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Agricultural pesticide regulatory environment for pollinator protection across geographical regions

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The alarming decline of pollinator populations has raised significant concerns worldwide and prompted the need for effective pesticide risk assessment within the Integrated Pest and Pollinator Management (IPPM) framework. This paper examines the diverse approaches to pollinator protection within the pesticide regulatory environments of the United States (US), the European Union (EU), and selected Asian countries. The US adopts a reactive approach, regulating pesticides only after evidence of harm emerges, while the EU embraces a proactive stance under the precautionary principle. The EU has implemented stringent regulations, including neonicotinoid bans, and conducts coordinated research on pesticide impacts. In contrast, some Asian countries face challenges with inadequate regulations, leading to adverse health and environmental consequences. This article highlights the need for comprehensive pesticide regulations across different regions to safeguard pollinators and mitigate the non-target risks associated with pesticide use.

KEYWORDS

agricultural pesticides, pesticide regulations, pollinator conservation, Integrated Pest Management (IPM), Integrated Pest and Pollinator Management (IPPM)

1. Introduction

The growing significance of protecting pollinators within the Integrated Pest and Pollinator Management (IPPM) framework has led to an increasing demand for non-Apidae pesticide risk assessment (Fischer and Moriaty, 2014; Biddinger and Rajotte, 2015; Franklin and Raine, 2019; Egan et al., 2020; Belien et al., 2021; Lundin et al., 2021). Although pesticides offer numerous anthropocentric benefits, concerns over their negative impact on human health and the environment have arisen (Rajotte, 1993). These concerns have prompted the regulatory change, leading to the passing of the Food Quality Protection Act (FQPA) in the US in 1996, which mandates the review and regulation of current pesticides and the introduction of new, safer classes of pesticides for consumers and the environment (Food Quality Protection Act of 1996, 1996; US EPA, 1999; Thayer and Houlihan, 2004). One aspect of promoting environmental safety has been the heightened focus on safeguarding beneficial organisms, particularly pollinators. Nevertheless, various political jurisdictions around the world employ different regulatory philosophies and approaches.

Currently, the United States (US) and the European Union (EU) have approached pollinator protection from different points of view. The US eschews the precautionary principle and only regulates pesticides after evidence of harm has been established. In contrast, the EU operates under the precautionary principle, whereby the regulatory environment assumes that pesticides could have uncertain or undesirable externalities and proactively regulates their usage (Ollinger et al., 1998; Suryanarayanan, 2015; Donley, 2019; Kudsk and Mathiassen, 2020). Consequently, pesticide regulations in Europe, especially for neonicotinoids, are more stringent, with most of their uses being banned within the EU (EC, 2009a, 2013, 2020; Dewar, 2019; Sgolastra et al., 2020; Demortain, 2021). In addition, the EU has undertaken centrally-coordinated research to determine the implications of neonicotinoid insecticide use on pollinators, whereas in the US, collaborations among agencies remain limited and fragmented. This article presents our views regarding the pesticide regulatory environment for pollinator protection across different geographic regions, particularly in the US, the EU, and some Asian countries. We selected these geographic regions for their significant global influence and leading roles in agricultural production and related international trade (Albright and Hadley, 2017; Bjerkem and Harbour, 2020; O'Rourke and Moodie, 2020).

2. Pesticide regulatory environment in the United States

In the US, the Environment Protection Agency (EPA) collects test data from pesticide manufacturers (registrants) to evaluate the potential effects of pesticides on human health and the environment (US EPA, 2022, 2023a). Under the Federal Environmental Pesticide Control Act (FEPCA) of 1972, the administrator of EPA must consider the risks associated with the use of a pesticide each time he makes a regulatory decision to ensure that the decision-maker, in considering all points of view, is ultimately responsive to broad public concerns in the complex process of balancing costs against benefits (Spector, 1975). Once the results demonstrate that the products pose no unreasonable threat to human health and the environment, the EPA administrator, based on input from scientists and analysts, will determine whether a specific pesticide will be registered (with or without restrictions). After the products enter the market, they will be re-evaluated periodically and as long as they meet the human and environmental safety standards, the license will be re-issued accordingly (US EPA, 2023a). In the US, the marketplace determines the product's success. The effectiveness of the product and its sales in competition with other products is determined by the customers. It is the manufacturer's decision, based on a business evaluation, that keeps the product on the market unless there are discoveries of significant human or environmental risk at which time the product will be reviewed again by EPA. Table 1 provides information related to pesticide regulation process in the US.

