

Brief Communication

Progress in the environmental risk assessment of plant protection products in Brazil: An overview of birds and mammals and soil organisms proposals

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Abstract

Since 2019, the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) has actively developed pesticide environmental risk assessment (ERA) frameworks adapted to Brazil's specific ecological contexts. This initiative, supported by funding from the Brazilian Ministry of Justice and in partnership with academic institutions, has led to a concerted effort to establish ERA protocols for various taxa, including birds and mammals, soil organisms, aquatic organisms, and reptiles and amphibians. The outcomes of this initiative were disseminated in two distinct workshops held in February and November of 2023, where the agency showcased its research to the technical-regulatory community. This article synthesizes the proposals for birds and mammals and soil organisms. First, we summarize the agency's proposals for both focal and generic species to be incorporated into the ERA and the methodologies for calculating exposure of these taxa to pesticides through agricultural practices, encompassing seed treatment and foliar applications. On this occasion, IBAMA also disclosed the risk assessment tool that the agency is developing for birds and mammals. IBAMA highlighted the knowledge gaps that must be bridged to progress from preliminary (lower-tier) to more comprehensive (higher-tier) assessments. Regarding soil organisms, during the workshop, the presenters shared findings on the most prevalent species of earthworms and enchytraeids in Brazil. They emphasized the need for additional data collection on a regional scale. The agency has also proposed methods for estimating soil organism exposure to pesticides at a screening level and identified specific data gaps that could be addressed to refine assessments at higher tiers. In summary, the workshop communicated the progress in establishing ERA guidelines, which we encapsulate here to benefit the technical-regulatory community. *Integr Environ Assess Manag* 2024;20:1793–1799. © 2024 The Author(s). *Integrated Environmental Assessment and Management* published by Wiley Periodicals LLC on behalf of Society of Environmental Toxicology & Chemistry (SETAC).

KEYWORDS: Avifauna; Mastofauna; Oligochaeta; Pesticide

INTRODUCTION

In a previous article (Cione et al., 2024), we discussed technical and regulatory changes represented by the new paradigm in pesticide registration in Brazil, where the pesticide dossier evaluation will progress from a Hazard-based classification system to a risk assessment that is now mandatory (Brasil, 2023). In the same article, we also indicated that since 2019, the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) has been engaged in developing environmental risk assessment (ERA) schemes adapted to local conditions (Instituto Brasileiro do Meio Ambiente [IBAMA], 2023a). In this sense, this article aims

to provide more granularity on the ERA propositions for (a) birds and mammals and (b) soil organisms, where information was primarily collated from presentations in a workshop held by the agency in November 2023 (IBAMA, 2023b, 2023c). Even though the presented premises may change when the final ERA guidelines are published, the update herein may provide insight into these regulatory changes occurring in Brazil and intends to inform local and global technical-regulatory communities.

As outlined by Cione et al. (2024), the inaugural ERA guideline issued by IBAMA in Brazil focused on pollinators, with discussions initiated in 2012 (IBAMA – Instituto Brasileiro do Meio Ambiente e Recursos Renováveis, 2012) and culminating with the publication of a risk assessment guideline in 2017 (Cham et al., 2017). It is important to note that the expertise gained during this process was leveraged and expanded upon in the preliminary considerations for ERAs concerning species and compartments. In these discussions, the agency, in close collaboration with local academic institutions, diligently identified the most prevalent species

This article contains online-only Supporting Information.

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Published 2 July 2024 on [wileyonlinelibrary.com/journal/ieam](https://onlinelibrary.wiley.com/journal/ieam).

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within agricultural landscapes, established the foundational premises for potential protection goals, and determined how an ERA could effectively evaluate the risks posed to these taxa by the agricultural application of plant protection products.

