

A draft concept for the assessment of non-intentionally added substances in food contact materials – comments

12th meeting of the EFSA FIP-Network, 21.-23.10.2025, Parma

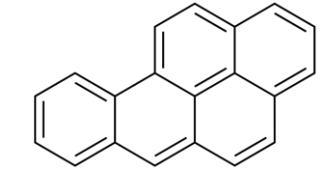
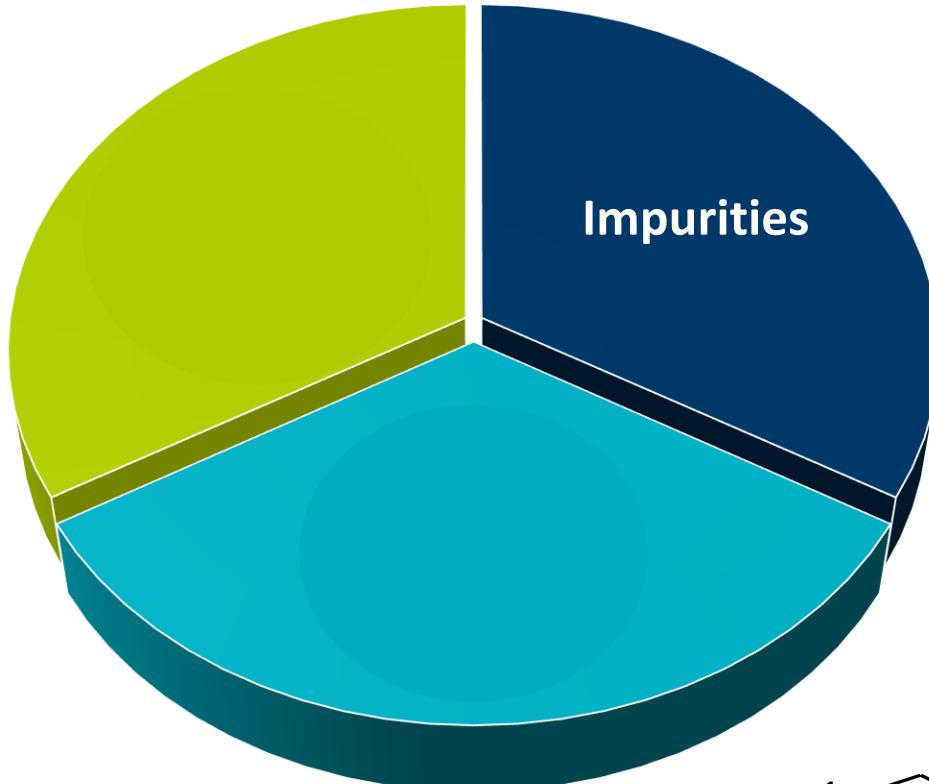
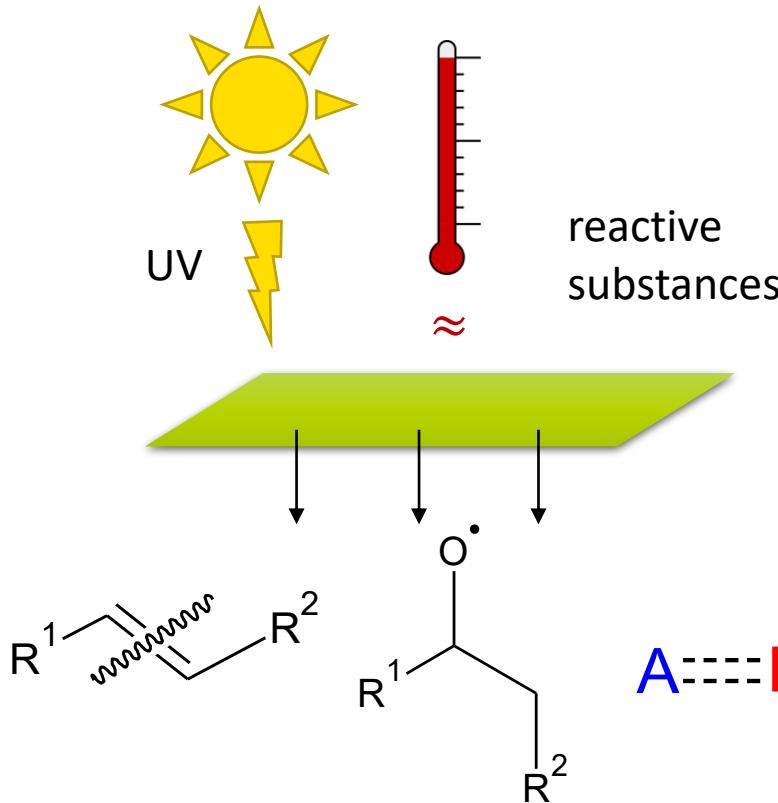
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Unit Safety of food contact materials

