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THE EVIDENCE BASE FOR SYSTEMS-BASED ENVIRONMENTAL RISK ASSESSMENT

Technical Support Document

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1. Why Current Regulatory ERA Fails: The Fundamental Problem

1.1 The Mathematical Impossibility

Risk quotients (RQ = Predicted Environmental Concentration / Predicted No-Effect Concentration) as regulatory thresholds offer an attractive solution to fundamental policy needs: expedience, decision predictability, and transparency. However, the current RQ-based design represents a multitude of separate zero-dimensional abstractions applied to a four-dimensional reality. This results in fundamental shortcomings: point estimates cannot capture landscape heterogeneity where exposure varies by orders of magnitude; single time points miss seasonal variations and cumulative exposure; additive assumptions fail for synergistic effects documented in field studies; and threshold concepts contradict evidence of low-dose effects.

1.2 Scale-Complexity Mismatch

Global inventories contain 350,000 chemicals; EU REACH registers 23,000 (Wang et al. 2020). Over 400 pesticide active ingredients are authorised across member states (European Commission, 2025). The current tiered approach to numerically refine isolated RQs until regulatory thresholds are passed has grown significantly over the last decades. Assessment reports reach 1,000 pages; authorisation requires 10+ years and up to €100,000 registration fees per product. This investment creates institutional momentum toward approval while each tier adds detail but narrows representativeness. Complexity and efforts added *within* the current RQs gridlock ERA. The focus on isolated details also hinders meaningful feedback loops in a highly variable, complex reality. Moreover, it causes delays and takes focus away from the fundamental problems of representativeness of real systems (Topping et al, 2020), and from undesirable systemic feedback loops in regulatory decisions (Schulz et al. 2021).

1.3 Documented Failures

Neonicotinoids approved through existing ERA caused population-level impacts on wild bees across European landscapes (Nicholson et al. 2024, European Academies Science Advisory Council 2023). Sulfoxaflor, approved as a safer alternative, was subsequently restricted due to comparable effects. Stream monitoring demonstrates pesticides are dominant stressors for vulnerable insects even where individual products passed ERA (Liess et al. 2021). Ecosystem decay exacerbates biodiversity loss beyond habitat loss (Chase et al. 2020). Effects cascade from genes to communities through indirect pathways invisible to current methods (Siddique et al. 2024).

2. Systems Solutions: Technical Implementation

Agent-based models simulate individuals within realistic landscapes tracking populations under multiple stressors. ALMaSS operates across European countries at landscape scales with daily time steps over decades, validated against field data. High-performance computing provides capacity through parallel processing (Maděra et al. 2025) and continental-scale models (e.g. Adde et al. 2023). Complex simulations inform simplified regulatory tools: identify emergent system-level properties and critical thresholds, derive simple metrics that correlate with outcomes, and validate against monitoring data. Machine learning emulates simulations for rapid assessment (Stolfi and Castiglione 2021). Acknowledging that **system understanding precedes threshold definition,** reverses thinking and redefines the paradigm to unlock the integration of existing but siloed expertise and data.

3. Precedents: Climate Science and Financial Regulation

Climate science evolved from simple models that ignored feedback loops (Schlesinger 1989) to integrated assessments with carbon budgets for temperature targets. IPCC systematic evaluation enabled continuous updating. Policy translated 2°C targets into sector-specific limits: binding limits that address complexity while remaining tractable.

Financial regulation assessed institutions individually pre-2008, missing systemic linkages (Farmer and Foley 2009, Haldane and May 2011). Post-economic crisis reforms implemented stress tests simulating cascade failures, automatic stabilisers, agent-based network models, and graduated interventions. For ERA: chemical stress budgets (analogous to capital buffers) establish ecosystem capacity before approvals, replacing binary classifications.

ERA requires cross-disciplinary collaboration integrating ecological realism (EFSA Scientific Committee et al. 2021, Sousa et al. 2022), connecting mechanisms across scales (Rosa et al. 2018, Caswell 1996), balancing false positives and negatives (Topping et al. 2015) and addressing key risk drivers. This is to advance coordinated decision-making across regulatory sectors.

4. Implementation: Feasibility and Pathways

4.1 Technical Capacity

Computational barriers no longer prevent implementation. HPC infrastructure exists, GPU acceleration provides 10-100x speedups (Maděra et al. 2025), automated pipelines (Vajpayee 2023) enable real-time integration, and machine learning enables rapid exploration. Data availability supports implementation through EU Horizon open datasets (European Commission 2025b) and transparency regulations. Pesticidovigilance (Milner & Boyd, 2017) could leverage existing monitoring infrastructure rather than creating parallel systems.

4.2 Institutional Coordination

The EU framework distributes authority among Commission directorates, member states, and agencies (EFSA, ECHA, EMA, JRC). Critical innovations: EU Chemical Systems Transition Task Force coordinating organisations; member state pilots demonstrating feasibility; policy integration in CAP, Water Framework Directive, Nature Restoration Law; upstream problem-solving consolidating tool development (Thomke and Fujimoto 2000).

4.3 Efficiency and Innovation

Workflow reversal consolidates work at the regulatory level: develop tools once and apply them consistently. This provides standardised data requirements, reduced burden, faster approvals for low-risk products, and better discrimination based on actual risk.

Innovation incentives shift toward sustainable chemistry: faster approvals, lower costs, and market differentiation for ecosystem-compatible formulations. Cross-disciplinary integration requires shared foundations, standardised ontologies, cross-scale methods, and validation frameworks (Sylvester et al. 2023). Moreover, a regulatory roadmap is needed to reposition and connect existing strengths and resources. Horizon Europe projects like PollinERA spearhead the demonstration of feasibility and offer transferable approaches.

Conclusions

Effective and innovation-fostering regulatory decision-making hinges on transparent regulatory thresholds. A strong legislative basis exists; however, advancing the current ERA falls short because zero-dimensional risk quotients cannot represent four-dimensional ecological reality, creating systematic blind spots documented by neonicotinoids, insect declines, and ecosystem decay. Systems solutions are technically feasible: simulation models at landscape scales, computing capacity, machine learning for regulatory tools, pesticidovigilance for validation. Precedents from climate and finance demonstrate tractability. Implementation requires EU Chemical Systems Transition Task Force, member state pilots, policy integration, and upstream problem-solving. The choice: perpetuate ecological “surprises” or embrace systems thinking.

Disclaimer

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