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Monitoring and evaluation of the regulation on pesticide labelling and packaging leaflets in Brazil: A conceptual model and indicators

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ABSTRACT
This study introduces a conceptual model for selecting and ranking key indicators to monitor and evaluate the outcomes of the current regulation of pesticide and wood preservative labelling and packaging leaflets in Brazil. Utilising a hybrid approach that integrates fuzzy logic with multicriteria decision-making methods (AHP and TOPSIS), the model identifies and ranks 69 key indicators aligned with the regulation's expected outcomes. This study addresses two critical gaps in the literature: i) the lack of conceptual models to define key indicators to evaluate the effectiveness of regulation on pesticide labels and leaflets at the national level; and ii) the need for a multi-criteria methodological approach combined with fuzzy logic theory to select and rank key indicators to monitor and evaluate the outcomes of pesticide labelling and packaging leaflet regulations. By mapping inputs, activities, outputs, and outcomes in a logical model, this study provides a systematic framework for regulatory agencies and stakeholders. These findings underscore the importance of stakeholder collaboration, capacity building, and alignment with international standards. Future research should explore the behavioural impacts of improved labelling and the scalability of this model to other regulatory contexts.

Section: RESEARCH PAPER

Keywords: pesticide labelling and packaging leaflets; monitoring and evaluation; indicators and metrics; multicriteria decision-making methods; fuzzy logic

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1. INTRODUCTION

Currently, there is growing concern regarding the use of agrochemicals, particularly pesticides, in food production systems, underscoring their dual role as both essential agricultural inputs and potential hazards. In this context, pesticide labelling and packaging leaflets constitute fundamental communication instruments that bridge multiple stakeholders across the agri-food chain, including manufacturers, health professionals, regulatory bodies, agricultural workers, and end consumers [1], [2].

From a manufacturing perspective, these labels and leaflets must comprehensively convey toxicological information, along with safety and environmental precautions. Globally, regulatory frameworks consider pesticide use legally admissible only when products strictly follow established labelling and packaging leaflet requirements [1], [2].

In Brazil, the expansion of pesticide utilisation has historically conferred competitive advantages, supported by a prolonged period of regulatory permissiveness that engendered environmental and human health implications that are still being elucidated [3].

The proliferation and intensification of pesticide applications have disproportionately affected rural populations, making them increasingly vulnerable to both direct and indirect exposure [4], [5]. Moreover, analytical findings from the Pesticide Residue Analysis Program in Food (acronym in Portuguese, PARA) showed that pesticide residue levels exceed regulatory thresholds in Brazilian food commodities [6].

To address these challenges and mitigate the associated risks to public health and quality of life among vulnerable populations, authorities have implemented and reinforced the Surveillance in Health of Populations Exposed to Pesticides (VSPEA) [7]. This initiative encompasses comprehensive measures, spanning prevention, surveillance, and integrated healthcare delivery. A significant component of this strategy was the development of the Interactive Indicators Panel, which supports the monitoring of implementation processes, enhances social oversight, and provides data-driven insights for health-sector stakeholders in action planning through systematic tracking of nationwide exogenous pesticide intoxication data [7].

The National Health Surveillance Agency (Anvisa) has adopted a strategic approach aimed at enhancing farmers' knowledge of agricultural inputs and at fostering a collaborative framework for pesticide control. Anvisa's mandate encompasses the critical evaluation of health-related information presented by manufacturers on labels and packaging leaflets, ensuring both the adequacy of content and the relevance of information to support the safe advancement of the agricultural sector [8].

In response to the challenges and persistent exposure risks faced by agricultural workers, Anvisa implemented a comprehensive regulatory framework in 2019, comprising multiple Resolutions of the Collegiate Directorate (RDC) and Normative Instructions (IN). Of particular significance is RDC 296/2019, enacted on 29 July 2019, which established detailed requirements for toxicological information on pesticide and wood preservative labels and package leaflets [9]. This resolution delineates specific criteria for manufacturers in the preparation of labels and leaflets, aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), thereby facilitating the international standardization of pesticide labelling practices in Brazil [9].

To enhance regulatory oversight and compliance assessment with RDC 296/2019 at the national level, this study proposes a conceptual model for the systematic selection and hierarchical organisation of monitoring and evaluation indicators. This framework specifically addresses the outcomes of current regulations pertaining to pesticide and wood preservative labelling and packaging leaflets in Brazil.

