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Letter to the Editor

A new regulatory paradigm for pesticide registration in Brazil: Comments on recent legislative amendments (Law 14.785/2023)

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Brazil, a country of immense ecological diversity, has emerged as a global agricultural powerhouse, playing a pivotal role in international food production (Ballarin et al., 2023). With over 20% of the world's species thriving in its six biomes (Ministério do Meio-Ambiente e Mudança do Clima, 2024), any changes to Brazil's regulatory framework that impacts its agricultural and livestock production can have far-reaching global implications (Abessa et al., 2019; Fearnside, 2016). This is particularly true for the regulation and registration of pesticides, a crucial aspect of Brazil's agricultural paradigm, given its status as one of the world's major food exporters (Oliveira et al., 2014).

On 27 December 2023, the Brazilian National Congress approved a new regulation for pesticide registration in Brazil, embodied by Law 14.785 (Brasil, 2023). The new Brazilian law represents a scientific shift in paradigm, particularly given that it now mandates the inclusion of pesticide risk assessments—encompassing both human and environmental assessments—as integral components of the dossier submission process. Before this legislative revision, the evaluation of pesticides' risks concerning human health and the environment was solely predicated on hazard classification, based on the outcome of toxicological and ecotoxicological studies that are part of the dossier submission. Consequently, this regulatory update holds the potential to align the Brazilian regulatory framework more closely with those of more established systems, such as those implemented in Europe and the United States. The primary objective of this letter is to discuss the recent regulatory shift. The authors do not intend to apply any judgments, even implications and/or impacts of this regulatory shift. The purpose of informing is to communicate and provide awareness at this point. The authors also plan to publish other papers where more detailed information will be provided per compartment (e.g., birds and mammals, soil organisms).

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ANTECEDENT AND PROSPECTIVE STATES OF THE PESTICIDE EVALUATION IN BRAZIL: IMPLICATIONS AND INTERRELATIONS WITHIN REGIONAL AND GLOBAL CONTEXTS

Retrospective background on the local context—Brazil

The Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) is the federal entity traditionally responsible for leading, executing, and making determinations regarding ecotoxicological and environmental fate studies as part of the evaluation process. Very similarly, ANVISA, the Brazilian Health Regulatory Agency, oversees the human health component of the evaluation. IBAMA and ANVISA support the Brazilian Ministry of Agriculture and Livestock (MAPA) from environmental and human safety perspectives, respectively. As for MAPA, the agency is responsible for the agronomic necessities for managing pests and diseases across Brazil. Before 2023, under the auspices of the antecedent regulations—Law 7802 of 1989 and Decree 4074 of 2002 (Brasil, 2002)—the adjudication concerning the authorization and subsequent market entry of products constituted a tripartite resolution among the three regulatory agencies; however, the issuance of the federal registration certificate was the purview of MAPA. This highlights MAPA's pivotal function in ensuring that Brazilian agriculture and growers are provided with the most efficacious solutions tailored to Brazil's agronomic requirements for the control of pests and diseases. This consideration is particularly important, given the country's continental dimensions and its predominantly tropical topography.

Environmental risk assessment (ERA) schemes in Latin America and preliminary discussions on the adoption of ERA guidelines in Brazil

As previously delineated, up until December 2023, the assessment of pesticide-related risks to environmental and human health within Brazil was predominantly executed through a hazard classification system—it is important to make clear that the classification did not imply non-registrability. Within the Latin American context, preceding

the year 2023, solely the Andean nations—comprising Bolivia, Colombia, Ecuador, Peru, and Venezuela—and Costa Rica had instituted ERA schemes as integral components of the agrochemical dossier appraisal process. The Andean countries conformed to the regulations of the Andean Manual (Secretaria General de la Comunidad Andina, 2002), whereas Costa Rica elected both to adopt and to adapt the European Food Safety Authority's (EFSA's) guidelines to suit its national context (ref).

Regarding Brazil, despite the absence of local requirements before 2023, in the last 3–4 years, IBAMA has been smoothly moving to an ERA approach, mainly regarding new ingredient actives submission, evaluating several compartments such as aquatic organisms, birds and mammals, soil organisms, and pollinators. Except for the latter case, none have local published ERA guidelines. Regarding pollinators, since 2017, an ERA scheme for pollinators became mandatory upon evaluation of new active ingredients when IBAMA published a Normative Instruction, namely, IN 02/2017 (IBAMA, 2017), and a guidance for ERA for pollinators (Cham et al., 2017).

