



European Test and Risk Assessment Strategies for Mixtures (EuroMix)

BfR Department Food Safety
BfR Department Pesticides Safety



EFSA Advisory Forum
Helsinki, 18th-19th September 2019



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Combined exposure via the diet



- exposure of consumers against mixtures of:
 - food contaminants
 - pesticides
- toxicological testing and risk assessment only done for single compounds

Need:

- strategy for risk assessment of mixtures
- methods for toxicological testing of mixtures



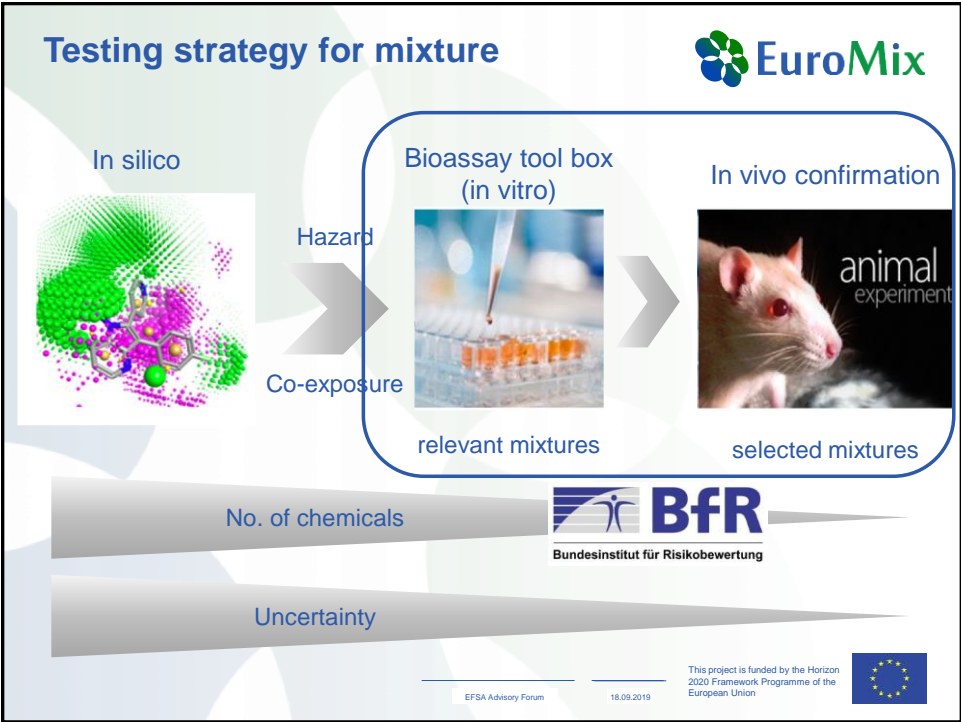
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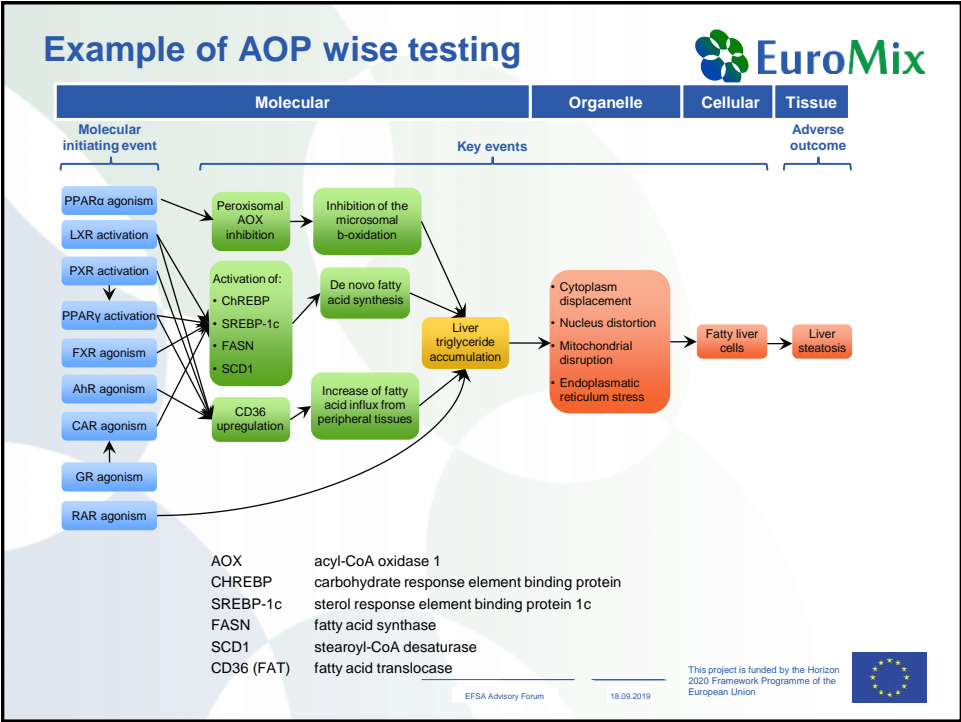
This project is funded by the Horizon
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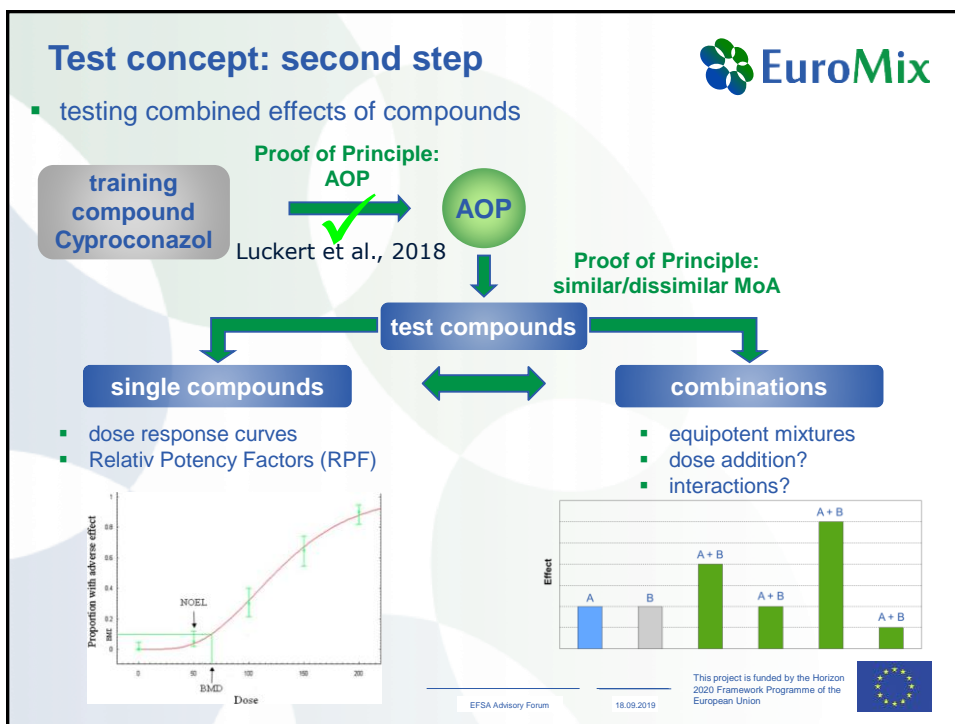
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AOP-wise mixture testing