The present article aims to summarize the changes being implemented by IBAMA, especially collected from a two-day workshop held in November 2023. In this sense, the authors intend to share the information as much as originally described by IBAMA during the workshop. This workshop is accessible on YouTube videos in Portuguese (IBAMA, 2023b, 2023c). It is important to remember that this is a snapshot from November 2023, and IBAMA keeps evolving in the implementation processes. As per their information, some Guiding Documents may still be published this year, while proper frameworks and complete guidance are not available (IBAMA, 2023b, 2023c). This brief communication summarizes an overview of birds and mammals and soil organisms proposals in this context. Meanwhile, to convey the full message articulated by IBAMA in the November 2023 workshop, a similar article about other taxa—such as aquatic organisms—is on page 1787.

BIRDS AND MAMMALS: RECENT UPDATES AND PROGRESS IN ERA PROPOSALS

To assess the risks to birds and mammals from the agricultural use of pesticides, IBAMA has historically used the USEPA Terrestrial Residue Exposure tool (T-REX) (IBAMA – Instituto Brasileiro do Meio Ambiente e Recursos Renováveis, 2012). However, the agency has transitioned toward adopting a methodology more aligned with the European Food Safety Authority (EFSA), utilizing an EFSA-specific exposure calculator instead of T-REX. The T-REX tool serves primarily as a screening tool (USEPA, 2012), typically deployed in the initial ERA tiers. Furthermore, during the workshop, the agency presented arguments concerning the challenges encountered in progressing to more advanced tiers of assessment when initial stages flagged by the T-REX tool indicated potential risks. In such instances, risk assessors would find themselves impeded at this juncture, particularly given that, from the authors' viewpoint, the Weight of Evidence (WoE) approach (USEPA, 2016) had not yet been delineated or considered as a viable alternative for further tiers in the pesticide evaluation. In summary, the major updates informed by IBAMA are indicated below and further outlined in the text.

- The EFSA approach is to be used for exposure calculation.
- Toxicity endpoints will use the study package delivered by the registrant.
- Toxicity and exposure will be used to determine the risk quotient.
- The risk quotient is to be compared with triggers.

Before the workshop held in November 2023, IBAMA was engaged in calculating risk quotients (RQs) by dividing observed exposure levels by the corresponding ecotoxicity data.

In the estimation of RQs, the agency employed Levels of Concern (LOC) as triggers, with an LOC of 0.5 for acute risks and an LOC of 1.0 for chronic risks (IBAMA – Instituto Brasileiro do Meio Ambiente e Recursos Renováveis, 2012), aligning with the LOC benchmarks established by the EPA for nonendangered species (USEPA, 2007). During the workshop (IBAMA, 2023b) regarding the risk assessment of birds and mammals, it was observed that the agency intends to adopt the Toxicity Exposure Ratio (TER) as a trigger, which is a European approach (European Food Safety Agency [EFSA], 2009). The TER is delineated as the ratio of a toxicological endpoint to the predicted or measured exposure level.

In alignment with the protection goals, it was proposed that mortality at the individual level would be deemed unacceptable and that nonsignificant effects on behavior and physiology should not adversely affect reproduction. Accordingly, trigger values have been established at a TER of 10 for acute risk, based on the ratio of the median lethal dose (LD50) to exposure, and at a TER of 5 for reproductive risk, based on the ratio of the No Observed Adverse Effect Level (NOAEL) to exposure. It has been noted that efforts are underway to adapt the EFSA guidelines to the Brazilian context, acknowledging the vast differences in biodiversity.

To address this challenge, during the Diffuse Right Fund (FDD in Portuguese) task force (Diário Oficial da União Oficial Gazette [DOU], 2019), the demand was delivered to academic specialists in Brazil who have been working on bird and mammal sightings. The latest update on this research indicates that 193 mammal species and four bat species visit crops like eucalyptus, soybean, sugarcane, and maize in regions like Atlantic Forest and *Cerrado* in São Paulo and Bahia states (IBAMA, 2023b). For birds, 1128 species were counted in similar crops in the Atlantic Forest in Southwest and Southern Brazil. It was reported that 244 of them are endangered species. Based on this survey, a proposition on indicator and generic focal species was done (IBAMA, 2023b).

