Advanced methodology for the prioritisation of contaminants and contaminant mixtures in the aquatic environment

(SOLUTIONS WP S2)

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SOLUTIONS WP S2

Advanced methodology for the prioritization…

- **Aims and Approach**
- **Wider Regulatory Context:**

  Legal Requirements for Mixture Risk Assessment in EU Legislation
- **Key Terms / Concepts**

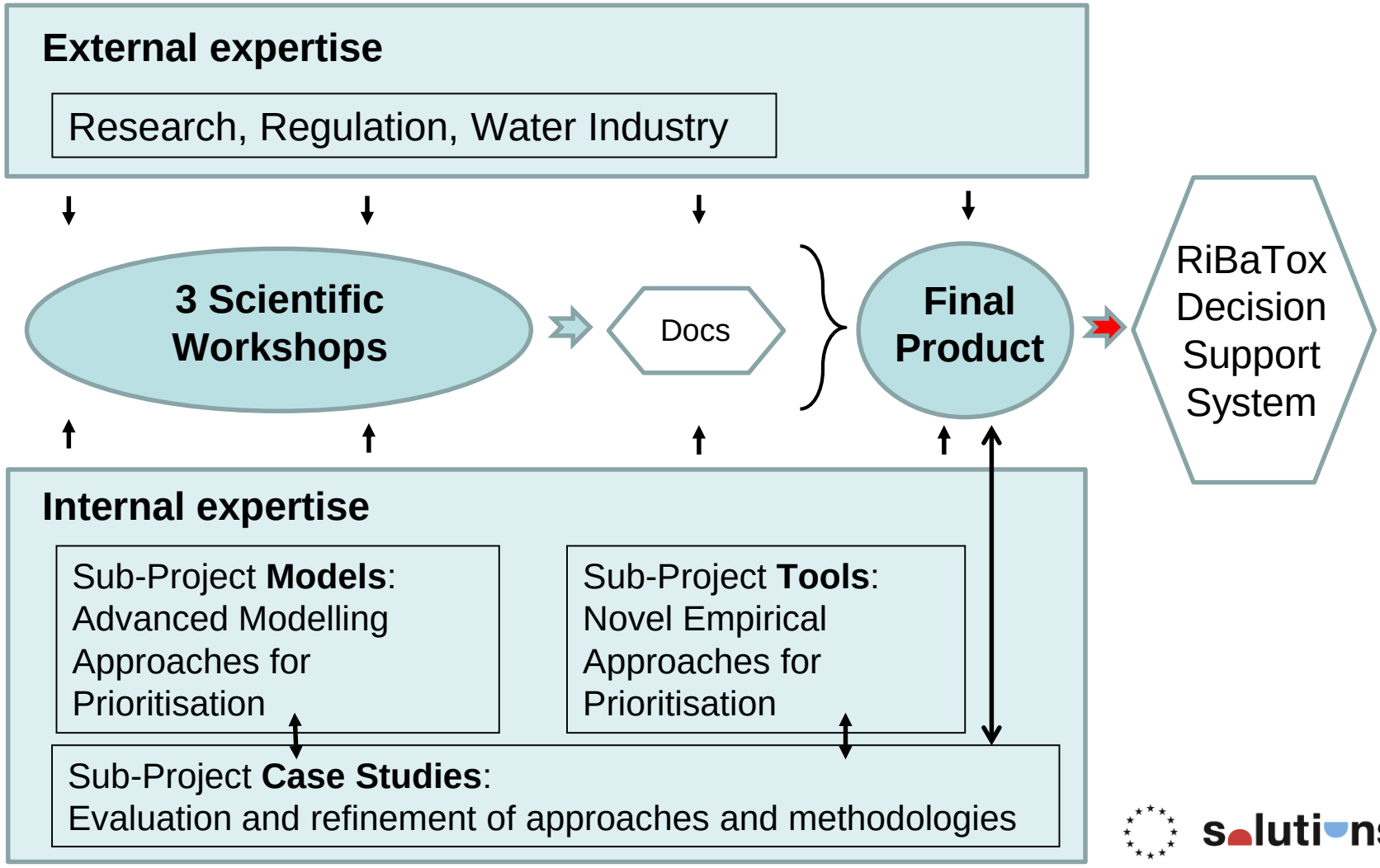
  Priority Mixtures

  Drivers of Mixture Toxicity

  Prioritisation

SOLUTIONS WP S2: Advanced methodology for the prioritisation of contaminants and contaminant mixtures in the aquatic environment:

An Integration and Coordination Activity



What we promised

- Proposal for an **advanced methodology** for the **solution oriented prioritisation** of contaminants and **contaminant mixtures** in the aquatic environment

