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Posted Date: 21 June 2023

doi: 10.20944/preprints202306.1556.v1

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Article

Food Risk Analysis: Towards a Better Understanding of “Hazard” and “Risk” in EU Food Legislation

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Abstract: For risk communication, it is important to understand the difference between “hazard” and “risk”. Definitions can be found in Codex Alimentarius and the European Union (EU) General Food Regulation (EC) No 178/2002. The use of these terms as synonyms or their interchange is a recurrent issue in the area of food safety, despite awareness-raising messages sent by EFSA (European Food Safety Authority) and other interested entities. A quick screening of EU’s food regulations revealed several inconsistencies. Hence, it was considered necessary to further investigate if regulations could act as a source for this problem. A software tool was developed to support the detection and listing of inconsistent translations of “hazard” and “risk” in certain EU food regulations. Subsequently, native-speaking experts working in food safety, from each EU country, were asked to provide their individual scientific opinion on the prepared list. All data was statistically analyzed after applying numerical scores (1-5) describing different levels of consistency. Results showed that the most common problem was the interchange of “hazard” with “risk” and vice versa. This lack of consistency can create confusion that can further translate into misjudgments at food risk assessment and communication level.

Keywords: risk analysis; risk communication; hazard; risk; food regulation; food safety

1. Introduction

Food safety remains a public health priority and a global responsibility of the governments of EU countries in their politics and long-term strategies [1–3]. Moreover, food safety is intensively discussed in the current context of climate change [4–8]. In an effort to minimize the contribution to global greenhouse gas emissions (GHG), food systems are undergoing some radical changes that will directly affect the field of food safety [9–13]. The move toward more sustainable food and agriculture presents new challenges not only for food risk assessors, but also for managers and the general public, which is composed of consumers [14]. Before the new challenges of future food systems can be addressed by redesigning food safety assessment strategies, it is essential to review and improve certain aspects that still affect the understanding of ‘food risk analysis’ as a whole [15]. Of particular importance in this case is risk communication and, concomitantly, a clear understanding of the specific terminology used in risk assessment and management [16,17].

The terms “hazard” and “risk”, in the context of food safety, first appeared more than 20 years ago in the Codex Alimentarius, then in Regulation (EC) No. 178/2002 [18] and other European Union regulations that are part of food law. Unfortunately, the distinction between these two has always been problematic [19]. There is a minimal number of studies on this topic, of which very few related to food safety. In an empirical study, Scheer et al. (2014) [20] concludes that “hazard” and “risk” are perceived very differently depending on the perspective of the stakeholders, regardless of their definition in the Codex Alimentarius [21]. Moreover, an online survey by Wiedemann et al. (2010) [22] revealed that numerous people cannot distinguish between the two notions, but rather mix hazard and risk aspects. In studies which are not related to food safety, the same issue appears,

indicating the exercise of differentiating between “hazard” and ‘risk’ is not an easy one. In 2020, Freudenstein et al. [23], concluded that risk communication needs to develop means for empowering the public to differentiate between hazards and risks after an online survey on the topic radiofrequency electromagnetic fields (RF EMF) and health. In the subsequent years, the European Food Safety Authority (EFSA) has repeatedly urged a distinction between the two terms [24,25].

In accordance with the Codex Alimentarius, the General Food Law Regulation (EC) No. 178/2002, adopted by the European Parliament and the Council, defined the two terms as follows:

- “Hazard” is a biological, chemical or physical substance in, or a condition of a food or feed that may have an adverse effect on health;
- “Risk” is a function of the probability of an adverse health effect and the severity of that effect resulting from a hazard.

These definitions are also reproduced in Regulation (EU) 2017/625 [26] with minor changes that do not effect the intended meaning, as follows:

- “Hazard” means an agent or condition that may have potentially harmful effects on human, animal or plant health, animal welfare or the environment;
- “Risk” is a function of the likelihood of an adverse health effect on human, animal, or plant health, animal welfare, or the environment and the severity of that effect resulting from a hazard.

In the European Community (EC) the definitions of “hazard” and “risk” should be uniformly adopted in national legislation. The message conveyed by legal documents must be unambiguous and leave no room for interpretation [27]. Risk communication in this form should minimise consumer confusion, promote understanding of risk assessment and risk management, and increase public confidence in food quality and safety measures [28]. Currently, food regulations adopted in English by the EC are translated into national languages, hence translations can be inconsistent. This is because either there are no appropriate expressions in other languages to distinguish between “hazard” and “risk” [29,30] or simply because translators themselves misunderstand the terminology.

The aim of this study is to identify, compare, and critically analyse the terms “hazard” and “risk” in the original English versions of some important food regulations (EU) 2002/178; (EU) 2004/852 [31]; (EU) 2004/853 [32]; (EU) 2017/625; (EU) 2019/1381 [33] and their equivalents in the official EU languages. We also compare the most recent regulation with the oldest in terms of the number of discrepancies confirmed by us and by experts. The analysis of the current state of official regulations will allow policy-makers to plan further awareness-raising activities in EU Member States in order to introduce correct terminology.

2. Materials and Methods

2.1. Selection of Regulations

Several EU food regulations were screened to find the most relevant to food safety, which include risk assessment terminology. These are, for example, hazard, risk, hazard analysis, risk assessment, risk analysis. Based on this criterion and their undeniable importance in practice, the following food regulations were selected: Regulation (EU) 2002/178 on general principles and requirements of food law, Regulation (EU) 2004/852 on food hygiene, Regulation (EU) 2004/853 on specific hygiene rules for food of animal origin, Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, and the single version of Regulation (EU) 2019/1381 on the transparency and sustainability of EU risk assessment in the food chain. All regulations are publicly available on EUR-Lex, the official website for European Union law [34]. With the exception of Regulation (EU) 1381/2019, which was available in a single version, an original act and the latest versions were extracted for each regulation. The most recent versions or new versions at the time of the search were as follows: 26/05/2021 version of Regulation (EU) 2002/178, 24/03/2021 version of Regulation (EU) 2004/852, 28/10/2021 version of Regulation (EU) 2004/853, 28/10/2021 version of Regulation (EU) 2017/625). In the comparison between the old and new versions of the

document, the so called legal act was considered the old version. The purpose of this comparison was to examine improvements in the translation of “hazard”, “risk” and related constructions such as “hazard analysis”, “risk assessment” and “risk analysis”.

2.2. Software Development

A software tool HA-RI was developed in Java (Spring Framework) to compare two regulations, one in English and one in another language, to find inconsistent translations of “hazard” and “risk” or other structures related to food risk assessment: Risk Assessment, Risk Analysis, Hazard Analysis. The tool was the solution for quick screening of multiple food regulations and their document versions. The tool was developed for individual use, but permission to access can be granted to users upon requests. For more details on the development and features, see Supplementary Material 1.

2.2.1. Creation of inconsistency tables for the EU languages

The input data for the software tool HA-RI were the first (in this case English) and second language, the URL address of the selected legislation for the first and second language and the words for hazard and risk for both selected languages. The form for entering the data into the program is shown in Figure 1. Figure 2 shows the part of the output document in PDF format where all inconsistencies and consistencies are marked in red and yellow, respectively. Finally, the tables of inconsistencies were created in Excel in a form suitable for statistical analysis and graphical representation.

Welcome!
The page below helps you find hazards and risks between two languages.
Please fill the form below and press "Process differences".

First language configuration

First Language Label

English

First Language URL

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&from=EN

First Language **Hazard** with synonyms. Add multiple words with ';' between them.

hazard

First Language **Risk** with synonyms. Add multiple words with ';' between them.

risk

First Language **Hazard Accepted Keywords**. Add multiple words with ';' between them.

First Language Accepted Keywords

First Language **Hazard Banned Keywords**. Add multiple words with ';' between them.

