PARMA SUMMER SCHOOL

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Food Safety Aspects of Integrated Food Systems

Regulating combined exposure to chemicals at EU level: the case of contaminants in food

efsa European Food Safety Authority

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Introduction

Important disclaimer: this presentation relates to the regulatory approach at EU level as regards combined exposure to contaminants in food and does not relate to regulatory approach at EU level to combined exposure to other chemicals (such as pesticide residues, chemicals in general).

This presentation will also highlight the challenges related to regulating at EU level combined exposure to contaminants

Principles of food safety law

General food law (Regulation (EC) 178/2002)

* a high level of protection of human health and animal health has to be pursued
* feed and food placed on the market shall be safe
* contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)

Principles of food safety law

General food law (Regulation (EC) 178/2002)

- 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
- 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

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From risk assessment to risk management

- 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

From risk assessment to risk management

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- Determination of foods/food groups significantly contributing to the exposure
- Food groups with frequent findings of high level of contamination
- Occurrence data of the contaminant/mycotoxin in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake

Ensuring high level of safety: Effective enforcement needed

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- Effective enforcement
  - risk based , frequent controls
  - representative sampling
  - analytical method : can be applied in many well-equipped laboratories (routine) , reliable results within a reasonable time at a reasonable cost
  - screening methodologies combined with confirmatory methods

Risk assessment – Combined exposure

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- Combined exposure to contaminants already to a certain extent addressed/being addressed by EFSA in their risk assessment (not exhaustive)
  - Dioxins and dioxin-like PCBs (29 compounds - Toxic Equivalency approach)
  - Non dioxin-like PCBs (6 marker substances out of 197)
  - PAHs (16 relevant PAHs –marker substance approach 1-4-8)
  - Perfluorinated alkylated substances (4 PFAS out of …)
  - Pyrrolizidine alkaloids (addition 28 compounds out of …)
  - Opium alkaloids morphine + 0,2 codeine)
  - Tropane alkaloids (addition 2 compounds out of …)

Risk assessment – Combined exposure

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- Combined exposure to contaminants already to a certain extent addressed/being addressed by EFSA in their risk assessment (not exhaustive)
  - Aflatoxins (addition - B1, B2, G1, G2)
  - Fumonisins (addition - FB1, FB2, FB3 -group health based guidance value)
  - Deoxynivalenol (DON) (addition - 3-acetylDON, 15-acetylDON, 3,15-acetylDON, DON-3-glucoside)
  - Mycotoxins and their modified forms (group health based guidance value – addition but combined with potency factors - relative potency factors zearalenone, T-2/HT-2 toxin, …)
  - Ergot alkaloids (addition - 12 compounds)
  - Tropane alkaloids (addition 2 compounds out of …)

Risk management – Combined exposure

- Combined exposure to contaminants already to a certain extent addressed by EU in their risk management / setting of maximum levels (MLs)
  - Dioxins and dioxin-like PCBs (29 compounds – ML refers to a Toxic Equivalent (TEQ)
  - Non-dioxin like PCBs (ML is sum of 6)
  - PAHs (16 relevant PAHs –marker substance approach ML for 1 Benzo(a)Pyrene and ML for 4 - sum of benzo(a) pyrene, benzo (a) anthracene, benzo(b)fluoranthene and chrysene)
  - Aflatoxins (ML for AFB1 – ML for AFTOT (sum of 4)
  - Fumonisins (ML for sum of B1 + B2)
  - Tropane alkaloids (ML sum of 2)
  - Pyrrolizidine alkaloids (ML sum of 21 = 14 pyrrolizidine alkaloids)
  - Opium alkaloids (ML sum of morphine + 0,2 codeine)
  - Ergot alkaloids (ML sum of 12 ergot alkaloids)

Risk management – combined exposure

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- Combined exposure to contaminants not taken into account /not addressed by EU in their risk management / setting of maximum levels (MLs)
  - Deoxynivalenol
  - T2-HT-2 toxin
  - Zearalenone
  - ….

  Why not?

EFSA opinion - Zearalenone

- The CONTAM Panel established 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.
- Relative potencies factors (RPFs) given on a molar basis for the metabolites of ZEN proposed by the EFSA CONTAM Panel

ZEN, ZENGlcs and ZENSulfs	1.0;
α-ZEL 60, α-ZELGlcs and α-ZELSulfs	**60**;
β-ZEL,β-ZELGlcs and β-ZELSulfs	0.2;
ZAN, ZANGlcs and ZANSulfs	1.5;
α-ZAL, α-ZALGlcs, α-ZALSulfs	**4.0**;
β-ZAL, β-ZALGlcs, β-ZALSulfs	2.0;
cis-ZEN, cis-ZENGlcs and cis-ZENSulfs	1.0;
cis-α-ZEL, cis-α-ZELGlcs and cis-α-ZELSulfs	**8.0;**
cis-β-ZEL, cis-β-ZELGlcs and cis-β-ZELSulfs	1.0

(ZEN: zearalenone; Glc: glucose; Sulf: sulfate; ZEL: zearalenol; ZAN: zearalanone; ZAL: zearalanol; ER: oestrogen receptor)

EFSA opinion – T2-HT2 toxin

- 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.
- 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.

Why not ? Drawbacks

- No (routine) analytical methods available
- No information on occurrence

EFSA : no full risk assessment possible because

- in many cases no information on toxicity individual compounds → toxicity of cone compound “extrapolated” to all other compounds
- No information on occurrence in food
- ….

→ Uncertainties

Conclusions – outlook

- Combined exposure to "similar" compounds to a certain ((very) limited) extent addressed from risk assessment /risk management point of view with lot of drawbacks /difficulties
- Combined exposure to "non-similar" compounds (different mycotoxins, different metals , …) not yet addressed from risk assessment/risk management point of view

- OUTLOOK:
- In order to ensure a high level of human health safety, need to address more combined exposure
- However drawbacks – challenges !

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Thank you for your attention !

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