This paper is structured into six sections, including this introduction. Section 2 presents a comprehensive literature review, examining relevant studies published between 2010 and 2023, focusing on central research themes. Section 3 outlines the research design and the methodological framework. Section 4 introduces the proposed conceptual model for ranking key monitoring and evaluation indicators. Section 5 provides a critical discussion of the model's distinctive features in relation to the existing literature, while acknowledging its limitations. Finally, Section 6 synthesises key findings and presents concluding observations.

The proposed framework aims to enhance regulatory compliance monitoring, while contributing to the broader discourse on effective pesticide management systems in agricultural production contexts.

2. LITERATURE REVIEW

A literature review was conducted, focusing on the central research subjects, namely: *i)* monitoring and evaluation, including logic model design; *ii)* Multicriteria Decision-Making (MCDM) methods, with an attempt to select the best methods to be considered in the applied phase; and *iii)* empirical studies on the adoption of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) on different continents.

The first literature search, focusing on the subjects "monitoring and evaluation" and "logic model design", was carried out on peer-reviewed articles indexed in the Scopus database, covering the period between 2010 and 2023. This search strategy focused only on the most highly cited publications on the referred subjects [10]-[13].

A second search regarding MCDM methods used the keywords "multiple criteria decision-making" ("MCDM") and "multicriteria decision-making", with the Boolean operator OR. This search strategy yielded 25,834 documents, and showed that several researchers have attempted to combine MCDM methods for different applications, such as the combination of the Analytical Hierarchy Process (AHP) [14], the Technique for Order Performance by Similarity to Ideal Solution (TOPSIS) [15], and the most cited hybrid approach for the decision problem in focus (3,457 documents).

Finally, a third literature search focused on adopting the GHS and regulations on pesticide labelling and packaging leaflets worldwide. The GHS is a comprehensive framework for classifying and labelling chemicals based on their hazard severity. It also outlines how hazard information should be communicated to users through hazard pictograms, hazard statements, and Safety Data Sheets [16].

Effective communication of chemical hazards and implementation of safety measures are critical for protecting human health and the environment. The synthesis of 12 key studies [17]-[28] underscores the multifaceted challenges in ensuring safe chemical practices, while highlighting innovative solutions to improve pesticide labelling, hazard communication systems, and the global adoption of the GHS. Together, these studies provide a comprehensive picture of the progress made and the hurdles that remain in advancing chemical safety globally.

Persson et al. [17] mapped the adoption of the GHS and found that developed nations achieved higher implementation rates due to their stronger regulatory and financial capacities.

Yazid et al. [18] further highlighted inconsistencies in chemical classification results among countries, pointing to the need for greater harmonisation. One significant issue identified by Yazid et al. [18] was the flexibility of the "building block" approach of the GHS, which allows countries to adopt only selected hazard categories. Although this flexibility accommodates national differences, it also leads to inconsistencies that undermine the universal applicability of the system. To address these challenges, Yazid called for standardised data sources and improved international coordination. Peterson et al. [19] and van der Kolk [20] added that performance indicators and stakeholder collaboration are essential to overcoming implementation barriers and ensuring the system's success.

Farías [21] explored the effects of pesticide-free labels on consumer perceptions, and found that these labels significantly enhanced the perceived product quality and value. Consumers with higher environmental awareness were particularly responsive, prioritising pesticide-free products in their purchasing decisions. This highlights the potential of labels not only as regulatory tools but also as instruments to drive consumer demand for safer and more sustainable agricultural practices.

Emery et al. [22] conducted a comprehensive review of the use of pictograms in pesticide hazard communication, focusing on the European Union's regulatory context. The findings highlighted that, while pictograms have the potential to improve comprehension, their effectiveness varies widely among user groups. Many workers, operators, and bystanders misunderstand the meaning of standardised pictograms, particularly in multicultural settings, where language barriers persist. The study highlighted the need for complementary verbal training to ensure that pictograms achieve their intended purpose. Emery et al. also noted the critical role of consistent, high-quality design in enhancing the efficacy of pictograms. By aligning pictograms with ergonomic principles and providing users with adequate training, the study suggests that hazard communication could become more inclusive and effective.

