

Sediment risk assessment in Europe

Comparison of environmental regulations

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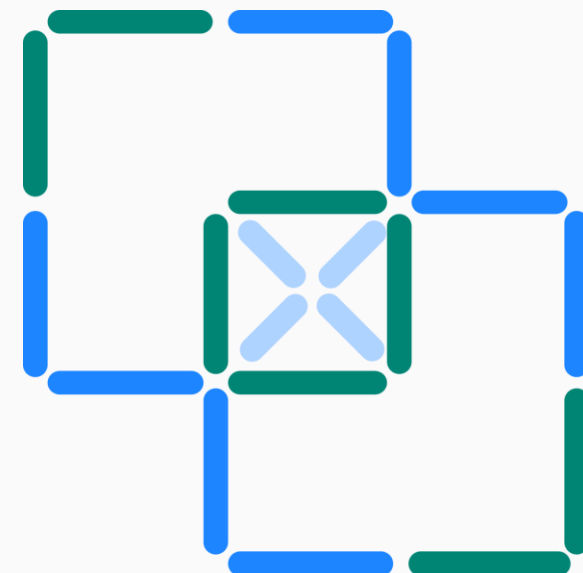


Partnership for the Assessment of Risks from Chemicals



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Chemicals risk assessment in Europe

Chemicals in the EU are mainly regulated based on their intended use.

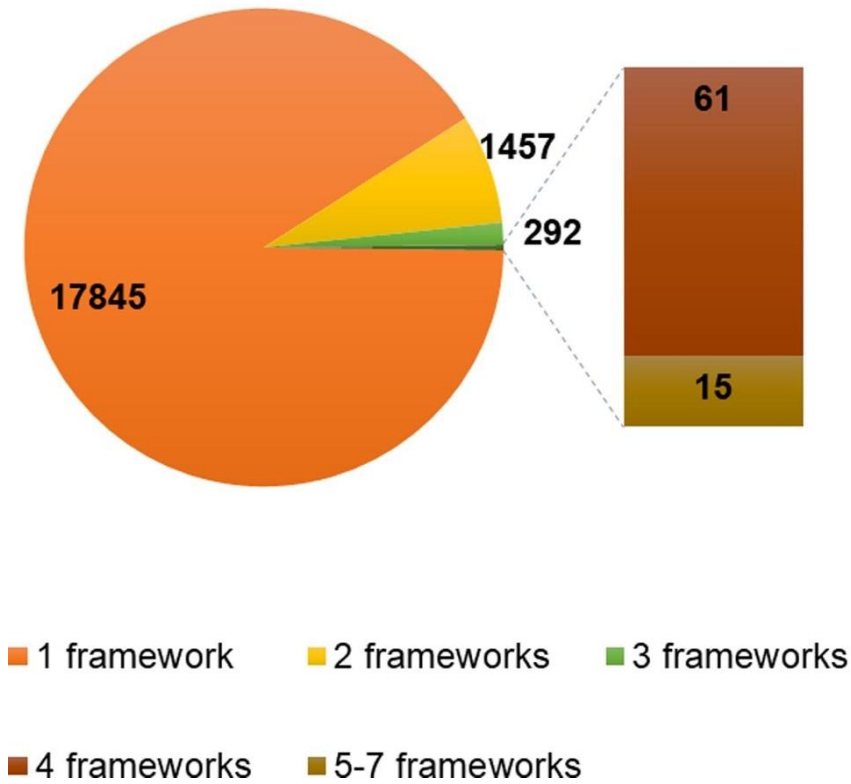
Legal Frameworks:

- **(EC) No 1907/2006, REACH** (*Registration, Evaluation, Authorisation and Restriction of Chemicals*) – EU's main chemical regulation: 26'865 substances (2008-2025)
- **(EU) No 528/2012, BPR** (*Biocidal Products Regulation*) – covers disinfectants, preservatives, etc.: 273 substances (2025)
- **(EC) No 1107/2009, PPP Regulation** (*Plant Protection Products*) – active substances, safeners, synergists: 354 substances (2025)
- **(EU) 2019/6, VMPPR** (*Veterinary Medicines Products Regulation*) – active ingredients in veterinary medicines: 237 substances (2025)
- Regulatory retrospective assessment in surface waters (Water Framework Directive)