First Language Banned Keywords

Second Language Label

Romanian

Second Language URL

https://eur-lex.europa.eu/legal-content/RO/TXT/PDF/?uri=CELEX:32002R0178&from=EN

Second Language **Hazard** with synonyms. Add multiple words with ';' between them.

pericol

Second Language **Risk** with synonyms. Add multiple words with ';' between them.

risc

Second Language **Hazard Accepted Keywords**. Add multiple words with ';' between them.

First Language Accepted Keywords

Second Language **Hazard Banned Keywords**. Add multiple words with ';' between them.

First Language Banned Keywords

Second Language **Risk Accepted Keywords**. Add multiple words with ';' between them.

First Language Accepted Keywords

Second Language **Risk Banned Keywords**. Add multiple words with ';' between them.

First Language Banned Keywords

Process differences

Figure 1. Inputs for the analysis of inconsistencies in Regulation (EU) 2002/178, English vs Romanian.

2.3. *Input from Food Expert*

In January 2022, lists of inconsistencies in legislations due to translations were formulated. The first invitation to experts who were supposed to comment on these inconsistencies was sent to native speakers of various official EU languages. The reason for requesting their assistance was the fact that we, the authors of the presented study, are native speakers of Romanian (RO) and Slovenian (SL) and might thus have different opinions when analyzing inconsistencies in the translation of “hazard” and “risk” between English and other official EU languages. The validation or invalidation of our results was therefore considered useful and crucial for the interpretation of the final result.

The request was addressed to experts with different backgrounds (e.g., veterinarians, food technologists, nutritionists, biologists, etc.) trained or active in food risk assessment and communication. The expert group was composed of EU-FORA (Food Risk Assessment Programme, EFSA) Cycle 2021-2022, EU-FORA alumni from previous cohorts, representatives from EFSA Focal Points, and other proposed experts. At least one expert with native language in the following main EU languages had to accept our invitation: Bulgarian (BG), Czech (CS), Spanish (ES), Danish (DA), German (DE), Estonian (ET), Greek (EL), French (FR), Croatian (HR), Italian (IT), Latvian (LV), Lithuanian (LT), Hungarian (HU), Dutch (NL), Polish (PL), Portuguese (PT), Romanian (RO), Slovak (SK), Slovenian (SL), Finnish (FI), and Swedish (SV). No expert in Maltese was available at the time of the study. We performed the inconsistencies assessment for all 23 EU languages, and our opinion was the only one given for Romanian (RO) and Slovene (SL) inconsistencies. In total, the opinions of twenty-seven experts for 22 EU languages were included in the present study.

2.4. *Analysis*

First, the experts provided synonyms for “hazard”, “risk”, and related structures in their own languages (Supplementary Material 2). Second, the selected regulations were reviewed by HA-RI. The act in English of each selected regulation was compared with the corresponding version in BG, CS, ES, DA, DE, ET, EL, FR, HR, IT, LV, LT, HU, NL, PL, PT, RO, SK, SL, FI, SV. The same was applied to the document versions mentioned in section 2.1.

Below is English language.

doc-first-language.p...7 / 2491%+🔍🔄⬇️🖨️⋮

‘Food’ shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC (*) and 92/73/EEC (*);

(e) cosmetics within the meaning of Council Directive 76/768/EEC (*);

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (*);

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

(h) residues and contaminants.

producing, processing or storing feed for feeding to animals on his own holding;

6. ‘feed business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

7. ‘retail’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

8. ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

9. ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a **hazard**;

10. ‘risk analysis’ means a process consisting of three interconnected components: **risk** assessment, **risk** management and **risk** communication;

11. ‘risk assessment’ means a scientifically based process consisting of four steps: **hazard** identification, **hazard** characterisation, exposure assessment and **risk** characterisation;

12. ‘risk management’ means the process, distinct from **risk** assessment, of weighing policy alternatives in consultation with interested parties, considering **risk** assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

Article 3

Other definitions

For the purposes of this Regulation:

1. ‘food law’ means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution

(*) OJ 22. 9.2.1965, p. 369, Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

(*) OJ L 297, 13.10.1992, p. 8.

(*) OJ L 262, 27.9.1976, p. 169, Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).

(*) OJ L 359, 8.12.1989, p. 1, Directive as last amended by Directive 92/41/EEC (OJ L 138, 11.6.1992, p. 30).

Below is Romanian language.

doc-second-languag...7 / 2491%+🔍🔄⬇️🖨️⋮

„Produsele alimentare” nu includ:

(a) hrana pentru animale;

(b) animalele vii, în afara cazurilor în care ele sunt pregătite pentru introducerea pe piață pentru consumul uman;

(c) plantele înainte de a fi recoltate;

(d) medicamentele în sensul specificat de Directivă 65/65/CEE (*) și 92/73/CEE (*) ale Consiliului;

(e) cosmeticele în sensul Directivei 76/768/CEE (*) a Consiliului;

(f) tutunul și produsele din tutun în sensul Directivei 89/622/CEE (*) a Consiliului;

(g) substanțele stupefiante sau psihotrope în sensul Convenției Unice asupra substanțelor stupefiante din 1961 și al Convenției Organizației Națiunilor Unite privind Substanțele Psihotrope din 1971;

(h) reziduurile și substanțele contaminante.

Articolul 3

Alte definiții

În sensul prezentului regulament:

1. „Legislație alimentară” înseamnă actele cu putere de lege și actele administrative referitoare la produse alimentare, în general, și la siguranța produselor alimentare în special,

(*) JO 22. 9.2.1965, p. 369, directivă astfel cum a fost modificată ultima dată prin Directiva 93/39/CEE (JO L 214, 24.8.1993, p. 22).

(*) JO L 297, 13.10.1992, p. 8.

(*) JO L 262, 27.9.1976, p. 169, directivă astfel cum a fost modificată ultima dată prin Directiva 2000/41/CE a Comisiei (JO L 145, 20.6.2000, p. 25).

(*) JO L 359, 8.12.1989, p. 1, directivă astfel cum a fost modificată ultima dată prin Directiva 92/41/CEE (JO L 138, 11.6.1992, p. 30).

producerea, prelucrarea, depozitarea, transportul sau distribuția hranei pentru animale, incluzând orice producător care produce, prelucurează sau depozitează hrană pentru animale în propria sa unitate;

6. „operator cu activitate în domeniul hranei pentru animale” înseamnă persoanele fizice sau juridice responsabile pentru asigurarea respectării cerințelor legislației alimentare în întreprinderea ce operează în sectorul nutriției animalelor aflată sub controlul său;

7. „ comerț cu amănuntul ” înseamnă manipularea și/sau prelucrarea produselor alimentare și depozitarea lor în punctele de vânzare sau livrare către consumatorul final și include terminalele de distribuție, operațiunile de catering, cantine de fabrică, catering instituțional, restaurante și alte operațiuni similare în domeniul serviciilor alimentare, magazine, centre de distribuție tip supermarket și puncte de vânzare en gros;

8. „introducerea pe piață” înseamnă deținerea produselor alimentare sau a hranei pentru animale în scopul vânzării, inclusiv oferirea pentru vânzare sau orice altă formă de transfer, indiferent dacă este gratuită sau nu, și înșușirea vânzării, distribuția și alte forme de transfer;

9. „risic” înseamnă o funcție a probabilității unui efect negativ asupra sănătății și gravitatea aceluși efect, determinat de un **pericol**;

10. „analiza **risicului**” înseamnă un proces constând din trei componente interconectate: evaluarea **risicului**, gestiunea **risicului** și comunicarea **risicului**;

11. „evaluarea **risicului**” înseamnă un proces cu baze științifice, constând din patru etape: identificarea **pericolului**, caracterizarea **pericolului**, evaluarea expunerii și caracterizarea **risicului**;

12. „gestiunea **risicului**” înseamnă procesul, diferit de evaluarea **risicului**, de apreciere a politicilor alternative prin consultarea părților interesate, luând în considerare evaluarea **risicului** și alți factori legitimi și, dacă este necesar, selectând opțiunile de prevenire și control adecvate;

Figure 2. Results after the analysis of inconsistencies in Regulation (EU) 2002/178, English vs Romanian.

