Monitoring and evaluation of food allergen labeling regulation: a selection and ranking model for compliance indicators and respective metrics

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Abstract - The aim of this article is to propose a selection and ranking model for compliance indicators and metrics concerning food allergen labeling regulations, after their implementation at national or regional levels. Within the institutional contexts in which the research is situated, it is assumed that this effort will provide the regulatory agencies as well as other actors involved in the implementation of food allergen labeling regulations, the proper tools for monitoring and evaluating their degree of compliance. During the applied phase, an empirical study on the food allergen labeling regulation in Brazil was developed, for validating the proposed model on a national basis. A logical framework for defining an initial list of indicators was combined with two multi-criteria decision making (MCDM) methods aiming at the selection and final ranking of indicators and metrics by category of legal requirements. The main results are a selection and ranking model for indicators and metrics for measuring the degree of compliance of a given food allergen labeling regulation, after its implementation; and a consistent set of indicators and metrics for monitoring and evaluating the food allergen labeling regulation in Brazil, ranked by each category of legal requirements.

1. Introduction

Nowadays, food labeling provides an important interface between manufacturing and distribution companies and consumers. Food labels bring information about the food and its ingredients, their nutrition value; origin; shelf life; and how to use and store the food.

To define the categories of information that must always be declared on a food label and to provide an appropriate framework for the control of voluntary labeling are the roles of food security regulators. In general, the information categories fall into two main classes: (i) information concerning public health and safety reasons; and (ii) information required to facilitate consumers’ healthy choice or to prevent misleading conducts of food manufacturing and distribution companies [1].

In this context, the aim of this article is to propose a model for selecting indicators and respective metrics for monitoring and evaluating (ME) the degree of compliance with food allergen labeling regulations, after their implementation at national or regional levels.
2. Theoretical background
A first systematic literature search focused on the theme “monitoring and evaluation” (ME) was performed on peer-reviewed articles indexed in Scopus; Web of Science; and Science Direct databases, covering the period between January 1980 and December 2016. The search strategy focused on the most highly cited publications about the referred theme [2; 3; 4; 5; 6]. Some attempts concerning these works will be detailed in the final version of this paper.

A second search focused on multi-criteria decision making (MCDM) methods, by using the keywords "multiple criteria decision-making", "MCDM", "multi-criteria decision-making", with Boolean operator OR. This search strategy yielded a total of 5,011 publications and revealed that several researchers have attempted to combine MCDM methods for different applications.

Finally, a third literature search focused on food labeling regulation, in general, covering the period between January 2000 and December 2016, yielded 50 publications. However, when this result was combined with the previous results associated with MCDM methods, we conclude that these methods have not been used by academicians and practitioners to select indicators and metrics for monitoring and evaluating the degree of compliance with food labeling regulations in general.

Considering the characteristics of food labeling regulations and the review of MCDM methods, the following methods were combined to the logical framework designed according to the W. K. Kellogg Foundation guidelines [7]. They are (i) Analytical Hierarchy Process (AHP) and Technique for Order Performance by Similarity to Ideal Solution (TOPSIS).

AHP was proposed by Saaty [8], 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, the AHP method is a pairwise comparison in a small part of the hierarchical structure and then between the higher level of hierarchical structure. However, this method presents some disadvantages, as follows: weighting each criterion has a significant influence on the final alternative score, as weighting criteria in this method are judgmental and based on decision maker preference.

The second selected method refers to the Technique for Order Preference by Similarity to Ideal Solution or TOPSIS, introduced by Hwang and Yoon [9]. 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).

3. Methodology
The research methodology followed a procedural framework of analysis based on a model developed by Dibbern et al. [10] to provide an underlying structure and an approved course of action. Firstly, a literature review focused on the central research themes: (i) monitoring and evaluation, including ME logical framework design; (ii) multiple-criteria decision making (MCDM) methods, with an attempt to select the best methods to be considered in the context of food labeling regulations, in general.

The literature review covered the main sources of peer-reviewed scientific publications about these themes, such as Scopus; Web of Science; and Science Direct. Additionally, Google Scholar was accessed to complement the search results. The analysis of current state of research on these central themes led to the identification of research gaps and unsolved problems in the field of monitoring and evaluation of food labeling regulations.

Secondly, formal modeling was used to develop a selection and ranking model for compliance indicators and metrics concerning food allergen labeling regulations, after their implementation at national or regional levels.

Third, an empirical study focusing on the food allergen labeling regulation in Brazil involved managers and specialists on Food Quality and Metrology to validate the proposed model from the perspective of its application in another national or regional contexts.
The model encompasses seven main steps: (i) analysis of objectives and expected results of a given food allergen labeling regulation; (ii) identification of key stakeholders interested in the implementation of regulation; (iii) definition of types of indicators (key indicators; complementary indicators; and specific indicators); (iv) definition of criteria for selection and classification of indicators, considering eliminatory and classificatory criteria; (v) proposition of ‘candidate’ indicators; (vi) application of AHP method for weighting criteria concerning the selection and ranking of proposed ME indicators; and (vii) use of TOPSIS method for the final ranking of the proposed indicators and respective metrics for monitoring and evaluation a given food allergen labeling regulation.