Proposition of indicator and generic focal species for birds and mammals

Regarding representative species, IBAMA informed us that the approach of indicator species (not real species, protective, for screening approach as worst case scenario), the generic species (considering information as crop growth stage, varied diet, guild), and then the focal species as the one determined for sighting will be considered (IBAMA, 2023b). The species selection aligns with the standards used by EFSA guidelines (Aagaard et al., 2023).

Considering Brazilian mammalian fauna, IBAMA stated that bodyweight distribution considering small species is <1 kg, medium species is 1–7 kg, and large species is >7 kg. The agency also reported (Table 1) the identification of indicator species and the generic focal species for mammals made available by the FDD consultants (IBAMA, 2020, 2021). Regarding birds, 947 species were reported; however, due to the considerable diversity in body weight, IBAMA acknowledged the difficulty of splitting them into three categories as

TABLE 1 Indicator and generic focal species for birds and mammals as indicated by IBAMA^a

Crop grouping	Mammals		Birds	
	Indicator species	Generic focal species	Scenario ^b	Generic focal species
Bare soil	Small granivorous	No data—use small granivorous from EFSA	–	–
Roots, tubercles, bulbs	Small herbivores	Small herbivores (roots)	BBCH > 10	Small omnivorous
		Small omnivorous (roots and insects)	BBCH > 11	Small omnivorous
		Small insectivores (insects)	–	Small granivores
Bush	Large herbivores	Large herbivores	BBCH 0-9/or application direct to soil	Small insectivores
Fruiting vegetables	Small herbivores	Small omnivorous	BBCH > 9	Small insectivores
		Large herbivores	–	–
		Small frugivorous	–	–
Cereals	–	–	BBCH ≥ 10 (considering winter cereal from Europe)	Small omnivorous
Cereals	–	–	BBCH 0-9/or application direct to soil	Small insectivores

Abbreviations: EFSA, European Food Safety Agency; IBAMA, Brazilian Institute of Environment and Renewable Natural Resources.

^aAs presented in the section for birds and mammals during the November 2023 risk assessment workshop (IBAMA, 2023b).

^bThe BBCH scale is used to identify the phenological development stages of plants.

done by the USEPA and EFSA. The FDD researchers suggested a range of body weights from 1.8 to 10,000 g. Therefore, the classification recommended is to consider small 4.8 g (passerine) up to 331 g (pigeon), medium 307 g up to 2 kg (*Psittacidae*), and large birds >2 kg.

Proposal for daily diet dose exposure calculation

IBAMA is currently discussing the diet approach based on residue unit determination (RUD, mg ai/kg food item), which is being considered as the ratio between the maximum residue limit (determined for trade and from a human exposure calculation as per the Human Health Agency, ANVISA) and the maximum rate of application. According to IBAMA, the acute risk will use 90th percentile RUD values for acute and geomean for reproductive risk.

The agency has suggested a crop grouping approach when calculating the RUD; as of now, IBAMA's proposal is 13 groupings based on the following criteria:

- Human Health directive (Agência Nacional de Vigilância Sanitária [ANVISA], Ministério da Saúde, 2012).
- Food item relevant to birds and mammals (B&M) (Aagaard et al., 2023).
- Vegetal morphology.
- Advice from specialists.
- Minor crops directive (Ministério Da Agricultura, Pecuária e Abastecimento, 2014).
- Guidance for Bee Risk Assessment (Cham et al., 2017).

Proposed crop grouping:

- Pineapple, coffee, sugarcane, ears/cereal grains, dicots.
- Monocots.
- Bush fruits.
- Orchard fruits.
- Fruit vegetables.
- Strawberry.
- Other seeds/grains.
- Roots, bulbs, tubercles.
- Seeds, seed bags, oilseed.