Boelhouwer et al. [23] extended this discussion by evaluating the impact of GHS-compliant hazard and precautionary pictograms on Safety Data Sheets (SDS) and labels. Their experimental results indicated that the presence of pictograms reduced the response time for retrieving safety information, particularly for physical hazards. However, the study found mixed results regarding overall comprehension, suggesting that while pictograms enhance accessibility, their full potential remains contingent on further refinement and user familiarity.

Choi et al. [24] introduced a Chemical Ranking and Scoring (CRS) method specifically designed for biocides, a category of chemicals widely used in household and industrial settings. This method integrates exposure and toxicity variables to systematically rank the health risks of biocides. This study addressed the limitations of existing CRS models, which often underestimate risks by neglecting biocide-specific toxicity indicators, such as inhalation and skin exposure.

Bagheri et al. [25] revealed that farmers in Iran struggled to understand pesticide pictograms due to unclear designs, low literacy levels, and the use of technical language. They emphasised that factors such as educational level and training are crucial for improving label comprehension. These findings underscore the importance of tailoring communication tools to the cognitive and cultural contexts of end users.

These challenges were echoed in Patel and Mukhopadhyay's [26] study in Central India, where the mean comprehension rate of existing pictograms was merely 52.2 %. Notably, the authors redesigned the pictograms to align with local ergonomic principles, such as familiarity, compatibility, and standardisation. This intervention significantly improved comprehension, raising it to 82.2 %, demonstrating the potential of user-centric design.

Besides label and pictogram comprehension, understanding user behaviour is pivotal for enhancing the efficacy of hazard communication systems. Bagheri et al. [27] applied the Theory of Planned Behaviour (TPB) to explore Iranian farmers' intentions to engage with pesticide labels. Their study showed that subjective norms and perceived behavioural control were significant predictors of farmers' intentions, whereas attitudes had minimal influence. This suggests that social pressure and perceived ease of use play a larger role in determining label engagement than personal beliefs. Additionally, the study identified practical barriers, such as age and extensive farming experience, which led many farmers to disregard label instructions, as they believed that their knowledge was sufficient.

Dugger-Webster and LePrevost [28] corroborated these findings, highlighting that demographic factors, technical knowledge, and cultural attitudes significantly influenced label comprehension. Both studies advocated training programs tailored to the needs of specific user groups, particularly those with limited literacy or technical expertise.

Collectively, these studies address the need for clear communication between the chemical product label and the end users regarding the theme of agrochemicals and pesticides, to ensure that farmers accurately interpret the information described on pesticide labels and package inserts, which guarantees safety and consequently reduces cases of human intoxication.

The aim of adopting the GHS is to achieve the international harmonisation of the information that chemical product labels contain.

Several authors have emphasised that the success of the implementation of the GHS depends on various factors, such as economic, educational, and social aspects, and varies from country to country. Two studies, [15] and [16], reinforced that performance indicators and stakeholder collaboration are essential for overcoming implementation barriers and monitoring the progress of the implementation of the GHS at the national level.

Despite the importance of the results achieved so far in advancing knowledge in the focused research theme, the analysis of these studies revealed research gaps and unsolved problems in the field of monitoring and evaluation (ME), focusing on pesticide labelling and packaging leaflet regulations, as it will be discussed in the next section.

3. RESEARCH DESIGN AND METHODOLOGY

This section outlines the research design to address the questions presented in Table 1. It follows a procedural model based on Correia et al. [29], which consists of three phases and five stages, providing a clear structure and a well-established course of action for this study. The research phases are *i)* motivation; *ii)* development; and *iii)* validation.

The first stage involves the definition of the problem and of a rationale for the research. The second stage entails conducting a thorough review of existing research on the core topics, identifying research gaps and unresolved matters in the specific field of study. The third stage refers to the research methodology. In contrast, the fourth stage deals with developing and applying a fuzzy-multicriteria model to select indicators for monitoring and evaluating the outcomes of Brazil's pesticide labelling and packaging leaflet regulation. Finally, in the last stage, the results and implications of this research are discussed.

Initially, a literature review was conducted, focusing on the central research topics, as described in Section 2. The current state of research analysis has led to the identification of two research gaps: *i)* the lack of conceptual models to define key indicators to evaluate the effectiveness of regulation on pesticide labels and leaflets at the national level; and *ii)* the need for a multi-criteria methodological approach combined with fuzzy logic theory to select and rank key indicators to monitor and evaluate the outcomes of pesticide labelling and packaging leaflet regulations.