The advanced methodology shall combine

- existing state-of-the-art approaches (⇨ NORMAN network),
- **novel experimental tools** (⇨ SOLUTIONS **SP T**),
- **improved model-based approaches** (⇨ SOLUTIONS **SP M**)

for the identification of

- **emerging pollutants** and hazardous transformation products,
- "**drivers of mixture toxicity**" and "**priority mixtures**"

(⇨ Communication from the Commission to The Council on "*The combination effects of chemicals*", COM(2012) 252 final)

The prioritisation procedure shall be

- tiered, resource-efficient and fit for regulatory purposes

Milestones

- **June 2014: 1st Workshop**

  Assessing the **state-of-the-art** and deriving recommendations for the development of advanced tools and methodologies in SOLUTIONS

- **December 2016: 2nd Workshop**

  Exploring options for integrating assessments of **mixture toxicity** and cumulative risks into prioritisation procedures

- **December 2017: 3rd Workshop**

  Discussing the **draft SOLUTIONS proposal** for an advanced prioritisation methodology

- **March 2018: Final Product**

  Proposal for an advanced methodology for the prioritisation of (single) contaminants and **contaminant mixtures** under the WFD

Priority Mixtures

a concept under construction

... the Commission will:

...

(2) Develop, by June 2014, and taking account of the opinion of the Scientific Committees, technical guidelines to promote a ***consistent approach to the assessment of priority mixtures across the different pieces of EU legislation.*** *...*

....

(Communication from the Commission to The Council on "The combination effects of chemicals", COM(2012) 252 final)

Compartmentalization of EU chemicals regulation

General Chemicals Control

- REACH – Regulation (EC) No 1907/2006
- CLP – Regulation (EC) 1272/2008

Special Uses of Chemicals

- Pesticides Authorisation – Regulation (EC) 1107/2009
- Biocidal Products – Regulation (EU) 528/2012
- Human Medicines – Directive 2001/83/EC
- Veterinary Medicines – Directive 2001/82/EC

Emission Control

- IPPC – Directive 2008/1/EC (new codified version of 96/61/EC)
  IED – Directive 2010/75/EU
- EIA – Directive 85/337/EEC

Quality of Environmental Media

- WFD – Directive 2000/60/EC
- DWD – Directive 98/83/EC
- Air Quality – Directive 2088/50/EC

Food Law

- Food Additives Authorisation – Directive 89/107/EEC
- Food Contact Materials – Regulation (EC) No 1935/2004 (repealed and replaced 89/109/EEC)
- Feed Additives Authorisation – Regulation (EC) No 1831/2003
- Feed Additives Assessment – Directive 2001/79/EC
- Pesticide Residues – Regulation (EC) No 396/2005

Non-Food Consumer Products

- General Product Safety – Directive 2001/95/EC
- Cosmetics – Directive 76/768/EEC

Occupational Health

- Workplace Health and Safety – Directive (89/391/EEC)

Legal Requirements for Mixture Risk Assessment

"… at present risk assessment on the combined effects of chemicals in a mixture is not commonly carried out, nor required by most EU regulations."

SCHER, SCENIHR, SCCS (EU Scientific Committees on Health and Environmental Risks, Emerging and Newly Identified Health Risks, and Consumer Safety) (2011) Toxicity and Assessment of Chemical Mixtures. European Commission, DG Health & Consumers, Brussels

Legal Requirements for Mixture Risk Assessment

Type of mixture	Is mixture toxicity taken into account in EU regulations?
Products **Mixtures intentionally produced and placed on the EU market:** UVCBs, MCS, preparations	**In general YES**
Process emissions **Mixtures of chemicals emitted from point sources or diffusive sources as a result of economic processes:** production, transportation, consumption, recycling, disposal	**In some cases**
Immissions / Multi-pathway exposure **NOT intentionally produced complex mixtures of chemicals from numerous products and processes co-occurring in:** environmental media, food, humans	**In general NO**

Legal Requirements for Mixture Risk Assessment

- **REACH:** PBT/vPvB assessment of MCS, UVCBs
- **CLP:** Assessment of intentionally prepared mixtures
- **IPPC/IED:** TEF approach for setting of ELVs for dioxins and furans from waste incineration plants
- **PPP and Biocidal Products:**
  Assessment of total product toxicity
- **Pesticide MRLs / PPP authorisation:**
  Method development for mixture risk assessment of multiple residues in food
- **WFD:** Methodologies for mixture risk assessment included in implementation guidelines

WFD – EQS for Mixtures

EQSs may be defined for grouped substances that exert a similar mode of action *and may be expressed according to the concept of Toxic Equivalent [TEQ] concentrations in environmental samples.*

European Communities (2011) Technical Guidance For Deriving Environmental Quality Standards, sections 2.7 and 7. Common Implementation Strategy for the Water Framework Directive (2000/60/EC), Guidance Document No. 27.