In order to ensure a transparent and public risk assessment, EPA develops policies, publishes guidance, and writes regulations that explain all necessary information. Therefore, all individuals, businesses, governments, or non-profit institutions can keep track of and participate in developing new regulations. In other words, EPA's decisions can be influenced by public opinion. The case of the insecticide sulfoxaflor (group 4C), a sulfoximine, is an example (IRAC, 2022). The product was approved by EPA in May 2013, however, its registration had been canceled in 2015 because of a lawsuit by the Pollinator Stewardship Council along with other pollinator advocates and beekeepers (Erickson, 2013; US EPA, 2015). One year later, the EPA re-evaluated the data and granted the pesticide to be used with certain restrictions on a few crops that "claimed to not attract bees" (US EPA, 2016a). In 2019, these "emergency use exemptions" were extended and since then, sulfoxaflor has been allowed on alfalfa, corn, grains, citrus, cucurbits, strawberry, etc. without restriction (Erickson, 2019; US EPA, 2019).

On the other hand, since the final decisions depend on only one person—the EPA administrator, this leaves room for politics as in the chlorpyrifos case (News Desk, 2021). Chlorpyrifos (group 1B), an organophosphate, has been used to control foliage and soil-borne insect pests since 1965 (IRAC, 2022). It was used for indoor pest control until 2000 in form of treated baits. However, this broad-spectrum insecticide is potentially harmful to humans, especially children. Chlorpyrifos effects on children include adverse birth outcomes (Perera et al., 2003), neurodevelopmental delays (Berkowitz et al., 2004; Rauh et al., 2006, 2011; Lovasi et al., 2011; Eskenazi et al., 2014), and impaired brain function (Christensen et al., 2009; Rauh et al., 2012; Rauh, 2018). These findings and pressure from environmental and labor groups persuaded regulators at EPA to re-approach the risk assessment (US EPA, 2016c). Based on this analysis and in 2016, chlorpyrifos was determined unsafe and recommended for a ban. However, this decision was ultimately reversed in 2017, mere 1 year before the intended ban. This reversal was taken despite the mounting evidence in the original assessment. Subsequently, a few years later, the ban was reinstated (Davenport, 2021). However, many pesticide registration cancelations have been done utilizing voluntary cancelation, which is industry-initiated. Voluntary cancelations are business decisions and greatly depend on economic reasons such as profitability, market size, etc. Once the product shows low performance and brings back lower economic returns, the registrants will voluntarily cancel it. There are cases of regulator-initiated bans, but they are limited because the process requires multiple agency resources and takes a long time. For example, the EPA succeeded in canceling carbofuran in 2009 (Erickson, 2011), and flubendiamide in 2016 (US EPA, 2016b). Despite the registrants challenging the banning decision during the appeal process, the EPA identified that these products resulted in unacceptable harm after further review, and therefore canceled the pesticides.

The US's false-negative policy orientation, assuming no harm when there may be harm, and waiting for evidence of harm before regulating, warrants pest management tools for the crop industry. This allows the US to stay in the top two agricultural-producing countries in the world (USDA ERS, 2021), however, the unintended consequences to non-target organisms are real, and it is crucial to reduce the risks to pollinators, first by assessing the effects of pesticides on pollinators other than just honey bees.

3. European Union's pesticide regulations

The European Union (EU), established in 1993, is a political and economic union of European countries that was created to promote peace and the well-being of its citizens (EU, 2021). Currently, the EU has 27 member states. In the EU, pesticide regulatory decisions are

TABLE 1 A timeline of the new pesticide registration process in US and EU [modified from Carroll (2016)].