The research methodology consisted of a formal modelling process used to develop a conceptual model to select indicators for monitoring and evaluating the outcomes of Brazil's pesticide labelling and packaging leaflet regulation. The focus on unaddressed research gaps led to the selection of the Analytic Hierarchy Process (AHP) [14] and the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) [15] methods, combined with fuzzy logic [30], considering the characteristics of these regulations and the review of MCDM methods.

The AHP method was proposed by Saaty [16], and the basic idea of this method is founded on a pairwise comparison based on the eigenvector. Widely used for subjective assessments by practitioners, academics, and policymakers, this method is a pairwise comparison in a small part of the hierarchical structure, followed by comparisons between the higher levels of the hierarchical structure. Pairwise comparisons of criteria were conducted using Saaty's nine-point scale (Table 2).

To implement the AHP method to assign weights to criteria for ranking and selecting indicators associated with the RDC

Table 1. Research design.

Phase	Stage	Research questions [Section]
Motivation	Problem definition and the rationale for the research.	Why should we develop a conceptual model for selecting and ranking indicators and metrics to monitor and evaluate the outcomes of the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil? [Section 1]
Development (What and How?)	State of research on central themes and identification of research gaps and unsolved problems.	What are the significant gaps in the existing knowledge regarding the adoption of the GHS, in which the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil aligns? [Section 2]
	Definition of the research methodology.	How can we select and rank indicators to monitor and evaluate the outcomes of the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil? Which decision-making methods should be integrated into a conceptual model for this purpose? [Section 3]
	Development and application of a multicriteria conceptual model for selecting key indicators for pesticide labelling and packaging leaflet regulation in Brazil.	Which components should be included in the logic model concerning the Brazilian regulation on pesticide and wood preservative labelling and packaging leaflets? [Section 4] Which indicators should be suggested for monitoring and evaluating the outcomes of this regulation in line with its logic model? [Section 4] Which criteria should be defined for ranking and selecting indicators for this purpose? [Section 4] Which indicators and metrics should be proposed to monitor and evaluate the outcomes of the Brazilian regulation on pesticide and wood preservative labelling and packaging leaflets? [Section 4]
	Validation (How to demonstrate the applicability of the conceptual model?)	Could the results of the application focusing on the RDC 296/2019 effectively demonstrate the adequacy and usefulness of the proposed model? [Section 5] What are the primary differentiating factors of this model compared to previous studies on the adoption of the GHS in different continents? What are the managerial implications of this research? [Section 5]

296/2019 outcomes, managers or experts who provide judgments or preferences must undergo a consistency test based on the pairwise comparison matrices' Consistency Ratios (C.R.). The C.R. of a pairwise comparison matrix is the ratio of the consistency index to the corresponding random value. For more details, refer to [14].

In the traditional AHP method, decision-makers are required to make crisp pairwise comparisons between alternatives based on their preferences. However, human judgment often involves uncertainty and subjectivity. Fuzzy logic was utilised in this model to assign fuzzy weights to criteria for selecting and ranking indicators to monitor and evaluate the outcomes of the focused regulation. Decision-makers might have difficulty precisely assigning crisp weights to criteria, due to subjective judgments or incomplete information, so fuzzy logic allows them to express the degrees of importance more flexibly, considering the uncertainties in their preferences [31].

The second method chosen to integrate the conceptual model was the TOPSIS method, introduced by Hwang and Yoon [15]. It is based on the concept that the chosen alternative should have the shortest distance from the Positive Ideal Solution (PIS) and the furthest distance from the Negative Ideal Solution (NIS).

Fuzzy logic can also be beneficial for decision-makers when using the TOPSIS method. It is a multicriteria decision-making technique, used to identify the best alternative among a set of options based on their similarity to the ideal solution and dissimilarity to the worst solution. In traditional TOPSIS, decision-makers are required to provide crisp numerical values for performance ratings of alternatives (i.e., the initial list of indicators). However, in real-world decision scenarios, uncertainty and vagueness are common. Fuzzy logic enables decision-makers to use linguistic variables (e.g., "very good", "somewhat poor") to express the relative performance of alternatives, considering the uncertainty in criteria evaluations [31].

Table 2. Saaty's nine-point scale [16].

