

AGRICULTURE AND ENVIRONMENT

Overhaul environmental risk assessment for pesticides

Align regulation with environmental reality and policy

By C. J. Topping¹, A. Aldrich², P. Berny³

Among aspects of agricultural intensification that have been criticized for negative impacts on biodiversity (1, 2), pesticides have been linked to declines in insects, birds, and biodiversity in aquatic systems (3–5). If pesticide use is to blame, even partially, then this raises questions both about pesticide use and the regulatory procedures that are used to protect the environment (4). Environmental risk assessment (ERA) of pesticides does not account for many

stressors that have intensified in recent years, such as climate change, habitat destruction, and increasing landscape homogeneity, the combination of which can aggravate effects of pesticides in nature. We describe how several assumptions underlying ERA may not hold in modern intensive agricultural landscapes, and the interaction among assumption violations may account for observed declines in biodiversity. Using European contexts to exemplify these global concerns, we review how regulatory ERA for pesticides has fallen out of step with scientific knowledge (4)

and societal demands for sustainable food production and suggest systematic and recently feasible changes for regulation.

OUTDATED ASSUMPTIONS

The aim of ERA is to determine whether use of a pesticide can be made safe for a receiving environment. The current regulatory procedure evaluates each product separately for each agronomic use—a single-product, single-crop assessment, resulting in authorization or nonauthorization of the product for that use. This approach makes the regulatory scheme tractable, and if the risk is managed appropriately and the product applied accordingly, then pesticides should not pose an unacceptable threat.

Under the European Union (EU) pesticide Regulation No 1107/2009, the ERA uses

¹Department of Bioscience, Aarhus University, Kalo, Denmark. ²Department of Ecotoxicology, Agroscope, Wädenswil, Switzerland. ³Department of Toxicology, Vetagro Sup Campus Vétérinaire, Marcy l'étoile, France. Email: cjt@bios.au.dk

Pesticide is applied in a vineyard in Haro, La Rioja, Spain. It is unlikely that an organism in a given field would face a single-product scenario.



Downloaded from <https://science.sciencemag.org/> on January 23, 2020

guidance documents that were developed according to the science of the early 1990s. A similar situation prevails in the United States, with some guidance being more than 20 years old. Subsequent guidance has attempted to improve flaws, largely by increasing complexity of assessments, maintaining the stepwise (tiered) approach. This relies on the assumption that managing risks through single-product, single-crop assessments provides sufficient ecosystem protection, and where harm is unavoidable, such as insecticide applications, that the ecosystem is sufficiently robust to recover. However, as monitoring studies now show, this is not the case. In our view, the binary ERA result of safe or unsafe does not consider the landscape by balancing environmental harm with ecological recovery because it does not address real spatial and temporal exposure.

Single product, single crop

Risk assessments are based on the use of a single pesticide in a specific crop. Yet,

the number of mixtures and sequential treatments with pesticides in the landscape can be very high (6) and is the norm across Europe (7). Similar situations are described in the United States, Australia, and elsewhere. Any organism spending time in a single field is unlikely to face a single-product scenario, necessitating the consideration of the application sequence in the ERA. The current approach also ignores scale of use; hence, once approved for a crop, the area over which that crop is grown is not considered.

Misrepresented dynamics

Under EU pesticide Regulation No 1107/2009, short-term side effects of pesticides are allowed. Where direct exposure to nontarget organisms makes harm unavoidable (for example, insecticides applied to kill insect pests may kill nontarget insects), the ERA requires recovery experiments to demonstrate recovery potential. For most species, recovery in the contaminated area is by emigration from source habitats. However, this

assumes a balanced source-sink dynamic that does not reflect intensive modern agriculture. The experiment, conducted for single fields or plots within an untreated area, does not represent the real ratio of source and sink habitat, something constantly changing because of continued agricultural intensification. The consequence is an underestimation of the risk in the long term (8) as source areas become depleted owing to dispersal of organisms into the sinks contaminated with pesticides.

In addition, in a mosaic of pesticide applications, wide-ranging animals (such as honey bees) are exposed to a cocktail of pesticides even more diverse than that applied to a single field. Current ERA also does not consider temporal dynamics. A declining population will be less resilient to future stressors, and thus, a spiral of decline may ensue. ERA ensures that assumptions regarding population health will be incorrect because multiple (regulated and nonregulated) stressors are ignored entirely.