	Years																			
	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
US	Dossier																			
					EPA review															
						Exclusive use														
											Minor uses									
												Generics 1								
												Adverse data review								
														Generics 2						
EU	Dossier																			
					MS review															
								Exclusive use												
													Minor uses							
										EU review										
																Generics				

Dossier: Registrants prepare data requirements and submit assessment reports for approval of pesticide active substances within the Code of Federal Regulations (in the United States; US EPA, 2023b) and Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) No 844/2012 (in the EU; EC, 2009b; EU, 2012). **Review:** Agency's determination of whether a pesticide meets or does not meet the standard for registration. **Exclusive use:** Also known as "regulatory data protection," a time-limited intellectual property rights protecting the supporting data from dossier studies and tests of the registrants for a period of 10 years (Carroll, 2016). No other company can use these data for commercial but the data owner. **Minor uses:** The extension of exclusive use period or the establishment of a new exclusive use period for the existing pesticides when there are new outbreaks of pests but no effective products are yet available on the market, or when the potential use is not large enough to justify the registration (OECD, 2009; US EPA, 2018). **Generics:** Pesticides containing the same active ingredients can be manufactured and sold by other companies.

based on the false-positive policy orientation, which proactively regulates their use assuming that pesticides will have uncertain or undesirable externalities. This is in contrast to the US policy where only human health and environmental impacts are evaluated, the 'worth' of the product being determined in the marketplace. The pesticide registration application must be passed along a chain of authorization procedures involving the European Food Safety Authority (EFSA), the European Commission (EC), and the member states. Thus, the EU has some of the strictest pesticide regulations in the world. The EC and the member states control the use and distribution of pesticides based on EFSA's studies. EFSA is in charge of assessing the risks associated with the use of pesticides by evaluating both acute and chronic pesticide exposures to human health, the environment, and non-target organisms. The EU policy also extends to imported commodities, and those that do not meet the EU standards will be refused to protect consumers from health hazards. While US EPA evaluates pesticides mainly based on test data submitted by the registrants, EFSA actively gathers scientific data and information from several independent sources including outsourcing research tasks to external organizations. An example of this concerning pollinator protection is the ring test, which involves many labs from academia to industry, government, and contract research organizations. The ring test is designed to assess the short and long-term effects of pesticides on bees after acute or chronic pesticide exposure. The ring test protocols are developed by recognized experts, all participating laboratories are expected to follow the protocols to have their results included in the regulatory assessment. Information related to the pesticide regulatory process in the EU is briefly presented in Table 1.

Based on its extensive experience over the last several years evaluating pesticide impacts on pollinators as requested by the EC, EFSA has begun developing a guidance document on pesticide risk assessment for bees, including honey bees, bumble bees, and solitary bees. The document provides scientific background and suggests risk assessment protocols, from lab to semi-field and field studies. Even though it is still under development, the inclusion of non-honey bees can be considered a step forward compared to the US EPA's guidance for assessing pesticide risks to bees, which only requires honey bees. The EU's precautionary system helps to avoid potential toxicity related to the use of and exposure to pesticides, which plays an important part in protecting non-target organisms, in particular minimizing risks to bees.

The precautionary principle in the EU also has trade-offs. Prohibiting a pesticide also means that crop growers will have to deal with pests by other means, which can lead to crop losses due to insect pest outbreaks (Oerke, 2006; Meissle et al., 2010; Hillocks, 2012; Chapman, 2014). The translocation of systemic pesticides into pollen and nectar has made them a special concern for bee health, however, that same systemic activity also makes them effective against pests. These systemic products are also key components of pesticide resistance management because they are highly selective and can minimize contact exposure to beneficial insects. For instance, in the apple crop, failure to apply pesticides to protect plants from major diseases such as apple scab or powdery mildew at the critical time of

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the season can lead to unmarketable fruits and increased fungicide costs later in the season (Peter, 2018; Peter et al., 2018; Crassweller et al., 2020). In addition, since the EU pesticide registration must be passed along a chain of authorization bodies including all member states, the process can be unnecessarily lengthy due to the inconsistency in member states' evaluations (Frederiks and Wesseler, 2019). This time lag in terms of efficiency can further increase the costs of delay (Pimentel et al., 1980; Kuchler et al., 1994; Bowles and Webster, 1995; Wilson and Tisdell, 2001; Giddings et al., 2013; Chapman, 2014; Lefebvre et al., 2015). Overall, the EU has taken a more proactive approach to protecting pollinators from the harmful effects of pesticides than the US. However, there is still more work to be done to ensure that these regulations are effective in protecting pollinators and other important species.