4. Illustrative case: monitoring and evaluation of food allergenic labeling regulation in Brazil

The main results are highlighted as follows: (i) a selection and ranking model for compliance indicators and metrics concerning food allergen labeling regulations, after their implementation at national or regional levels; and (ii) a consistent set of indicators and metrics for monitoring and evaluating the compliance of the Brazilian food allergen labeling regulation, generated during the empirical study developed in this country.

The matrix creation of quantitative monitoring and evaluation indicators has to start characterizing the categories of legal labeling requirements in Brazil, identifying the relevant issues to be evaluated in each category, as can be seen in table 1, which is the first step of the proposed methodology.

| Category of legal requirements                                                                 | Information to be presented on the allergenic food label                                                                 |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Attendance of mandatory information on packaged food labels, including allergens and derivatives, following Anvisa Resolution RDC nº 259, of September 20, 2002 [11]. | Name of the sale food, List of ingredients, Net contents, Origin identification. Name or business name and address of the importer in the case of imported food, Batch identification, Expiration date, Instructions on preparation and food use, when necessary. |
| The intentional presence of allergenic foods and their derivatives, according to Anvisa Resolution RDC nº 26, of July 2, 2015 [12]. | The statement "Allergic: It contains [common names of foods that cause food allergies].", The statement "Allergic: It contains derivatives of [common names of foods that cause food allergies].", The statement "Allergic: It contains [common names of foods that cause food allergies] and derivatives," as appropriate. |
| The possibility of cross contamination with allergenic foods and their derivatives, according to Anvisa Resolution RDC nº 26, of July 2, 2015 [11]. | The statement "Allergic: May contains [common names of foods that cause food allergies]." |
| Attendance of mandatory declaration on packaged food labels - "It contains gluten" or "It does not contain gluten" - according to Brazilian Law No. 10,674 of May 16, 2003 [13]. | The statement "It contains gluten" or "It does not contain gluten," as appropriate. |
| Mandatory information adequacy on allergenic labels and derived packaged foods about applicable regulations' parameters. | Mandatory information adequacy - parameter "expression", Mandatory information adequacy - parameter "clarity," Mandatory information adequacy - parameter "visibility," Mandatory information adequacy - parameter "font size," Mandatory information adequacy - parameter "color contrast," Mandatory information adequacy - parameter "highlight." |
After that, as a second step, it is necessary to identify the key stakeholders of the regulation to be monitored and evaluated, which in this case are: (i) National Sanitary Surveillance Agency (Anvisa); (ii) State and Municipal Sanitary Surveillance Agencies (Visa); (iii) food manufacturers and importers; (iv) allergic consumers, including associations.

Step 3 consisted of defining the types of indicators that will be required to meet different interests identified in step 2, namely: key indicators; complementary indicators; and specific indicators.

Step 4 comprised to determine the eliminatory criteria (must be attended) and classificatory criteria to select and rank the indicators, using the hybrid AHP-TOPSIS method. The criteria chosen for the addressed problem were:

- **Eliminatory criteria:** (i) stakeholder information needs’ attendance; (ii) traceability over time; (iii) representativeness (in relation to regulation objectives and requirements);
- **Classificatory criteria:** (i) measurability; (ii) information availability; (iii) objectivity; (iv) simplicity.

In Step 5, it was to propose the initial matrix of the candidate indicators, considering the legal requirements described in table 1. In this step, the authors decided to deploy the ME matrix in five matrices associated to categories of legal requirements of the applicable regulation.

In Step 6 the AHP method was used to define the weights of the four classification criteria, namely; (i) measurability; (ii) availability, when necessary; (iii) objectivity; and (iv) simplicity. It was evaluated in Step 7 the existence of conflicts of choice between two or more options of indicators, through the quantitative analysis, with the support of the TOPSIS method.

The indicators chosen in Step 5, by using the hybrid AHP-TOPSIS method, are summarized in table 2.

