presence of contaminants in feed and food but are also applicable (to acertaion extent) to other chemical hazards in the food chain

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Application of principles of general food law → challenges risk manager

- a **high level of protection of human health and animal health** has to be pursued
  - Strict regulatory level – analytical challenges – sensitivity of analysis
- **free movement** within the European Union of feed and food compliant with EU legislation
  - Need for uniform enforcement – comparable analytical results across the Europan Union - interpretation of analytical results

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Application of principles of general food law → challenges risk manager

* In order to achieve the general objective of a high level of protection of human health and animal health, **EU feed and food legislation shall be based on risk analysis** (process consisting of three interconnected components: risk assessment-risk management-risk communication)

* Risk assessment shall be based on the **available scientific evidence** and undertaken in an **independent, objective and transparent manner → EFSA**

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Application of principles of general food law → challenges risk manager

- Scientific risk assessment:
  - **assessment of the risks related to the presence of a contaminant in foodstuffs for human health / establishment of a tolerable intake / health based guidance value**
  - **exposure assessment: human exposure (average and 95 percentile) Particular attention to vulnerable groups of population, high level consumers, …**
  - **risk characterisation: human exposure assessed in relation to the health based guidance value**

--> is the basis for the management measures to be taken

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Outcome risk assessment → challenges risk manager

- **Regulatory measures to be based on the outcome of the risk assessment**

- Robustness of the risk assessment – challenges

  - Lack of (useful) toxicity data
  - Lack of sufficient (reliable) occurrence data
  - Lack of sufficient food consumption data

  → Uncertainties in exposure assessment and in the overall risk assessment

  → Basis for the risk management measures to be taken

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Outcome risk assessment → challenges risk manager

- Risk assessment : health based guidance value → new approaches (The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC)…)

- MOE: an MOE of > 10000 is considered to be of low health concern
- TTC: exceedance of TTC indicates a potential health concern → need for toxicity data to perform risk assessment

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Challenges risk manager – contaminants

- Determination of foods/food/feed groups significantly contributing to the exposure
  - Lack of occurrence data – are all food/feed groups covered and identified

- Food/feed groups with frequent findings of high level of contamination
- Occurrence data of the contaminant in the various food/food groups
  - Lack of (reliable) occurrence data – are all regions covered? /are all production conditions covered ? –are all climate situations covered ?

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Challenges risk manager - contaminants

- contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)→ setting a regulatory level following the ALARA principle
- The degree of severity of the application of this principle depends on the relation exposure - tolerable intake
  - **Challenge**: determination what can be achieved by applying good practices across the EU / world – (≠good practices, occurrence data availble following good practices)

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Other legitimate factors – challenges

Risk management shall take into account the results of risk assessment, **other factors legitimate** to the matter under consideration and the precautionary principle where appropriate

Other legitimate factors: considered on a case by case basis

* Cost – benefit considerations (impact assessment)
* Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations)
* Feasibility/achievability by applying good practices
* Analytical achievability/feasibility

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Driving forces for initiating new EU-legislation on contaminants

- New /updated risk assessments
- Contamination incidents with “new” (not yet regulated) contaminants
- Emerging contaminants
- Changing production conditions/ climate change
- International developments within the Codex Alimentarius
- Identified problems with current legislation
- New challenges: mixtures, combined exposure, …

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Challenges as a consequence of changing weather conditions – mycotoxins

- Tension between MLs based on the application of prevention / ALARA versus changing climate/weather conditions and year to year variation
- Approach to tackle the year-to-year variation of *Fusarium* toxins/mycotoxins from a legal point of view
- Increasing prevalence of aflatoxins in Europe (increased levels of aflatoxins in the South-East of Europe in 2012 – 2013)
- Increased levels of Fusarium toxins in maize in (large parts of the) EU in harvest 2013 and 2014
- …

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Challenges as a consequence of changing weather conditions – mycotoxins

Fusarium toxins in maize (harvest 2013 and 2014)

- shortage of supply for food maize millers experienced/ expected
- Possible temporary derogation discussed – not granted
- Reasons:
  - certain MS not convinced of shortage of supply
  - exposure to certain mycotoxins already close or exceeding the health based guidance value
- Follow-up
  - shortage of supply problems experienced following non-granting derogation
  - root-cause analysis

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Challenges as a consequence of changing weather conditions – mycotoxins

- Regulatory challenges following increased prevalence of mycotoxins in feed and food following climate change
- Observations: Increased prevalence of mycotoxins at higher levels in cereals produced in the EU. Major cause is climate change and in particular the extreme weather conditions during critical growth stages of cereals in particular maize. However also other causes (agricultural practices) might contribute
- Additional challenge: parent compound + modified forms : occurrence higher / analyticial challenges

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Need for a comprehensive strategy: Challenge !