Scale	Linguistic scale
1	Equally important
2	Equally to moderately more important
3	Moderately more important
4	Moderately to strongly important
5	Strongly important
6	Strongly to very strongly more important
7	Very strongly more important
8	Very strongly more important to absolutely important
9	Absolutely important

4. RANKING AND SELECTING INDICATORS FOR MONITORING AND EVALUATING THE OUTCOMES OF THE FOCUSED REGULATION IN BRAZIL

Based on the methodology outlined in Section 3, a conceptual model comprising eight stages was applied to rank and select indicators for monitoring and evaluating the outcomes of Brazil's pesticide and wood preservative labelling and packaging leaflets regulation, focusing on the RDC 296/2019 [9]. Five specialists in the fields of Monitoring and Evaluation (ME) and Metrology participated in the applied phase of this study.

4.1. Stage 1: Analysing the objectives and expected outcomes of the focused regulation

In the first stage, the aspects of the RDC 296/2019 that should be subject to monitoring and evaluation were identified through a qualitative content analysis [32]. The results of this analysis included the cases of evidence of the existence of the problem, the objectives of the regulation, the expected outcomes, and the categories of legal requirements to be subject to monitoring and evaluation. It is worth highlighting the expected outcomes and the categories of legal requirements as defined in the RDC 296/2019 [9].

The expected outcomes encompass *i)* the alignment of the toxicological information on labels and leaflets of pesticides with internationally used guidelines; *ii)* a better understanding of the risks of these products for farmers, minimising potential harmful effects on human health; *iii)* the provision of clearer precautions to avoid harm to people who apply and handle pesticides and related products; *iv)* the maintenance of standardised warning symbols and phrases; *v)* the standardisation of instructions for accidents, including alarm symptoms, first aid, antidotes, and information for medical professionals; *vi)* the assurance of safe access to products and services subject to health surveillance for the population; *vii)* the improvement of regulatory quality in health surveillance.

In turn, the categories of legal requirements of the RDC 296/2019 are *i)* label model; *ii)* leaflet model; and *iii)* instructions for filling out the medical information.

4.2. Stage 2: Identifying key stakeholders

In this stage, key stakeholders interested in this regulation were mapped, as follows:

- Health Surveillance Agency (Anvisa): a federal entity responsible for the toxicological evaluation of agrochemical products, the formulation of RDC 296/2019, and monitoring and evaluation of results during its implementation;
- State and Municipal Health Surveillance Agencies: responsible for the inspection and evaluation of the compliance regulation on pesticide labelling and packaging leaflets, and related products;
- Manufacturers and sellers of pesticides, related products, and wood preservatives;
- Health professionals, whose active engagement in the implementation of pesticide labelling and packaging leaflet regulations is essential for safeguarding human health and the environment, while promoting the responsible and safe use of pesticides in the agri-food chain;
- Farmers, who carry out the preparation and application of pesticides, related products, and wood preservatives in the field;
- Population: consumers of products from the agri-food chain.

4.3. Stage 3: Building the logic model of the regulation on pesticide and wood preservative labelling and packaging leaflets

The third stage involves building the logic model concerning the focused regulation, according to [13], as a basis for suggesting an initial list of indicators associated with each category of legal requirements, to meet the different interests of the stakeholders.

The logic model is a systematic and visual representation that outlines the regulation's theory of change, showing how inputs, activities, outputs, and outcomes are connected to achieve the regulation's intended goals and objectives [13]. It presents a clear and logical sequence of cause-and-effect relationships, showing how resources and efforts lead to specific outputs, desired outcomes, and impacts.

The logic model serves as a valuable tool that helps stakeholders—especially regulatory agencies—understand the underlying assumptions of a regulation, plan its implementation, monitor progress, and evaluate its effectiveness. It supports regulation design, facilitates communication among stakeholders, and enables evidence-based decision-making throughout the regulation's entire lifecycle.

4.4. Stage 4: Suggesting an initial list of key indicators in line with the logic model

In this stage, an initial list of key indicators was proposed, considering the three categories of legal requirements of RDC 296/2019, mentioned in item 4.1. Due to space limitations, this list could not be presented in this paper, but it can be found in [30].

Table 3. Criteria for selecting and ranking indicators.