Definition of exposure scenarios for seed treatment uses

Regarding seed treatment uses at Tier 1, IBAMA is considering a diet of 100% seed, and as such, the daily dietary dose (DDD) is estimated according to:

$$DDD = \frac{FIR}{BW} \times C, \quad (1)$$

where DDD is the daily dietary dose (mg active substance/kg body weight per day); FIR the food intake rate (g seed per day); BW the body weight of model and/or focal species (g); and C the concentration of the active substance/seed (mg active substance/seed).

Table 2 summarizes the specific body weight and food consumption rate used in ERA for seed treatment.

TABLE 2 An example of a seed treatment scenarios for bird and mammal exposure as indicated by IBAMA^a

Scenario	Generic focal species	Body weight of generic focal species (g)	Food intake rate (FIR, g seed/day)
Small treated seed (<0.5 cm)	Small bird granivores	11	4.34
	Small mammal granivores	15	3.45
Large treated seed (>0.5 cm)	Small bird granivores	17	5.82
	Small mammal granivores	15	3.45

Abbreviation: FIR, food intake rate; IBAMA, Brazilian Institute of Environment and Renewable Natural Resources.

^aAs presented in the section for birds and mammals during the November 2023 risk assessment workshop (IBAMA, 2023b).

Definition of exposure scenarios for foliar applications

At the screening level for foliar applications, the exposure is calculated considering the DDD for the indicator species, with no differentiation from crop BBCH and just one food source.

IBAMA has suggested the following equations to calculate exposure:

$$\text{Acute DD} = \text{FIR} \times \sum_i \frac{(\text{AR} \times \text{RUDI} \times \text{MAF}_{\text{acute}})}{\text{BW}}, \quad (2)$$

and

$$\text{Reproductive DDD} = \text{FIR} \times \sum_i \frac{(\text{AR} \times \text{RUDI} \times \text{MAF}_{\text{repro}, i} \times \text{ftWA})}{\text{BW}}, \quad (3)$$

where Acute DD is the acute dietary dose (mg active ingredient/kg body weight); FIR the food intake rate (g fresh weight diet per day); BW the body weight of model/focal species [g]; single food items in the diet: AR is the application rate (kg active substance./ha); RUDI the residue per unit dose for food item *i* (mg active substance/kg); $\text{MAF}_{\text{acute}}$ the multiple application factor to be used for acute exposure estimation; Reproductive DDD the reproductive daily dietary dose; $\text{MAF}_{\text{repro}, i}$ the MAF for reproduction assessments for food item *i*; and ftWA_i the time-weighted average (TWA) factor, calculated by a moving time window, for food item *i*.

An example of an exposure calculation and an exposure scenario is shown, respectively, in Tables 3 and 4.

Proposition of a locally developed risk exposure tool

During the workshop (IBAMA, 2023b), IBAMA unveiled to the attendees a nascent exposure assessment tool designed to evaluate risks to avian and mammalian species, named “G.A.M.B.A.” (“Gerenciador de Avaliação do Risco de Aves e Mamíferos,” which translates to Bird and Mammal Risk Assessment Manager). This tool is currently in the developmental phase under the agency’s auspices. Throughout the presentation, the following observations were conveyed:

- The tool will incorporate the equations outlined in the preceding sections (Equations 1–3) to calculate the exposure and associated risks to B&M.
- By using acute and chronic endpoints, G.A.M.B.A. will have the functionality to ascertain the presence of risks automatically indicated within the interface using color coding: red and green to denote risk and absence of risk, respectively.
- The tool will also facilitate refinements such as adjusting for body weight, food item weight, ftWA, and soil incorporation as specified by the product’s label. A default value may be utilized when the label does not provide guidance.

TABLE 3 An example used by IBAMA for the exposure calculation based on the EFSA approach^a

Crop group	Risk assessment category	Indicator model species	Diet	BW (g)	FIR (g diet per day)	RUD
Crop group 1	Acute bird	Small omnivorous bird	Dicot foliage	27	62.06	84.8
All orchard and field crops listed in Appendix E	Reproductive bird	Small omnivorous bird	Monocot foliage	27	31.65	47.2
	Acute mammal	Small omnivorous mammal	Monocot foliage	23	31.41	117.8
	Reproductive mammal	Small omnivorous mammal	Monocot foliage	23	31.41	47.2

Abbreviations: BW, body weight; EFSA, European Food Safety Agency; FIR, food intake rate; IBAMA, Brazilian Institute of Environment and Renewable Natural Resources; RUD, residue unit determination.

