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From Scientific Evidence to EU Food Safety Regulation (with a focus on contaminants)

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Overview presentation

- Basic principles
- From risk assessment to risk management
- Risk management measures
- Risk management tools
- Challenges
- Conclusion

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Regulation (EC) No 178/2002 of the European Parliament and the Council

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

(General Food Law Regulation)

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GENERAL FOOD LAW
Scope and objectives

* Applies to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals **"farm to fork" approach**

* Provides that food law shall pursue one or more general objectives of a **high level of protection of human health** and the **protection of consumers' interests** and of, where appropriate, **the protection of animal health** and welfare, plant health and the environment

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GENERAL FOOD LAW
Objectives

* Provides that food law shall aim to achieve the **free movement** in the European Union of feed and food manufactured or marketed according to the general principles and requirements of food law

* Provides that when **international standards** exist or their completion is imminent, they shall be taken into consideration in the development of food law, except where such standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law

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GENERAL FOOD LAW
Risk analysis

* In order to achieve the general objective of a high level of protection of human health, **EU feed/food legislation shall be based on risk analysis** (process consisting of three interconnected components: risk assessment-risk management-risk communication) except where this is not appropriate to the circumstances or the nature of the measure (e.g. labelling)

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

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GENERAL FOOD LAW
Risk management

* **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

- E.g. contaminants legitimate factor: feasibility and achievability of levels through prevention at reasonable economic cost

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Contaminants - 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 – the type of risk management measures depends on several factors

Risk management measures

The nature of the risk management measures is determined by

- The outcome of the risk assessment (health concern, inconclusive, no health concern, uncertainties related to the conclusions)
- The availability and representativeness of available occurrence data (geographical, sufficient period)
- The type of contaminant
- Other legitimate factors

Other legitimate factors to be considered when regulating contaminants

Considered on a case-by-case basis:

* Cost–benefit considerations (*impact assessment*)

* Feasibility/achievability by applying good practices (*regional differences in the EU, impact climate change*)

* If safety cannot be guaranteed by setting maximum levels or other regulatory measures for all consumer groups → to be complemented by consumption advice

Other legitimate factors to be considered when regulating contaminants

Considered on a case-by-case basis:

* Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations)

* Analytical achievability/feasibility by routine methods to ensure effective enforcement

* …

Which foods to be targeted

- Foods/food groups significantly contributing to the exposure
- Food groups with frequent findings of high level of contamination
- Occurrence data of the contaminant in the various food/food groups

(Regulatory) instruments/tools to prevent/reduce contamination

- Prevention of major importance, by applying good agricultural/ manufacturing/storage practices ("*prevention better than cure*")

- (Regulatory) risk management tools: maximum levels, action levels, benchmark levels, source-directed measures, codes of practices, encouraging/obliging application of GAP, GMP, … (see next slides)