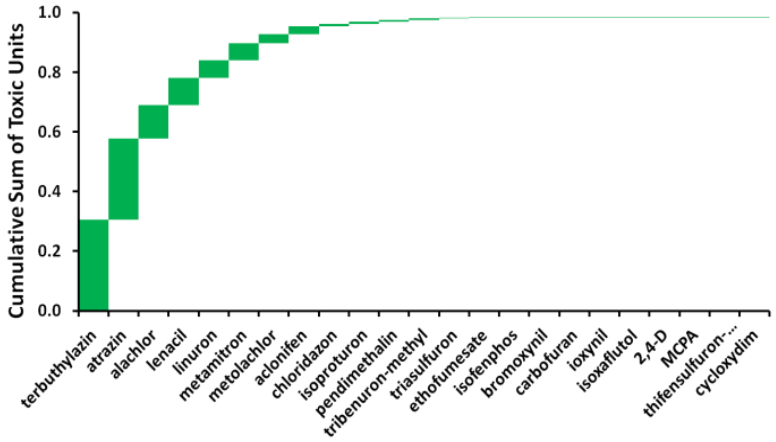
- How should the term "*similar mode of action*" be interpreted exactly?
- How should groups of substances with a similar mode of action (MoA) been identified practically?
- How to deal with missing knowledge about MoAs?
- Is the concept Toxic Equivalent [TEQ] concentrations always appropriate?
- Are there alternative options for defining EQS for mixtures which are not site-specific?

The “Drivers” Concept:

Examples for the identification of drivers of mixture toxicity under the assumption of concentration addition

23 pesticides at the levels found in surface waters:

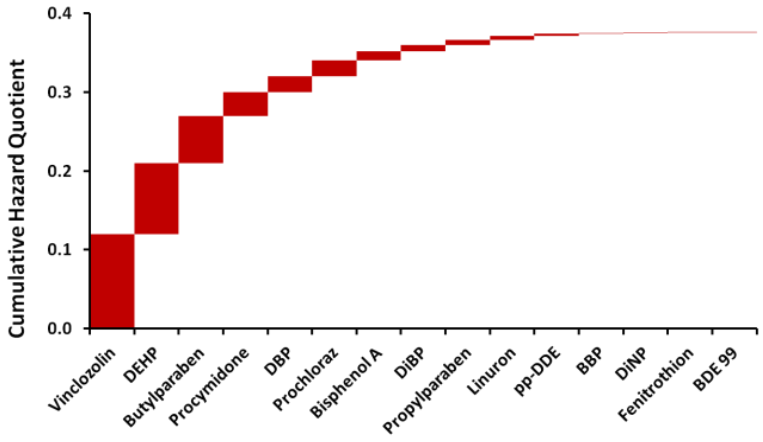
Five compounds (21%) explain 80% of the combined algal toxicity



Data from Finizio et al. 2005, Agr Eco Env 111, 111-118; Junghans et al. 2006, Aquatic Toxicology 76, 93-110

15 anti-androgenic chemicals at estimated human exposure levels:

Five substances (33%) contribute 80% of the cumulative hazard index



Data from Kortenkamp and Faust 2010, Int J Androl 33, 463-474

Drivers

- **Site specific**
- **Endpoint specific / Species specific**

If model-based

- **depending on the validity of the mixture toxicity model:**
  - Dose Addition may lead to a different ranking than Independent Action
  - Ranking may be wrong in case of synergistic or antagonistic interactions
  - Applicability of regulatory approaches derived from dose addition questionable

Regulatory Approaches Derived from Dose Addition

DA *Dose (Concentration) Addition*	$E_{mix} \leq x$ if	$\sum_{i=1}^{n} \frac{d_i}{EDx_i} \leq 1$	$\frac{d_i}{EDx_i} = TU_i$ TU = *Toxic Unit*
PODI *Point of Departure Index*	No significant effect if	$\sum_{i=1}^{n} \frac{EL_i}{POD_i} \leq 1$	EL = Exposure Level POD = LOEL, NOAEL, NOEC
HI *Hazard Index*	No reason for concern if	$\sum_{i=1}^{n} \frac{EL_i}{AL_i} \leq 1$	EL = Exposure Level AL = Acceptable Level = ADI, DNEL, …
PEC/PNEC Summation	No unacceptable risk if	$\sum_{i=1}^{n} \frac{PEC_i}{PNEC_i} \leq 1$	PEC = Predicted Environ-mental Concentration PNEC = Predicted NEC

- Consistent with DA under some simplifying assumptions
- Typically more conservative than the scientific DA concept

Prioritisation

WFD requires the risk-based identification of

- **“Priority substances”** (⇨ “progressive reduction“)
- **“Priority hazardous substances”**
  (⇨ “cessation or phasing-out of discharges, emissions and losses”)

Other prioritization aims

- **… for further action**
- **… for risk assessment**
- **… for …**

Other prioritization criteria

- **… hazard-based / effect-based**
- **… exposure based**
- **…**

Thank you