- **Prevention**
  - Resistent/tolerant varieties
  - Agricultural practices (<-> environmental constraints)
  - Storage and transport conditions
  - …
- **Mitigate the toxic effects** of mycotoxins
  - Mycotoxin binders
  - Mycotoxin detoxifying products /additives
  - ….
- **Detoxification**
  - Acceptability criteria
  - …
- **Last but not least – Regulation / regulatory measures**
  - Maximum levels
  - Guidance levels
  - …

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Need for a comprehensive strategy: Prevention - Challenges

- **Prevention**
  - Resistent/tolerant varieties
  - Agricultural practices
  - Storage and transport conditions
  - ...
- **Drawbacks**
  - Absence of economic incentives
  - Environmental constraints
  - Economic constraints
  - Triggers to effectively implement the good practices
  - Win-win situation: how to achieve this and how to convince farmer and other food business operators of this

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Mycotoxins – parent compound – modified forms

- Deoxynivalenol
- Nivalenol
- Zearalenone (Relative potency factors)
- T-2/ HT-2 toxin (Relative potency factors)
- Fumonisins (EFSA opinion awaited)

Challenges:

- Modified forms → occurrence Higher → potential health problems
- Analytical challenges

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Deoxynivalenol and its modified forms

- EFSA assessed the risk to animal and human health related to DON, 3-acetyl-DON (3-Ac-DON), 15-acetyl-DON (15-Ac-DON) and DON-3-glucoside in food and feed.
- Since 3-Ac-DON and 15-Ac-DON are largely deacetylated and DON-3-glucoside cleaved in the intestines the same toxic effects as DON can be expected. The TDI of 1 µg/kg bw per day, that was established for **DON was therefore used as a group-TDI for the sum of DON, 3-Ac-DON, 15-Ac-DON and DON-3-glucoside (also ARfD for sum)**

Nivalenol and its modified forms 03/2017

- Tolerable daily intake (TDI) for nivalenol (NIV) of 1.2 µg/kg body weight (bw) and an acute reference dose (ARfD) of 14 µg/kg bw
- The only phase I metabolite of NIV identified is de-epoxy-nivalenol (DE-NIV) and the only phase II metabolite is nivalenol-3-glucoside (NIV3Glc).
- NIV3Glc can occur in cereals amounting up to about 50% of NIV. There are no toxicity data on NIV3Glc, but as it can be assumed that it is hydrolysed to NIV in the intestinal tract it should be included in a group TDI and in a group ARfD with NIV.

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Zearalenone and its metabolites - EFSA opinion April 2016

The CONTAM Panel found it appropriate to set a group TDI of 0.25 µg/kg bw per day expressed as ZEN equivalents for ZEN and its modified forms. To account for differences in in vivo oestrogenic potency, each metabolite was assigned a potency factor relative to ZEN to be applied to exposure estimates of the respective ZEN metabolites.

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Zearalenone and its metabolites - EFSA opinion April 2016

- Relative potencies factors (RPFs) given on a molar basis for the metabolites of ZEN proposed by the EFSA CONTAM Panel
- ZEN 1.0; ZENGlcs and ZENSulfs 1.0; **α-ZEL 60; α-ZELGlcs and α-ZELSulfs 60**; β-ZEL 0.2; β-ZELGlcs and β-ZELSulfs 0.2; ZAN 1.5; ZANGlcs and ZANSulfs 1.5; **α-ZAL 4.0; α-ZALGlcs, α-ZALSulfs 4.0**; β-ZAL 2.0; β-ZALGlcs, β-ZALSulfs 2.0; cis-ZEN 1.0; cis-ZENGlcs and cis-ZENSulfs 1.0; **cis-α-ZEL 8.0; cis- α-ZELGlcs and cis- α a-ZELSulfs 8.0;** cis-β-b-ZEL 1.0; cis-β-ZELGlcs and cis-β-ZELSulfs 1.0
- ZEN: zearalenone; Glc: glucose; Sulf: sulfate; ZEL: zearalenol; ZAN: zearalanone; ZAL: zearalanol; ER: oestrogen receptor.

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T-2 and HT-2 toxin and its metabolites - EFSA opinion 11/2016

- Tolerable Daily Intake (TDI) for T2 and HT2 of 0.02 µg/kg body weight (bw) per day (from 0,1 µg/kg bw)and an acute reference dose (ARfD) of 0.3 µg for T2 and HT2/kg bw
- Group TDI and a group ARfD for T2 and HT2 and its modified forms. Potency factors relative to T2 for the modified forms were used to account for differences in acute and chronic toxic potencies. Relative potency factors (RPFs) assigned to the modified forms were all either 1 or less than 1.

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T-2 and HT-2 toxin and its metabolites - EFSA opinion 11/2016

- Relative potency factors (RPFs) for chronic effects of modified forms of T2:

RPF= 1: T2, T2-3-Glc, T2-3-diGlc, T2-3-Sulf,T2-3-GlcA, 3-Ac-T2, 3-Fer-T2, 19-HO-T2

HT2, HT2-3-Glc, HT2-diGlc HT2-GlcA, HT2-MalGlc

RPF=0,3: 19-HO-HT2, NEO, NEO-Glc

RPF = 0,1: T2-triol, T2-triol-Glc, T2-tetraol, T2-tetraol-Glc

Glc: glucoside; diGlc: diglucose; Sulf: sulfate; GlcA: glucuronic acid; Ac: acetyl; Fer: feruloyl; MalGlc: malonylglucose; NEO: neosolaniol.

