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

J P Medeiros[1], **M F L Almeida**[1]

[1] Graduate Program in Metrology, Pontifical Catholic University of Rio de Janeiro, Rio de Janeiro, 22451-900, Brazil

fatima.ludovico@puc-rio.br

Abstract. Pesticide labelling and packaging leaflets are essential communication instruments between pesticide companies, health professionals, regulatory agencies, farmers, and consumers within the agri-food chain. This paper presents a conceptual model for ranking indicators to monitor and evaluate the outcomes of the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil. The model applied to the Resolution of the Collegiate Board – RDC 296/2019, published by the National Health Surveillance Agency (Anvisa) in Brazil, could effectively demonstrate its adequacy and usefulness to help the Agency to monitor and evaluate label and packaging leaflet compliance with the regulatory framework on a national scale. The main results can be summarized as follows: (i) a fuzzy multicriteria tool for ranking indicators associated with the categories of legal requirements of the RDC 296/2019; and (iii) a set of 69 indicators ranked by these categories to be subsequently selected by the Agency.

1. Introduction

Nowadays, there is a growing concern about the responsible use of chemical substances in food production, especially pesticides, considered essential inputs for agricultural production and maintaining high productivity levels. Pesticide labelling and packaging leaflets are essential communication instruments between pesticide companies, health professionals, regulatory agencies, farmers, and consumers of final products in the agri-food chain. From the perspective of pesticide manufacturers, labels and packaging leaflets fixed or attached to the products should contain toxicological information, safety, and environmental warnings. In turn, regulatory agencies worldwide have determined that registered pesticides may only be legally used if they comply with the label and packaging leaflet legal requirements [1-3].

Brazil is one of the world's major food producers and exporters, and it ranked among the top countries in terms of pesticide use due to its significant agricultural production. For this sector, the National Health Surveillance Agency (acronym in Portuguese, Anvisa) declares its purpose to ensure that farmers in the coming years have more knowledge about the products used, making them partners in the control of the use of pesticides. It is responsible for Anvisa to evaluate the information related to human health submitted by companies in their labelling and packaging leaflets regarding the adequacy of their content and the relevance of the conveyed information needed to safely and efficiently meet the advancement of the agricultural sector. For this sector, the National Health Surveillance Agency (acronym in Portuguese, Anvisa) declares its purpose to ensure that farmers in the coming years have more knowledge about the products used, making them partners in the control of the use of pesticides. It is responsible for Anvisa to evaluate the information related to human health submitted by companies in their labelling and packaging leaflets regarding the adequacy of their content and the relevance of the conveyed information [4].

In the last decade, several cases of intoxication occurred in Brazil due to the inappropriate use of pesticides. According to the National Health Surveillance Report of Populations Exposed to Pesticides, more than 86 thousand cases of poisoning due to the inappropriate use of pesticides by rural producers were reported in 2018 [5].

Given the repercussion of events and the constant exposure of individuals who manipulate and apply such chemicals, Anvisa approved in 2019 a set of Resolutions of the Collegiate Directorate (acronym in Portuguese, RDC) and a Normative Instruction (acronym in Portuguese, IN). This research focused on the RDC 296/2019, approved on July 29, 2019, which provides legal requirements regarding toxicological information for pesticides' and wood preservatives' labels and package leaflets [6]. This Resolution provides a series of items to be followed by manufacturers when preparing labels and leaflets for pesticides, related products, and wood preservatives. All the standards established in it are harmonized with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) to achieve standardization of pesticide labels and packaging leaflets in Brazil following international practices.

From the perspective of helping Anvisa to monitor and evaluate compliance with the RDC 296/2019 on a national scale, this work presents a conceptual model for selecting and ranking indicators to monitor and evaluate the outcomes of the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil.

The paper is structured in five sections, with this introduction being the first. Section 2 summarizes the literature review, which examines previous works published between 2010 and 2023, focusing on the central research subjects. Briefly outlined in Section 3 is the research design and methodology. Section 4 introduces a conceptual model to rank indicators for monitoring and evaluating the expected outcomes of the current regulation on pesticide and wood preservative labelling and packaging leaflets in Brazil. Lastly, in Section 5, we discuss the distinctive features of the proposed model compared to previous studies analyzed in the literature review and provide a synthesis of the concluding remarks.

