100,000 visitors are expected this season), which carries the risk of importing invasive species (Curr. Biol. (2022) *32*, R247–R249). Keeping climate warming below 1.5 degrees would have the biggest benefit. Failing that, the authors call to reduce human impact by improving the management of tourist visits and infrastructure plans.

Threatened biodiversity in ecosystems like Antarctica, coral reefs and shrinking lakes is already reasonably well studied and research has helped to raise awareness of the growing threats. Other ecosystems including those in the deep sea (Curr. Biol. (2022) *32*, R807–R810) and in the deep subsurface (Curr. Biol. (2021) *31*, R415–R417) remain largely unexplored and are at risk of falling victim to the anthropocene before science has even had a chance to investigate them.

Join the dots

In the last months of 2022, it has been remarkable to observe how the separate global summits on climate and on biodiversity followed each other as if the problems discussed were unrelated, and both did not dent the widespread enthusiasm for another round of global overconsumption for Christmas, with political leaders declaring their undying commitment to unlimited growth, and the investment in new fossil fuel extraction including even new coal mines.

As Unai Pascual from the University of Bern, Switzerland, and colleagues have elaborated in a recent policy paper, transformative governance across these areas is needed to meet the challenges facing our globalised society (BioScience (2022) *72*, 684–704). Based on their analyses of four case studies including forest ecosystems, marine ecosystems, urban environments, and the Arctic, the authors conclude that "building on such transformative governance principles is not only possible but essential to effectively keep climate change within the desired 1.5 degrees Celsius global mean temperature increase, halt the ongoing accelerated decline of global biodiversity, and promote human well-being."

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Essay

Pesticide licensing in the EU and protecting pollinators

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Intensive agriculture is reliant on pesticides to control crop pests, but these chemicals can have negative environmental consequences. This has resulted in repeated calls for pesticide risk assessments to be modified to better protect ecosystem services such as pollination. However, the pesticide licensing process is complex, and consequently there is often confusion between risk assessments where the environmental impact of pesticide use is considered, and risk management where licensing decisions are made. Using bees as a case study, we provide a roadmap for how pesticides are licensed for use in the European Union. By outlining the regulatory process, we highlight key data gaps that need to be addressed to generate a holistic approach to environmental risk assessment. Such an approach is vital to protect pollinators and wildlife more broadly from the unintended consequences of pesticide use.

In 1962, Rachel Carson published the best-seller *Silent Spring*, in which she outlined the environmental impact of pesticide use. *Silent Spring* resulted in then-commonly used pesticides such as DDT being banned globally from agricultural use, and consequently pesticide risk assessments are now required prior to licensing[1]. Despite this, 60 years later, intensive agriculture is still dependent on pesticides (e.g., insecticides, herbicides, fungicides), with widely documented negative environmental consequences from their use[2–4]. For example, neonicotinoid insecticides can have severe negative impacts on pollinators[4,5], which has resulted in restrictions in the European Union (EU). New-generation insecticides such as sulfoxaflor and flupyradifurone can also have detrimental impacts on beneficial insects[2,6] and sulfoxaflor is now also banned from agricultural use outdoors. These examples are emblematic of a broader pattern where a pesticide is licensed for use, found to have a negative environmental impact, and is banned or restricted, only to be replaced with another pesticide with negative environmental impacts. This continuing cycle has resulted in repeated calls for pesticide risk assessments to be modified[6–8]. However, these risk assessments are complex and there is often a disconnect between risk assessments, whereby the safety profile of a pesticide is determined, and risk management, where licensing decisions are made. Consequently, pesticide regulation can appear opaque and confusing. Here, using pollinators as an example, we outline how pesticides are licensed for use in the EU, where concentrations of pesticides detected are typically lower than in other western agricultural environments[9,10] and more pesticides are restricted or banned[11]. In reviewing the limitations of the licensing procedure in the EU, we suggest areas of future research required to create a more rigorous approach to risk assessment both in the EU and globally.