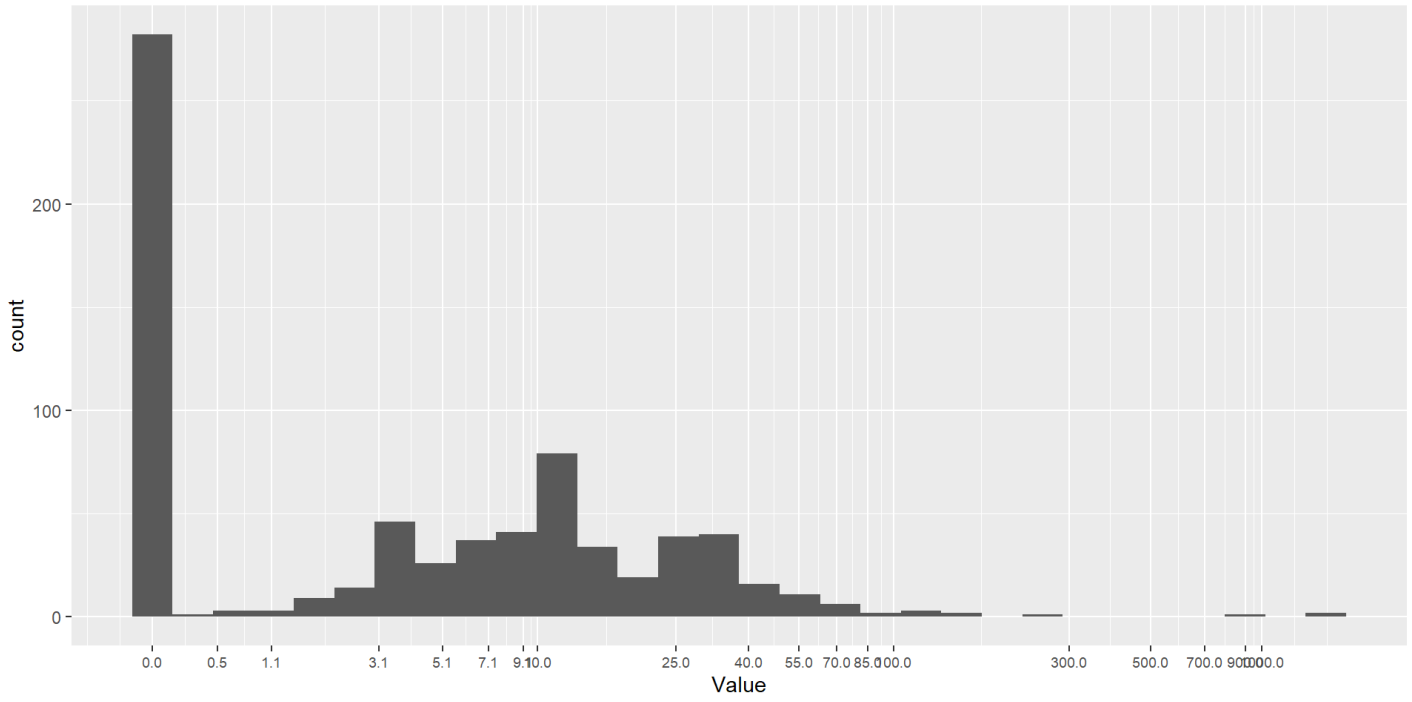
- EU-Measures to reduce the contaminant level in food are determined on a case-by-case basis and can be a combination of several approaches/tools into one strategy (see next slides).

(Regulatory) instruments/tools to prevent/reduce contamination

- Presence of contaminant in food to a certain extent unavoidable, depending on the type of contaminant and available prevention measures!
- Maximum levels are set at a level "As Low As Reasonably Achievable" (ALARA) by applying good practices. The degree of severity of the application of this principle depends on the relation exposure - tolerable intake.
- The setting of maximum levels is always combined with sampling provisions and requirements for the methods of analysis for enforcement

Example data on sum of T-2 and HT-2 toxin in oat milling products (717 results of which 438 quantified results)