4. A brief overview of pesticide use and regulatory environment in some Asian countries

Agricultural pesticides are widely used in Asia, however, at present, the misuse of agrochemicals has become a serious concern and major challenge in many Asian countries (Berg, 2001; Abhilash and Singh, 2009; Ali et al., 2014; Gianessi, 2014; Liu et al., 2015; Skretteberg et al., 2015; Schreinemachers, 2019; Dhoj et al., 2021). Pesticide overuse during the last 20 years with unsafe pesticide practices led to adverse health and serious environmental consequences (Nguyen and Tran, 1999; Wilson, 2000; Briones and Felipe, 2013; Schreinemachers et al., 2017, 2020; Schreinemachers, 2019). Increasing poison risks for pesticide handlers, their families, and consumers have been documented (Fernando, 1995; Balali-Mood et al., 2012; Gupta, 2012; Panuwet et al., 2012; Fiedler et al., 2015; Thetkathuek et al., 2017; Mohammad et al., 2018; Montgomery et al., 2020) and pesticide exposure was linked to various acute and chronic health issues, ranging from skin rashes to vomiting, even internal organ failures and cancer (Mohammad et al., 2018; PAN Asia Pacific, 2019; Hughes et al., 2021; Kangkhetkron and Juntarawijit, 2021). The significant adverse impacts of excessive agrochemical use include air, soil, and water pollution, and the killing of non-target organisms in the ecosystem (beneficial insects, birds, aquatic animals, etc.; Williamson, 1998; Regional Office for Asia and the Pacific, 2015; Sharma et al., 2019; Schreinemachers et al., 2020; Dhoj et al., 2021). Currently, the problem of overusing pesticides in Asia is becoming severe, primarily due to the growth of commercial farming and the lack of pesticide regulations (Kay, 2002; Ajayi and Place, 2012; Briones and Felipe, 2013; Otsuka et al., 2016; Schreinemachers, 2019; FAO, 2022b).

Being part of the largest and most populous continent, Asian countries are growing fast and leading in agricultural production; however, food insecurity still exists, with almost 25% of people in the Asia-Pacific region currently facing a shortage of food (FAO, 2022a). With the wide variations in climate, Asia is a global hotspot for biodiversity, including insects, mites, nematodes, vertebrates, etc. (Atwal, 1976; Muraleedharan, 1992; Waterhouse, 1993), and various pest species can dominate and cause huge agro-economical losses (Naylor, 1996; Wilson, 2000; Stenseth et al., 2003; Singleton et al., 2010; Wyckhuys et al., 2020). In order to address food insecurity in Asia, the current agricultural system has to improve yields by expanding commercial farming and increasing crop productivity. Most farmers wrongly believe that pesticides are the only solution to deal with crop loss due to pests and to get more profit and better production from farming (Heong et al., 2008; Christos, 2009; Escalada et al., 2009; Berga and Tam, 2012; Lorenz et al., 2012; Schreinemachers et al., 2015; Nguyen et al., 2016; Schreinemachers, 2019; Dhoj et al., 2021; Galli et al., 2022).

In many countries, pesticides are even considered the remedy for pest issues by using the same word for "pesticide" and "medicine" in their local language (Dhoj et al., 2021). Indeed, "pesticide" is called "thuốc trừ sâu" in Vietnam, "ຢາປາບສັດຕູພືດ" in Laos, and "農藥（农药）" in China, etc., in which "thuốc," "ຢາ," and "藥（药）" means "medicine." Farmers often lack access to the information and resources they need to protect their crops, leading them to seek advice from pesticide traders. However, these traders are often not experts in pest control and may have biased economic interests. This is particularly true in remote areas of China, where the available pesticides are dependent on traders, and where there are no education or training programs for farmers on pesticide use. As a result, empty plastic bags of pesticides are often abandoned as trash, and the smell of pesticides can be detected in villages even outside of application times. Meanwhile, in South and Southeast Asia countries such as India, Thailand, and Vietnam, pesticides are easily available and various identical products on the market have been sold under different trade names, which is confusing and somehow encourages excessive use (Abhilash and Singh, 2009; Gupta, 2012; Pham et al., 2012; Bhardwaj and Sharma, 2013; Hoang, 2015). Moreover, many farmers in Asian developing countries such as Vietnam and Thailand lack training in good agricultural practices, including IPM. Many farmers are not able to tell the difference between beneficial insects and insect pests, nor are they aware of the risks of agrochemicals (Fernando, 1995; Escalada et al., 2009; Berga and Tam, 2012; Lorenz et al., 2012; Nguyen et al., 2016; Alwang et al., 2019; Galli et al., 2022). According to a report by the Pesticide Action Network (PAN) Asia Pacific in 2019, the majority of surveyed farmers were not aware of safe pesticide practices, they often lacked information on the pesticides they used, and having direct contact with pesticides was common because "using protective clothing was uncomfortable" (Schreinemachers et al., 2015, 2017, 2020; PAN Asia Pacific, 2019).