The efforts behind the process that culminated in the publication of the pollinator guidelines involved IBAMA's collaboration with foreign regulatory agencies such as the USEPA, Canada's PMRA, and EFSA. Altogether, this process represented an essential milestone in a strong movement from Brazilian authorities to shift from a hazard-classification to a science-based risk assessment approach and may be seen as an example of collaboration between different regulatory agencies, which can potentially influence other agencies in the region. Moreover, the process behind developing the pollinator ERA guidelines may be instructive regarding developing new ERA guidelines for other taxa soon.

The Herculean undertaking of implementing new ERA guidelines: Developing a local framework or conforming to international standards?

The approval of new Law 14.785 has the potential of bringing Brazil closer to the regulatory science in place not only in developed countries but also in some of its neighboring countries. New risk assessment schemes must be developed to enable the regulatory agencies and registrants to perform ERAs for several ecological compartments, such as aquatic organisms, birds and mammals, soil organisms, and reptiles and amphibians. In the latter case, Brazil may be among the first countries to require an ERA for this taxon; the European Union is still discussing guidelines for reptiles and amphibians (EFSA; EFSA Panel on Plant Protection Products and their Residues, 2018). Collectively, these regulatory changes may signify a major challenge since potentially new ecotoxicological studies may be required (e.g., ecotoxicological studies with reptiles and amphibians), modeling tools need to be adopted and adapted to local scenarios, and data gaps need to be addressed to provide the necessary local input parameters (e.g., weather data, soil, and hydrological data, crop parametrization) to be used in the modeling tools.

In addition to that, in parallel to the discussions in the Brazilian National Congress leading to the approval of Law 14.785, since 2019, IBAMA has started the debate of new ERA processes and the identification of knowledge gaps. As indicated in the text, the agency's previous experience implementing an ERA scheme for pollinators influenced much of this discussion. To enable the development of new guidelines, the agency was funded by Diffuse Right Fund (FFD in Portuguese) grants from the Ministry of Justice, and a comprehensive network of academics was set up to address the challenges of new ERA schemes on the additional taxa, considering the Brazilian agricultural landscape as well.

Despite the impact of the COVID pandemic and, therefore, some delays in the publication of guidance documents intended to support new ERA schemes, there was an impressive evolution in the way regulatory science progressed in most of the four areas, namely, aquatic organisms, birds and mammals, soil organisms, and reptiles and amphibians. As a result, in 2023, IBAMA presented their progress in two virtual workshops, the “Technical-scientific bases of the Environmental Risk Assessment of Pesticides” (IBAMA, 2023). Despite diligent efforts from academia and regulatory agencies and the progress presented in the workshop, one could observe the lack of crucial information, such as environmental fate data to build modeling scenarios and the need to define local focal species, their habits, and environmental conditions. Filling these knowledge gaps is critical to properly establishing a complete, robust, tiered approach to risk assessment.

In the two workshop presentations, it was made clear that the criteria and directives of the EFSA substantially influenced the proposed new ERA framework, particularly concerning the evaluation of birds and mammals, as well as soil organisms. A point of concern regarding this influence is that Brazil has a different agricultural scenario due to its tropical climate, especially regarding agricultural practices and pest and disease pressure (Furley et al., 2018). Furthermore, the political imperatives and catalysts within each region are notably disparate. This is especially pertinent for Brazil, which still needs to attain the regulatory sophistication necessary to embrace an analogous scheme. Additionally, there is a need to develop and/or adapt standardized ecological tests for local species and, in the case of reptiles and amphibians, to develop new ecotoxicological tests. Consequently, the uncritical adoption of political agendas from other regions could significantly influence the decision-making process within Brazil's agricultural sector.

FINAL REMARKS

Based on the considerations above, the authors believe that from a technoregulatory point of view, there are elements for establishing Tier 1 (screening level) for aquatic organisms, soil organisms, birds, and mammals. At the same time, the implementation of higher tiers needs more discussion. Ideally, these discussions should include the regulatory agencies, academia, and the regulated sector, aiming to address current knowledge gaps and the implementation of a tiered ERA scheme that not only considers the local reality but can protect the environment while still supporting Brazilian agriculture.