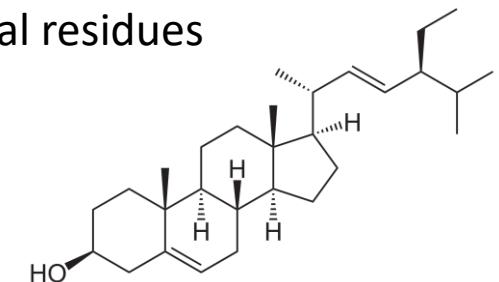
Department Food and Feed Safety in the Food Chain

What are “non-intentionally added substances” (NIAS)?

- NIAS are not added on purpose, but are present as



contaminants like (heavy) metals, PAH, residues from synthesis, natural residues



How to evaluate NIAS?

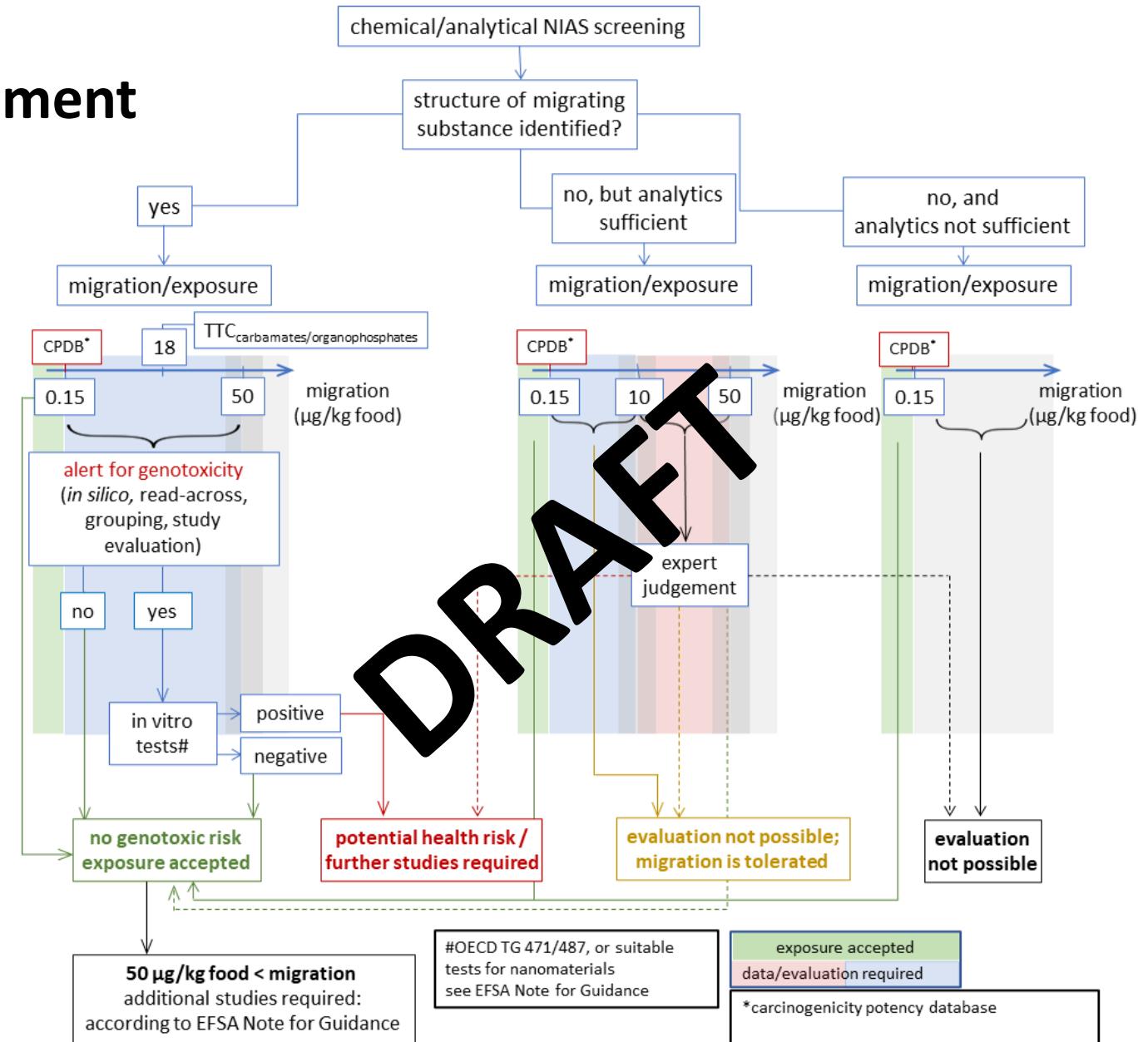
- according to food contact materials law, **NIAS = IAS** (Article 3(1)a of Reg. (EC) 1935/2004)
- data on **any migrating substance** for toxicological assessment necessary