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 Harmonized System of Classification and Labeling of Chemicals (GHS) in different continents.

A first literature search focused on the subjects "monitoring and evaluation" and "logic model design" was performed on peer-reviewed articles indexed in the Scopus database, covering the period between 2010 and 2023. This first search strategy focused only on the most highly cited publications about the referred subjects [7-10]. A second search regarding multicriteria decision-making (MCDM) methods employed the keywords "multiple criteria decision-making", "MCDM", and "multicriteria decision-making", with Boolean operator OR. This search strategy yielded 25,834 documents and revealed that several researchers have attempted to combine MCDM methods for different applications, being the combination of the Analytical Hierarchy Process (AHP) [11] and Technique for Order Performance by Similarity to Ideal Solution (TOPSIS) [12] 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 yielded 34 publications. However, when these last results were combined with the previous ones associated with MCDM methods, we concluded that these methods have not yet been used by academicians and practitioners to rank and select indicators for monitoring and evaluating the degree of label and packaging leaflet compliance with applicable regulations 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 [13]. GHS plays a pivotal role in promoting responsible chemical management, aiming to enhance sustainability in chemical production and usage. By determining the specific characteristics of a given chemical (e.g., toxicity type), necessary steps can be taken to regulate and manage it safely and sustainably throughout its entire life cycle [14].

Among the analyzed empirical studies [14-25], several authors emphasize that the success of implementing GHS and regulations on pesticide labelling and packaging leaflets depends on various factors, such as political, economic, educational, and social aspects, which vary from country to country. 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 monitoring and evaluation (ME) field, focusing on pesticide labelling and packaging leaflets regulations, as discussed in the third 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 Rocha et al. [26], 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.

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 Globally Harmonized System of Classification and Labeling of Chemicals, in which the current regulation on pesticide and wood preservative labeling 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 monitoring and evaluation indicators for pesticide labeling and packaging leaflet regulation in Brazil.	Which components should be included in the logic model concerning the Brazilian regulation on pesticide and wood preservative labeling 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 labeling and packaging leaflets? [Section 4]
Validation (How to demonstrate the applicability of the conceptual model?)	Discussion of the results and implications of this research.	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 Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in different continents? What are the managerial implications of this research? [Section 5]

The first stage involves defining the problem and providing 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 led to the identification of two research gaps: (i) the first refers to the inexistence of conceptual models to define indicators to evaluate the standardization of information on pesticide labels and leaflets; (ii) the second gap is concerned with the use multicriteria decision support methods combined with fuzzy logic theory to select and rank 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) [11] and the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) [12] methods combined with fuzzy logic [27], considering the characteristics of these regulations and the review of MCDM methods.

The AHP method was proposed by Saaty [11], and the basic idea of this method is leaning 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 and then between the higher level of the hierarchical structure. Pairwise comparisons of criteria were conducted using Saaty's nine-point scale (Table 1).

Table 1. Saaty's nine-point scale [11]

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

To implement the AHP method to assign weights to criteria for ranking and selecting indicators associated with the RDC 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 [11].

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 utilized 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 [28].

The second method chosen to integrate the conceptual model was the TOPSIS method, introduced by Hwang and Yoon [12]. It is based on the concept that the chosen alternative should have the shortest distance from the positive ideal solution (PIS) and the farthest 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 [29].

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 [6]. Five specialists in the Monitoring and Evaluation (ME) and Metrology fields 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 are identified through a qualitative content analysis [30]. The results of this analysis included the cases of evidence of the existence of the problem; objectives of the regulation; expected outcomes, and categories of legal requirements to be subject to monitoring and evaluation. Important to highlight here the expected outcomes and categories of legal requirements as defined in the RDC 296/2019 [6].

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, minimizing 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 standardized warning symbols and phrases; (v) standardization 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; (viii) 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' active engagement in the implementation of pesticide label 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 perform 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 consists of building the logic model concerning the focused regulation, according to [10], as a basis for suggesting an initial list of indicators associated with each category of legal requirements that will be required 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, illustrating how inputs, activities, outputs, and outcomes are connected to achieve the regulation's intended goals and objectives. It presents a clear and logical sequence of cause-and-effect relationships, showing how resources and efforts lead to specific outputs and, ultimately, desired outcomes and impacts. The logic model helps stakeholders, particularly the regulator agencies understand the underlying assumptions, plan its implementation, monitor progress, and evaluate its effectiveness. It is a valuable tool for regulation design, communication, and evidence-based decision-making throughout its lifecycle.