In conclusion, the newly established paradigm constitutes a significant transformation within Brazil's technical and regulatory landscape. This shift heralds the potential requirement for environmental research involving novel species. As previously delineated, implementing standardized ecotoxicological tests for local and new species is financially and temporally demanding, escalating the complexity of study design, execution, and subsequent interpretation. These factors suggest that ERA could be a powerful tool in bolstering Brazil's sustainability objectives, acknowledging that sustainability is an amalgamation of environmental, societal, and economic aspects.

AUTHOR CONTRIBUTION

Ana P. Cione: Conceptualization; writing—original draft; writing—review and editing. **Gustavo S. Santos**: Writing—review and editing. **Mario del Giudice Paniago**: Writing—review and editing. **Marina Sales**: Writing—review and editing. **Fábio Casallanovo**: Writing—review and editing.

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CONFLICT OF INTEREST

All authors declare that the Syngenta companies employ them as declared in their affiliations.

DATA AVAILABILITY STATEMENT

Since this letter represents an opinion, there are no experimental data to be provided. The sources of information are already mentioned in the references section.

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REFERENCES

Abessa, D., Famá, A., & Buruaem, L. (2019). The systematic dismantling of Brazilian environmental laws risks losses on all fronts. *Nature Ecology & Evolution*, *3*, 510–511. https://doi.org/10.1038/s41559-019-0855-9

Ballarin, A., Uchôa, J., Santos, M., Almagro, A., Miranda, I., Silva, P., & Oliveira, P. (2023). Brazilian water security is threatened by climate change and human behavior. *Water Resources Research*, *59*(7), e2023WR034914. https://doi.org/10.1029/2023wr034914

Brasil. (2002). *Decree 4074/2002. Regulaments law nº 7.802*. https://legislacao.presidencia.gov.br/atos/?tipo=DEC&numero=4074&ano=2002&ato=dbdQTR61UNNpWTbb6#:~:text=REGULAMENTA%20A%20LEI%20N%C2%BA%207.802,E%20EMBALAGENS%2C%20O%20REGISTRO%2C%20A

Brasil. (2023). *Lei nº 14.785 de 27/12/2023*. https://legis.senado.leg.br/norma/38039732/publicacao/38057865

Cham, K. O., Rebelo, R. M., Oliveira, R. P., Ferro, A. A., Viana-Silva, F. C., Borges, L. O., Sareetto, C. O. S. D., Tonelli, C. A. M., & Macedo, T. C. (2017). *Manual de avaliação de risco ambiental de agrotóxicos para abelhas*. Brasília: Ibama/Diqua (p. 105).

EFSA Panel on Plant Protection Products and their Residues. (2018). Scientific opinion on the state of the science on pesticide risk assessment for amphibians and reptiles. *EFSA Journal*, *16*(2), e05125. https://doi.org/10.2903/j.efsa.2018.5125

Fearnside, P. M. (2016). Brazilian politics threaten environmental policies. *Science*, *353*, 746–748. https://doi.org/10.1126/science.aag0254

Furley, T. H., Brodeur, J., Silva de Assis, H. C., Carriquiriborde, P., Chagas, K. R., Corrales, J., Denadai, M., Fuchs, J., Miglioranza, K. S. B., Caramés, D. M. M., Navas, J. M., Nugegoda, D., Planes, E., Rodriguez-Jorquera, I. A., Orozco-Medina, M., Boxall, A. B. A., Rudd, M. A., & Brooks, B. W. (2018). Toward sustainable environmental quality: Identifying priority research questions for Latin America. *Integrated Environmental Assessment and Management*, *14*(3), 344–357.

IBAMA. (2017). *Instituto Brasileiro do Meio Ambiente—2º workshop sobre bases técnico-científicas*.

IBAMA. (2023). da Avaliação de Risco Ambiental de Agrotóxicos. https://www.youtube.com/watchv=YDJVMBA3HiM

Ministério do Meio-Ambiente e Mudança do Clima. (2024). *Biodiversidade*. https://www.gov.br/mma/pt-br/assuntos/biodiversidade-e-ecossistemas

Oliveira, C. M., Auad, A. M., Mendes, S. M., & Frizzas, M. R. (2014). Crop losses and the economic impact of insect pests on Brazilian agriculture. *Crop Protection*, *56*, 50–54.

Secretaria General de la Comunidad Andina. (2002). *Andean technical manual for the registration and control of chemical pesticides for agricultural use* [Spanish]. Official gazette. Lima (PE) (p. 9). http://www.comunidadandina.org/DocOficialesFiles/resoluciones/RESOLUCION2075.pdf