After screening, the results were recorded and the surveys were prepared as tables in Excel for the native experts. The inconsistencies to be discussed with the native experts were very specific and related to particular paragraphs of food legislation where deviations from the correct translation were found. For each inconsistency, the exact location in the legislation was provided by page and paragraph so that it could be easily verified in the case. An observation in the form of an objective question to the native speaker (e.g., “Is ‘hazard’ translated as ‘risk’?”, etc) to obtain his or her response was provided (Supplementary Material 3). Different combinations of terms lead to selected inconsistencies, e.g., H-R is when, “risk” is used instead of “hazard” (Table 1).

Table 1. Different combinations of terms for the inconsistencies.

Short name (Code)	Regulation in English	Translation into national language
R-H (1 or T1)	Risk	Hazard
H-RF (2 or T2)	Hazard	Risk Factor
RA-RD (3 or T3)	Risk Assessment	Risk Determination
H-SD (4 or T4)	Hazard	Source of Danger
H-R (5 or T5)	Hazard	Risk

T1, T2, T3, T4, and T5 were used for the agreed number of inconsistencies between experts and authors, while T1a, T2a, T3a, T4a, and T5a for the number of inconsistencies detected by authors in Supplementary Material 5.

Our opinion was not included in the survey to obtain an objective response from the experts. To quantify the results, a scoring system for the responses was introduced. The quantitative codes ranged from 1 to 5, as explained in Table 2. The inconsistencies found by us were marked with 5. Our definition of terms was based on Regulation (EU) 2002/178 and Regulation (EU) 2017/625, as well as synonyms previously provided by the experts. The experts’ response ranged from 1 to 5 (Supplementary Material 4). If more than one expert responded for the same language, the individual responses were not compared but their common reply as average value of their individual scores.

Table 2. Scoring system.

Score	Legend
1	consistent translation
2	rather consistent translation
3	unsure
4	rather inconsistent translation
5	inconsistent translation

First, the results were to show the total number of inconsistencies between the old and the new version of the regulations. Only the inconsistencies identified by us and confirmed by the experts were considered. To get a clear idea of where these agreed inconsistencies are located at the level of the regulations, a pivot table was created (Supplementary Material 5). Second, the analysis of the results allowed the comparison between all subfamilies/ groups of EU languages (Table 3) in terms of overall inconsistencies. Finally, correlations were made using the criteria in Table 4.

Table 3. Subfamilies / groups of languages of the EU.

Indo-European Family			
Subfamily (Language Group No)	Division	Subdivisions	Languages
Germanic (Language Group 1)	West Germanic	Anglo-Frisian	English
		Netherlandic-German	German, Dutch
		East-Scandinavian	Swedish, Danish

Italic (Language Group 2)	Romance/Latin	Ibero-Romance	Spanish, Portuguese
		Gallo-Romance	French
		Italo-Dalmatian	Italian
		Eastern Romance	Romanian
Slavic (Language Group 3)	South Slavic	Western	Croatian, Slovene
		Eastern	Bulgarian
	West Slavic	Czech-Slovak	Slovak, Czech
		Lekhitic	Polish
Baltic (Language Group 4)	-	-	Lithuanian, Latvian
Uralic (Group Language 5)	Finno-Ugric	Finnic	Finnish, Estonian
		Ugric	Hungarian
Celtic (Language Group 6)	Insular	Goidelic	Gaelic
Hellenic (Language Group 7)	-	-	Greek
Semitic Family			
Afro-Asiatic / Afrasian / Hamito-Semitic / Semito-Hamitic / Erythraean (Language Group 8)	Semitic	Central-Semitic	Maltese

Table 4. Accession of member states to the EU.

European Union			
Year of EU Adherence (Accession)	Year Difference	Years of Membership	Country/Countries
1957 (Accession 1)	-	65	France, Italy, Germany, Belgium, Luxembourg, The Netherlands
1973 (Accession 1)	29	49	Denmark, Ireland, United Kingdom (Brexit 2020)
1981 (Accession 2)	21	41	Greece
1986 (Accession 2)	5	36	Spain, Portugal
1995 (Accession 2)	9	27	Austria, Finland, Sweden
2004 (Accession 3)	9	18	Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia, Slovenia
2007 (Accession 3)	3	15	Romania, Bulgaria
2013 (Accession 3)	6	9	Croatia

The vast majority of EU languages belong to the Indo-European language family. The three main subfamilies are Germanic, Romance, and Slavic. The others are Baltic, Celtic, Hellenic and Uralic. Maltese is a special language. It is a Central Semitic language, derived from late medieval Sicilian Arabic with Romance overlays, spoken by the Maltese people. It is the national language of Malta and the only official Semitic language in the European Union.

2.5. Statistical Analysis

Given the ordinal variables, a Spearman’s rank correlation coefficient was calculated. For this purpose, the variables were coded (Tables 1–4). The variable “agreement” was introduced to determine the agreement between our assessment and the experts (Tables 2 and 3). Statistical calculations about expert confirmed inconsistencies were performed for the old version of Regulations (EU) 2002/178, 2004/852, 2004/853, 2017/625, the new version of the same regulations and

the regulation (EU) 2019/1381. The relationship was considered significant when the p value was less than 0.05.

Comparisons between selected ordinal variables were performed using the Kruskal-Wallis test. The statistically significant difference was confirmed when the p value was less than 0.05.

2.6. Clustering

Finally, a clustering of languages by the number of inconsistencies was performed. The selected variables were: R-H, H-RF, RA-RD, H-SD, and H-R (shown in Table 1). After optimization, we selected the hierarchical Ward method for clustering, except for Regulation (EU) 1381/2019, where the average (Figure 8) and the centroid hierarchical method (Figure A3) were used.

The Cubic Clustering Criterion (CCC) [35] was used to determine the number of clusters. When CCC was greater than 2, the number of clusters was relevant (groups of languages that are well separated). The clusters were represented by dendrograms.

Codes written in SAS for Windows were used for the graphical representations (bars and pies), comparison tests, clustering, and dendrograms (SAS Institute Inc., Cary, NC, U. Sas® 9.4. *SAS Inst. Inc., Cary, NC, USA* 2017).

3. Results

To perform the analysis of “hazard” and “risk” use in existing food legislation, a six step procedure was followed (Figure 3). Upon selection of relevant regulations, languages and experts, HA-RI software tool was applied to create an initial list of inconsistencies for selected regulations and languages. These lists of inconsistencies were evaluated by us and experts.

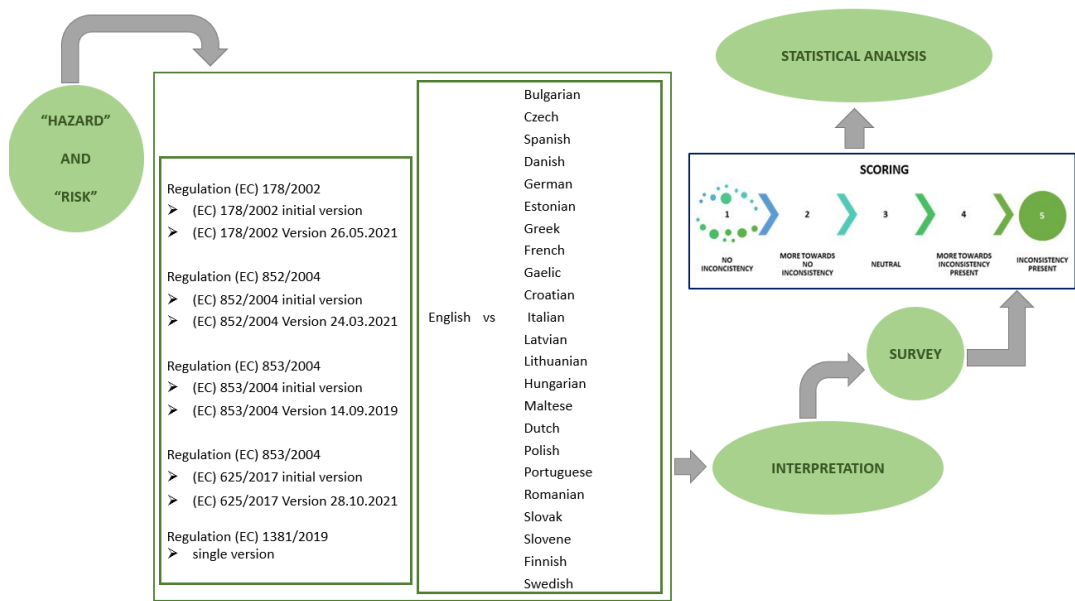


Figure 3. The scheme of the procedure consisted of six steps: (1) selection of terms, in this case “hazard” and “risk”, (2) selection of regulations, (3) selection of languages and sending invitations to participate to the national food experts, (4) interpretation or search for discrepancies, (5) survey: drawing up lists of discrepancies related to the selected languages and sending the corresponding list to the national expert, and finally performing (6) statistical analysis of the collected fulfilled surveys and conclusions.