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

In this stage, an initial list of 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 can be accessed in [31].

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 [32], five criteria for selecting good quality indicators were used in this stage, as presented in Table 2.

Table 2. 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.

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

In this stage, the AHP method combined with fuzzy logic [28] 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 [11, 27].

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?

Afterwards, the computational tool Fuzzy AHP Software® [34] was used to calculate the weights of the five criteria presented in Table 2. The results of the assignment of weights to the criteria defined by pairwise comparisons of the criteria are presented in Table 3, including the consistency rations (CR) inferior to 0.1, as defined in [11].

Table 3. 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 4 presents the matrix of paired comparison of decision criteria with triangular fuzzy numbers (TFN), calculated through the average participant judgments (P1, P2, P3, P4 and P5).

Table 4. Matrix of paired comparison of decision criteria with triangular fuzzy numbers

Criterion	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 5 shows the final weights calculated with the computational tool Fuzzy AHP Software®. These weights were considered in the next stage for ranking the proposed indicators by category of legal requirements of the RDC 296/2019.

Table 5. 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

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.

This evaluation comprised the following steps: (i) establishment of matrices for the quantitative assessment of indicators by category 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 fuzzy negative ideal solution (FPIS and FNIS) and definition of the distance to FPIS (D+) and to FNIS (D-); and (iii) determination of the relative closeness to the ideal value and ranking of the indicators by category 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 calculation of the proximity coefficient (CCi) values, following [29]. Subsequently, the values of these matrices were normalized and weighted according to weights assigned to the five criteria, as depicted in Table 5.

The matrices of positive total distance (D+) and negative total distance (D-) were generated, and the proximity coefficient (CCi) values were calculated using Excel® spreadsheet support, according to

[29]. Due to space limitations, these matrices could not be presented in this paper but can be accessed in [31].

By way of illustration, we present one of the four matrices, i.e., the matrix of indicators for the label model, corresponding to the right column of the label (Table 6).

Table 6. Decision matrix of indicators for the label model (right column of the label) evaluated in light of criteria C1 to C5

Indicators for Label Model (ILM) [Right column of the label]	Criteria														
	C1			C2			C3			C4			C5		
ILM1 – Inadequacy of the label due to the absence of the statement "BEFORE USING THE PRODUCT, READ THE INSTRUCTIONS ON THE LEAFLET CAREFULLY"	7.0	9.0	9.0	4.2	6.2	8.2	3.0	5.0	7.0	3.4	5.4	7.4	2.2	4.2	6.2
ILM2 – Inadequacy of the label due to the absence of phrases related to general precautions.	7.0	9.0	9.0	4.2	6.2	8.2	2.6	4.6	6.6	3.0	5.0	7.0	2.2	4.2	6.2
ILM3 – Inadequacy of the label due to the absence of phrases related to precautions during the preparation of the mixture.	7.0	9.0	9.0	4.2	6.2	8.2	2.6	4.6	6.6	3.4	5.4	7.4	1.8	3.8	5.8
ILM4 – Inadequacy of the label due to the absence of phrases related to precautions during handling.	7.0	9.0	9.0	4.2	6.2	8.2	3.4	5.4	7.4	3.4	5.4	7.4	1.4	3.4	5.4
ILM5 – Inadequacy of the label due to the absence of phrases related to precautions for seed treatment	7.0	9.0	9.0	4.2	6.2	8.2	3.0	5.0	7.0	3.8	5.8	7.8	1.8	3.8	5.8
ILM6 – Inadequacy of the label due to the absence of phrases related to precautions during product application.	7.0	9.0	9.0	4.2	6.2	8.2	3.4	5.4	7.4	3.4	5.4	7.4	1.8	3.8	5.8
ILM7 – Inadequacy of the label due to the absence of phrases related to precautions after product application	7.0	9.0	9.0	3.8	5.8	7.8	2.6	4.6	6.6	3.8	5.8	7.8	2.2	4.2	6.2
ILM8 – Inadequacy of the label due to the absence of a first aid	7.0	9.0	9.0	4.6	6.6	8.6	3.4	5.4	7.4	4.2	6.2	8.2	3.0	5.0	7.0
ILM9 – Inadequacy of the label due to the absence of an antidotes and treatment section.	7.0	9.0	9.0	4.2	6.2	8.2	3.8	5.8	7.8	4.2	6.2	7.8	2.2	4.2	6.2
ILM10 – Inadequacy of the label due to the absence of an emergency contact numbers section.	7.0	9.0	9.0	5.0	7.0	9.0	3.4	5.4	7.4	4.2	6.2	8.2	3.0	5.0	7.0
ILM11 – Inadequacy of the label due to the absence of the label stripe according to the RDC 296/2019.	7.0	9.0	9.0	4.6	6.6	8.6	4.2	6.2	8.2	4.6	6.6	8.6	2.6	4.6	6.6
Fuzzy weight	0.27	0.27	0.27	0.24	0.24	0.24	0.12	0.12	0.12	0.25	0.25	0.25	0.12	0.12	0.12