Criterion	Description
C1- Relevance	It must reveal the degree of relevance of the measurement concerning the considered dimension and meeting the information needs of stakeholders.
C2 - Measurability	It should have a measurable capacity and excellent precision without ambiguity. The cost of data collection is justified by the benefits generated from the resulting information of the indicator.
C3 - Timeless	The information comprising this indicator must be current and obtainable in a timely manner for its use.
C4 - Reliability	It should come from reliable sources, be integral, and without the possibility of result manipulation. The measurement must be objective, truthful, and verifiable.
C5 - Traceability	It should be traceable and contain necessary information from reliable sources that can be accessed whenever necessary.

4.5. Stage 5: Defining criteria for selecting and ranking indicators

Taking into account the types of indicators needed to meet the different stakeholders' interests, the criteria to be fulfilled for ranking and selecting the indicators were determined in the next stage.

Based on the methodological approaches adopted by the International Bank for Reconstruction and Development / World Bank [33], five criteria for selecting good quality indicators were used in this stage, as presented in Table 3.

4.6 Stage 6: Weighting selection criteria applying the fuzzy AHP method

In this stage, the AHP method combined with fuzzy logic [31] was used so that the five study participants could use linguistic variables (e.g., "very good", "somewhat poor") to express the relative importance of each criterion, considering the inherent uncertainty in this type of judgment [14], [34].

The judgment of the criteria consisted of responses to two fundamental questions: "Which of the two criteria is more important, considering the choice of indicators to monitor the outcomes of the regulation in focus?", and "What importance intensity can be associated with this criterion compared to the other?".

The results of the assignment of weights to the criteria, defined by pairwise comparisons of the criteria, are presented in Table 4, including the Consistency Ratios (CR) inferior to 0.1, as defined in [14].

Table 5 presents the matrix of paired comparisons of decision criteria with triangular fuzzy numbers (TFN), calculated through the average participant judgments (P1, P2, P3, P4, and P5).

Table 6 shows the final weights calculated with the computational tool Fuzzy AHP Software® [35]. These weights were considered in the next stage for ranking the proposed

Table 4. Criteria weights and Consistency Ratios (CR) of the matrices with the judgments of participants (P1 to P5).

Criterion	P1	P2	P3	P4	P5
C1- Relevance	0.264	0.306	0.304	0.323	0.298
C2 - Measurability	0.244	0.238	0.240	0.256	0.255
C3 - Timeless	0.105	0.113	0.110	0.101	0.100
C4 - Reliability	0.264	0.211	0.232	0.212	0.245
C5 - Traceability	0.006	0.133	0.113	0.108	0.102
Consistency Ratio (CR)	0.006	0.040	0.022	0.044	0.027

Table 5. Matrix of paired comparisons of decision criteria with triangular fuzzy numbers.

	C1	C2	C3	C4	C5
C1	(1.00;1.00;1.00)	(1.00;1.00;1.00)	(1.00;2.76;4.00)	(1.00;1.88;4.00)	(1.00;2.16;4.00)
C2	(1.00;1.00;1.00)	(1.00;1.00;1.00)	(1.00;2.16;4.00)	(1.00;1.00;1.00)	(1.00;2.04;4.00)
C3	(0.25;0.36;1.00)	(0.25;0.46;1.00)	(1.00;1.00;1.00)	(0.25;0.39;1.00)	(1.00;1.00;1.00)
C4	(0.25;0.53;1.00)	(1.00;1.00;1.00)	(1.00;2.54;4.00)	(1.00;1.00;1.00)	(1.00;2.35;4.00)
C5	(0.25;0.46;1.00)	(0.25;0.48;1.00)	(1.00;1.00;1.00)	(0.25;0.42;1.00)	(1.00;1.00;1.00)

Table 6. Weights assigned to the criteria for ranking indicators.

Criterion	Weight
C1- Relevance	0.272
C2 - Measurability	0.243
C3 - Timeless	0.119
C4 - Reliability	**0.246**
C5 - Traceability	0.121

indicators by the categories of legal requirements of the RDC 296/2019.

4.7. Stage 7: Ranking indicators by regulatory categories using the fuzzy TOPSIS method

After assigning weights to the five criteria using the fuzzy AHP method, the quantitative evaluation of the degree of fulfilment of the proposed indicators to these criteria was initiated using the fuzzy TOPSIS method [15], [31], [36].