RPFs have been rounded up to half an order of magnitude, i.e. to either 1, 0.3 or 0.1.

"multiple component" contaminants ergot alkaloids

Ergot alkaloids: discussion on possible maximum levels for ergot alkaloids on the **sum of the following 12 ergot alkaloids : ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine and their respective -inine forms.**

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"multiple component" contaminants Pyrrolizidine alkaloids (PA)

- Currently discussion on possible regulatory measures as regards the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements
- The sum of the following 17 pyrrolizidine alkaloids (in accordance with the CONTAM Panel recommendation) was put forward for agreement at the Standing Committee on 19 June as basis for the discussion on possible maximum levels for pyrrolizidine alkaloids

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"multiple component" contaminants Pyrrolizidine alkaloids (PA)

- 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,
- Senkirkine

One delegation indicated that it is appropriate to include also europine, europine-N-oxide, heliotrine and heliotrine-N-oxide given the very high levels of these pyrrolizidine alkaloids found in certain spices.

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"multiple component" contaminants tropane alkaloids (PA)

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

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"Multiple component" contaminants PFAS / BFRs / Chlorinated paraffins Outlook

- Perfluoroalkylated substances (PFAS): EFSA opinion awaited (PFOS/PFOA, other PFAS).
- Brominated Flame Retardants outcome of EU monitoring to be assessed – Update of EFSA opinions needed?
- Request to EFSA to assess the risk related to the presence of chlorinated paraffins in feed and food
- glycoalkaloids, quinolizidine alklaoids, phthalates, ...

MOE < value above which no health concern (10000, 25000 → risk management

Challenges

MOE < 10000 / 25000 /

→ risk management measures needed to ensure a high level of public health protection

→ ALARA

→ Ultimate target

Pyrrolizidine alkaloids, acrylamide, glycidyl esters, furan, …

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> TTC – basis for risk management 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.

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> TTC – basis for risk management Alternaria Toxins

Awaiting the carrying out of the compound specific toxicity data, it is appropriate to consider the need to set maximum levels for Alternaria toxins of most concern in foods in which they can occur at high levels in order to ensure a high level of human health protection, in particular for vulnerable groups of the population

→ **Discussions are currently ongoing** for which **Alternaria toxins** (alternariol, alternariol monomethyl ether, tenuazonic acid or tentoxin) and **for which food commodities possible maximum levels should be established** awaiting the carrying out of the compound specific toxicity data

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New concerns – method development
Mineral oil

- Commission recommendation for gathering data on the presence of mineral oil in food and on the sources of the presence in food
- Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food (*OJ L 12, 17.1.2017, p. 95)*

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New concerns – method development Microplastics – nanoplastics in food

- EFSA statement on the presence of microplastics and nanoplastics in food, with particular focus on seafood (May 2016)

- Need for occurrence data

- Need for analytical methods

- Issue closely followed up. Presence of microplastics in food is an issue in the European Commission's plastic (recycling) strategy.

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Acrylamide

What ?

- Acrylamide forms from sugars and asparagine that are naturally present in many foods during high-temperature cooking (frying, baking, roasting and also industrial processing at +120°C and low moisture).

Risk assessment

- EFSA concluded that the presence of acrylamide is a public health concern

Objective of regulatory risk management

- To reduce the presence of acrylamide in food as much as possible and this with respect of traditional culinary practices.

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Acrylamide

Which regulatory risk management measure most effective for protection of public health?

* Mandatory application by all concerned food business operators of mitigation measures to reduce the presence acrylamide in food. The mitigation measures to be applied take into account the size and the nature of establishment, with the clear objective to achieve a reduction by setting strict levels to be used as a benchmark. Complementary, maximum levels for certain foods to be set in a second phase.

→ 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

* Home cooking contributes significantly to exposure, therefore need for awareness campaigns towards consumers.

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Acrylamide

Examples of conflicting (public health) objectives when applying measures to reduce the presence of acrylamide:

- Higher temperature during storage of potatoes results in lower levels of acrylamide but requires (larger) use of sprout suppressing (chemical) agents
- Breakfast cereals with higher fibre content have higher levels of acrylamide
- The use of asparaginase significantly lowers the presence of acrylamide e.g. processed cereal based foods for infants and young children, but asparaginase (as produced with GM material) is not allowed to be used in organic products.
- Measures to reduce the presence of acrylamide increases the presence of other possible harmful substances (e.g. furan in coffee).
- …

Acrylamide – additional challenges

- Which Food Business Operators have to apply which mitigation measures → guidance document
- Uniform enforcement across the EU
- **Benchmark levels ≠ maximum levels**
- Initiation of the discussion on maximum levels for certain foods

Additional challenges in case of contamination incident covering large part of EU

- Harmonised risk assessment
  - EFSA, national risk assessment bodies
- Harmonised risk communication
  - Real risk versus perceived risk
- Harmonised risk management
  - Regulatory levels
  - interpretation of analytical results
  - Processing factors
  - Measures to be taken as regards certain products (e.g; processed products already on the market)
- Media attention
- ...

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Thank you for your attention !

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