Histogram: all results



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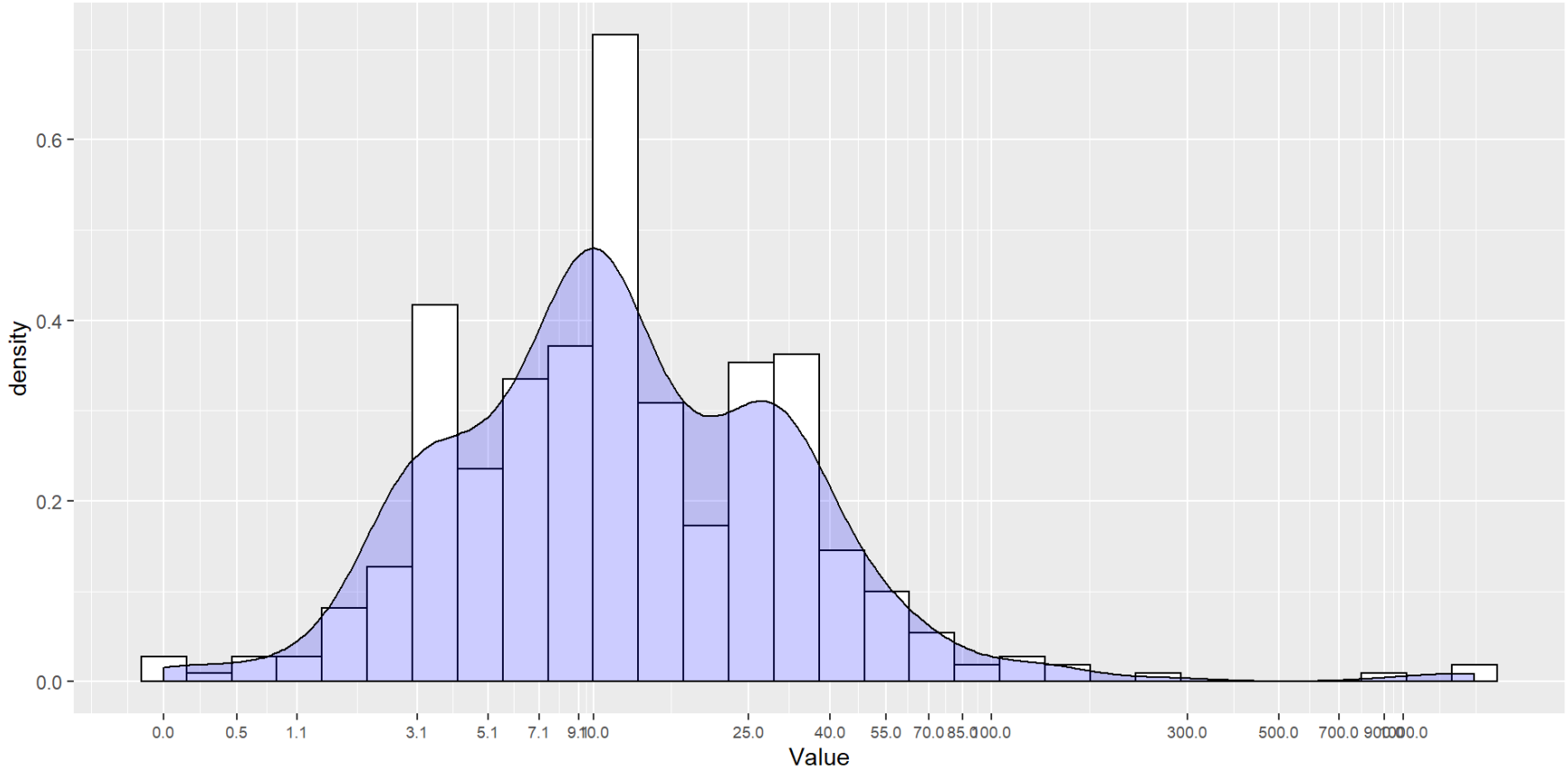
Histogram/density of quantified results



Maximum levels: complement and strengthen the prevention

- Regulatory standards (*maximum levels*):

- ensure a high level of human health protection
- provide legal certainty
- avoid trade barriers in the EU market
- oblige/stimulate food business operators to effectively apply the good practices/ prevention measures
- regulatory level to control compliance for imported foods
- provide (in addition) a tool/benchmark for control authorities for the control of the correct/effective application of prevention measures/good practices by each actor in the chain

Maximum / action / guidance / indicative/benchmark levels

- **Maximum levels**
  - Feed and food placed on the market **shall compl**y with the maximum levels. Maximum levels are safety levels. **Feed and food not compliant** with the maximum levels (taking into account the measurement uncertainty) **shall not be placed on the market** or withdrawn/recalled from the market.
- **Guidance values**
  - Feed and food placed on the market **should comply** with the guidance levels. Guidance for accepting or rejecting lots. Guidance levels are established taking into account the toxicity for humans, sensitivity of different animal species. **Some flexibility possible in enforcement**.

Maximum / action / guidance / indicative/benchmark levels

- **Action levels**
  - Action levels are established **in combination with maximum levels**. Action levels are set at a lower level than a maximum level in order **to stimulate a pro-active approach to reduce the presence of the contaminant in feed and food**. These action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination.
- **Indicative levels**
  - **Indicative levels are not safety levels**. **Exceedance of the indicative values trigger actions /investigations** to be undertaken: investigations on the sources and the reasons for the increased levels and related mitigation measures, on the fate during processing and any other relevant investigations.