### Table 2. A general list of ME indicators for regulation in focus, ranked by legal requirements' category.

| Legal requirements’ category | Indicators (I)                                                                 | Position in the ranking |
|-----------------------------|-------------------------------------------------------------------------------|-------------------------|
| The presence of general mandatory information on allergen packaged food labels and derivatives. | I2 - Label inadequacy due to the absence of ingredient list.                  | 1st                     |
|                             | I3 - Label inadequacy due to information lack of net contents.                | 1st                     |
|                             | I4 - Label inadequacy due to the absence of origin identification.            | 2nd                     |
|                             | I6 - Label inadequacy due to the absence of batch identification.            | 3rd                     |
|                             | I7 - Label inadequacy due to information lack of expiration date.            | 4th                     |
|                             | I1 - Label inadequacy due to the absence of the name of seller.              | 5th                     |
|                             | I8 - Label inadequacy due to the absence of preparation instructions and use of packaged food, when necessary. | 6th                     |
|                             | I5 - Label inadequacy due to the absence of the firm name or business name and importer address, in the case of imported food. | 7th                     |
| The intentional presence of allergenic foods and their derivatives. | I9 - Label inadequacy due to the absence of the statement "Allergic: It contains [common food names that cause food allergies]". | 1st                     |
|                             | I10 - Label inadequacy due to the absence of the statement "Allergic: It contains derivates of [common food names that cause food allergies]". | 1st                     |
|                             | I11 - Label inadequacy due to the absence of the statement "Allergic: It contains [common food names that cause food allergies] and derivates, as appropriate". | 1st                     |
| The possibility of cross-contamination with allergenic foods and their derivatives. | I12 - Label inadequacy due to the absence of the statement "Allergic: It may contain [common food names that cause food allergies]". | 1st                     |
The presence of the mandatory statement "It contains gluten" or "It does not contain gluten" on packaged food labels.

I13 - Label inadequacy due to the absence of the statement "It contains gluten" or "It does not contain gluten," as appropriate. 1st

Mandatory adequacy information on labels of allergenic and derivatives' packaged foods about the applicable regulations' parameters.

I17 – Label inadequacy in one or more mandatory information concerning parameter "font size." 1st
I16 - Label inadequacy in one or more mandatory information concerning parameter "visibility." 2nd
I14 - Label inadequacy in one or more mandatory information concerning parameter "expression." 3rd
I18 - Label inadequacy in one or more mandatory information concerning parameter "color contrast." 4th
I15 - Label inadequacy in one or more mandatory information concerning parameter "clarity." 5th
I19 - Label inadequacy in one or more mandatory information concerning parameter "highlight." 6th

By way of illustration, in table 3 we present the metrics associated to the eight ME indicators ranked in the first position in each legal requirements’ category.

Table 3. Metrics associated to the eight ME indicators ranked in the first position in each legal requirements’ category.

| Indicators (I) | Metrics (M) |
|----------------|-------------|
| I2 - Label inadequacy due to the absence of ingredient list. | M2.1 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to absence of ingredient list (by food category or by health surveillance area) [without unit].
M2.2 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to absence of ingredient list / total of labels of allergenic and derivatives’ packaged foods (by food category or by health surveillance area) [%]. |
| I3 - Label inadequacy due to information lack of net contents. | M3.1 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to information lack of net contents (by food category or by health surveillance area) [without unit].
M3.2 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to information lack of net contents / total of labels of allergenic and derivatives’ packaged foods (by food category or by health surveillance area) [%]. |
| I9 - Label inadequacy due to the absence of the statement "Allergic: It contains [common food names that cause food allergies]". | M9.1 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to the absence of the statement "Allergic: It contains [common food names that cause food allergies]" (by food category or by health surveillance area) [without unit].
M9.2 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to the absence of the statement "Allergic: It contains [common food names that cause food allergies]" / total of labels of allergenic and derivatives’ packaged foods (by food category or by health surveillance area) [%]. |
| I10 - Label inadequacy due to the absence of the statement "Allergic: It contains derivates of [common food names that cause food allergies]". | M10.1 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to the absence of the statement "Allergic: It contains derivates of [common food names that cause food allergies]" (by food category or by health surveillance area) [without unit].
M10.2 – Number of non-conforming labels of allergenic and derivatives’ packaged foods due to the absence of the statement "Allergic: It contains derivates of [common food names that cause food allergies]" / total of labels of allergenic and derivatives’ packaged foods (by food category or by health surveillance area) [%]. |
From the results presented in this section, it was possible to demonstrate the applicability of the proposed model. The definition of indicators and respectively metrics were developed and applied in the institutional context of the regulation on labeling of allergenic foods in Brazil [14]. The main result of this research consists of a list of 19 indicators ranked by degree of compliance with the classification criteria and legal category requirements. Due to space limitations, we presented only the metrics associated to the ME indicators ranked in first position in each legal requirements' category. Nevertheless, all the metrics can be found in detail in Criollo [15].

5. Conclusion
Evaluating the degree of compliance with food labeling regulations is still an open problem for academicians, practitioners, and policymakers. In this paper, an attempt was made to present a conceptual model for monitoring and evaluating food allergen labeling regulations, with the support of two multi-criteria decision methods.

The applicability of an integrated MCDM approach for selecting and ranking indicators and metrics for monitoring and evaluating the degree of compliance with food allergen labeling regulations at national or regional levels could be demonstrated through an empirical study on the Brazilian regulation on this issue. In general, the results of this research can contribute for the continuous improvement of the whole food
allergen labeling regulation process after its implementation and an effective communication of agencies involved in food safety research, regulation and education.

6. References

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