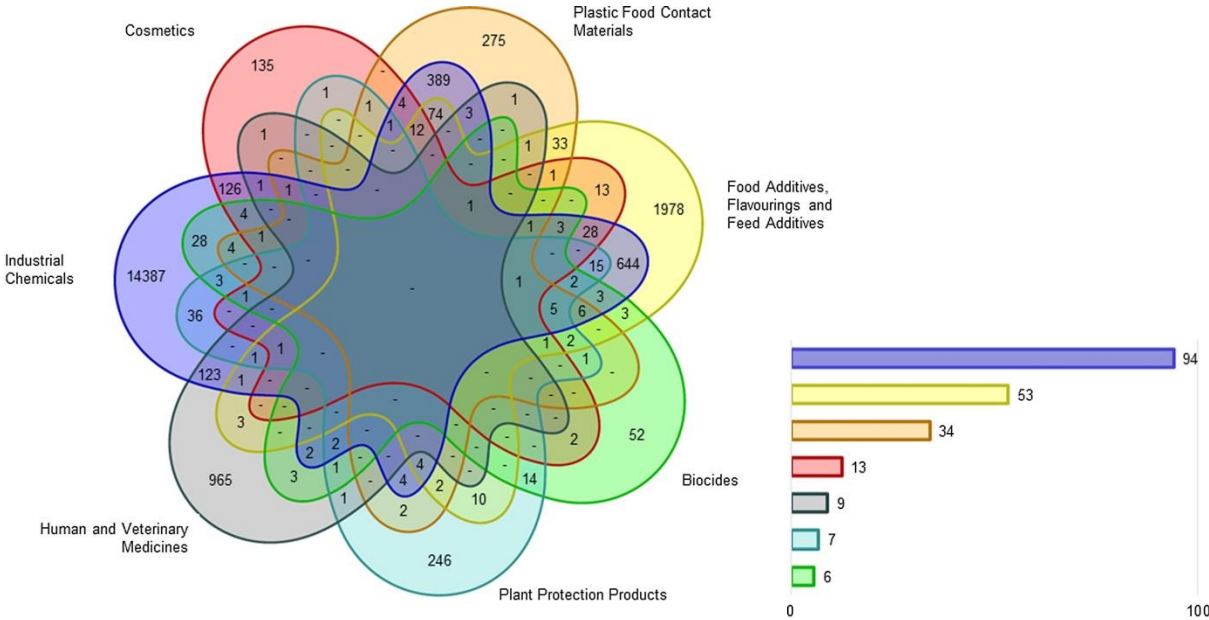
One chemical with multiple uses may have multiple assessments.

“Almost one-tenth of identified substances were listed in more than one framework”

Number of substances in 1–7 frameworks in the EU



Distribution of substances identified in ≥ 2 regulatory areas



One chemical can fall under multiple prospective regulations depending on its use.

Do the environmental risk assessments for the aquatic compartment of a chemical regulated under prospective regulations and under the retrospective Water Framework Directive (WFD) differ in the assessment of environmental protection?

- Examine the practical implementations and outcomes of environmental risk assessments in different regulations, with a focus on plant protection products and the aquatic environment.
- Case studies: imidacloprid and deltamethrin.

Key steps in EU chemicals ERA process

1. Hazard Assessment

- Selected surrogate organisms tested for acute and chronic effects of a chemical to derive ecotoxicological endpoints.
- Each regulation requires a minimum number of studies to establish an ecotoxicological threshold level.

2. Exposure Assessment

- Estimate levels of exposure for people/environment.
- Prospective assessments calculated Predicted Environmental Concentrations (PECs) based on assumptions of use and emission, whereas for the retrospective risk assessments, environmental concentrations are measured (MEC).

3. Risk Characterization

- Combine hazard and exposure info to evaluate risk as quotient under consideration of the level of uncertainty in the assessment.

Exceedance of exposure over the effect concentration leads to a refinement of the risk assessment and implementation of risk mitigation measures.

Protection goals

- **Same overall protection goal** of all regulations is to protect the environment from adverse effects on biodiversity and ecosystems.
- **Differences in its definition** (PPPR: Prevention of “unacceptable effects on the environment”; BPR: “ensuring a high level of protection of both human and animal health and the environment”)
- **Differences in the level of protection**
 - Certain degree of effects is tolerable under some regulations (e.g. recovery in PPPR).
 - Differences in consideration of uncertainty through Assessment Factors.