The final results in Table 7 correspond to 11 proposed indicators for the label model (right column of the label).

Table 7. Ranking of indicators for the label model (right column of the label) by proximity coefficient (CCi)

Indicators for Label Model (ILM) [Right column of the label]	D+	D-	CCi	Ranking
ILM1 – Inadequacy of the label due to the absence of the statement "BEFORE USING THE PRODUCT, READ THE INSTRUCTIONS ON THE LEAFLET CAREFULLY"	1.81	3.59	0.665	5
ILM2 – Inadequacy of the label due to the absence of phrases related to general precautions.	1.89	3.49	0.649	10
ILM3 – Inadequacy of the label due to the absence of phrases related to precautions during the preparation of the mixture.	1.90	3.49	0.647	11
ILM4 – Inadequacy of the label due to the absence of phrases related to precautions during handling.	1.87	3.53	0.654	9
ILM5 – Inadequacy of the label due to the absence of phrases related to precautions for seed treatment	1.82	3.58	0.663	7
ILM6 – Inadequacy of the label due to the absence of phrases related to precautions during product application.	1.81	3.58	0.664	6
ILM7 – Inadequacy of the label due to the absence of phrases related to precautions after product application	1.85	3.54	0.657	8
ILM8 – Inadequacy of the label due to the absence of a first aid	1.55	3.87	0.714	3
ILM9 – Inadequacy of the label due to the absence of an antidotes and treatment section.	1.65	3.75	0.695	4
ILM10 – Inadequacy of the label due to the absence of an emergency contact numbers section.	1.52	3.92	0.721	2
ILM11 – Inadequacy of the label due to the absence of the label stripe according to the RDC 296/2019.	1.48	3.96	0.728	1

5. Discussion and final remarks

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 the RDC 296/2019 could effectively demonstrate its adequacy and usefulness to help the Agency monitor and evaluate labels and packaging leaflets compliance nationally.

The results presented in Section 4 refer to a fuzzy multicriteria model for ranking indicators associated with the evaluation questions; and a set of 69 indicators ranked by category of the RDC 296/2019 legal requirements, to be subsequently chosen by the Regulatory Agency. In Section 4 (Item 4.7), we illustrated 11 indicators associated with one of the categories, i.e., the label model (right column of the label).

We highlight here the combination of fuzzy logic and two decision-making methods (AHP and TOPSIS methods) as a differential characteristic compared to previous empirical studies on the adoption of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and pesticide labelling and leaflets regulations in different continents [14-25].

The proposed model for ranking indicators, supported by the fuzzy AHP and fuzzy TOPSIS methods and the resulting indicators from its application, could benefit stakeholders involved in the regulation process of pesticide labelling and leaflets in the country. Notably, they can help Anvisa to monitor and evaluate compliance with the regulatory framework published in July 2019.

Overall, from the perspective of minimizing the exposure of rural producers/farmers to pesticides that may pose a risk to their health or are not in compliance with current health legislation, the results of this study can contribute to the continuous improvement of the entire regulatory process for pesticide labelling and leaflets during its implementation in Brazil and effective communication among research, regulatory, and chemical safety agencies.

