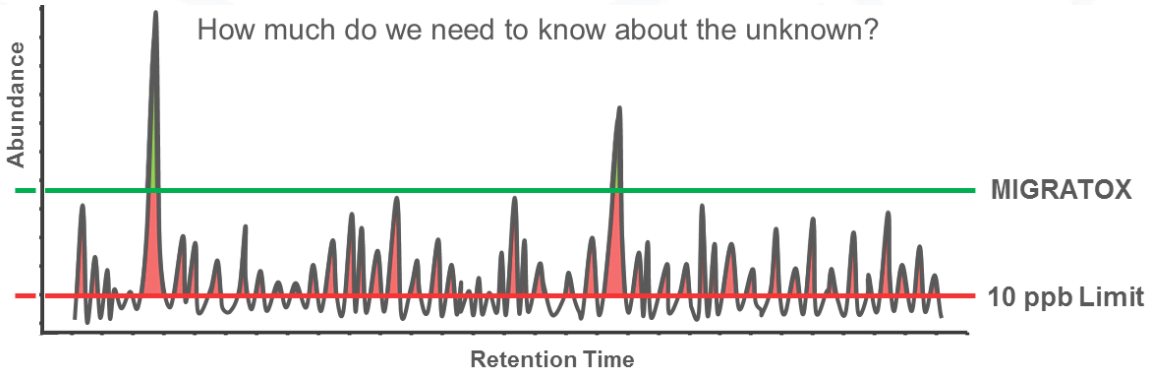
Project „MIGRATOX“

In-vitro bioassays to support safety assessment of NIAS

In most food contact materials (FCM) a large number of non-intentionally added substances (NIAS) can be detected. There are currently no reliable and cost-efficient methods for the identification and toxicological evaluation of all detected NIAS. Therefore, the use of *in-vitro* bioassays was recently recommended by the Internation Life Science Institute (ILSI) and by the European Parliament to simplify the safety assessment of food packaging. Big international food companies are already working on the implementation of bioassay testing for FCM.

Application of the Threshold of Toxicological Concern to Migrates

If the migration of substances with high toxicological potential (e.g. genotoxic substances, endocrine disruptors) can be excluded by *in-vitro* bioassays, it is no longer necessary to identify and evaluate all NIAS above 10 ppb. In this case by refering to the threshold of toxicological concern (TTC) a substance can be assumed as safe even without identification and toxicological testing up to a daily intake of 90 µg/person. This simplifies the risk assessment of unknown NIAS substantially.



10 ppb Limit: All 45 Peaks above 10 ppb have to be identified und evaluated.

MIGRATOX : Highly toxic substances can be excluded by *in-vitro*-tests → Evaluation only necessary for the 2 Peaks above the Threshold of Toxicological Concern

Genotox tests: Can substances in the migrate damage the DNA?

Currently the biggest challenge for the safety assessment of unknown NIAS is to rule out genotoxic substances. Genotoxic substances can damage the DNA, and therefore have the potential to cause cancer, even at extremely low concentrations. There are many different classes of chemicals that can be genotoxic, and it is often not possible to rule them all out based on chemical analysis alone. Therefore bioassays are used for state-of-the-art genotoxicity testing. Currently there are many promising approaches on the use of bioassays for FCM testing, but no standardized, validated and generally accepted test methods, with sufficient sensitivity.

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Development and validation of standardized *in-vitro* tests for FCM

The aim of the MIGRATOX project is a well-defined guideline how bioassays can be used for the safety assessment of food packing, that is based on validated, standardized test methods.

- Comparison and evaluation of different *in-vitro* assays for their suitability for FCM testing (Focus: genotoxicity)
- Optimization and validation of sample preparation and *in-vitro* bioassays
- Standardization of test protocols and determination of quality parameter: sensitivity, (inter-laboratory) reproducibility, false-positiive and false-negative rates, effect of sample matrice

Collaborations with food authorities and strong international industry partners shall ensure the acceptance of the developed test strategies!

Advantages for project members:

The idea of the project is to let the industry take part in this ongoing development, and give the industry the opportunity to get informed at a very early stage.

- Regular project meetings with internationally renowned experts to **get informed about project results and new developments**
  - Presentation of results – first anonymised results of application of the biotests on samples, validation data, chances and pitfalls for the application of the bioassays
  - Update on new literature and legal developments in this field
- Possibility to **actively participate** in the development of the new testing approaches
- **Analysis of own samples** with *in-vitro* bioassays already in early phases of development to have an **early warning in case of positive results**
  - Genotoxicity, AhR activity (Dioxins, PCBs), cytotoxicity, endocrine activity

Membership Fee:

Small and middle enterprises (< 250 employees):	3 samples included,	5.000 € / year
Large enterprises (> 250 employees)	7 samples included,	10.000 € / year

In-vitro bioassays will play an important role in the future of food packaging testing!

Better be part of this development, and get informed at an early stage, then let yourself surprise!

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