ECHA, EU WFD

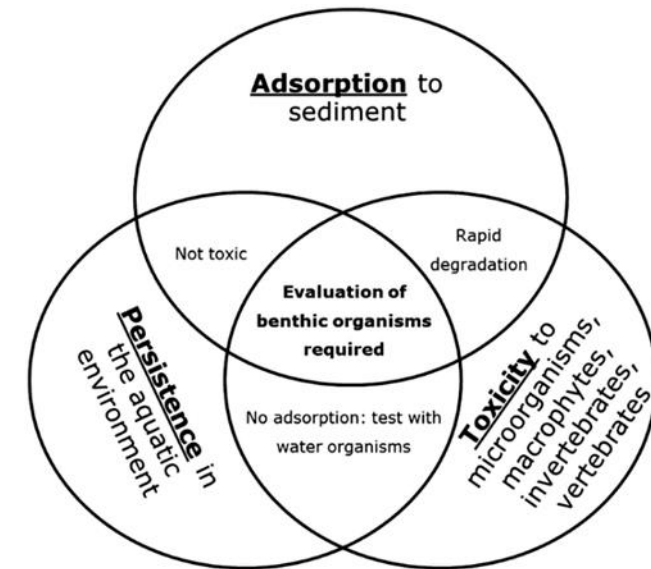
Available data	Assessment factor
One long term test (NOEC or EC10)	100
Two long term tests (NOEC or EC10) with species representing different living and feeding conditions	50
Three long term tests (NOEC or EC10) with species representing different living and feeding conditions	10

Protection goals

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- **Differences in the level of protection**
 - Certain degree of effects is tolerable under some regulations (e.g. recovery in PPPR).
 - Consideration of uncertainty through Assessment Factors.
 - Realistic worst-case definition/implementation among regulations.

Data requirements for ERA

- **Data requirements and ERA process differ** to some degree between prospective regulations.
- Data core set for pelagic organisms.
- **Sediment effect assessment included in aquatic risk assessment** of all prospective regulations (REACH, PPPR EC 1107/2009, BPR EC 528/2012, VMPR EU 2019/6) as **conditional requirement**.



Source: Theoretical basis for defining triggers for sediment toxicity studies. (Maund et al. 1997).

Requirements for ERA: triggers for sediment assessment



REACH guidance, sediment toxicity is needed:

- For substances manufactured or imported into the EU in quantities over 1000 tons per year.
- For substances that are potentially capable of depositing on or sorbing to sediments to a significant extent.

BPR EC 528/2012, ERA shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota, following the use of the biocidal product.

- When accumulation of an active substance in an aquatic sediment is indicated or predicted by environmental fate studies.
- For product type 21 (Antifouling products) within the respective PT (triggered by emission pathways).

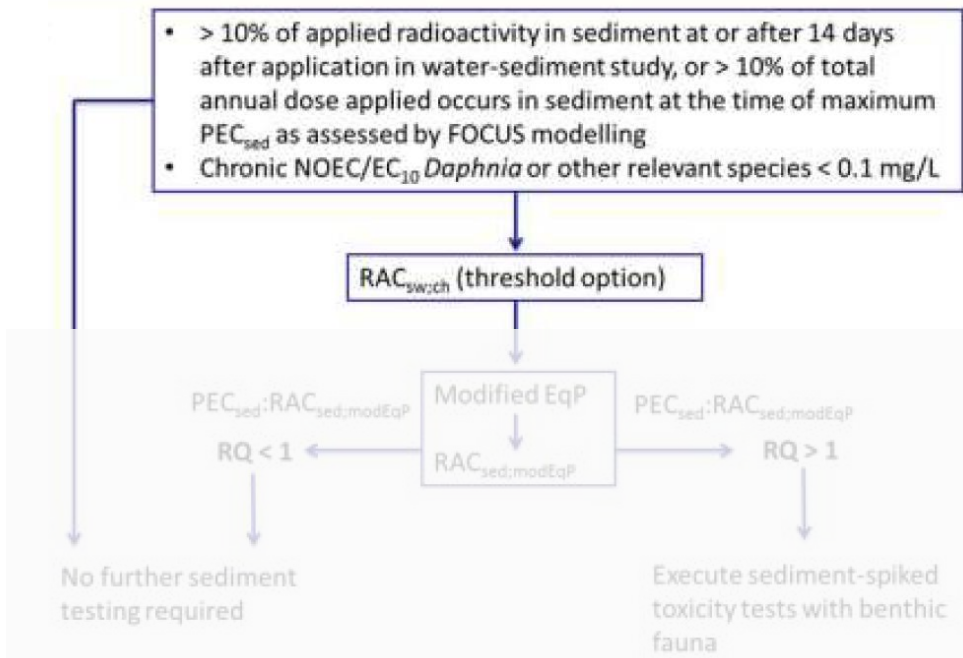
When $\log K_{ow}/K_{oc} \geq 3$: trigger value for sediment effects assessment.