^aAs presented in the section for birds and mammals during the November 2023 risk assessment workshop (IBAMA, 2023b).

TABLE 4 An example of an exposure scenario for birds and mammals at Tier 1^a

Crop grouping	Scenario	Generic focal species	Guild	Body weight/lower (g)	Diet
Root, tubercles, bulbs	BBCH0-9 or application to the soil	Small bird insectivore	Insectivorous	9.2	100% soil arthropodes
Root, tubercles, bulbs	BBCH > 10	Small bird omnivore	Omnivorous	272	50% seeds, 50% invertebrates

^aAs presented in the section for birds and mammals during the November 2023 risk assessment workshop (IBAMA, 2023b).

It is pertinent to recognize that IBAMA has not engaged in discussions regarding subsequent stages in the ERA for birds and mammals as of the current date.

SOIL ORGANISMS: RECENT UPDATES AND PROGRESS IN ERA PROPOSALS

Like the context described for B&M, developing a risk-based framework for soil organisms represents a huge paradigm change in assessing the safety of pesticides in Brazil. The rationale presented by IBAMA was to check whether there is a need to assess toxicity for other species of soil macro- and microorganisms than the default ones currently required (earthworm acute) and whether the ecosystem services in Brazil could be ensured based on the species sensitivity to be considered (IBAMA, 2023c). Questions regarding assessing in- and off-crop were raised, as well as which mathematical models would be appropriate to calculate exposure by considering the Brazilian agricultural practices, including agricultural soil type, comparison with artificial tropical soil (SAT), and so forth. It was mentioned that the EFSA approach is currently the model being followed, including its triggers and, eventually, its higher tiers. In the 2nd IBAMA workshop, emphasis was placed on the effects of some chemicals on enchytraeids, earthworms, and macro- and microarthropods, as per testing ecotoxicological procedures (IBAMA, 2023c).

Proposition of exposure estimation—Use of exposure tools

In developing a Tier 1 exposure scenario, IBAMA has provided a comprehensive overview of the Brazilian territory, detailing the distribution of soils and the potential for pesticide exposure across the nation. In a thorough exercise, the agency incorporated data from these scenarios into the soil exposure tool *Escape* to calculate the Soil Predicted Environmental Concentration (PEC_{SOIL}). The input parameters used within *Escape* to calculate the PEC_{SOIL} (e.g., pesticide half-life, soil density, soil depth) and the scenarios' characterization (e.g., GPS coordinates, soil texture, soil pH) are detailed in Supporting Information Tables S1 and S2, respectively. As articulated by the agency (IBAMA, 2023c), the decision to use the *Escape* tool during the Tier 1 screening phase was predicated on the belief that in addition to soil density, soil exposure assessment tools should integrate parameters such as organic carbon content, wilting point, and field capacity.

The agency chose the 90th percentile of PEC_{SOIL} values to use as a target to select potential worst-case scenarios. It resulted in the identification of 267 different locations, predominantly in Brazil's Southern and Southwestern regions (IBAMA, 2023c). This output was subjected to a subsequent refinement process, initially isolating 10 locations. From this subset, IBAMA selected the worst-case scenario as a representative benchmark for the PEC_{SOIL} calculation (IBAMA, 2023c). This pivotal scenario facilitated the characterization of soil input parameters, which are delineated in Table S2, and these parameters are designated to be utilized as default values within the *Escape* tool.

After exposing the findings above, IBAMA suggested that progression to more advanced tiers would need additional refinements, which, at Tier 2, would incorporate crop-specific scenarios and daily temperature variations (IBAMA, 2023c). Regarding Tier 3, IBAMA posited that using numerical models would be advisable. However, it was noted that no specific numerical scenarios were mentioned during the workshop (IBAMA, 2023c).