Pesticides are a major anthropogenic stressor for bees

Bees are vital pollinators of crops and wildflowers, but are routinely exposed to pesticides[12]. In risk assessments prior to licensing, regulators test the toxicity of pesticides to confirm they do not pose a significant risk to honeybee mortality at field-realistic concentrations[7]. However, research from the last two decades has shown that pesticide exposure can have a host of sub-lethal effects. For example, field-realistic concentrations of neonicotinoids can impair bee foraging, learning, thermoregulation, flight and fecundity, with downstream consequences for reproductive success[4,5,13]. Sub-lethal assessments are not a mandatory requirement within risk

assessment and as such may not be considered prior to a pesticide being licensed for use. This is because, firstly, internationally standardised laboratory-based protocols are not designed for addressing sub-lethal effects; and secondly, it is extremely challenging to quantitatively link most individual-level effects to impairment at the population level or, for eusocial bees, even at the colony level. Nevertheless, quantifying these effects is vital because, while lethal and sub-lethal effects clearly differ at the individual level, both can have similar consequences at a population level if a pesticide impairs or prevents reproduction.

Overview of the application process

The licensing process is split into two parts — risk assessment and risk management. Risk assessment determines the risk that a pesticide poses to the environment, and risk management concerns licensing and policy (Figure 1). An application for a new active substance starts with a pesticide company conducting or commissioning research organisations to carry out risk assessment studies with the active ingredient (the active substance without co-formulants) and representative formulation (formula containing active ingredient and co-formulants) (Figure 1). Some studies (described in further detail below) are mandatory under EU Commission Regulation (Number 283 and 284/2013) but non-mandatory studies can also be included. Once these studies have been conducted, the application for the approval of an active ingredient is submitted by a pesticide company to a 'rapporteur member state' who produces an assessment report (the Draft Assessment Report, DAR).

The rapporteur member state is chosen by the applicant usually based on the relative importance of the substance in a given member state, and the specific competencies of member states. The rapporteur member state performs a check of compliance of the dossier with the data requirements, and potentially asks the applicant for further information. They evaluate the studies and derive relevant toxicity and exposure for the assessment report (DAR; Figure 1). The assessment report contains all studies commissioned by the pesticide company, even if the results are not favourable to the applicant, and all published scientific literature deemed relevant for the risk assessment. The European Food Safety Authority (EFSA) coordinates the peer review of the risk assessment process, which involves risk assessors from the different member states of the EU using data from the draft assessment report (Figure 1). EFSA produces and publishes a 'conclusion' reporting whether the representative uses of the active ingredient pose a high or low environmental risk.

Once EFSA's recommendation is made, the European Commission produces a draft regulation, which is reviewed by the Standing Committee on Plants, Animals, Food and Feed (ScoPAFF), made up of representatives from each Member State (risk management). The ScoPAFF committee makes recommendations, which the EC responds to and adopts into regulation. In the case of a