Requirements for ERA: triggers for sediment assessment



EC 283/2013, Article 8.2.5.4: Impact on sediment-dwelling organisms required when accumulation of an active substance in aquatic sediment is indicated or predicted by environmental fate studies.

EFSA Journal 2013; 11(7):3290; EFSA Journal 2015; 13(7):4176 Scientific opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water :



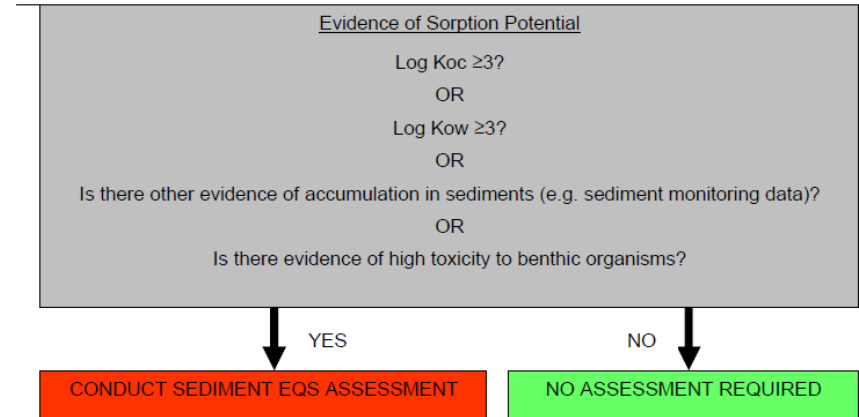
- Metabolites/degradation products: testing with tier 1 sediment organisms if distribution in sediments.
- Recommended spiked sediment bioaccumulation tests with benthic invertebrates for substances that show significant bioaccumulation in fish tests ($BCF > 2'000$ L/kg), when the substance is persistent in sediment (half-life >120 days in the water-sediment fate study) and $\log Kow > 3$. Also if triggers not exceeded but concern raised from read across information or other 'expert judgement'.

Requirements for ERA: triggers for sediment assessment



EU Water Framework Directive 2000/60/EC WFD:

- Sediment-bound chemicals should not be ignored. Matrix recommended for long-term trend monitoring (or biota).
- Environmental quality standards (EQS) for the protection of benthic organisms for priority substances derived.



Swiss Water Protection Act, WPA, and Ordinance, WPO:

³ The water quality shall be such that:

- a. the temperature conditions are near-natural;
- b. the water, suspended matter and sediments contain no persistent synthetic substances;
- c. other potential water pollutants which could enter the water as a result of human activities,
 - do not accumulate in the plants, animals, micro-organisms, suspended matter or sediments,

Requirements for ERA: triggers for sediment assessment



EU Water Framework Directive 2000/60/EC WFD:

- EQS for sediments not implemented in regulation.
- Few countries have decided to monitor priority substances in sediments.
- Several European countries have established sediment quality criteria for river basin specific pollutants (not in regulation). Nevertheless, they are rare compared to EQS for water and biota.