The English language was the language of reference. The Gaelic language had no inconsistencies. The total number of the selected five types of inconsistencies (R-H, H-RF, RA-RD, H-SD, H-R, explained in Table 1) that we identified was 657, of which 361 (54.95 %) were in the older version, 288 (43.84 %) in the newer version, and 8 (1.21 %) in Regulation (EU) 2019/1381. A total of 610 inconsistencies or 92.84 % were agreed between us and experts, of which 336 (55.08 %) were in

the older version, 267 (43.77 %) in the newer version, and 7 (1.15 %) in Regulation (EU) 2019/1381 (Table 5).

Table 5. Total number of inconsistencies identified by experts and us.

Language (short name)	Old Version		New Version		Single Version	
	Experts (confirmed inconsistenci es)	Our determinatio n of No of inconsistenci es	Experts (confirmed inconsistenci es)	Our determinatio n of No of inconsistenci es	Experts (confirmed inconsistenci es)	Our determinatio n of No of inconsistenci es
Bulgarian (BG)	4	10	2	3		
Czech (CS)	19	19	15	15		
Spanish (ES)	9	11	13	14		
Danish (DA)	25	29	20	20		
German (DE)	3	3	4	4	2	2
Estonian (ET)	20	20	5	5	1	1
Greek (EL)	39	39	36	36	2	2
French (FR)	10	10	6	6		
Croatian (HR)	16	16	16	16		
Italian (IT)	13	13	14	14		
Latvian (LV)	4	6	4	6		
Lithuanian (LT)	48	48	25	25		
Hungarian (HU)	10	14	7	16	0	1
Maltese (MT)	-	5	-	4		
Dutch (NL)	10	10	9	9		
Polish (PL)	26	26	19	19		
Portuguese (PT)	20	20	20	20		
Romanian (RO)	23	23	19	19		
Slovak (SK)	1	2	2	4		
Slovene (SL)	31	31	25	25		
Finnish (FI)	4	4	5	5	2	2
Swedish (SV)	1	2	1	3		
Sum	336	361	267	288	7	8

In most cases our observations on the inconsistencies and awarded scores (Table 2) were confirmed by the native experts. However, there were a few cases where the experts found the use of “hazard” and “risk” as synonyms acceptable for reasons of linguistic freedom (Table 3; Table 5). For example, for the Slovak language for the new regulation, 4 inconsistencies were identified, but only 2 were confirmed by the experts (Table 5).

The substitution of word "hazard" with the word "risk" was most frequently observed in the Italic group, followed by the Slavic, Germanic and Baltic groups (Figure 4). In other language groups such as Hamito-Semitic, Uralic and Hellenic, the mentioned substitution was rare.

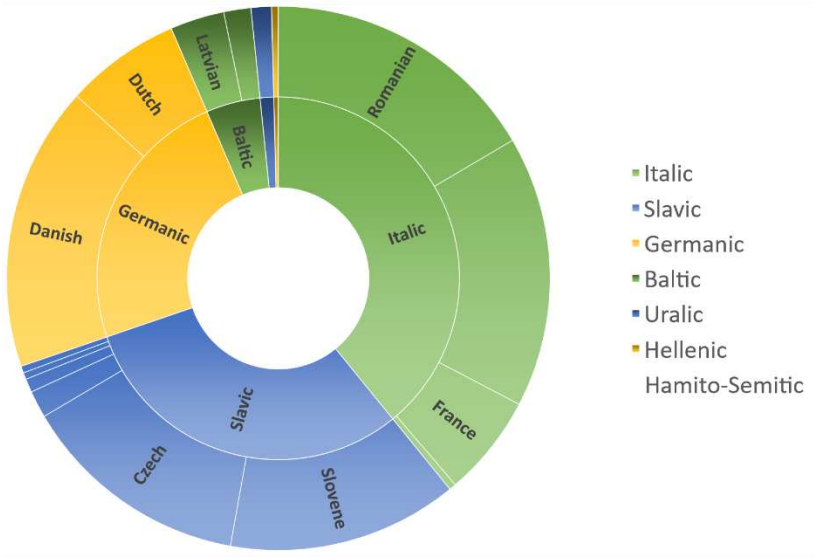


Figure 4. Language-specific proportions of expert-confirmed inconsistencies in Regulations (EU) 2002/178, 2004/852, 2004/853, 2017/625 and 2019/1381 where "hazard" was interchanged with "risk". The highest number of inconsistencies was found in the Italic language group.

Substitution of the word “risk” with the word "hazard" was more common in Slavic, Uralic, Baltic, Italian and Germanic language (Figure 5). Maltese from the Hamito-Semitic group had a small number of substitutions, Greek from the Hellenic group none.

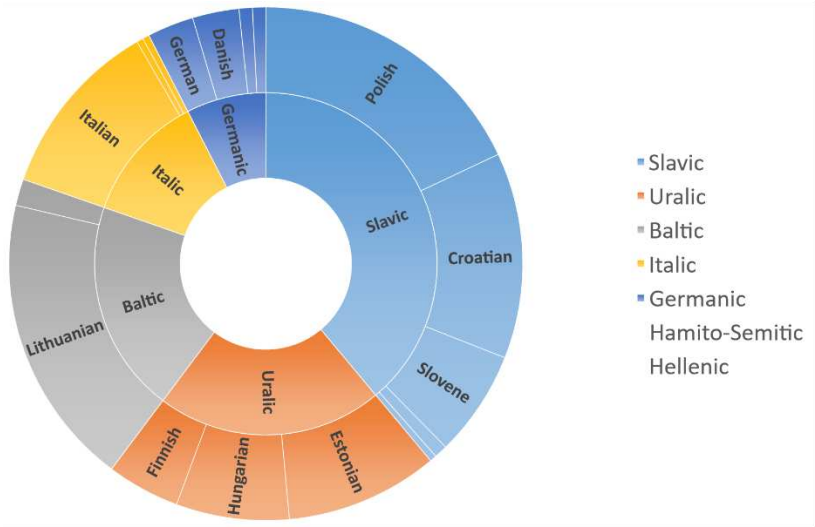


Figure 5. Language-specific proportions of expert-confirmed inconsistencies in Regulations (EU) 2002/178, 2004/852, 2004/853, 2017/625 and 2019/1381 where "risk" was interchanged with "hazard". The highest number of inconsistencies was found in the Slavic group.

3.1. Number of Inconsistencies in the Old Version of Regulations No. 2002/178, 2004/852, 2004/853 and 2017/625

The highest number of inconsistencies identified by consensus between our and the experts’ assessment in the old version of regulations was found for LT (48), EL (39), and for SL (31); for the other, the number of inconsistencies was less than 30 (Figure 6a). The lowest number was found and confirmed for SV (1) and SK (1).

