SESSION II: REQUIREMENTS AND CHALLENGES IN VARIOUS LEGISLATIONS EFSA'S VIEW

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EUROPEAN FOOD SAFETY AUTHORITY

SUBSTANCES IN FOOD AND FEED

Contaminants:

- Chemical contaminants are substances that are **unintentionally** present in food or feed.
- No applicants are involved, so no dossier is submitted.
- The test battery from EFSA SC 2011 cannot be followed in this case and the risk assessment is based on data from literature.

Regulated substances:

- Chemicals that are **intentionally** present in food or feed.
- Applicants are involved, a dossier is submitted.
- The test battery from EFSA SC 2011 is followed for most of regulated substances (except pesticides) and literature search.
- Grouping approach may be followed (flavouring group evaluations).
- Genotoxicity of mixtures (component approach followed).

EFSA'S GENOTOXICITY ASSESSMENT

- Genotoxicity assessment of substances is carried out by the experts of EFSA's Scientific Panels or Member States Authorities (pesticides). These assessments are following EFSA's Genotoxicity Testing Strategies and relevant guidance documents, when applicable.

- The **Cross-cutting Working Group on Genotoxicity** aims to ensure a harmonised interpretation and implementation of EFSA's genotoxicity testing strategies among Panels and Units:

  - Provides support to the different EFSA Units/Panels in the evaluation of genotoxicity data sets/scientific literature for assessments where different views have been expressed in the respective Panels or within the same Panel.

  - Provides advice on the interpretation of genotoxicity data in the light of the genotoxicity strategy and provides advice on the interpretation of equivocal and complex genotoxicity test results.

The use of MOE for genotoxic and carcinogenic substances

Contaminants:

An MOE >10,000 for human safety

Feed flavourings:

Only for target animal safety

MOE > 10,000 for long living animals.

The use of the Threshold of Toxicological Concern (TTC) for substances that have the potential to be DNA-reactive mutagens and/or carcinogens (0.0025 µg/kg bw per day)

Contaminants

Non-intentionally added substances: e.g. unavoidable impurities in food contact materials and food additives

Components in feed additives

PESTICIDE ACTIVE SUBSTANCES

Differences:

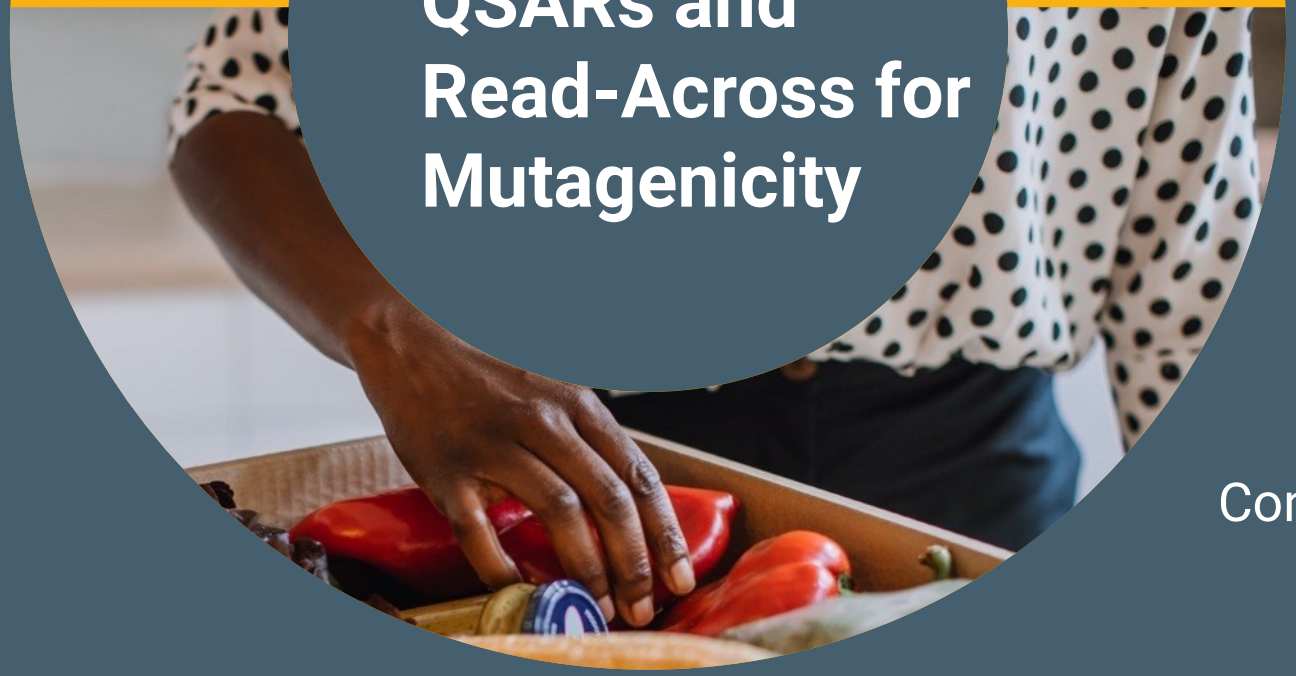
- Regulation (EU) No 1272/2008 and the approval criteria:
  - An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as **Germ cell mutagen category 1A or 1B.**
- Regulation (EU) No 283/2013 on data requirements:
  - Additional test in the basic *in vitro* test battery: **gene mutation in mammalian cells**.
  - ***In vivo*** study always required, even if negative results are obtained *in vitro*.

PESTICIDE ACTIVE SUBSTANCES

Commonalities:

- **Same endpoints** need to be addressed:
  - Gene mutation
  - Clastogenicity
  - Aneugenicity
- **Literature review included**
- **Genotoxicity** is *per se* an endpoint
- A concern for genotoxicity would prevent setting of health-based guidance values, unless a threshold is demonstrated (e.g. carbendazim as aneugenic substance).

The use of QSARs and Read-Across for Mutagenicity



Pesticide transformation products and impurities

Components in mixtures: e.g. smoke flavourings

Compendium of botanicals

Flavouring group evaluations

Contaminants: e.g. nitrosamines

EFSA'S VIEW - CHALLENGES

- EFSA has not applied quantitative analyses for the assessment of gene mutations and clastogenicity of substances present in food and feed.
- However, a health-based guidance value (HBGV) can be established for substances that are aneugenic, but not clastogenic nor causing gene mutations.
- EFSA recognises that there are currently no internationally accepted guidelines for quantitative genotoxicity assessment. Development of such guidelines would require discussion between relevant experts and other stakeholders in order to reach consensus.
- Application of such an approach would also need to take into account the legislative restrictions in different sectors.
- EFSA is periodically updating its Guidance documents and new methodologies and approaches will be considered in the MoE and Genotoxicity testing strategies future guidance revisions.

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