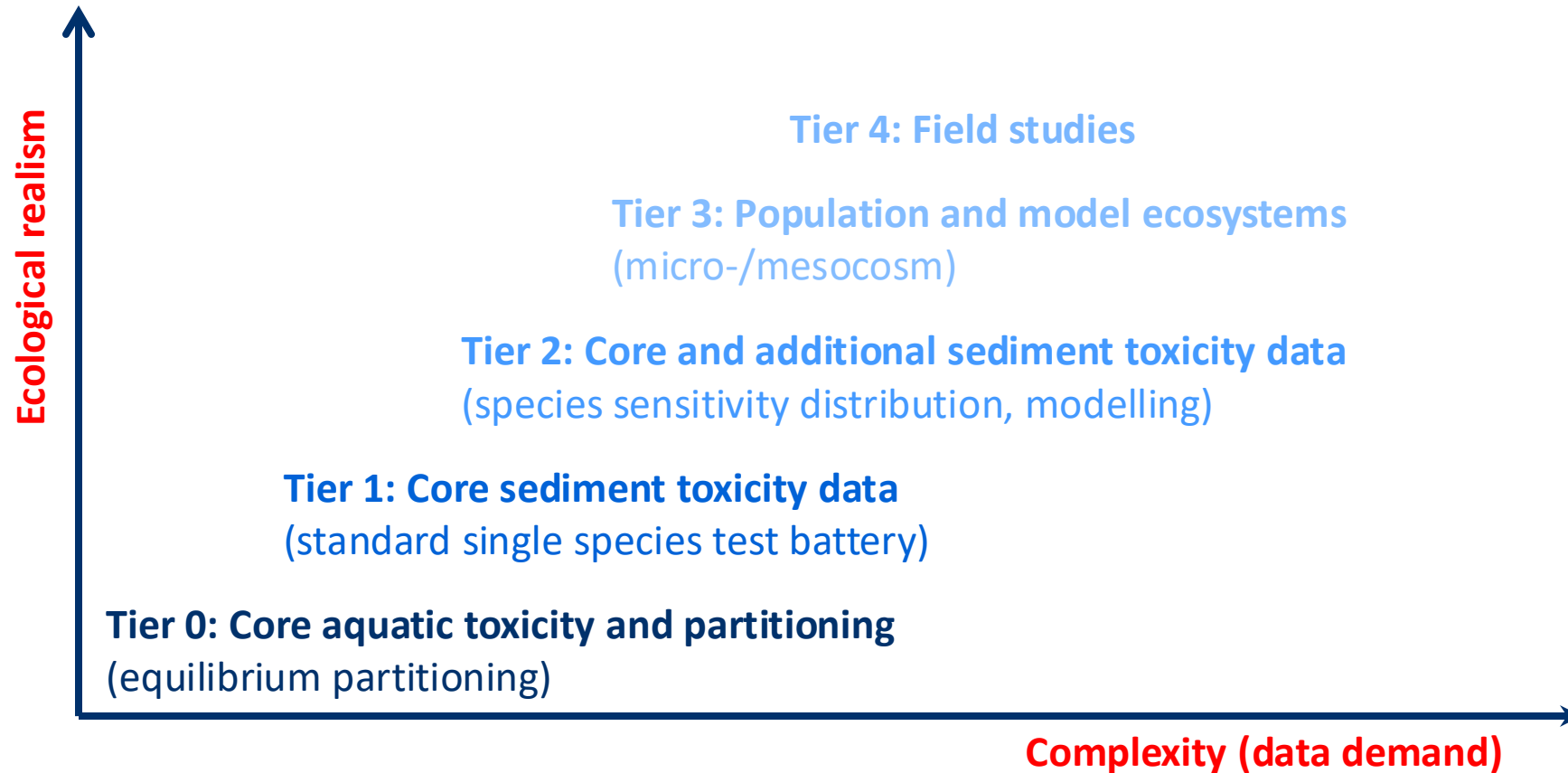


Swiss Water Protection Act, WPA, and Ordinance, WPO:

- Some cantons use sediments/SPM for long-term trend monitoring of metals/PAHs/PCBs. Specific campaigns for other chemicals on case-by-case basis.
- Threshold values for sediments not implemented in regulation (water and biota).

