

PARC

European Partnership for the Assessment
of Risks from Chemicals

WP6

Innovation in regulatory risk assessment

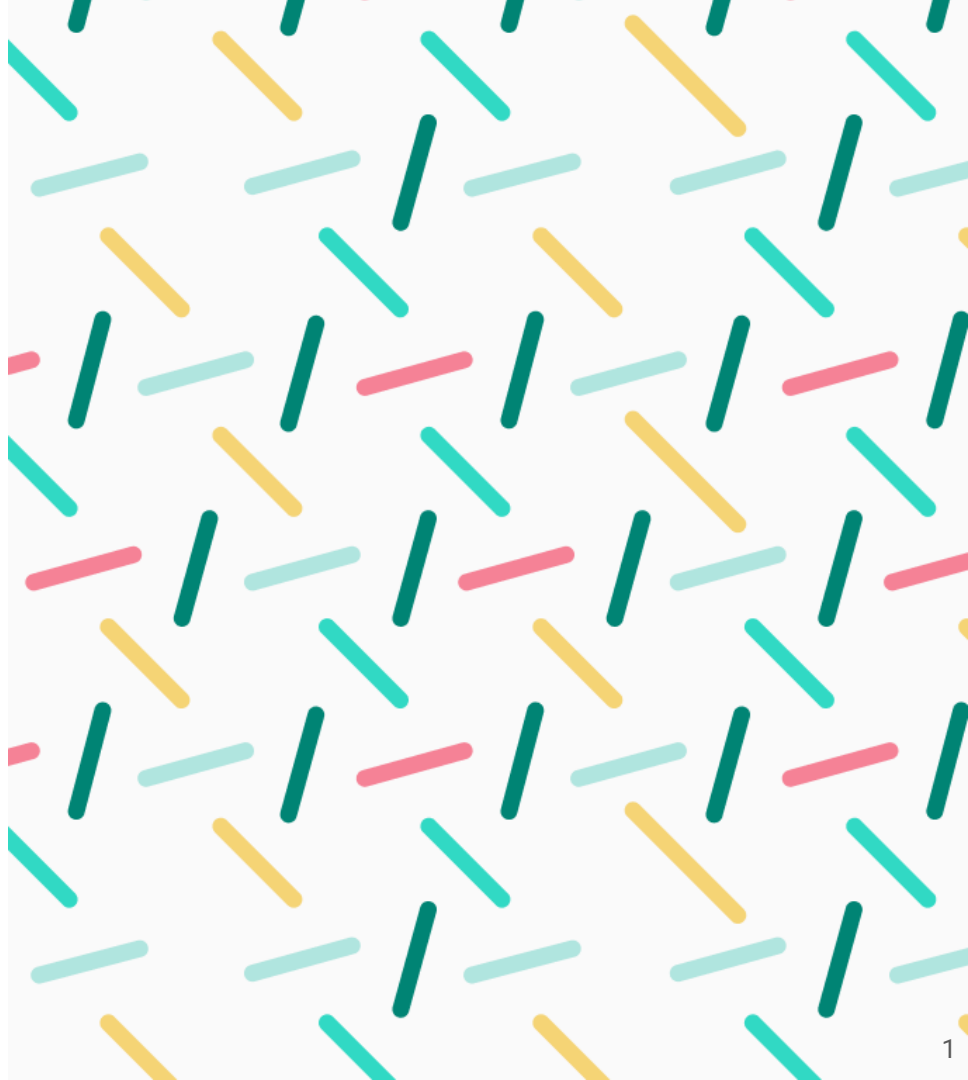
T6.3

Review of risk assessment methodologies

Nacionalno vozlišče, Ljubljana 15.12.2025

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Task 6.1 IATA (Integrated approach to testing and assessment):