References
[1] Rother H A 2018 *J. Environ. Sci. Health* **4** 10
[2] Dugger-Webster A, LePrevost C E 2018 *Curr. Opin. Environ. Sci. Health* **4** 19
[3] Pelaez V, Silva L and Araújo E 2013 *Sci. Public Policy* **40** 644
[4] Agência Nacional de Vigilância Sanitária 2023 *Agenda regulatória* Available at https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/agenda-regulatoria
[5] Brasil Ministério da Saúde Secretaria de Vigilância em Saúde Departamento de Vigilância em Saúde Ambiental e Saúde do Trabalhador 2018 *Agrotóxicos na Ótica do Sistema Único de Saúde*. Brasília: Ministério da Saúde
[6] Brasil Agência Nacional de Vigilância Sanitária 2019 *Resolução RDC 296/2019* Available at http://portal.anvisa.gov.br
[7] Weiss C H 1998 *Evaluation* 2.ed. (Upper Saddle River, NJ: Prentice-Hall)
[8] Patton M Q 1982 *Practical Evaluation* (Beverly Hills, CA: Sage)
[9] Owen J M and Rogers P G 1999 *Program Evaluation: Forms and Approaches* London: Sage
[10] W K Kellogg Foundation 2004 *Logic Model Development Guide* (Michigan: W K Kellogg Foundation)
[11] Saaty, T L 2008 *Int. J. Services Sciences* **1**(1) 83
[12] Hwang C L and Yoon K 1981 *Multiple Attributes Decision Making Methods and Applications* (Berlin: Springer)
[13] Unece 2023 *Globally Harmonized System of Classification and Labelling of Chemicals*. Available at https://unece.org
[14] Persson L et al. 2017 *Sustainability* **9** article ID 2176
[15] Peterson P J, Mokhtar M, Chang C and Krueger J 2010 *J. Environ. Manage.* **91** 1202
[16] Boelhouwer E *et al*. 2013 *J. Saf. Res.* **46** 145
[17] Shin S, Moon H I, Lee K S, Hong M K and Byeon S-H 2014 *Int. J. Environ. Res. Public Health* **11** 12001
[18] Emery S B *et al*. 2015 *Hum. Ecol. Risk Assess.* **21**(4)1062
[19] Farías P 2020 *Sustainability* **12**(21) 8912
[20] Yazid M F H A, Choo G and Mokhtar M 2020 *Saf. Health Work* **11**(2) 152
[21] Choi Y-H *et al.* 2020 *Int. J. Environ. Res. Public Health* **17** 1970
[22] Bagheri A, Emami N, Damalas CA 2021 *Pest Manag. Sci.* **77** 2903
[23] Bagheri A, Pirmoazen S and Allahyari M S 2021 *Environ. Sci. Pollut. Res.* **28** 17812
[24] Shalaby S E S et al. 2022 *Egypt. J. Chem.* **65**(6) 367
[25] Patel G and Mukhopadhyay P 2022 *Hum Ecol Risk Assess* **28**(1) 22
[26] Rocha W L L, Almeida M F L and Calili R F 2023 *Sustainability* **15**(1) article ID 682
[27] Zadeh L A 1965 *Inf. Control.* **8** 338
[28] Chang D Y 1996 *Eur. J. Oper. Res.* **95** 649
[29] Chen C T 2000 *Fuzzy Sets Syst.* **114** 1
[30] Krippendorff K 2018 *Content Analysis* 4th ed. (Washington DC: Sage Publications, Inc)
[31] Medeiros J P 2021 *Monitoring and evaluation of regulation on pesticides, related products, and wood preservatives labeling and packaging leaflets in Brazil* M.Sc. Dissertation Available at https://doi.org/10.17771/PUCRio.acad.54323
[32] Görgens M and Kusek J Z 2009 *Making Monitoring and Evaluation Systems Work* Washington, DC: The International Bank for Reconstruction and Development. The World Bank
[33] Onlineoutput 2023 *Software fuzzy AHP*. Available at http://www.onlineoutput.com/fuzzy-ahp-software/