

Institution: University of Sheffield		
Unit of Assessment: A-05 Biological Sciences		
Title of case study: Improving the effectiveness of European pesticide environmental risk assessment		
Period when the underpinning research was undertaken: 2000–2014		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Lorraine Maltby	Role(s) (e.g. job title): Professor of Environmental Biology	Period(s) employed by submitting HEI: 1988–present
Period when the claimed impact occurred: August 2013–July 2020		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Pesticides are a vital element of modern agriculture, yet they can pose significant environmental risks. The European Food Safety Authority (EFSA), which is responsible for developing scientific regulatory guidance for pesticides, drew on Professor Maltby's research on environmental risk assessments (ERAs) to provide guidance for the protection of aquatic ecosystems to support EU directive No 1107/2009. As a result since 2015, any company wishing to register a pesticide in the EU has conducted a risk assessment according to this guidance. Maltby also designed and delivered a series of training events for EFSA staff and regulators from across the EU to ensure effective implementation of the guidance and approval of applications under the new directive. Maltby's research has thus had impact on the production and use of pesticides across Europe.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>Pesticides are a vital element of modern agriculture, and in 2018, 370,000 tonnes of pesticide with a value of more than €10 billion were applied in the EU. However, pesticides are designed to have biological activity and can adversely affect non-target organisms and, hence, biodiversity, putting the benefits that people derive from ecosystems services at risk.</p> <p>As such, all pesticides must undergo a regulatory ERA before they can be authorised for marketing and use in the EU. The purpose of the ERA is to provide the scientific evidence necessary for risk managers to decide whether the environmental impacts of the use of the pesticide are acceptable and, if so, under what conditions. However, these ERAs are often based on toxicity data measuring a very limited number of responses, using very few species that are exposed to pesticides under highly standardised conditions. The ability of such data to provide the information necessary to protect complex and variable natural communities has been questioned, and the need for improved ERAs with greater ecological relevance has been identified by scientists and policymakers. Research conducted by Maltby has contributed to a deeper understanding of pesticide impacts and ERAs by demonstrating the following:</p> <p>The drivers and consequences of interspecific variation in species sensitivity to toxicants</p> <p>Maltby's work showed that species sensitivity distributions (SSDs) can inform on the adverse ecosystem effects arising from the use of insecticides and fungicides if they are based on the</p>		

most sensitive taxonomic group, which is dependent on the mode of action of the pesticide, with species habitat and geographical distribution being less important factors. This work validated the use of SSDs in the regulatory assessment of pesticide risk [R1, R2].

A conceptual framework for setting ecologically based protection goals for risk assessment

Maltby proposed a framework for spatiotemporal differentiation in ecological protection goals and, building on experimental studies, proposed a tiered approach for assessing the ecological risk of chemicals to freshwater ecosystems. This research had direct relevance to how risk assessment can be harmonised across major EU environmental legislation [R3].

The development and validation of a tiered approach to ERAs

This research provided experimental evidence that lower-tier approaches for the assessment of acute effects were sufficiently protective of ecosystem-level effects for the majority of insecticides investigated. Situations were also identified where further evaluation was necessary (i.e., compounds with novel chemistries or delayed effects). This work [R4] validated the tiered risk assessment approach proposed in [R3]

The ecological implications of chemical effects on non-tested organisms

Maltby's work demonstrated the urgent need for ecologically relevant regulatory risk assessment tools and approaches and proposed a roadmap for addressing the major knowledge gaps [R5]. In addition, it demonstrated the greater sensitivity of aquatic fungi to some agricultural fungicides than others, as well as the potential implications for ecosystem processes and food web dynamics [R6].

3. References to the research (indicative maximum of six references)

- R1.** Maltby, L., Blake, N., Brock, T. C. M., & Van den Brink, P. J. (2005). Insecticide species sensitivity distributions: the importance of test species selection and relevance to aquatic ecosystems. *Environmental Toxicology and Chemistry*, 24(2), 379–388.
<https://doi.org/10.1897/04-025r.1>
- R2.** Maltby, L., Brock, T. C. M., & van den Brink, P. J. (2009). Fungicide Risk Assessment for Aquatic Ecosystems: Importance of Interspecific Variation, Toxic Mode of Action, and Exposure Regime. *Environmental Science & Technology*, 43(19), 7556–7563.
<https://doi.org/10.1021/es901461c>
- R3.** Brock, T. C. M., Arts, G. H. P., Maltby, L., & Van den Brink, P. J. (2006). Aquatic risks of pesticides, ecological protection goals, and common aims in European Union legislation. *Integrated Environmental Assessment and Management*, 2(4), e20–e46.
<https://doi.org/10.1002/ieam.5630020402>
- R4.** van Wijngaarden, R. P. A., Maltby, L., & Brock, T. C. M. (2014). Acute tier-1 and tier-2 effect assessment approaches in the EFSA Aquatic Guidance Document: are they sufficiently protective for insecticides? *Pest Management Science*, 71(8), 1059–1067.
<https://doi.org/10.1002/ps.3937>

R5. Maltby, L., Arnold, D., Arts, G., Davies, J., Heimbach, F., Pickl, C. and Poulsen, V. (eds.) (2010). *Aquatic macrophyte risk assessment for pesticides*. SETAC Press & CRC Press, Taylor & Francis Group. Available on request.