- Development and testing of IATAs for regulatory purposes
- Pre-validation of test methods used in IATA
- Evaluation of IATAs, using weight of evidence approaches for integrating human data and data from traditional and novel (test) methods and including characterisation of uncertainty
- Development and/or expansion of (quantitative) Adverse Outcome Pathways
- Development of a workflow for assessing the human relevance of AOPs, as well as the relevance of associated test methods and tools
- Development of computational modelling approaches for integrating outputs from non-animal methods and tools towards quantitative hazard assessment
- Identification and validation of effect biomarkers

Task 6.2 Integrative exposure and risk assessment

- Aggregate exposure modelling from different sources and routes
- Linking internal exposure to external aggregate exposure and vice versa
- Mixture risk assessment
- Ecological risk assessment

Task 6.3. Review of risk assessment methodologies

- Evaluate the performance and efficiency of current regulatory methodologies, processes and frameworks. Identify knowledge gaps and suggest improvements in legislation when relevant.
- Tools to help enforcement of legislation with focus on articles
- Develop a decision support system

Task 6.4. Transposing results to regulatory risk assessment methodologies

- Propose efficient risk assessment processes
- Develop regulatory and legally accepted risk assessment and management methods for chemical mixtures
- Develop regulatory and legally accepted risk assessment and management methods for articles in circular material flow.
- Develop regulatory and legally accepted risk assessment and management methods for complex situations often with severe knowledge gaps.
- Facilitate the regulatory acceptance and use of new methods

PARC T6.3 _Case study 2

Evaluating the effectiveness of risk management measures



Objective

Identify, characterize, assess, and compare risk management measures in terms of the effectiveness of risk reduction.

Research questions

- What are the characteristics of successful risk management measures?
- How can the effectiveness of risk management measures be measured?
- What are the main obstacles towards successful risk management measures?
- How can assessment and management be further developed to support a non-toxic environment?

Methods

1. Systematic Review according to COSTER guidelines - Jozef Stefan Institute
2. Interview study with risk assessors and risk managers - Stockholm University
 - Semi-structured interviews with respondents working within the field of policy and regulation
 - Thematic focus relating to results from systematic review
 - Cross-sectoral focus
3. Follow-up study from the systematic review - Jozef Stefan Institute

T6.3_CS2

Identification and review of methods for evaluating the effectiveness of risk assessment for reducing risk

Literature overview of the effectiveness, from an environmental perspective, of the main types of measures:

- Legal measures (restriction, authorisation, classification, guideline values, chemical tax)
- Supervisory and communicatory measures
- Technical measures (WWTT, dredging and capping, treatment of landfill leachates, non-toxic alternatives to antifouling paint)

→ Significant gaps in knowledge

→ Difficult to assess due to interaction between several factors

T6.3_CS2_Progress Y1



Literature review protocol drafted and confirmed by partners

Literature search and review underway;

- systematic literature search: over 1000 hits (scopus, web of science)
- lack of literature focused on efficiency of the methods
- focus on „grey literature“ (reports, studies...)

PARC T6.3 _Case study 3

*Evaluation of the efficiency of EU
OSH legislation and REACH
authorisation/restriction processes
to control occupational chemical
exposure*



Objectives and methods used

- evaluate the efficiency and coherence of the current regulatory practises for controlling occupational chemical exposure
- propose improvements to the regulatory process and define criteria for selection of preferred regulatory option(s).

To clarify how regulatory information is utilized for workplace chemical risk assessment and risk mitigation in practice, supporting both regulatory decision making and providing guidance for workplaces

- study on the existing regulatory documents to identify case examples of the different options to regulate occupational chemical exposure (either under OSH, REACH or both)
- for each selected substance, a short description of the regulatory process(es) and its outcome

T6.3_CS2_Progress Y1



Literature review protocol drafted and confirmed by partners

General literature search and review underway;

- systematic literature search: over 300 hits (scopus, web of science)

Regulatory review underway

Survey with inspectors and management of the companies using hazardous substances is underway (to be completed by 31.1.2024)

Semi structured interviews with stakeholders (authorities, public bodies, governmental agencies, ...)

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