Ecotoxicology

Some shortcomings of the ecotoxicological aspects of ERA are well known. The sensitivity of a few surrogate species is assumed to reflect the sensitivity of all organisms. Often, the choice of surrogate species is based on which species can be reared in the laboratory. Uncertainty in estimating impacts on one species on the basis of impacts on another is addressed with assessment factors (multipliers for the toxicity/exposure ratio, defined according to expert judgment in the uniform principles of Regulation No 1107/2009). For example, a no-effect dose for a surrogate species is assumed protective for all species if the ratio to the estimated exposure is greater than the assessment factor. The value of the assessment factors (typically between 2 and 100) varies with nontarget group and the amount of available data because the factors should address all ERA uncertainties.

Ecological interactions

Trophic interactions are not part of ERA today, even though indirect effects have been recognized as being important (for example, in EU pesticide Regulation No 1107/2009). However, EU and U.S. ERA schemes currently do not consider indirect effects (the partial exception being some aquatic mesocosm studies). This is a major factor when considering whether ERA is actually protective and has potentially profound knock-on effects in ecosystems.

Tiered and deterministic

The current approach to regulatory ERA is based on a tiered and mostly deterministic approach in order to rapidly identify substances of low concern, using assessment factors to cover for all uncertainties in the approach. Pesticides too toxic to pass the first tier (for example, toxicity/exposure ratio below an assessment value of 10 for acute toxicity in birds) enter a refinement approach aimed at reducing the perceived risk for assessed species. The assessment factors decrease with each step of the tiered approach as more data are available, implying that uncertainty in the assessments decreases with each step. However, increased specificity increases the risk of missing effects on other species. For example, the risk to other birds in cereal fields could be refined on the basis of exposure of skylarks feeding on seedlings (as the focal species in the refined assessment) but then miss effects on earlier- or later-breeding species. Hence, risk managers accept that use of pes-

ticides that pass a refined risk assessment may potentially pose a high concern, yet no formal safety loop is in place to take timely action to fix potential oversights. Once pesticides are considered safe, they are placed on the market for 10 years, with restrictions based only on single use and single crop, not on scale of use. Over time, it has become apparent that certain aspects were overlooked or simply unknown, and adverse effects occur at larger spatiotemporal scales.

AN INTEGRATED SYSTEMS APPROACH

The regulatory community is recognizing increasing scientific knowledge and the shortfalls it highlights in the ERA. Recent scientific opinions by the European Food Safety Authority (EFSA) address scientific progress by

“The overall picture is of a need to move to a more holistic (systems) view, which integrates far more than current environmental risk assessment.”

increasing ERA complexity in a context-specific way within the tiered and deterministic approach. However, continually patching and expanding a conceptually flawed ERA is not seen by many risk assessors as a solution to address the real use of pesticides (9). Although the concept of balancing the risks of harm per pesticide per use seems sensible, the actual use of pesticides in the real world renders it scientifically naïve. Calls for pesticide vigilance (10) highlight that the “hypothesis” of there being no long-term harm to the environment generated by the application of ERA needs to be evaluated. Whereas monitoring may catch mistakes eventually, an improved prospective ERA would reduce the damage occurring in the first place.

Recently, recommendations from the Scientific Advisory Mechanism (SAM) to the EU call for a critical evaluation of pesticide regulatory assessment (11). Similarly, regulators in Germany have called for dramatic change (9). The overall picture is of a need to move to a more holistic (systems) view, which integrates far more than current ERA. The first-tier data requirements for toxicological and fate parameters should be maintained for a comparative risk assessment. But the process should then feed into a landscape analysis based on modeling, which would make the tiered, refined risk assessment under current ERA redundant.

The systems approach can be considered at administrative and social-ecological levels. At the administrative level, there is currently a unidirectional flow of information from risk assessor to risk manager to farmer, which is separate from monitoring (if any exists). An integrated-systems approach based on a multidirectional flow of information and involvement of stakeholders could change focus from assessing single products to developing strategies for landscape management. The approach needs to integrate modeling and monitoring to cross-validate assessments and mechanistic understanding. Landscape management would provide an opportunity to tailor mitigation strategies to local contexts and link these to other agricultural management policy instruments (such as subsidy claims). Regular review and changes to authorization would be driven post-market by pesticide vigilance, taking agronomic as well as environmental monitoring into account. This would require focusing on cross-compliance and coherence between different, sometimes conflicting directives affecting the agroecosystem.

To be scientifically relevant and provide the rich spectrum of data for transparent risk management, the systems approach needs to be social-ecological, incorporating agronomic and ecological impacts and better integrating stakeholders in the process. For example, the farmer plays a pivotal role in the system but is currently largely ignored. By contrast, under a new approach, they would become part of the system, informing monitoring by communicating their pesticide use and giving feedback about the socioeconomic impact of the management decisions of pesticide authorization. In turn, the uncertainties in ERA and monitoring outputs should be communicated in a comprehensible way so that the farmer is apprised of the potential risks. Rather than “perfecting” the ERA by addressing all possible toxicological effects and exposure routes (increase in complexity), the new approach needs to be focused on the relevant system aspects.