R6. Lin, R., Buijse, L., Dimitrov, M. R., Dohmen, P., Kosol, S., Maltby, L., Roessink, I., Sinkeldam, J. A., Smidt, H., Van Wijngaarden, R. P. A., & Brock, T. C. M. (2012). Effects of the fungicide metiram in outdoor freshwater microcosms: responses of invertebrates, primary producers and microbes. *Ecotoxicology*, 21(5), 1550–1569.
<https://doi.org/10.1007/s10646-012-0909-0>

4. Details of the impact (indicative maximum 750 words)

Maltby's research has contributed to the scientific basis for decision-making activities regarding the approval of pesticides across the EU since August 2013 and, in particular, the process incorporated for the assessment of all new pesticides since 2015.

Pathway to impact

Maltby's body of research provided new insights into ERAs that were of direct relevance to EU legislation on pesticide use and were incorporated into guidance on pesticide use.

The research provided understanding and evaluation methods for the environmental risks that pesticides pose to aquatic ecosystems and was incorporated into a major regulatory guidance document published by the EFSA in July 2013, citing nine of Maltby's publications [S1]. This EFSA guidance aimed to improve the robustness, ecological relevance and effectiveness of pesticide ERAs for European pesticide approval in light of an EU change from prescriptive to risk-based environmental legislation.

With regard to the foundation EFSA guidance document, [S1], research by Maltby was used to justify:

- The use of SSDs to derive regulatory acceptable pesticide concentrations.
- The importance of interspecific variation in toxicological sensitivity.
- The selection of toxicity data for use in SSDs.
- The recommendation of test species for fungicide risk assessment.

In addition, Maltby's research [R3-R6] was:

- Used to provide the scientific underpinning linking specific protection goals and reference tiers in a tiered risk assessment scheme and to define effect classes for evaluating micro-/mesocosm studies (experimental systems that examine the natural environment under controlled conditions).
- Used to validate the tiered approach and, in particular, the use of geometric and SSD approaches.
- Cited as one of the main reasons why revision of the guidance was necessary. R5 was used for setting specific protection goals for aquatic vascular plants and was used to justify the testing methods.

- Used to highlight the need for ERAs to consider the impact of pesticides on aquatic microorganisms (which was not the case at that time, i.e., in 2011–2012) and provided the justification for fungicide SSDs.

Impact on pesticide approval and use in the EU

In 2014, the EFSA guidance document [S1] informed the implementation of EU Regulation (EC) No 1107/2009 [S2] (2015) [S2] concerning the placement of plant protection products on the market (products considered pesticides that protect crops or desirable or useful plants). EU Regulation (EC) No 1107/2009 was implemented by all EU Member States, including the UK, for all applications relating to pesticides submitted from 01/01/2015 onwards [S2].

As of March 2020, ERAs encompassing 76% of the 90 pesticides evaluated by the EU since 2016 have directly cited the EFSA guidance [S3]. The use of the EFSA guidance has resulted in 22% of these pesticide registrations not being approved for use in the EU due to unacceptable environmental impacts [S3].

Impact on EU regulatory practice

To ensure robust adoption, the EFSA required a means of strengthening the dissemination of its new ERA guidance and modelling practices [S1]. In 2014, the EFSA commissioned Maltby, along with colleagues from Wageningen University, the Netherlands, to deliver a series of 3-day specialised training courses. Maltby was chosen based on her scientific standing, expertise, and key contributions to the development of the EFSA guidance. The aim of these courses was to explain the scientific principles and key research underpinning the EFSA guidance and to communicate the scientific opinions underpinning the practical implementation of ERAs. These invitation-only courses were offered to people who were responsible for implementing the guidance across the EU, including EFSA staff (46% of attendees), EU Member State Pesticides and Residues regulators (44% of attendees) and scientific panel/committee members (9% of attendees). 108 people attended the first six courses [S4]. A further course was delivered in 2019, with another planned for 2021. So far, more than 150 participants have attended the training courses, and over 90% of participants agreed that the courses facilitated their regulatory work [S4].

Maltby's research has strongly influenced the ERAs conducted since the 2015 implementation of a regulation based on the guidance for the assessment of all new pesticides in the EU. Her research contribution was recognised in December 2020 when she was awarded an OBE for services to Environmental Biology, Animal and Plant Sciences [S5].

5. Sources to corroborate the impact (indicative maximum of 10 references)

- S1.** EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters EFSA Journal 2013; 11(7):3290, <https://doi.org/10.2903/j.efsa.2013.3290>. (sections: 2.1.4.2; 5.6.2; 8.4; 7.1; 7.2.5.1; 4.2.2; 9.3.3; 4.2.2; 8.4.4; 3.5; 5.5.2; 7.2.7; 8.4.3; 9.3.2; 8.4.2 and 9.3.2)
- S2.** EU 2015. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_aquatic.pdf

- S3.** List of all European pesticide applications and approvals. EFSA. 'Conclusion on Pesticides'. Database of EU pesticides risk assessment peer review (<https://www.efsa.europa.eu/en/publications?f%5B0%5D=date%3Acustom%3A2015-01-01%3A2020-03-01&f%5B1%5D=type%3A331>).
- S4.** Specialised training courses on certain aspects of food safety risk assessment for members of EFSA's Scientific Committee/Panels and their working groups, open to EFSA staff –final report <https://doi.org/10.2903/sp.efsa.2017.EN-1346>.
- S5.** New Year's Honours List 2021 announced December 2020.