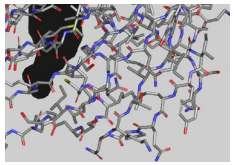
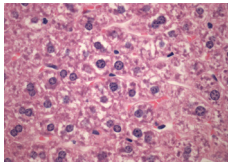
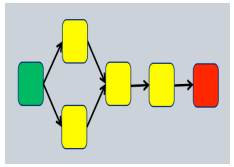
EuroMix results

For information about project results and publications visit the Euromix website:

www.euromixproject.eu

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EuroMix participants

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Ministry of Health, Welfare and Sport

WAGENINGEN UR
For quality of life

anses
French agency for food, environmental and occupational health & safety

INRA
SCIENCE & IMPACT

INERIS
controlling risks for sustainable development

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EuroMix

European Test and Risk Assessment Strategies for Mixtures

Every day, we are exposed to a mixture of multiple chemicals via food intake, inhalation and dermal contact. The risk to health that may result from this depends on how the effects of different chemicals in the mixture combine, and whether there is any synergism or antagonism between them. The number of different combinations of chemicals in mixtures is infinite and an efficient test strategy for mixtures is lacking. Furthermore, there is a societal need to reduce animal testing, which is the current practice in safety testing of chemicals.

The EuroMix project will deliver a mixture test strategy and test instruments using novel techniques as recently proposed by the Joint Research Centre (JRC) of the European Commission. The tests will result in data needed for refining future risk assessment of mixtures relevant to national food safety authorities, public health institutes, the European Food Safety Authority (EFSA), the European Chemical Agency (ECHA), industry, regulatory bodies and other stakeholders. Ultimately, this will provide information for future risk management decisions on the safety of chemicals in mixtures to be taken by the European Commission and the Codex Alimentarius.

Expected outcomes

- An efficient evaluation process of the safety of mixtures, ensuring adequate protection of public health.
- First tier screening of chemicals to be included in mixture testing based on literature research, quantitative structural activity relationships (QSAR) and real life exposure profiles.
- Guidance on the use of *in vitro* tests to test mixture effects on key events of Adverse Outcome Pathways.
- A refined strategy for grouping chemicals into cumulative assessment groups and prioritising data gaps.
- A harmonised approach to assessing risk including information on possible additive, synergistic or antagonistic effects of the chemicals in the mixtures at real life exposure levels.
- An open access web based model and data platform available to all stakeholders that will remain available beyond the project's lifetime.
- Guidance and training material on the use of the test strategy and refined risk assessment of mixtures.
- Discussion on acceptance of the test strategy and exposure assessment methodology by international organisations (e.g. EFSA, ECHA, OECD, WHO/FAO Codex Alimentarius, US-EPA and DG SANTE).
- Reduction in the use of laboratory animals once the mixture testing is accepted due to reliable *in silico* and *in vitro* approaches to assess the toxicity of chemical mixtures.

Approach and methods

- Grouping and prioritisation of chemicals to be included in mixture testing based on literature research and *in silico* approaches for a limited number of toxicological effects such as fatty changes in the liver, skeletal malformation and an example of an endocrine effect.
- Testing of chemicals and their mixtures on key events of Adverse Outcome Pathways including the toxicological profiles as identified by EFSA.
- Verification of *in silico* methods and the *in vitro* bioassay toolbox for mixture testing against in vivo animal tests. Comparison of the predicted exposure with biomarkers measured in humans.
- Performing risk assessments of mixtures twice; first with conventional data and then with results from the novel test methods developed in the project. A 'retain and refine' approach will be followed to address the completeness and uncertainties of the risk assessment.
- Integration of modelling approaches linking external to internal exposure doses, assessing cumulative risk and taking account of uncertainty.
- Make use of high performance parallel computing and cloud computing facilities in a protected governmental ICT environment.
- The organisation of training, workshops and stakeholder conferences to discuss the new test strategy for mixture risk assessment with the WHO/FAO Codex Alimentarius, DG SANTE, the US-EPA and relevant stakeholders.

Objectives

The overall objective of the project is to establish and to disseminate new, efficient, validated test strategies for the toxicity of chemicals in a mixture aiming to deliver refined information for future safety assessment of chemicals. This includes exposure assessment via multiple exposure routes.

Specific objects are:

- Determine a refined grouping strategy for cumulative assessment groups.
- Establish criteria for prioritisation of chemicals for carrying out mixture testing.
- Verify the reliability of *in silico* methods and *in vitro* bioassays against *in vivo* animal tests.
- Determine how to extrapolate the results of *in vitro* bioassays and *in silico* models to humans.
- Develop harmonised tools and models for performing realistic assessment of chemical mixtures.