New ERA tools are available

Achieving systems ERA is a tall order, but new data, approaches, and technology are available. Detailed landscape simulation models exist for a substantial and increasing part of the EU. These are able to represent current farming practices and pesticide use and represent terrestrial environmental

fate at landscape-scale [for example, (8)]. Based on Common Agricultural Policy (CAP) subsidy data to provide farm, field, and crop mapping, as well as topographic and satellite data available in the EU, they create a detailed dynamic simulation of farming and pesticide use and fate as well as simulate the distribution and abundance of a range of focal species. Environmental context is directly incorporated, including spatiotemporal interactions. These tools are suggested in EFSA's scientific opinions for landscape scale assessments [for example, (12, 13)] and ongoing EFSA work on multiple stressors and bees have recently seen use to support an evaluation of the Dutch crop protection policy (14).

Mixture effects are starting to be addressed in human RA by using cumulative assessment groups. The same basic principles would work for ERA. Effects of combined toxicity can be elucidated and quantified by using a model deviation ratio (measuring deviations from the assumption of additivity) (15). Current EFSA work focuses on combining this approach with quantitative structure-activity relationship (QSAR) modeling to classify pesticides into similar groups and predict their combined toxic effects. This addresses the issues of predicting effects of pesticide mixtures by using a system that is easily expandable and adjustable as more toxicological information becomes available. In order to classify pesticides, we need to base the selection of focal species and their toxicology on our current knowledge and experience of ecologically relevant and sensitive species.

Combining such simulation and mixture approaches would mean that a pesticide would be evaluated in terms of how it would be incorporated into an application schedule. Authorization would relate to scale of use and the application of mitigation measures, which would be incorporated into local landscape conditions. Thus, a balance between harm and recovery could be achieved. In the EU, this could be policed through the existing CAP subsidy scheme. It would be facilitated by a classificatory approach to pesticides that would allow control of use of groups of pesticides rather than individual products. The current toxicity approach would still be used to screen for extreme cases in a comparative assessment. ERA should identify hot spots for monitoring, and monitoring should provide a reality check of the ERA tools. Thus, in response to monitoring, the level of authorized use might be adjusted considering pesticide impacts and changes in the real world (for example, shifts in cropping patterns). This ERA process would provide more information

on the local context for the national risk managers but entails tighter controls on post-authorization use.

Goals and structure must change

Policy goals for ERA are changing, yet ERA practice does not reflect this. In the EU, the pesticide Regulation No 1107/2009 is due for refit, but even the current regulation is ahead of current ERA in ecological realism, being targeted at protection of ecosystems. The EU has also launched the Green Deal, including reference to sustainable food production with fewer pesticides. The refit will, however, not make the paradigm shift from a single-product, single-crop ERA to an ecologically and agronomically realistic systems approach. This would require wider changes to authorization and protection goals, and therefore regulations. Protection goals would need to be considered in terms of overall system impacts. Authorization would no longer be a binary condition of safe or unsafe but instead would transparently communicate the accepted risk and regulate use in a sustainable way, similar to efforts to improve how antibiotics are used.

Yet, administrative systems are often very resistant to change. In the case of the EU regulatory system, few ERA guidance documents are currently available, despite numerous scientific opinions and proposed guidelines by EFSA, because no single body has the responsibility to initiate the guidance process. Guidance may take many years to develop once initiated, which becomes more critical because many non-EU countries (such as Brazil) use procedures adapted from the European scheme.

To alleviate these issues, SAM strongly suggests giving risk assessors "complete autonomy to determine all working procedures, methods, data requirements..." (11), which should help speed up the working process by removing the requirement that such mandates must be issued by the European Commission (EC). However, change of this magnitude cannot happen overnight. Therefore, we suggest several steps. Lessons learned from previous ERA and monitoring studies should be used to group pesticides and focus the ERA to avoid under- or overestimation of risk. Inclusion of spatiotemporal effects into the single-product, single-crop ERA should be expedited by including landscape-scale and year-on-year effects, as already suggested by EFSA (12, 13). This can be done reasonably quickly under the current regulatory framework if an EC or European Parliament mandate is forthcoming. A multiple stressor approach (landscape modeling and pesticide mixture approaches) should be implemented for nontarget arthropods

and bees, those being the most urgently needed, and expanded to further groups subsequently. Development should begin on pesticide vigilance systems linked to EU-wide prospective ERA, incorporating the systems view of impacts of use and restrictions of pesticides. A standing working group of scientists and stakeholders should be created and empowered to implement and maintain the systems ERA, considering new knowledge. Meanwhile, the policy, legal, and advocacy foundations should be prepared to implement the systems approach and pesticide vigilance in future regulations. This should include the EU collation and provision of pesticide use data collected under the Sustainability Directive.