Ecotoxicological studies: data requirements

Recommended tiered approach for sediment effect assessment

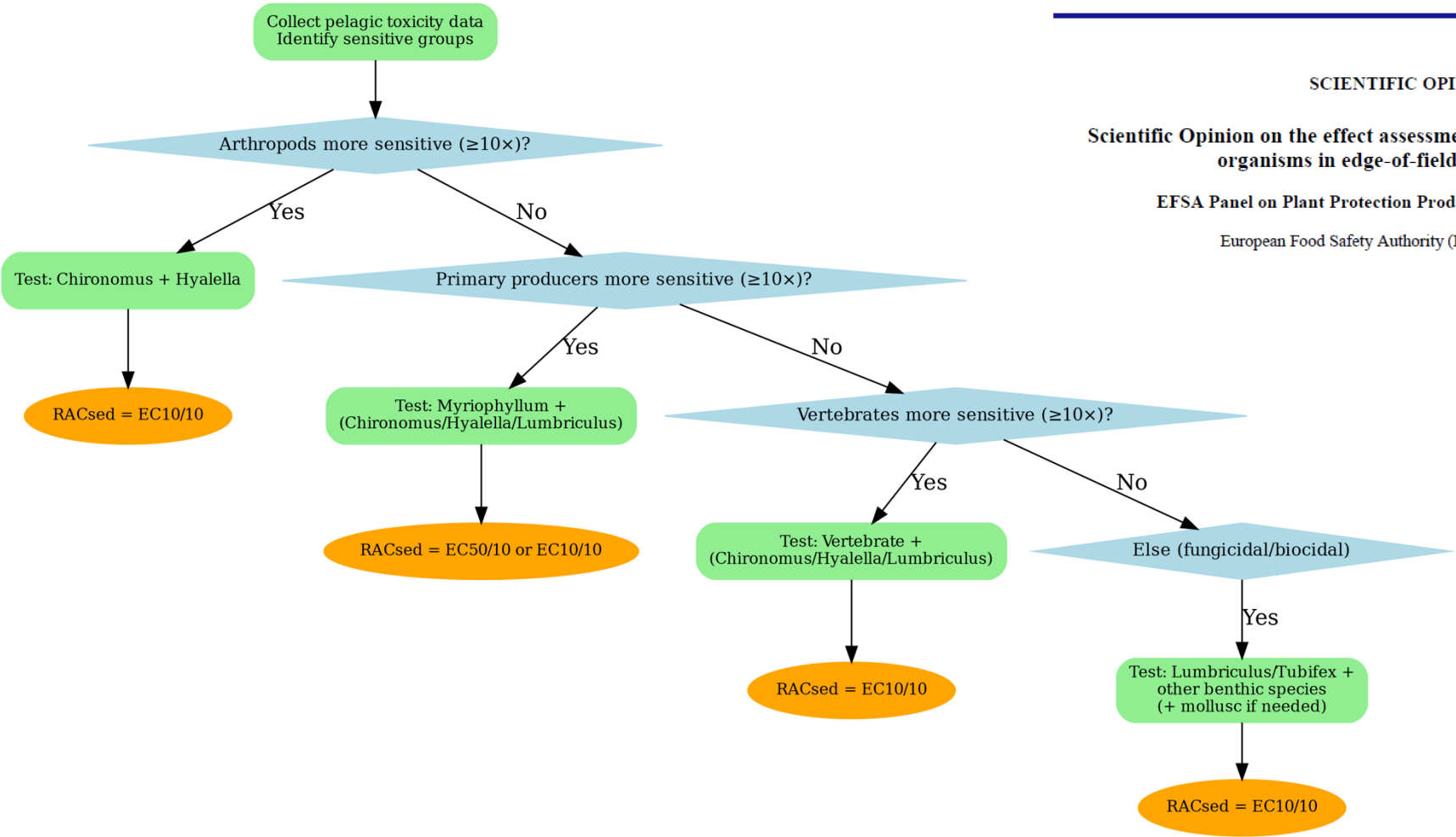


Ecotoxicological studies: data requirements

REACH	Long-term standard tests are preferred. Registrants should choose the most appropriate and sensitive test protocol(s) based on, for example, substance properties/uses and provide a justification for the choice. ▪ OECD 218: <i>Chironomus sp.</i> ▪ OECD 225: <i>Lumbriculus variegatus</i> ▪ OECD 29: <i>Myriophyllum spicatum</i>
BPR	Long-term standard tests preferred. ▪ <i>Chironomus sp.</i> For insecticidal substances or substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development. ▪ Oligochaete, with endobenthic sediment ingester (<i>Tubifex sp./ Lumbriculus sp.</i>) ▪ Amphipod (<i>Hyaella azteca, Gammarus sp.</i>) as complementary (third) species. Alternatively a second sediment.
VMPR	Spiked sediment tests, but can be water spiked if difficult to spike sediment: ▪ OECD 218, 233: <i>Chironomus sp.</i> ▪ OECD 225: <i>Lumbriculus variegatus</i>

Ecotoxicological studies: data requirements

Decision scheme



SCIENTIFIC OPINION

Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water¹

EFSA Panel on Plant Protection Products and their Residues^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