This evaluation included the following steps: *i)* establishment of matrices for the quantitative assessment of indicators by the categories of legal requirements of the regulation under consideration, filling them with linguistic terms, represented by triangular fuzzy numbers provided by the five participants; *ii)* definition of the Fuzzy Positive Ideal Solution and the Fuzzy Negative Ideal Solution (FPIS and FNIS), and definition of the distance to the FPIS (D+) and to the FNIS (D-); and *iii)* determination of the relative closeness to the ideal value, and ranking of the indicators by the categories of legal requirements of the regulation under consideration.

According to the categories of legal requirements identified in stage 1, namely label model (central and right columns of the label), leaflet model, and instructions for filling out the medical information, four decision matrices of indicators were built for the calculation of the proximity coefficient (CCi) values, as presented in [30]. Subsequently, the values of these matrices were normalised and weighted according to the weights assigned to the five criteria, as depicted in Table 6.

Matrices of the positive total distance (D+) and the negative total distance (D-) were generated, and the proximity coefficient (CCi) values were calculated using Excel® spreadsheet support, according to [15], [31], [36]. Owing to space limitations, these matrices cannot be presented in this paper but can be accessed in [30].

5. DISCUSSION

The findings presented in Section 4 of the study on monitoring and evaluating Brazil's pesticide labelling and leaflet regulation RDC 296/2019, align with and extend the existing body of literature, revealing several noteworthy contributions, limitations, and implications for policy and management. By integrating fuzzy logic with multicriteria decision-making (MCDM) methods, this study provides a conceptual framework that addresses two research gaps: *i)* the lack of conceptual models to define key indicators to evaluate the effectiveness of regulation on pesticide labels and leaflets at the national level; and *ii)* the need for a multi-criteria methodological approach combined with fuzzy logic theory to select and rank key indicators to monitor and evaluate the outcomes of pesticide labelling and packaging leaflet regulations.

The study distinguishes itself from previous works by combining the Analytical Hierarchy Process (AHP) and the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) within a fuzzy logic framework. This hybrid approach refines key indicator selection for regulatory monitoring and evaluation, ensuring greater flexibility and adaptability in addressing the inherent uncertainties of qualitative and quantitative assessments. In contrast, prior studies, such as Yazid et al. [18] and Peterson et al. [19], primarily focused on standardised performance indicators without leveraging such advanced, integrated methods.

Unlike studies focused on high-income nations, such as those by Persson et al. [17] and Emery et al. [22], this research addresses the unique challenges of pesticide regulation in a major agricultural exporter, such as Brazil. By aligning local practices with international standards, the study advances the applicability of the Globally Harmonized System (GHS) in a context characterised by diverse socio-economic and environmental conditions.

The development of a logic model that maps inputs, activities, outputs, and outcomes provides a systematic and visual representation of the regulation's Theory of Change (ToC). This tool aids in stakeholder communication and decision-making, addressing a key gap identified by Boelhouwer et al. [23] in hazard communication practices.

The identification and ranking of 69 indicators tailored to Brazil's RDC 296/2019 offers a more nuanced evaluation framework than previous works, which often relied on generic indicators or narrowly focused metrics. These indicators address critical aspects of toxicological information, safety precautions, and standardisation requirements.

Despite its contributions, the study is not without limitations. The reliance on expert judgment for indicator selection introduces potential biases, which, although mitigated by fuzzy logic, remain a concern. This limitation is consistent with critiques in the literature regarding expert-driven MCDM approaches (e.g., Emery et al. [22], and Choi et al. [24].

Furthermore, the scalability of the proposed framework to other regulatory contexts or sectors is yet to be established. The focus on compliance monitoring also leaves the downstream impacts of labelling improvements, such as changes in user behaviour and risk perception, unaddressed. While the study provides a thorough analysis of regulatory compliance, it does not directly address downstream impacts on user behaviour, such as farmers' comprehension and application of safety guidelines. Previous studies, such as Bagheri et al. [25], [27] and Patel and Mukhopadhyay [26], emphasised the need to evaluate the end-user engagement with hazard communication tools.

The proposed model offers a replicable framework for monitoring and evaluating compliance with labelling regulations, supporting Anvisa's role in ensuring that pesticide use aligns with international safety standards.

The emphasis on comprehensive key indicator selection needs capacity building among regulators and stakeholders.