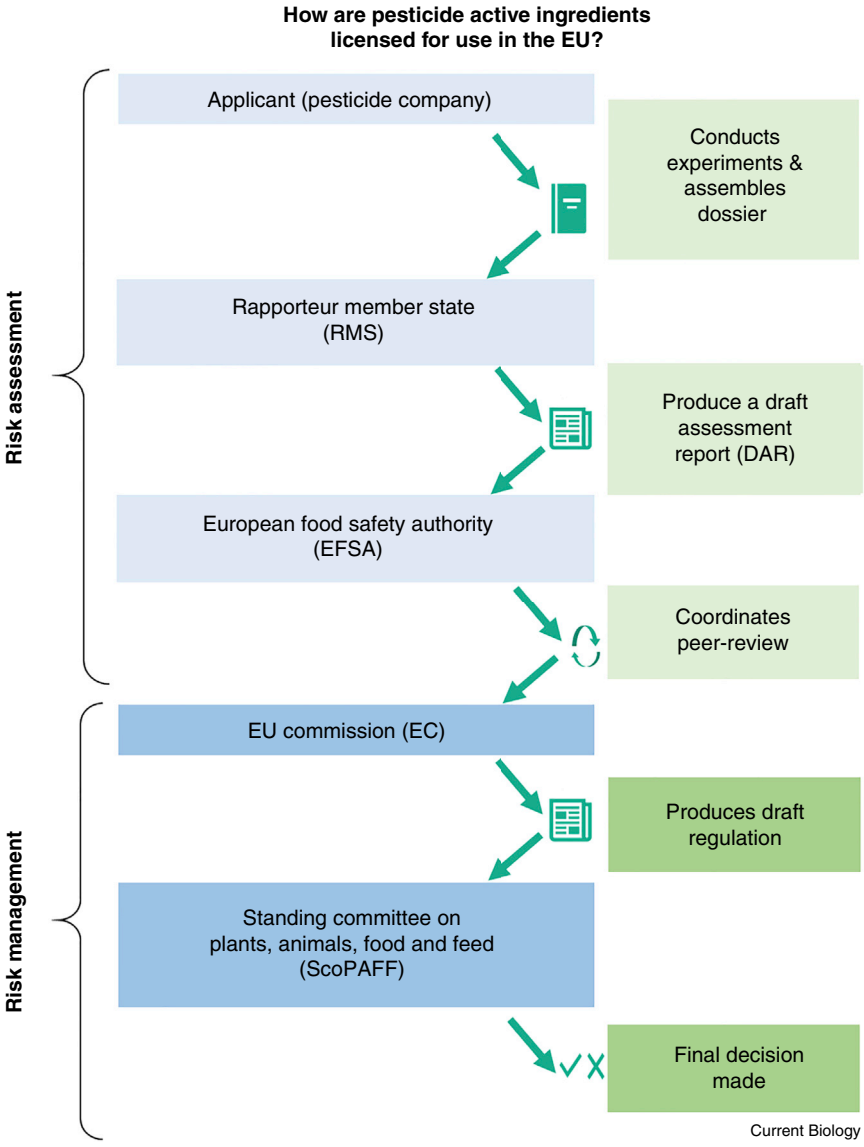

Figure 1. The process by which a novel pesticide (active ingredient) is licensed for use in the EU.
Blue boxes indicate the organisations responsible for each action step, which are shown in green boxes. Light colours indicate risk assessment, dark colours indicate risk management.

successful outcome for pesticide use, authorisation is granted for 10 years, after which time any active substance undergoes a new evaluation. Both steps (risk assessment and risk management) are then repeated at a zonal level (i.e., south, central, and north EU) for intended label uses, which may differ from the representative EU uses. This is the first time commercial plant protection products (rather than active ingredients) are evaluated. Once the product is authorised by member states in that zonal area, the pesticide company can start advertising and selling their product. Once the product is being used, no real-world data are required to be collected to assess its environmental impact.

Risk assessment

EFSA's aim when conducting pesticide risk assessments is to determine if the use of a specific pesticide will have an adverse effect on an ecosystem. Here, we focus on two aspects of this process: how EFSA draws their conclusions, and which data are included in the draft assessment reports from which these conclusions are based.

First, how does EFSA make their recommendations? EFSA determines the potential environmental risk of a pesticide's active ingredient, which informs the authorisation process. Risk assessment is based on the principle of 'protection goals'. 'Generic protection goals' included in the regulation (i.e., Regulation (EC) Number 1107/2009) are poorly defined protection statements which are ambiguous about how to quantify unacceptable levels of risk. Therefore, Specific Protection Goals (SPGs), which quantify the acceptable magnitude of an effect on target species such as pollinators, are agreed upon by the risk managers. For example, the SPG in the newest EFSA guidance document[14] is a 10% reduction in the colony 'strength' (number of workers) of honeybee colonies foraging next to treated fields. Consequently, if a certain pesticide is found to reduce honeybee colony strength by more than 10%, then it will be determined to be high risk.

Second, which data are included in the risk assessment? While the aim of environmental risk assessment is to protect whole ecosystems and populations, a reductionist approach is used, with simplified methodologies and model species. In the case of insect pollinators, honeybees (*Apis mellifera)* are used as a model species. Within a target group (e.g., bees), risk assessment is centred on a tier-based system. In the lower-tier assessments, the mandated requirements are honeybee acute oral and contact toxicity tests with adults, and chronic tests with adults and larvae. Toxicity tests characterise lethality of active ingredients in a dose–response manner for acute or chronic (i.e., 10 day) toxicity. These data are then used together with an exposure prediction which considers the application rate and the 'ShortCut Value' (SV). The SV summarises worst-case exposure assumptions and is modelled using Monte Carlo simulations, which incorporate residues in pollen and nectar in relation to food consumption. This varies depending on the type of application, crop attractiveness, and exposure scenario (i.e., acute, chronic, larval).