Maximum / action / guidance / indicative/benchmark levels

- **Benchmark levels**
  - **Benchmark levels** are not safety levels but reflect the level which can be achieved on a consistent basis by applying mitigation measures to reduce the presence of the contaminant as low as reasonably achievable. Therefore, benchmark levels are performance indicators to be used by food business operators to measure the efficacy of the applied mitigation measures

Risk management tools used – to be used

- Maximum levels (e.g. aflatoxins, ochratoxin A)
- Maximum levels with derogations – regional /specific traditional food processing/production methods (e.g. dioxins, PAHs)
- Maximum levels combined with code of practice for prevention and reduction
- Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels and source-directed measures (dioxins and PCBs)

Risk management options used – to be used

- Maximum levels with additional data collection / monitoring
- Maximum levels combined with dietary advice
- Dietary advice only
- Code of practice
- Data collection / monitoring
- Data collection / monitoring with indicative levels
- Obligatory mitigation tools to reduce presence combined with benchmark levels

Contaminants for which maximum levels have been established - Regulation (EU) 2023/915

- **Mycotoxins**: aflatoxins, ochratoxin A, patulin, Fusarium-toxins (zearalenone, fumonisins, deoxynivalenol, T-2 and HT-2 toxin), ergot sclerotia, ergot alkaloids, citrinin
- **(Heavy) metals**: lead, cadmium, mercury, inorganic tin, inorganic arsenic, nickel
- **Other environmental contaminants**: dioxins, dioxin-like PCBs, PAH, non-dioxin-like PCBs, PFAS
- **Processing/industrial contaminants:** 3-MCPD, inorganic tin, PAH, 3-MCPD esters and glycidyl esters, furan and methylfurans, …(acrylamide: no ML –benchmark levels)
- **Inherent plant toxins**: erucic acid, opium alkaloids, pyrrolizidine alkaloids, tropane alkaloids, hydrocyanic acid, Δ-9-THC,
- Nitrates, melamine, perchlorate

Challenges

General Food Law requirement:

All feed and food placed on the EU market must be safe.

EU Feed and food safety legislation has to ensure a high level of animal and human health protection.

→**New challenges/risks** : climate change, evolving dietary patterns, novel foods, circular economy, … …

Challenge to have (proactive) development of EU feed and food safety legislation to continue to ensure a high level of animal and human health protection

Challenges related to climate change

- In particular an issue for mycotoxins (in particular *Fusarium* toxins
- Increased prevalence due to climate change / extreme weather conditions
- Year to year variation
- Geographical variation
- Achievability of levels by applying agricultural practices, prevention measures and mitigation tools
- Effective application of available prevention measures, mitigation tools
- Farm to Fork strategy – Strategy on Biodiversity → consequences for agricultural practices, prevention measures and mitigation tools

Evolving dietary patterns

- More plant-based food (meat-replacers)
- Alternative sources of proteins (lupins)
- Algae (heavy metals, iodine)
- Insects
- New hazards (quinolizidine alkaloids in lupins)
- **Risk assessment needs to be updated** (quinolizidine alkaloids; consumption data, exposure)
- **Risk management needs to proactively adapt** to these changes

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Challenges changing dietary patterns for risk assessment

- Exposure assessment:
  - Trends to plant-based diets : meat replacers, imitates, plant proteins, algae, …
  - Food consumption surveys → not necessarily reflecting the most recent dietary trends
  - Lack of occurrence data on certain contaminants in "new" foods
  - Increased risk of certain contaminants in certain foods due to increased exposure → requires updates of risk assessment

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Challenges changing dietary patterns for risk management

- Lack of occurrence data
- New/unknown contaminants in these new foods
- No methods validated for the analysis of regulated contaminants in new foods
- No experience on good practices to prevent/reduce presence of contaminants – what is achievable by applying good practices?

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Challenge: regulating /managing the risk from combined exposure to contaminants

- **Combined exposure to "similar" compounds** to a certain (limited) extent addressed from risk assessment /risk management point of view with lot of drawbacks /difficulties
  - In many cases no information on toxicity individual compounds → toxicity of one compound "extrapolated" to all other compounds (or Toxic Equivalent Factors (TEF) or Relative Potency Factors (RPFs)
  - No (routine) analytical methods available
  - No information on occurrence in food

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Challenge: regulating /managing the risk from combined exposure to contaminants

- **Combined exposure to "non-similar" compounds** (different mycotoxins, different metals , …) not yet addressed from risk assessment/risk management point of view

- In order to ensure a high level of human health safety, **need to address (more) combined exposure - however drawbacks – challenges** !

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CONCLUSION

A lot achieved !

A lot still to be done !

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Thank you for your attention !

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