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Reforming EU chemical risk assessment: from regulatory bottlenecks to systems solutions

Christopher John Topping, Noa Simon Delso, James Henty Williams, Johan Axelman

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REFORMING EU CHEMICAL RISK ASSESSMENT

FROM REGULATORY BOTTLENECKS TO SYSTEMS SOLUTIONS

Christopher John Topping, Noa Simon Delso, James Henty Williams, Johan Axelman

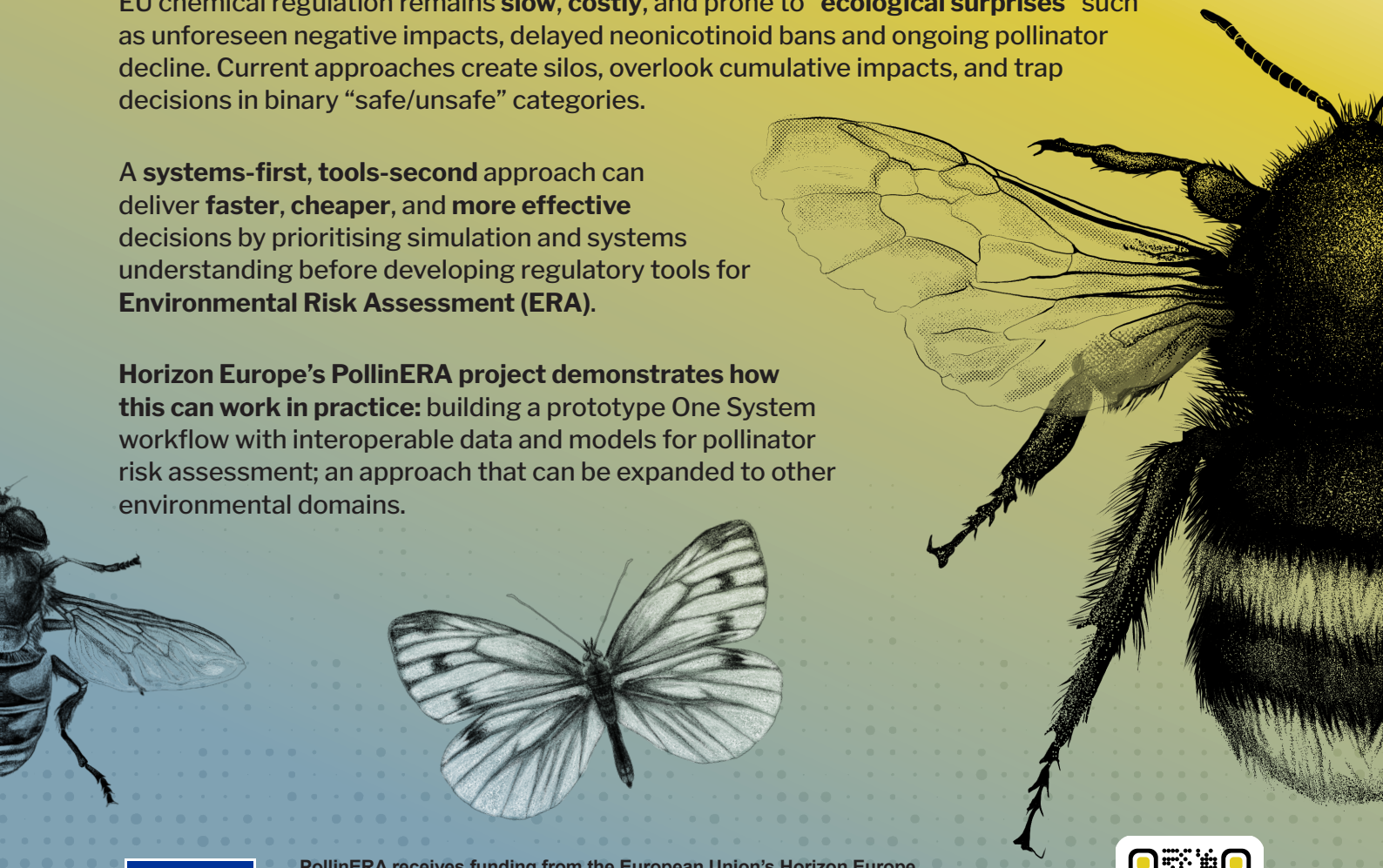
pollinera-horizon.eu

Executive summary

EU chemical regulation remains **slow**, **costly**, and prone to "**ecological surprises**" such as unforeseen negative impacts, delayed neonicotinoid bans and ongoing pollinator decline. Current approaches create silos, overlook cumulative impacts, and trap decisions in binary "safe/unsafe" categories.

A **systems-first**, **tools-second** approach can deliver **faster**, **cheaper**, and **more effective** decisions by prioritising simulation and systems understanding before developing regulatory tools for **Environmental Risk Assessment (ERA)**.

Horizon Europe's PollinERA project demonstrates how this can work in practice: building a prototype One System workflow with interoperable data and models for pollinator risk assessment; an approach that can be expanded to other environmental domains.



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The problem

Regulatory gridlock with environmental consequences

Current system failures

- **SCALE:** 100 000 000 Ha cropland in the EU, Number of new chemicals and reassessments beyond regulatory capacity.
- **DELAY:** 10+ years for approvals; up to €100,000+dossier costs per product.
- **SURPRISES:** Products cleared as "safe" later restricted (e.g. neonicotinoids and glyphosate).
- **FRAGMENTATION**: Siloed legal frameworks (PPP, biocides, VMP, pharmaceuticals, REACH).