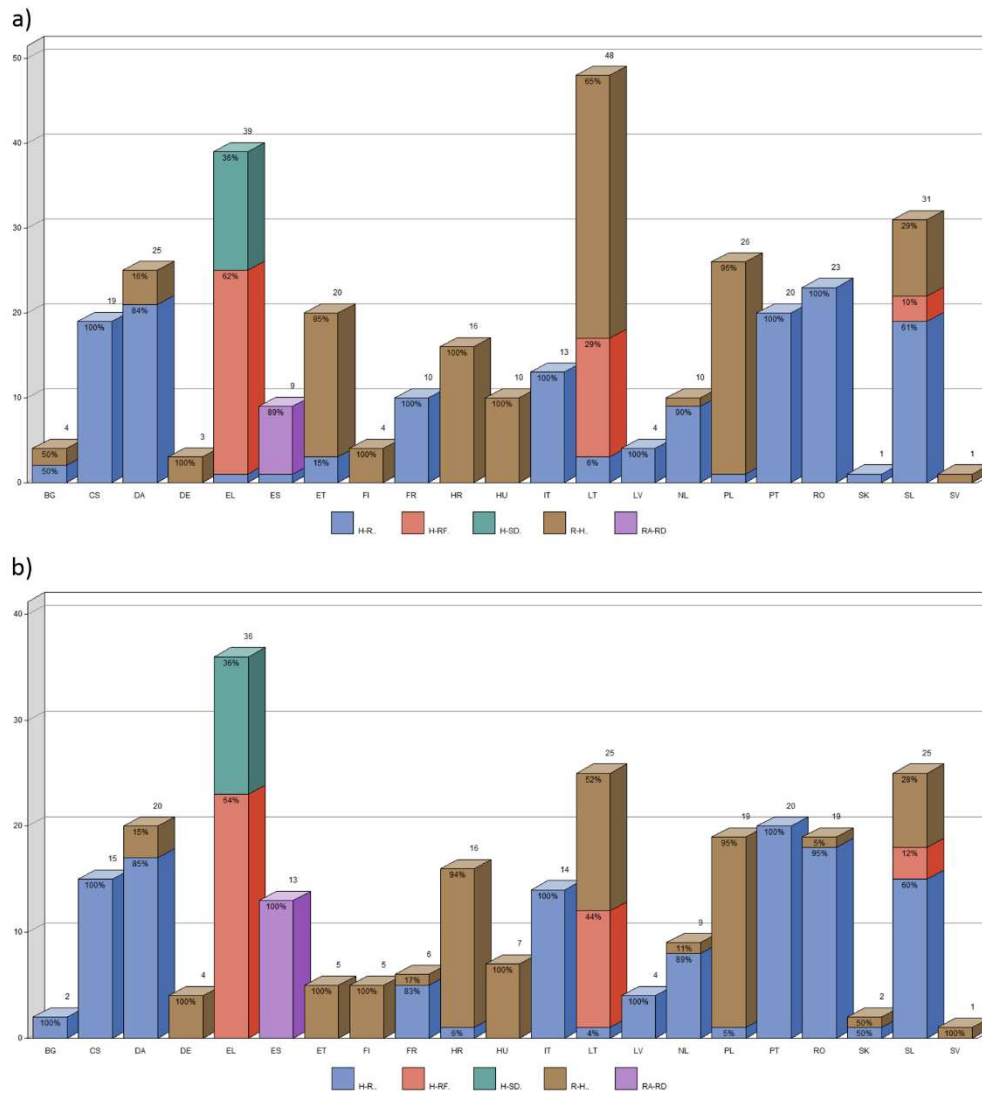


Figure 6. The number of matches between our and the experts' ratings of inconsistencies for a given language, proportion of the type of inconsistencies: H-R (blue), H-RF (red), H-SD (green), R-H (brown), and RA-RD (purple) and with respect to the old version (a) and new version (b) regulations. In case of multiple experts ratings, the average rating of all experts in the respective language group was calculated. The short names of the languages are listed in Table 5.

Figure A1 (a) in Appendix shows the number of inconsistencies in old versions of regulations No. 2002/178, 2004/852, 2004/853 and 2017/625 found by our (author) assessment.

3.2. Number of Inconsistencies in the New Version of Regulations No. 2002/178, 2004/852, 2004/853 and 2017/625

The highest number of inconsistencies identified by consensus between our and the experts' assessment in the new version of regulations was for EL (36), followed by LT (25) and SL (25); for the others, the number of inconsistencies was less than 25 (Figure 6b). The lowest number was found and confirmed for SV (1).

The number of expert-confirmed inconsistencies in the new version of Regulations (EU) 2002/178, 2004/852, 2004/853, 2017/625 was 20.5 % lower than in the old version of the same regulations.

Figure A1 (b) in Appendix shows the number of inconsistencies in new versions of regulations No. 2002/178, 2004/852, 2004/853 and 2017/625 found in our assessment.

3.3. Number of Inconsistencies in the Single Regulation (EU) No 2019/1381

The Regulation No. 2019/1381 was the newest by the date of publication. Not surprisingly, the number of inconsistencies identified by consensus between our and the experts’ assessment per language was very low (the highest was 2) (Figure 7) compared to the regulations with old and new versions. In addition, we found one inconsistency in Hungarian. However, the national experts did not agree on this case. Figure A2 in Appendix shows the number of inconsistencies identified by the authors.

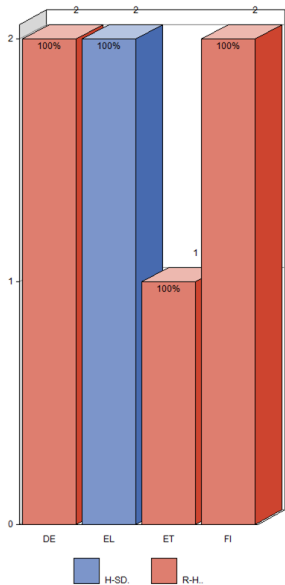


Figure 7. The number of agreements between our and the experts’ ratings of inconsistencies for a given language, proportion of the type of inconsistencies: H-SD (blue) and R-H (red) and with respect to the single Regulation (EU) No 2019/1381. In case of multiple expert ratings, the average rating was calculated for all experts of the respective group. The short names of the languages are listed in Table 5.

3.4. Correlations between the Variables

In the old/new versions of regulations No. 2002/178, 2004/852, 2004/853 and 2017/625 as well as in the single regulation No. 2019/1381, some relationships among variables, for example, “agreed scores between authors and native food experts”, “language groups”, “different languages” and “accession years”, were statistically significant based on the results of Spearman rank correlation coefficients calculations. The Spearman rank correlation coefficients calculations are presented in Tables A1–A3 in Appendix A.

In the case of old versions of Regulations No. 2002/178, 2004/852, 2004/853 and 2017/625, the relationships between “different languages” or “language groups” with “evaluators” in general ($p=0.0381$) and “the year of the state’s accession to the EU” with “groups of languages” or “language groups” ($p<0.0001$) were the main factors determining the number of inconsistencies found (in this case R-H, H-RF, RA-RD, H-SD, and H-R). In the new versions of these regulations, the same relationships were still open except “groups of languages” with “evaluators”.

In the case of the single Regulation EU No. 2019/1381, no statistically significant correlations were found for the above listed variables.

3.5. Comparisons by Using Kruskal Wallis Test

Comparison of the type of authors/experts agreed inconsistencies between old/new Regulations No. 2002/178, 2004/852, 2004/853 and 2017/625, and Regulation 1381 revealed a statistically significant difference ($p=0.03$).

3.4. Clusters

In the old versions of Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625, language EL was in the separate cluster (green) due to the highest number of inconsistencies (Figure 8). The group of languages ET, HU, HR, PL, and LT belonged to the cluster (brown) with a percentage of R-H substitutions above 65% and the total number of inconsistencies between 10 and 48. Languages CS, PT, RO, DA, and SL formed the cluster (red) with a proportion of H-R over 61% and a total number of inconsistencies between 19 and 31. The cluster of language group consisting of FR, NL, and IT (inside the blue) had a proportion of H-R over 90%, but the number of inconsistencies was low – between 10 and 13. The remaining languages of the old versions were also placed in the blue cluster, which had a smaller number of R-H and H-R type of inconsistencies than the second and third cluster (from 1 to 9).