If the quantified risk is greater than the Specific Protection Goal (see above) in lower tier testing, then the pesticide company will likely commission higher-tier risk assessments. Higher-tier assessments are more field-realistic and may include semi-field studies in large tunnels, or field experiments (for an example, see Campbell *et al.*[15]). In semi-field trials, honeybee colonies are placed in large flight cages with a bee-attractive crop (e.g., canola), treated with the highest rate recommendation, representing a worst-case scenario. Measures such as colony health, worker mortality, brood development and foraging activity are recorded. Field experiments involve placing honeybee colonies next to fields treated with the pesticide of interest and likewise monitoring the health of colonies. While field experiments are the most representative studies conducted in risk assessments, they often have low levels of replication[16], and control plots are often contaminated with other pesticides, limiting their interpretation[17].

Risk management and policy

Pesticide risk assessments will only be effective at protecting the environment if they accurately identify risk and if policy makers act accordingly when it is detected. Once EFSA have made their conclusion (Figure 1), the decision to license an active ingredient for use is in the hands of the risk managers, i.e., the European Commission and representatives of the Member States. Risk assessments identify risk, but licensing, implementation, and policing are political and so lobbying and misinformation can influence decision making. The EC produces draft regulation, which is then reviewed by the ScoPAFF committee. The committee will consider multiple factors, including social and economic aspects such as alternative pest management options and the risk assessment conclusions from EFSA. Importantly, the EU has it written into law that if a pesticide poses an 'unacceptable' environmental risk (e.g., greater than the Specific Protection Goal), then it cannot be licensed for use (Regulation (EC) Number 1107/2009). In other words, if risk assessments are rigorous, environmental law is in place to ensure active ingredients that pose an environmental threat are not licensed for use. Similar laws should be adopted by other governing nations outside of the EU to ensure a guaranteed level of protection.

Developing a holistic approach to risk assessment

While the law is in place to ensure pesticides that pose an unacceptable environmental risk are not licensed for use in the EU, pesticides harmful to pollinators have been approved for use relatively recently[2,4,7]. This has resulted in repeated calls for regulators to modify risk assessments and move towards a more holistic approach incorporating non-*Apis* bees, sub-lethal impacts and interaction effects between multiple stressors[2,7,16]. But how feasible is this suggestion in the present, and how could it be developed in the future? Here, we make some suggestions for implementing and developing a holistic approach to risk assessment.

Risk assessment in the EU is focused on honeybees, which leads to a number of limitations[7,16]. Honeybees are social and live in managed colonies of ~50,000 bees, which can buffer the impact of pesticides compared with other bee species, most of which are solitary or live in much smaller colonies[4]. Most wild bees either nest in soil or collect nesting material (leaves, soil, etc.) which may be contaminated with pesticides[12,18] and risk assessments with honeybees do not consider these exposure routes. Toxicity can differ between bee species[19], and there are examples of pesticides having negative effects on non-*Apis* bees, but not honeybees[4]. Mandating toxicity assessments with non-*Apis* bees such as bumblebees[20] and solitary bees[19] in lower-tier testing would help with this limitation, but would still fail to encompass other native bees and pollinators. In a recently-published EFSA 2022 draft guidance document[14] it was suggested that extrapolating known honeybee toxicity to non-*Apis* bees by incorporating body size would provide greater coverage to non-*Apis* bees. This could be implemented immediately and is a useful first step towards a more holistic approach to risk assessment[14,21], although further studies with more pesticide groups are required to determine if this extrapolation accurately represents and protects wild bees. Developing and mandating repeatable higher-tier assessments of several non-*Apis* bees that incorporate sub-lethal impacts (e.g., fecundity[22]) is essential for the long-term protection of bees and their pollination services.

As a consequence of anthropogenic change, bees are often co-exposed to a plethora of different pesticides, as well as other stressors such as poor nutrition, parasites, and climate change. These stressors can interact to exacerbate their negative effects[23], but currently these interactions are not considered within mandated risk assessments. Methodologies currently used in risk assessments (e.g., toxicity assessments) could be modified to incorporate other commonly occurring anthropogenic stressors such as poor nutrition[24], parasites[20] or additional pesticides[25], but the sheer number of potential interactions means that a full assessment of interacting stressors would not be possible experimentally. However, in cases where environmental stressors are ubiquitous (e.g., poor nutrition in agricultural environments or *Varroa* in honeybees), developing and ring-testing fully crossed methodologies that incorporate these key stressors is an important step towards holistic risk assessment.