Missed opportunities

No space between "approve" and "ban" for adaptive management. By missing this middle ground, regulators lose powerful tools for risk management, such as controlled usage limits, spatial restrictions, or conditional approvals. These could keep beneficial pest control options available while managing environmental risks appropriately.

The solution

Chemical stress budgets

A systems-first ERA framework

Transform chemical regulation by implementing "chemical stress budgets" – analogous to climate-carbon budgets – that manage environmental risk at the ecosystem scale.

Key principles

- **SIMULATION BEFORE REGULATION:** use advanced models to understand whole-system dynamics before designing simplified and reality-aligned tools.
- **THRESHOLDS FIRST:** Set environmental stress budgets before product approvals.
- **INTEGRATED MONITORING:** Real-world data via pesticidovigilance.
- **GRADUATED RESPONSES:** Flexible management options instead of binary decisions.
- **OPEN AND INTEROPERABLE:** Shared models linking chemical loads to biodiversity outcomes.

Workflow reversal

CURRENT

Product-by-product assessment → Binary safe/unsafe decision → Market access or ban (losing valuable management options)

NEW

Ecosystem thresholds established (stress budgets) → Differentiated management strategies utilising regionally applied toxic load thresholds and mitigation measures

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A case study

PollinERA
A prototype for systems-based ERA

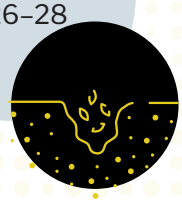
Horizon Europe's PollinERA project provides a working example of how a systems-first approach can transform chemical risk assessment.

- **PROTOTYPE WORKFLOW:** Builds a One System framework for pollinator ERA.
- **INTEROPERABLE DATA & MODELS:** Integrates ecotoxicological data, monitoring schemes, and advanced simulations (TKTD, agent-based, QSAR).
- **SYSTEMS UNDERSTANDING FIRST:** Uses simulation to capture ecosystem-level dynamics before deriving regulatory tools.
- **TRANSFERABLE CONCEPT:** Although developed for pollinators, the framework can be expanded to other species, stressors, and ecosystems.

PollinERA demonstrates that EU-funded research can deliver the simulation capacity, interoperability, and practical workflows needed for the next generation of regulatory ERA.

Policy roadmap

PHASE 1
2026–28



FOUNDATIONS

- EU Chemical Systems Transition Task Force (Commission + EFSA, ECHA, EMA, EEA, DG AGRI, DG SANTE, DG ENV).
- Launch open-source ecosystem simulation prototypes and effective monitoring data integration.
- PollinERA prototype workflow informs task force design.
- Pilot pesticidovigilance in 5 Member States.

PHASE 2
2028–30

TOOLS

- Derive simplified "regulatory speed limits" from system simulations.
- Feedback loops between monitoring and models.
- Integrate chemical stress budgets into CAP, Water Directive, Biodiversity Strategy.

PHASE 3
2030–32

INTEGRATION

- EU-wide adoption of system-informed, graduated risk classification.
- Automated monitoring–response systems.
- Fully interoperable ERA frameworks across chemical sectors.

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Benefits for EU policy objectives

Proof of concept – PollinERA

- Demonstrates that systems-first, simulation-based tools to support regulatory ERA are technically feasible today, not a distant vision.
- Shows that interoperable data and models can be combined into a working prototype for pollinator ERA, ready to expand to other ecosystems.
- Validates that whole-system modelling can generate actionable regulatory insights, bridging science and policy.

Economic and administrative efficiency

- Workflow reversal saves resources and improves scientific rigour: instead of repeatedly refining product-level assessments, thresholds are set once at system level and applied consistently across product evaluations.
- Reduces duplication of effort across agencies and applicants, cutting administrative costs (currently averaging €100,000+ per approval).
- Provides industry with predictable regulatory pathways, lowering investment risk and incentivising sustainable innovation.
- Maintains market access for moderately risky products under conditional management, avoiding unnecessary bans.

Environmental and social value

- Proactively manages cumulative risks, avoiding costly "ecological surprises" (e.g., pollinator collapses) that undermine public trust.
- Protects biodiversity and ecosystem services, supporting EU 2030 Biodiversity targets.
- Reinforces food security and agricultural resilience by ensuring sustainable use of crop protection tools.

Political alignment

- **Competitiveness**: Lowers compliance costs, accelerates approvals, and rewards innovation.
- **Resilience & food security**: Ensures sustainable chemical use in farming systems.
- **Sustainability**: Directly supports EU commitments under the Green Deal, Zero Pollution, and Biodiversity Strategies.

Recommendations

- **EUROPEAN COMMISSION**
  Establish Chemical Systems Transition Task Force; ensure alignment with Horizon Europe outputs such as PollinERA.
- **MEMBER STATES**
  Join pilot monitoring initiatives; contribute to interoperable data platforms.
- **EU AGENCIES**
  Form joint working groups on simulation models, ML tools, and monitoring integration.

Conclusion

PollinERA shows that a systems-first approach, based on simulation and interoperability, can shift chemical ERA from fragmented, binary decisions to adaptive, whole-system management. By embedding these lessons into EU regulation, Europe can strengthen competitiveness, resilience, and environmental protection simultaneously.

Find the scientific evidence and relevant research here