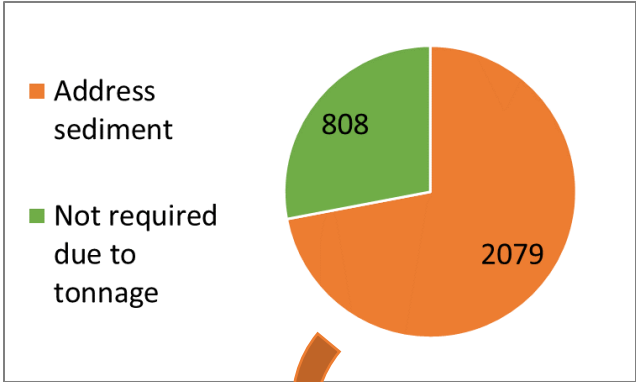
Ecotoxicological studies: data requirements

Analysis of the ecotoxicity data submitted within the framework of the REACH Regulation. Part 3. Experimental sediment toxicity assays

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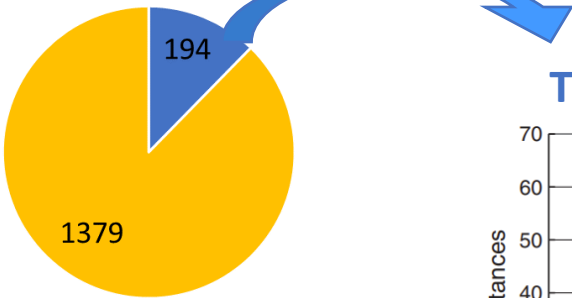


«Availability of experimental data for sediments is lower than for water column sphere.

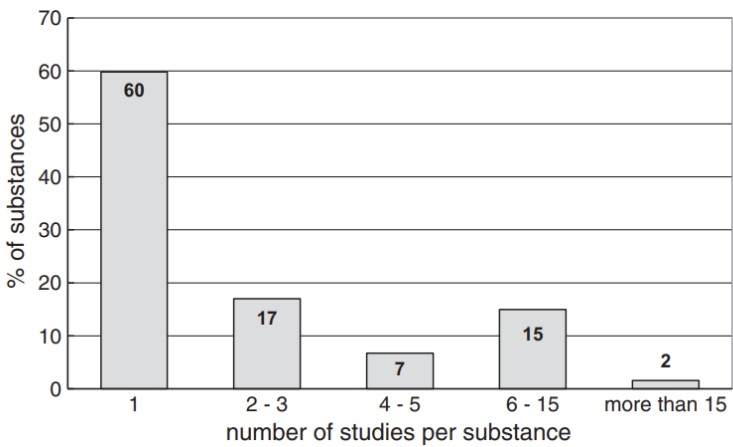
REACH can help to increase availability of data on toxicity to the sediment organisms.»

Tier 0: Core aquatic toxicity and EqP

- Experimental (or testing proposal)
- Waived

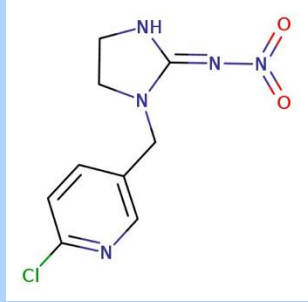


Tier 1/2: Sediment toxicity data



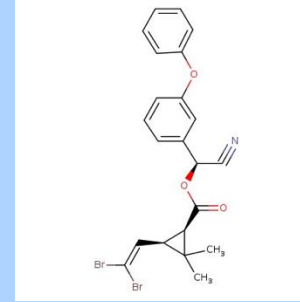
Studies reported: 610

Case study results



Imidacloprid

CAS Nr: 138261-41-3
Neonicotinoid



Deltamethrin

CAS Nr: 138261-41-3
Pyrethroid

Imidacloprid

1. Hazard Assessment

REACH	PPPR	BPR	VMP	WFD
Not publicly available	- No evidence of potential accumulation in sediment in fate studies - High toxicity to sediment-dwelling organisms ignored (lowest endpoints from the tested organisms in the pelagic database reported for <i>C. riparius</i> and <i>Chironomidae</i> and <i>Baetidae</i> being the most sensitive among macrozoobenthos species in mesocosm studies).	No information on triggers for sediment assessment	Not publicly available	- Log K_{oc} < 3 (2.8) - No evidence of potential accumulation in sediment
	No sediment effect assessment	PNEC _{sediment} = 0.026 µg/kg	Based on aquatic data	No sediment effect assessment

Imidacloprid

2. Exposure Assessment

REACH	PPPR	BPR	VMP	WFD
Not publicly available	Risk assessment for sediment dwellers performed based on water concentrations, no exposure data for sediments	No information on triggers for sediment assessment PEC= <0.0001-14'73 µg/kg d.w.	Not required as used limited for small pets	No monitoring data for sediments Literature MECs=0.8-25.2 µg/kg d.w.