In 2016, the China Ministry of Agriculture took a step forward among developing Asian countries by issuing guidance aimed at assessing the environmental risks of pesticides on honey bees, which covered two species, *Apis mellifera* and *A. cerana* (Ministry of Agriculture of the People's Republic of China, 2016). However, despite the issuance of this guidance, research on the risks posed by pesticide exposure to bees in China remains limited, as highlighted in studies by Tan et al. (2019) and Wen et al. (2021). Although information on pesticide registration, laws, and regulations can be accessed through the China Pesticide Information Network webpage,[1] the lack of training programs for farmers is still a challenge (Fang and Liu, 2018; Sun, 2018).

Changing pesticide usage behavior is a long-term challenge because making a switch from heavily depending on agrochemicals to good agricultural practices like IPM is a complex process

1 http://www.chinapesticide.org.cn/

requiring a lot of resources, training, and capacities (Escalada et al., 2009; Lorenz et al., 2012; Pham et al., 2012; Hoang, 2015; Mohammad et al., 2018). We believe the first step should be taken by the government by carrying out background education and training farmers in IPM to raise their awareness about the risks of highly hazardous pesticides and provide information on crop protection alternatives (Singh, 2012; Schreinemachers et al., 2015). Several studies have shown that the adoption of IPM can take place on Asian farms, reducing pesticide use and maintaining productivity and profitability (Dinakaran et al., 2013; Pretty and Bharucha, 2015; Wyckhuys et al., 2019). Promoting safe methods of farming production is necessary for agriculture extension systems. Also, nationwide surveys on agrochemical status and the establishment of a national pesticide situation with communication between stakeholders are crucial to operating a detailed registration procedure. Therefore, transparency of industry and government procedures may be required in some regions. Fining traders selling unlabeled and highly hazardous pesticides, encouraging access to safer pest control products (e.g., biocontrol), and establishing a monitoring system are some of our recommendations for the current Asian pesticide regulation. Besides, the continued support from Western countries on IPM practices and international collaboration together with trust between stakeholders is important (Thorburn, 2013, 2015).

Overall, in Asian developing countries, the implementation of IPM and IPPM is still at the early stage. There is a growing awareness and interest in these practices among these countries, and indeed many organizations such as FAO and PAN, Ministry of Agriculture in some countries like China, India, Vietnam, and Thailand are actively working to promote their adoption. However, significant efforts are needed to overcome the challenges and guarantee the long-term success of these practices in the region.

5. Conclusion and recommendations

In conclusion, pesticide regulatory environments vary across different regions. To enhance pesticide regulations in the US, it is recommended to adopt a comprehensive approach that considers scientific research, public opinion, and the precautionary principle. Regulatory agencies, such as the US EPA should continue to prioritize thorough risk assessments and periodic re-evaluations of registered pesticides to ensure ongoing safety. Additionally, public input should be actively sought and considered in decision-making processes to reflect societal concerns and values. Strengthening transparency and accountability within regulatory bodies can further enhance public trust. The EU's proactive approach, involving rigorous risk assessments conducted by independent authorities like the EFSA, can serve as a valuable model. Emphasizing the precautionary principle, which prioritizes the protection of non-target organisms and ecosystems, can guide regulatory decisions for other regions as well. In regions facing challenges with pesticide misuse and overuse like Asian countries, efforts should be directed toward educating farmers on proper pesticide application and promoting IPM practices. Strengthening regulations, increasing enforcement, and providing accessible alternatives can contribute to minimizing adverse health and environmental impacts. A balanced approach that considers scientific evidence, public input, and precautionary measures can lead to more effective and sustainable pesticide regulations globally. Collaboration between scientific institutions, regulatory agencies, and industry stakeholders is crucial for generating reliable data, promoting responsible pesticide use, and exploring sustainable alternatives.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

NP, ER, and GS conceived the plan of this study and wrote sections of the manuscript. NP wrote the first draft of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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