EuroMix

- in vitro**

Bioassay tool box (in vitro)


 - All toolbox assays show similar results
 - in vitro* toolbox successfully tested for mixtures
 - Paper in preparation
- in vivo**

in vivo confirmation


 - Data collection and analysis is still ongoing

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Overview WP9

Partner institutions involved



Objectives

- highlight challenges in the regulatory context of mixtures and provide recommendations
- consider the tiered mechanism-based test strategy and exposure assessment methodology for mixtures
- assess how EuroMix can contribute to a harmonised approach between Europe, WHO/IPCS & US-EPA

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Task 9.1

Mixtures and implementation strategy in Europe

- Preparation of an overview:
 - How mixture testing and higher tier modelling are addressed in current regulatory toxicology
 - Provide recommendations on approaches & assessment strategies

CRITICAL REVIEWS IN TOXICOLOGY
2018, VOL. 48, NO. 9, 796–814
<https://doi.org/10.1080/10408444.2018.1541964>

REVIEW ARTICLE

Overview on legislation and scientific approaches for risk assessment of combined exposure to multiple chemicals: the potential EuroMix contribution

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Task 9.2



Recommendations for risk managers


- Recommendations to risk managers in the EU regarding implementation of a harmonized assessment of combined exposure to multiple chemicals and regulatory needs such as greater harmonization between EFSA, OECD and WHO were suggested



- 1. *Implementation into the European regulatory framework***
 - A cross-cutting legal mandate for performing risk assessments of combined exposures to multiple chemicals is recommended
 - Risk managers need to set down rules on how to manage identified risks across different regulatory silos and to provide clear guidance on the acceptable degree of uncertainties

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Task 9.2 – Main results



Task 9.2 – recommendations for risk managers

- 2. *Ensuring the accessibility and transparency of the assessment tools***
 - Sufficient financial resources to operate the EuroMix toolbox is needed
- 3. *Further development of methods***
 - Development of alternative regulatory strategies for the assessment of combined exposure to multiple chemicals needs to identify optimal in vitro models and to define a screening tool box for regulatory purposes.
- 4. *Further promotion of cooperation and strengthen of existing networks***
 - Set up a network involving European and Non-European authorities as well as international organisations
 - Organisation of two meetings a year (stakeholders, risk managers, risk assessors) to synchronise the work and to agree on new developments is proposed

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Thank you for your attention!