Overall, the risks must be communicated to the public, whose choices will ultimately determine the future of agricultural production and landscapes. Recent studies about the plight of biodiversity have already alerted the public, which is now putting pressure on industry, farmers, and regulators. The time is therefore right. This future view of pesticide ERA and regulation cannot address all concerns nor remove all uncertainties. However, we should not let the perfect be the enemy of good. We can retarget ERA to address better the key environmental questions. This will always be a compromise that needs to be balanced with input from all stakeholders. However, it is feasible, and the need for action is urgent. ■

REFERENCES AND NOTES

1. F. Sánchez-Bayo, K. A. G. Wyckhuys, *Biol. Conserv.* **232**, 8 (2019).
2. C. A. Hallmann *et al.*, *PLOS ONE* **12**, e0185809 (2017).
3. M. A. Beketov, B. J. Kefford, R. B. Schäfer, M. Liess, *Proc. Natl. Acad. Sci. U.S.A.* **110**, 11039 (2013).
4. C. A. Brühl, J. G. Zaller, *Front. Environ. Sci.* **7**, 177 (2019).
5. P. Mineau, M. Whiteside, *PLOS ONE* **8**, e57457 (2013).
6. S. Fryday, H. Thompson, D. Garthwaite, "Background information for considering risk of exposure to multiple pesticides," Department of Environment Food and Rural Affairs (DEFRA) project PS2354 (DEFRA, 2011).
7. D. Garthwaite *et al.*, *EFSA Support. Pub.* **12**, 846E (2015).
8. C. J. Topping *et al.*, *Environ. Toxicol. Chem.* **33**, 1499 (2014).
9. T. Frische, S. Egerer, S. Matezki, C. Pickl, J. Wogram, *Environ. Sci. Eur.* **30**, 8 (2018).
10. A. M. Milner, I. L. Boyd, *Science* **357**, 1232 (2017).
11. Group of Chief Scientific Advisors, "EU Authorisation Processes of Plant Protection Products From a Scientific Point of View," Scientific Advisory Mechanism Report (EU Publications, 2018).
12. EFSA Panel on Plant Protection Products and their Residues (PPR) *et al.*, *EFSA J.* **16**, e05125 (2018).
13. EFSA Panel on PPR, *EFSA J.* **13**, 3996 (2015).
14. A. Tiktak *et al.*, "Geïntegreerde Gewasbescherming nader beschouwd. Tussenevaluatie van de nota Gezonde Groei, Duurzame Oogst (Planbureau voor de Leefomgeving, 2019).
15. E. Carneseccchi *et al.*, *Environ. Int.* **133** (Part B), 105256 (2019).

ACKNOWLEDGMENTS

We thank S. More and J. H. Williams for comments and R. Luttik for initial discussions. All authors are members of the EFSA Panel on Plant Protection Products and their Residues. All views expressed herein are the authors' alone and do not necessarily represent positions of EFSA or of the authors' employers.

10.1126/science.aay1144

Overhaul environmental risk assessment for pesticides

C. J. Topping, A. Aldrich and P. Berny

Science **367** (6476), 360-363.
DOI: 10.1126/science.aay1144

ARTICLE TOOLS	http://science.sciencemag.org/content/367/6476/360
RELATED CONTENT	http://science.sciencemag.org/content/sci/367/6476/378.full http://science.sciencemag.org/content/sci/367/6476/380.full http://science.sciencemag.org/content/sci/367/6476/384.full http://science.sciencemag.org/content/sci/367/6476/388.full http://science.sciencemag.org/content/sci/367/6476/392.full http://science.sciencemag.org/content/sci/367/6476/369.full
REFERENCES	This article cites 14 articles, 2 of which you can access for free http://science.sciencemag.org/content/367/6476/360#BIBL
PERMISSIONS	http://www.sciencemag.org/help/reprints-and-permissions

Use of this article is subject to the [Terms of Service](#)

Science (print ISSN 0036-8075; online ISSN 1095-9203) is published by the American Association for the Advancement of Science, 1200 New York Avenue NW, Washington, DC 20005. The title *Science* is a registered trademark of AAAS.

Copyright © 2020, American Association for the Advancement of Science