A complementary approach recently proposed by ESFA is to use agent-based modelling combined with data from sentinel (monitored) honeybee colonies to assess interaction effects on a landscape scale for retrospective risk assessment[26]. In this approach, honeybee colonies would effectively serve as 'a canary in the coalmine' to identify key interaction effects that pose a threat to bees. However, while this is an encouraging and welcomed first step, quantifying the impact of a singular active ingredient and determining how it interacts with other anthropogenic stressors are challenging in a field setting. Furthermore, wild bees with completely different life history strategies and stressors would not be considered[27]. Developing higher-tier assessments with non-*Apis* bees that consider a range of sub-lethal and interaction effects is therefore a key priority (see above). There is also a need to develop field experiments that test the wider impact of pesticides on pollinators, beyond model species (e.g., Rundlöf *et al.*[4] and Woodcock *et al.*[28]). Finally, post-licensing monitoring akin to that conducted with pharmaceuticals[29] could incorporate wild bees, but as of yet, no formalised methodology has been developed that accurately quantifies the environmental impact of pesticides at the landscape scale. Developing methodologies that allow researchers to conduct post-licensing monitoring is key to creating a truly holistic risk assessment process and is arguably the most difficult challenge facing regulators over the next decade.

Concluding remarks

The European Commission has recently announced the ambitious target of reducing pesticide use by 50% by 2030. Importantly, the proposal states that they do not intend to ban pesticides, but rather replace them with safe, sustainable alternatives. Globally, scientists have repeatedly called for environmental risk assessments to be modified[2,29] and EFSA and the EC are clearly responding to this, and the slow march towards a more holistic approach to pesticide risk assessment is underway[14]. Here, we have outlined the pesticide regulatory process in the EU, in the hope that by generating a broader understanding of the pesticide licensing process, we can stimulate research in this topic to create a more rigorous approach to pesticide risk assessment globally. A failure to do so will result in continued decline in the pollination services that we rely on for sustainable food production.

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AUTHOR CONTRIBUTIONS

H.S. wrote the first version of the manuscript. All authors contributed to subsequent drafts.

DECLARATION OF INTERESTS

H.S. and F.M. declare they have no competing interests. A.L. and A.I. are employed by the European Food Safety Authority (EFSA). However, the present article is published under the sole responsibility of the authors and may not be considered as an EFSA scientific output. The positions and opinions presented in this article are those of the authors alone and do not necessarily represent the views or any official position or scientific works of EFSA.

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Q & A

Joseph LeDoux

Joseph LeDoux is a University Professor and the Henry and Lucy Moses Professor of Science, and Professor of Neural Science, Psychology, Psychiatry, and Child and Adolescent Psychiatry at New York University. He also directs the Emotional Brain Institute at NYU. His work is focused on the brain mechanisms of emotion, memory, and consciousness. LeDoux has received numerous awards for his research, including the Fyssen Prize in Cognitive Science, The Karl Spencer Lashley Prize from the American Philosophical Society, and the William James Award from the Association for Psychological Science. He is an elected member of the American Academy of Arts and Sciences and of the National Academy of Sciences USA and is the 2023 President-Elect of the Association for the Scientific Study of Consciousness. LeDoux is the author of several books, including The Emotional Brain, Synaptic Self, Anxious *(2016 APA William James Book Award), and* The Deep History of Ourselves *(finalist for the 2020 Pen America E.O. Wilson Award for Literary Science Writing). His forthcoming book,* The Realms of Existence*, is due out in October 2023. As a side line, he is the lead singer and songwriter in the rock band The Amygdaloids and in the acoustic duo So We Are.*

What turned you on to science in the first place? I grew up in small town in South Louisiana in the 'boomer' generation. Like many of my cohort, as a teen I wanted to be a rock and roller. I was not inclined towards science. I did poorly in math in high school, and the only science class I remember taking is chemistry. My major in college at Louisiana State University was business administration, and I steered clear of science there as well, except for a class that, these days, would be called 'physics for dummies.' I went on to receive a master's in marketing, also at LSU, during which I got interested in psychology, and, in particular, why people buy the stuff they buy. The last