In the new versions of Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625, language EL was again in the separate cluster (green) due to the highest number of inconsistencies. The brown cluster of inconsistencies included HR, HU, PL, LT with R-H exceeding 52% and ranging from 16 to 25 inconsistencies. The cluster (red) consisted of CS, IT, DA, RO, PT and SL with H-R percentage over 60% and the total number of inconsistencies ranging from 14 to 25. The blue cluster of languages had two types of inconsistencies R-H or/and H-R and their total number was between 1 and 13.

In the case of single Regulation (EU) No 2019/1381, languages were divided into two clusters, with only EL included in the second cluster.

Figure A3 in the Appendix shows the division into clusters in terms of the number of inconsistencies identified solely by us using the exact translations of risk and hazard. The result was similar to the classification in Figure 8. The clustering of the different EU members did not result in a particular group of countries, but showed that the same translation problems exist in all countries. However, EL was shown in a separate cluster because only this language had the combination H-SD (35.9%) and H-RF (61.5%) and the proportion did not differ between the new (brown) and the old (blue) regulation (Figure 8). ES was an exception and was positioned in the blue cluster, but with a separate branch for the old regulation, which only had a proportion of RA-RD (72.7%) and a small proportion of H-R (27.3%). The same is true for ES in the new regulation (RA-RD 92.9%, H-R 7.1%). The low proportion of H-R is the reason why it was positioned in the blue cluster.

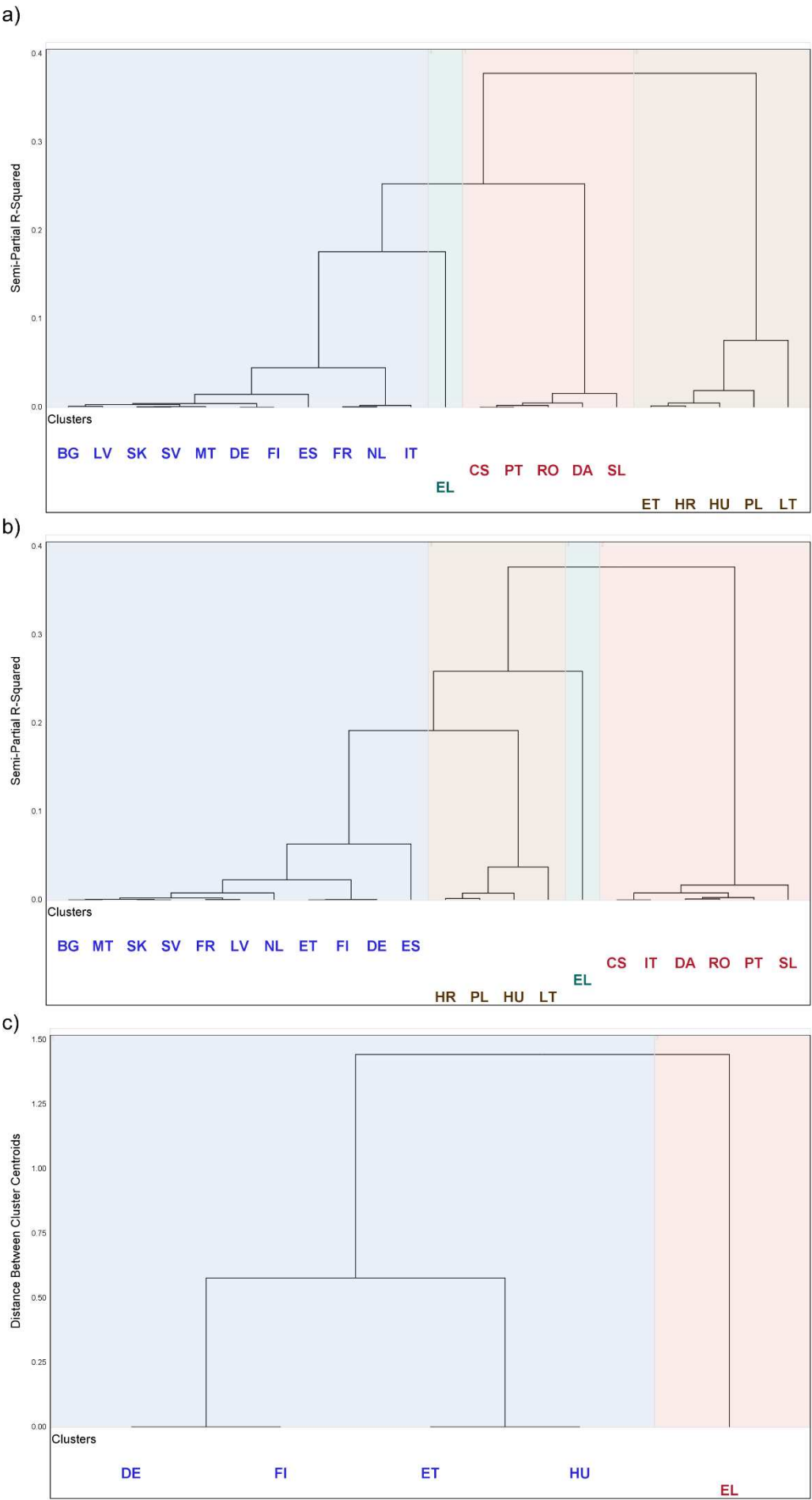


Figure 8. Clustering of languages with respect to the number of R-H, H-RF, RA-RD, H-SD and H-R inconsistencies agreed between us and the experts in a) old Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625 (Ward method of clustering), b) new Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625 (Ward method of clustering) and c) single Regulation EU No. 1381 (average method of clustering). The short names of the languages are listed in Table 5.

4. Discussion

To the best of our knowledge, no study has yet been carried out to investigate the inconsistencies in the translation of "hazard" and "risk" in EU food legislation. With the presented analysis of selected EU regulations dealing with food safety, we focus on the inconsistencies in the translations of "hazard" and "risk", opening the possibility of harmonizing EU regulations even at a higher level. The program HA-RI and the automatic search for inconsistencies, the prepared lists of inconsistencies and their assessment represent efficient tools for the evaluation and harmonisation of the EU legislation.

The number of inconsistencies (the number agreed upon between us and national food experts) decreased significantly when comparing the "old" and "new" regulations, from 336 to 267 (Table 5). However, some problems remain. Some countries have successfully reduced the number of inconsistencies between old and new legislation (e.g., LT, ET), while others remained the same or nearly the same (e.g., EL, PT) or even increased them (e.g., ES). Problems in translation may arise from insufficient knowledge on the part of the translators, but also from the lack of appropriate terminology in the national languages. It is expected that these problems will be overcome over time. A good example is the latest Regulation 2019/1381, where relatively few inconsistencies in translations were found, indicating that the new terminology has already taken hold.

Overall, Lithuanian (LT) showed a high number of inconsistencies. Most of them were related to the interchangeability of "hazard" with "risk". The same interchange was frequently observed in languages that scored high in the total number of inconsistencies, such as in Slovene (SL), Polish (PL), Danish (DA), Romanian (RO) and Portuguese (PT) (Table 5, Figure 4). The same languages with the exception of Lithuanian and Polish revealed inconsistencies related to the interchangeability of "risk" with "hazard" Table 5, Figure 5.

Another language that showed an overall high score was Greek. The issues in Greek language (EL) were more related to the fact that "hazard" was carried over either as a "source of danger" (πηγή κινδύνου) in Regulation No. 178/2002, which also contains the section defining the terms, and in Regulation No. 852/2004, or as a "risk factor", which was so defined and used in Regulation No. 625/2017. In Regulation No. 625/2017, the same term "hazard" is defined differently and used in this form throughout the regulation, although it is the same exact term that was already defined in Regulation No. 178/2002. The new term for "hazard" in this newer 2017 regulation is "risk factor" ('παράγοντας κινδύνου'). This could lead to a confusion and misunderstanding.