Problem:

- **Identification** of NIAS
- very often **toxicological data** do not exist
- experimental data (analytical/toxicological) hard to generate when **pure substance** not available
- high costs

Draft concept for NIAS assessment

- Workflow and quality criteria for analysis
- Toxicological assessment based on identification and amount of migration
- Integration of NAMs, acceptance of low migrating NIAS
- Method development for mixtures testing ongoing



Awareness of NIAS



Generated with Microsoft Copilot

- Stakeholders are well aware of NIAS
- Concern for sole responsibility for assessment
- Pragmatic approach is required

Feedback for draft guideline – general remarks

- Idea of the concept is welcomed
- Concerns about misinterpretation along the supply chain
- Concerns about cost pressure
- Concern about excessive animal testing
- Misunderstood scope

Scope for NIAS Risk Assessment Concept

- Concept was written for **assessment of applications** for BfR Recommendations on food contact materials
- **NOT intended for compliance testing** of finished articles
- The **toxicological part** may, however, serve as guidance for assessment of specific findings e.g. aromatic amides as impurities in printed paper,
- The assumption of 1kg food intake per person per day is consumed to be used unless specific applications are reviewed
- BfR **Guideline for the safety assessment of substances for the manufacture of food contact materials and articles** is to be considered as well
- 50ppb: BfR observes legal provisions (NIAS = IAS)

Feedback for draft guideline – remarks analytics

- No/poor availability of NIAS standards
- No harmonized screening methods
- No harmonized rules for semi-quantification
- High uncertainty of quantification
- High interlaboratory variation in NIAS screening
- Excessive effort required for batch-to-batch testing

Analytical uncertainties are not avoidable when dealing with NIAS → expert judgement is required!

Feedback for draft guideline – remarks toxicology

- Questions about non-use of TTC concept
- Assessment of oligomers

Why not TTC?

- TTC concept is screening tool, not risk assessment tool
- TTC must not be applied for substances that require the submission of toxicological data
- Examples where TTC does not match SML:
 - Phthalates (DBP, DHP)
 - BPA

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