Effects

Findings regarding earthworms. As part of the FDD project (DOU, 2019) and per current submission requirements, earthworm species' representativeness for ecotoxicity and use in the ERA were discussed.

Regarding the study of earthworms, IBAMA acknowledged the presence of indigenous species across the nation, yet emphasized the necessity for targeted research in specific regions to address data deficiencies, such as species identification (IBAMA, 2023c). In the workshop session dedicated to the impacts of pesticides on earthworms, the agency reported that *Dichogaster soliens*, *Pontoscolex corethrurus*, and *Dichogaster gracilis* are among the most prevalent species encountered in agricultural zones. Furthermore, IBAMA identified seven species of earthworms as particularly significant, abundant, and widely recognized throughout the country, including *P. corethrurus*, four species of *Dichogaster*, and two species of *Amyntas*. During the workshop (IBAMA, 2023c), it was recognized in a presentation performed by local academics that currently, none of these species are utilized in regulatory studies or are amenable to cultivation for laboratory testing. Furthermore, the academics commented on the potential variability in sensitivity among these species, which may need a "correction factor" to account for these

interspecies differences. The workshop presentation has also outlined several challenges in this area of research:

- *P. corethurus* different strains need genetic analysis of the population test;
- Large-scale production to supply regulatory laboratory testing for *P. corethurus* and *Amyntas gracilis*; and
- More research is needed for *Dichogaster*.

Findings regarding enchytraeids. During the 2nd IBAMA workshop, a special session on enchytraeids was presented (IBAMA, 2023c). It was demonstrated that the Atlantic Forest biome is currently the most highly researched, with Pantanal, Pampa, and Caatinga being the least researched. The genera identified in Brazil are *Achaeta*, *Buchholzia*, *Cernosvitoviella*, *Enchytraeus*, *Fridericia*, *Guaranidrilus*, *Hemienchytraeus*, *Marionina*, *Tupidrillus*, and *Xetadrilus*. There are currently 42 species described, 34 of them new ones.

The *Enchytraeus* session concluded that the knowledge around these species is low, even though these species occur widely in Brazilian territory, both in cultivated and in native areas. The genetic composition of *Enchytraeus* differs from the European ones, and there is a significant quantity of unknown species.

The *Enchytraeus spp.* and *Fridericia spp.* are the most common in agricultural areas, while the *Guaranidrilus spp.* are most often found in native areas. The *Enchytraeus spp.* are easily cultivated in the laboratory and have good potential as a bioindicator.

FINAL REMARKS

This brief communication encapsulates the information shared by IBAMA regarding the ERA for birds, mammals, and soil organisms as part of a very important shift in the Brazilian regulatory paradigm imposed by Law 14.785/2023 (Brasil, 2023; Cione et al., 2024), positioning Brazil in closer alignment with the regulatory science standards of developed nations. Furthermore, these guidelines align with the sustainability objectives pursued by the Brazilian agricultural sector.

AUTHOR CONTRIBUTION

Ana Paola Cione: Conceptualization; data curation; project administration; supervision; validation; writing—original draft; writing—review and editing. **Gustavo Souza Santos:** Writing—review and editing. **Fábio Casallanovo:** Writing—review and editing.

ACKNOWLEDGMENT

There are no funders to report.

CONFLICT OF INTEREST

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

DISCLAIMER

The peer review for this article was managed by the Editorial Board without the involvement of Ana Cione, Gustavo Souza Santos, and Fábio Casallanovo.

DATA AVAILABILITY STATEMENT

Since this brief communication conveys a summary from a workshop, there are no experimental data to be provided. The sources of information are mentioned in the References section.

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SUPPORTING INFORMATION

Table S1. Inputs PEC_{soil} calculation at Tier 1.

Table S2. Characterization of the exposure scenario to estimate PEC_{soil} at Tier 1.

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