In the case of Spanish, the problem started already with the translation of "risk assessment" in Regulation No. 178/2002. "Risk assessment" is defined as "determinación del riesgo" or "risk determination" instead of the more appropriate expression "evaluación de riesgo". Most food experts involved agreed that the translation does not reflect the intended meaning and is open to interpretation. An accurate translation is available and therefore there is no reason for inconsistencies. In the languages of the Romance family, "hazard" is translated with a word more equivalent to "danger" (e.g., "danger" in French, "peligro" in Spanish, "perigo" in Portuguese, "pericolo" in Italian, "pericol" in Romanian). The countries speaking these languages joined the EU as follows: 1957 - France, Italy, 1986 - Spain, Portugal and 2007 - Romania. There is a difference of 29 years between the accession of France and Italy and the accession of Spain and Portugal. There is another difference of 21 years between the accession of Spain and Portugal and the accession of Romania. A slight increase in translation inconsistencies was noted, with older Romance-speaking member states having fewer inconsistencies than newer members: France and Italy compared to Portuguese and Romanian with Spanish standing out.

The results suggest that inconsistencies in the translation of “hazard” and “risk” exist in all EU countries at the level of food regulations. They may therefore be a potential source of confusion for stakeholders, who should be able to distinguish between the two terms in order to be aware of and actively engage in the food safety issue.

5. Conclusions

In summary, food regulations translated from English into other official EU languages constantly interchange "hazard" and "risk". Furthermore, the results have shown that the translation of food regulations and the subsequent corrections depend on the selected group of experts who undertake this task.

It is strongly recommended that risk managers, with the support of risk assessors, adequately train staff responsible for translating food regulations at national level for each EU Member State. Terminology should be clearly explained and always used as defined. Definitions should be re-evaluated and corrected as necessary. These measures can lead to better harmonisation of food regulations in the EU and thus to a better understanding of food safety. It is also advisable to correct all existing food regulations that contain this type of terminology and ensure the correctness of future documents.

Author Contributions: Conceptualization, T.L. and L.T.; methodology, T.L. and L.T.; software, L.T.; validation, L.T.; formal analysis, L.T.; investigation, A-A.C.; data curation, A-A.C. and L.T.; writing—original draft preparation, A-A.C. L.T. and T.L.; writing—review and editing, A-A.C., T.L. and L.T.; supervision, T.L. and L.T. All authors have read and agreed to the published version of the manuscript.

Funding: The project was funded by EFSA as part of the European Food Risk Assessment Fellowship Programme (EU-FORA), cohort 2021 – 2022, under agreement GP/EFSA/ENCO/2020/04 -GA1. Scientific evaluations are independent and do not represent the opinion of EFSA.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Acknowledgements: The authors would like to acknowledge the support of EFSA and express their special thanks to the EU-FORA Fellows and representatives of EFSA Focal Points for their contribution to this study. Special thanks also go to Mihai Macrea, senior full stack developer, who helped to create the software tool for identifying inconsistencies-based comparisons.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

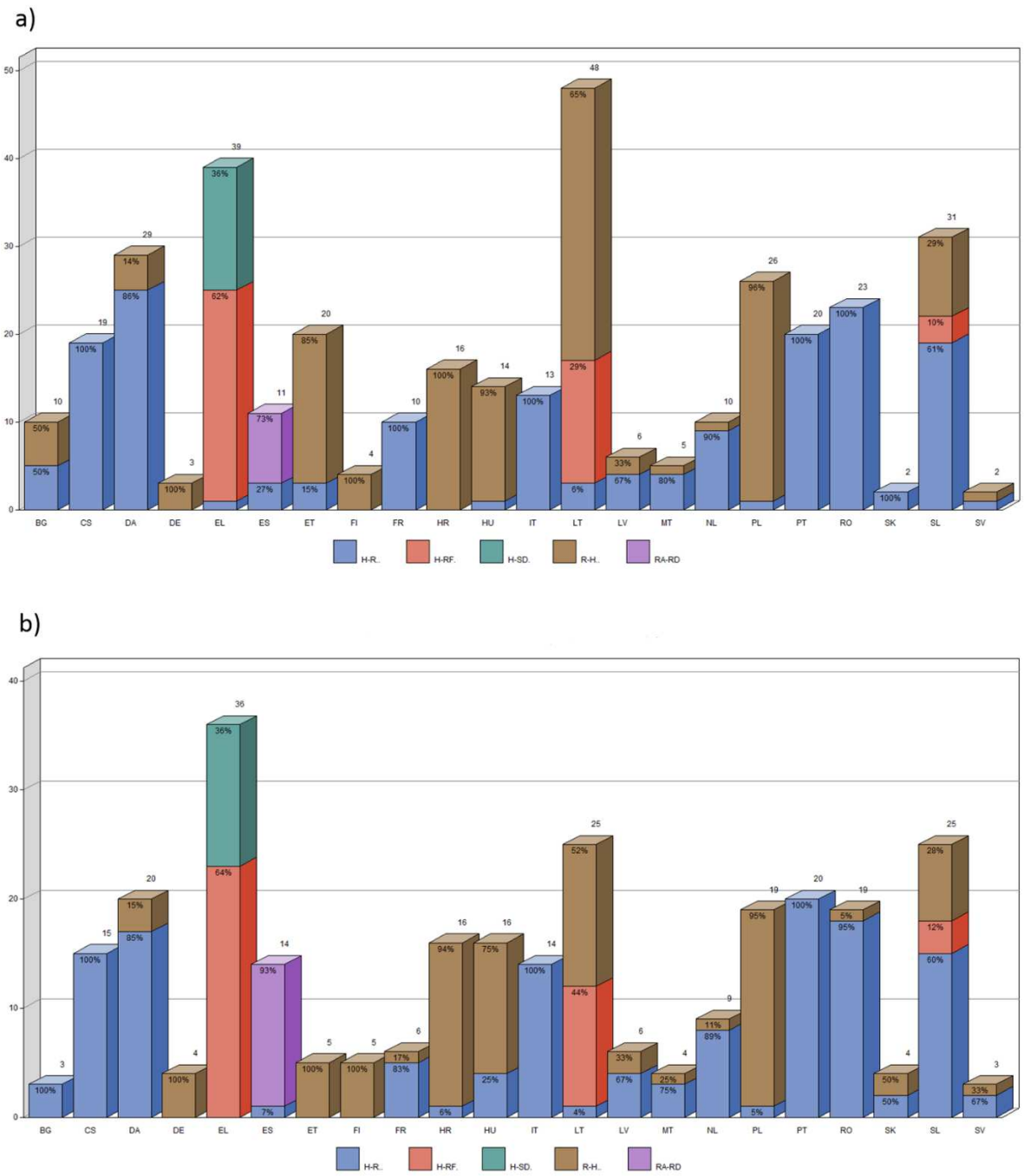


Figure A1. Number of inconsistencies found by the authors, proportion of type of inconsistencies: H-R (blue), H-RF (red), H-SD (green), R-H (brown), and RA-RD (violet) and regarding old (a) and new (b) regulations No. 2002/178, 2004/852, 2004/853 and 2017/625. In case of multiple experts ratings, the average rating of all experts in the respective language group was calculated. The short names of the languages are listed in Table 5.

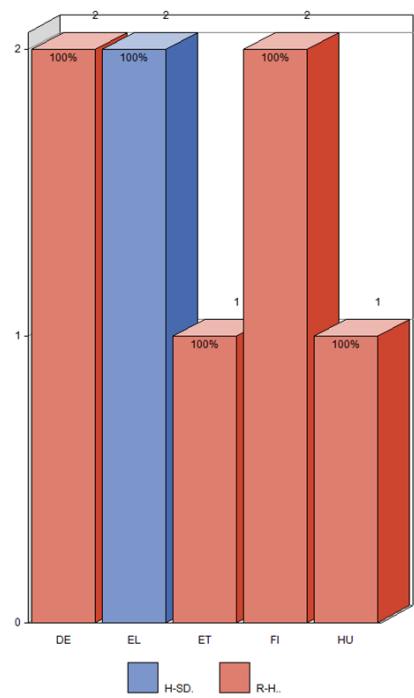


Figure A2. Number of inconsistencies found by the authors, proportion of type of inconsistencies: H-SD (blue) and R-H (red) in Regulation No. 1381. In case of multiple experts ratings, the average rating of all experts in the respective language group was calculated. The abbreviated names of the languages are listed in Table 5.