3. Risk Assessment

WFD	PPPR	BPR	VMP	REACH
N.a.	N.a.	0.00000064-218	N.a.	N.a.

Deltamethrin

1. Hazard Assessment

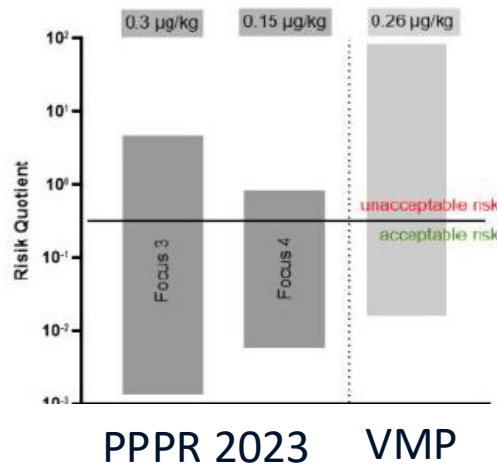
REACH	PPPR	BPR	VMP	WFD
Not performed	- Log K_{oc} = 7.01 (mean value from values between 5.66 - 7.11) - High toxicity to sediment-dwelling organisms	Log K_{oc} = 7.01 (mean value from values between 5.66 - 7.11)	Not publicly available	Log K_{oc} = 7.01 (mean value from values between 5.66 - 7.11)
	0.15 µg/kg - Derivation method: NOEC 1.5 µg/kg d.w., 2.5% TOC, AF=10 (suggestion from ongoing renewal, effective n.a.)	- PNEC_{sediment} = 16.12 µg/kg d.w. - Derivation method EqP	- PNEC_{sediment} = 0.26 µg/kg d.w. - Derivation method EqP	- QS_{sediment} = 0.3 µg/kg d.w. - Derivation method NOEC 3 µg/kg d.w., 5% TOC, AF=10

Deltamethrin

2. Exposure Assessment

REACH	PPPR	BPR	VMP	WFD
Not publicly available	- FOCUS Step 3: PEC=0.00022-0.7 µg/kg d.w. - FOCUS Step 4: PEC= 0.0009-0.13 µg/kg d.w. (effective ERA PEC= 5.3 - 0.059 µg/kg w.w.)	N.a.	- Dairy cow: PEC=0.15/0.26 µg/kg d.w. - Beef cattle: PEC=0.26/ 1.05 µg/kg d.w. - Sheep: PEC= 21.68 µg/kg d.w. - Lamb: PEC=0.0042 µg/kg d.w.	No monitoring data for sediments Literature MECs=<10-50 µg/kg d.w.

3. Risk Assessment



UK PAR: states that “The mode demonstrated the PEC_{sediment} to drop below the sediment dweller (Chironomid) PNEC of 0.26 µg/kg (d.w.) on Day 17 when a worst-case scenario of 3 days treatment is considered. Therefore, a 2 to 4 weeks exclusion period, to mitigate the potential risk indicated for sediment dwelling organisms, is appropriate”

- Literature monitoring data:

$$\text{Risk Quotient} = <10-50 / 0.3 >> 1$$

Conclusions and recommendations

- Differences in data availability, reporting, and validation across regulations hinder harmonized assessments and clear risk identification. Joint database across regulations is fundamental.
- Multiple, overlapping uses of substances require integrated models that account from cumulative emissions from various uses and shared data to improve realism in risk assessments. Consider aggregated exposure from combined uses and the cumulative effects of mitigation measures.
- Triggers for sediment assessment are most often only based on chemical properties, which rely on test results highly dependent on test conditions. Harmonisation across regulations is needed. Other, monitoring data is needed to proof potential accumulation in sediments.
- Outcome of ERA under one regulation should trigger a re-assessment under another regulation.

Contact

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