Training programs and resource allocation are essential to operationalise the proposed framework, ensuring consistency in monitoring and evaluation.

By focusing on clear and standardised toxicological information, the study supports safer pesticide application, contributing to reduced incidences of poisoning and environmental harm. This aligns with global efforts to enhance sustainability in agricultural practices.

The adoption of a multicriteria methodological approach and its findings holds potential for adaptation in other developing economies that face similar challenges in aligning local practices with the GHS standards. The study's integration of fuzzy logic into regulatory monitoring frameworks sets a precedent for addressing complexity and uncertainty in diverse policy contexts.

6. CONCLUSIONS

This paper presented a conceptual model for ranking indicators to monitor and evaluate the expected outcomes of the current regulation on Brazil's pesticide and wood preservative labelling and packaging leaflets. The application of the model focusing on legal requirement categories established in RDC 296/2019 could effectively demonstrate its adequacy and usefulness in helping Anvisa monitor and evaluate label and packaging leaflet compliance nationally.

This study's application marks a significant step forward in hazard communication research. It bridges gaps identified in previous literature, providing practical tools for regulatory agencies, while highlighting areas for further exploration. Future research should focus on the behavioural impacts of improved labelling and leaflet compliance, the scalability of the proposed framework, and its adaptation to other regulatory contexts. These steps are critical for realising the broader goal of harmonising chemical safety practices globally.

The key strength of this study lies in its development and application of an advanced framework for ranking indicators associated with regulatory compliance. The inclusion of fuzzy logic to manage uncertainties in expert judgment significantly enhances the robustness and adaptability of the evaluation process. This innovation addresses a critical gap in the existing literature, in which traditional MCDM methods often fail to account for the ambiguities inherent in qualitative assessments.

Moreover, the study's focus on Brazil—a leading agricultural producer—introduces a vital perspective to the global discourse on pesticide regulation. While much of the prior research has concentrated on high-income nations, this study emphasises the challenges and opportunities unique to developing economies, such as resource constraints, linguistic diversity, and regional disparities in regulatory enforcement. By aligning local practices with the Globally Harmonized System (GHS), the research contributes to the international standardisation of pesticide labelling, while considering the socioeconomic realities of the Global South.

The identification and ranking of 69 key indicators tailored to the RDC 296/2019 categories further demonstrate the study's practical utility. These indicators provide a comprehensive framework for regulatory agencies, such as Anvisa, to effectively monitor and evaluate compliance, ensuring that pesticide labelling and leaflets clearly and reliably communicate safety information.

The findings hold significant implications for regulatory agencies, policymakers, and industry stakeholders. First, the study underscores the need for stakeholder collaboration. Engaging farmers, pesticide manufacturers, and public health officials in the evaluation process can foster a shared understanding of regulatory goals and ensure that labels and leaflets meet the diverse needs of end-users. This aligns with global best practices in regulatory design, which emphasise inclusivity and participatory approaches. Second, the study contributes to the broader sustainability agenda by promoting safer pesticide application practices. By improving the clarity and comprehensiveness of labelling information, the regulation can reduce incidents of human and environmental harm, supporting sustainable agriculture and public health outcomes.

Building on these findings, future studies should explore several avenues to advance the field:

- Investigate how improved labelling and leaflets influence farmers' comprehension, decision-making, and safety practices. Experimental studies could assess the effectiveness of redesigned labels in reducing pesticide misuse and associated health risks.
- Evaluate the applicability of the proposed framework to other regulatory domains, such as pharmaceuticals or industrial chemicals. Comparative studies could identify the contextual factors that influence its effectiveness.
- Examine the potential of digital tools, such as mobile apps or blockchain, to enhance data collection, indicator monitoring, and stakeholder communication. These technologies could address resource constraints and improve regulatory transparency.
- Conduct longitudinal evaluations to assess the regulation's impact over time, tracking changes in compliance rates, public health outcomes, and environmental indicators.
- Compare the implementation of similar regulations in different countries to identify best practices and common challenges. Such studies could serve as a basis for efforts to harmonize pesticide labelling standards globally.

AUTHORS' CONTRIBUTION

Conceptualisation: J.P.M., M.F.L.A; methodology: J.P.M., M.F.L.A; writing—original draft preparation: J.P.M.; writing—review and editing: M.F.L.A. All authors have read and agreed to the published version of the manuscript.

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