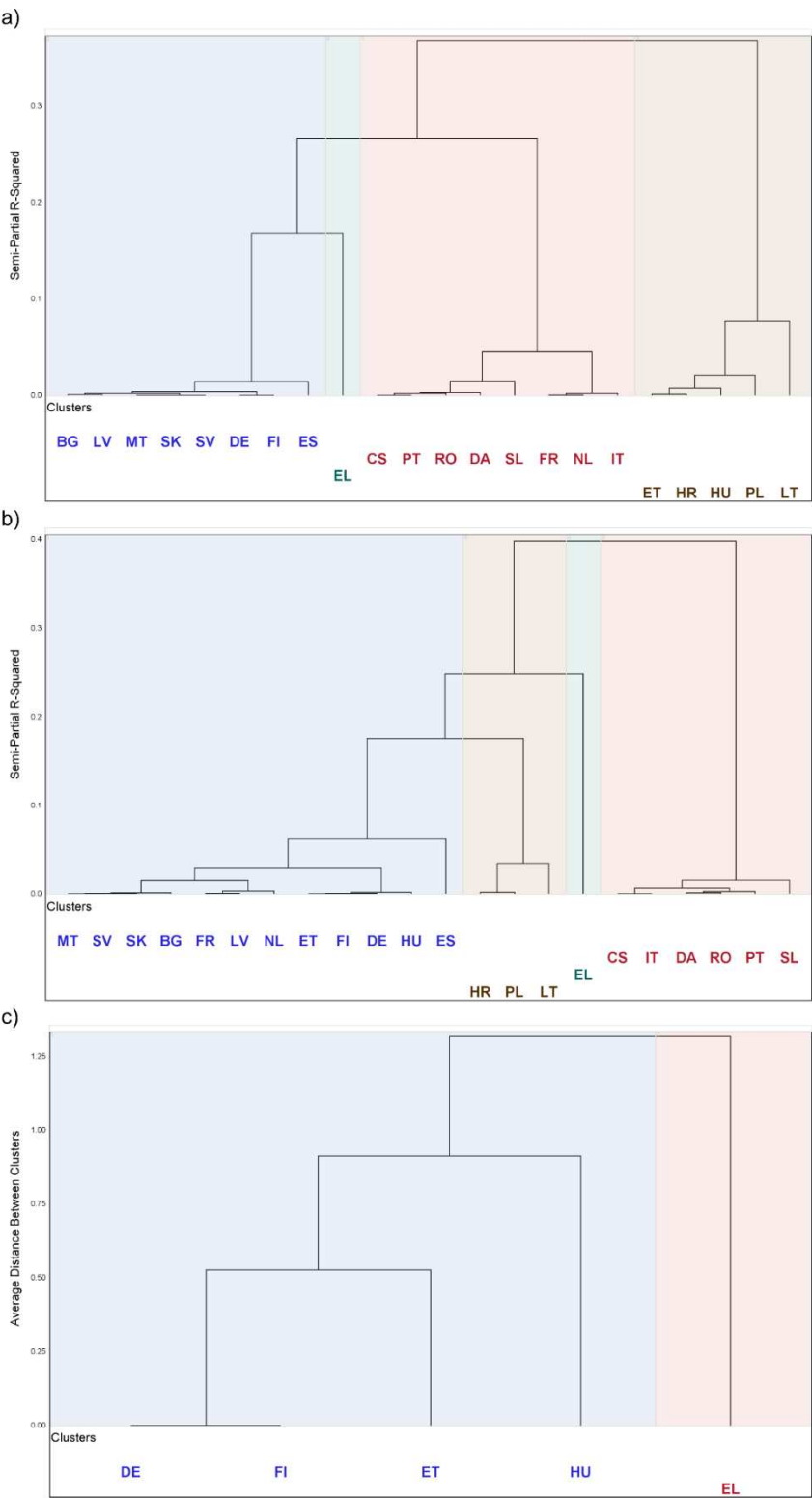


Figure A3. Clustering of languages with respect to the number of R-H, H-RF, RA-RD, H-SD and H-R inconsistencies identified by us (authors) based on exact translations of hazard and risk in a) old Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625 (Ward method of clustering), b) new Regulations EU No. 2002/178, 2004/852, 2004/853 and 2017/625 (Ward method of clustering) and c) single Regulation EU No. 1381 (centroid method of clustering). The short names of the languages are listed in Table 5.

Table A1. Spearman's rank correlation coefficients calculated for the variables of the OLD versions of Regulations EU No. 2002/178, 2004/852, 2004/853, 2017/625. Accession years are shown in Table 4. Groups of languages and different languages are shown in Table 3. Parameters in the rows of each table column are (1) Spearman's rank correlation coefficients; (2) Prob > |r| under H0: Rho=0; (3) Number of observations. Rank correlation coefficients with p<0.05 are highlighted in red.

	Agreed scores between authors and native food experts	Groups of Languages	Years of EU Accession	Different Languages
Agreed scores between authors and native food experts	1.00000	-0.04940	-0.05344	0.10923
		0.3493	0.3113	0.0381
	361	361	361	361
Groups of Languages	-0.04940	1.00000	0.44076	-0.05212
	0.3493		<.0001	0.3234
	361	361	361	361
Years of EU Accession	-0.05344	0.44076	1.00000	0.30134
	0.3113	<.0001		<.0001
	361	361	361	361
Different Languages	0.10923	-0.05212	0.30134	1.00000
	0.0381	0.3234	<.0001	
	361	361	361	361

Table A2. Spearman's rank correlation coefficients calculated for the variables of the NEW versions of Regulations EU No. 2002/178, 2004/852, 2004/853, 2017/625. Accession years are shown in Table 4. Groups of languages and different languages are shown in Table 3. Parameters in the rows of each table column are (1) Spearman's Rank Correlation Coefficients; (2) Prob > |r| under H0: Rho=0; (3) Number of observations. Rank correlation coefficients with p<0.05 are highlighted in red.

	Agreed scores between authors and native food experts	Groups of Languages	Years of EU Accession	Different Languages
Agreed scores between authors and native food experts	1.00000	-0.19834	-0.18237	-0.10139
		0.0007	0.0019	0.0859
	288	288	288	288
Groups of Languages	-0.19834	1.00000	0.44684	-0.03616
	0.0007		<.0001	0.5411
	288	288	288	288
Years of EU Accession	-0.18237	0.44684	1.00000	0.34442
	0.0019	<.0001		<.0001
	288	288	288	288
Different Languages	-0.10139	-0.03616	0.34442	1.00000
	0.0859	0.5411	<.0001	
	288	288	288	288

Table A3. Spearman's rank correlation coefficients calculated for the variables of the SINGLE regulation EU No. 2019/1381. Accession years are shown in Table 4. Groups of languages and different languages are listed in Table 3. Parameters in the rows of each table column are (1) Spearman's Rank Correlation Coefficients; (2) Prob > |r| under H0: Rho=0; (3) number of observations.

	Agreed scores between authors and native food experts	Groups of Languages	Years of EU Accession	Different Languages
Agreed scores between authors and native food experts	1.00000	0.00000	-0.53452	-0.25198
		1.0000	0.1723	0.5472
	8	8	8	8
	0.00000	1.00000	0.50000	0.47140
Groups of Languages	1.0000		0.2070	0.2383
	8	8	8	8
	-0.53452	0.50000	1.00000	0.47140
Years of EU Accession	0.1723	0.2070		0.2383
	8	8	8	8
	-0.25198	0.47140	0.47140	1.00000
Different Languages	0.5472	0.2383	0.2383	
	8	8	8	8

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