CHAPTER 18

Common regulatory issues and proposals to harmonize nutrition and health claims regulations

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18.1 Overview of traditional Balkan foods and the European Union quality schemes

The Balkans are a region of intertwined cultures that have shaped the local cuisine. This is reflected in the variety of traditional dishes in the region, which incorporate multicultural elements determined by living together in the same geographical area. An example is the rich cuisine around the Black Sea region of the Balkans popular in dishes like *moussaka*, *storceag* (sheatfish soup), Greek salad, *sarma*, etc. (Fig. 18.1). Due to the history, culture, and gastronomic heritage of the Balkan countries, traditional foods with specific indications, such as protected designation of origin (PDO), protected geographical indication (PGI), or traditional speciality guaranteed (TSG), are generally preferred over the mass-produced industrial food products. In the last years, the number of foods registered under the European Union (EU) quality schemes (i.e., PDO, PGI, and TSG) increased significantly, especially in case of PDO and PGI (Albuquerque, Oliveira, & Costa, 2018). The products containing these indications are recognized as traditional foods that are made taking into account the grandparents' ancient recipes and their knowledge. This has contributed to their success on the market.

Traditional products registered under the EU quality schemes have the right to use dedicated logos (Fig. 18.2), which are trademarks recognized at EU level. Registered traditional foods are then included in an EU database of protected products called DOOR—the EU Database of Origin and Registration (European Commission (EC), 2020a).

The requirements for labeling traditional Balkan foods are those applied throughout the EU common food market, soliciting a clear indication of the name and origin of the product. In the early 1990s, two EU regulations laid down instructions regarding PDOs, PGIs, and TSGs:

- Council Regulation (EEC) No. 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (EC, 1992a),

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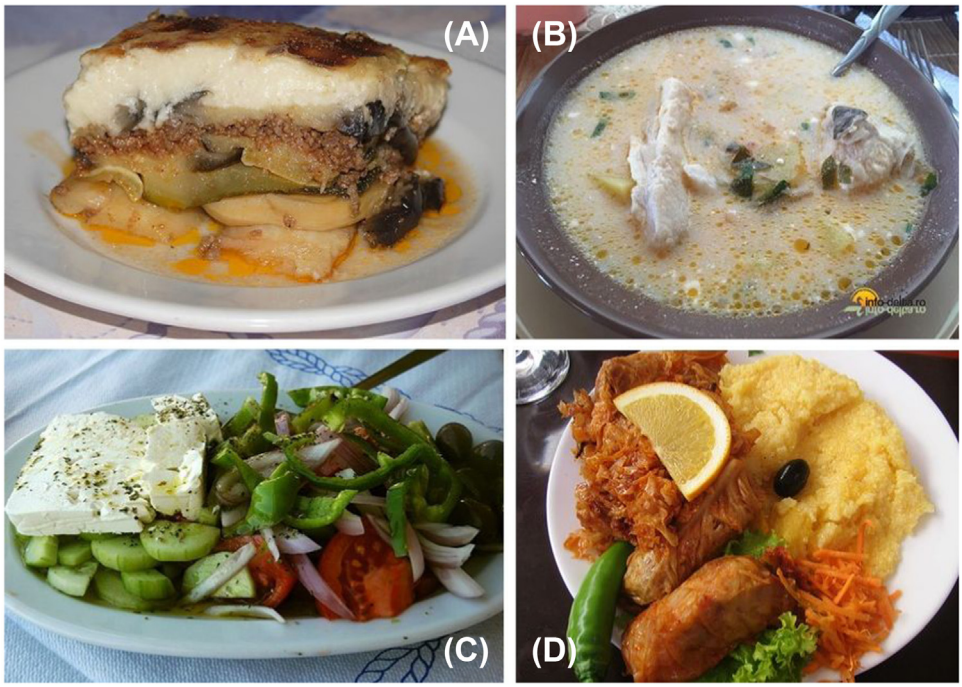

Figure 18.1 Traditional foods from the Balkans around the Black Sea region: (A) Greek *moussaka* (Wikipedia, 2020a); (B) *storceag*—sheatfish soup from Dobrogea region of Romania (Infodelta, n.d.); (C) Greek salad (Wikipedia, 2020b); and (D) *sarma* (Wikipedia, 2020c).

Figure 18.2 The EU trademarks (logos) for the protected designation of origin, protected geographical indication, and traditional speciality guaranteed products (EC, 2020a).

which was later repealed and replaced by Council Regulation (EC) No. 510/2006 (EC, 2006a).

- Council Regulation (EEC) No. 2082/92 on certificates of specific character for agricultural products and foodstuffs (EC, 1992b), which was later repealed and replaced by Council Regulation (EC) No. 509/2006 (EC, 2006b).

On November 21, 2012, the European Parliament and the Council of the EU adopted Regulation (EU) No. 1151/2012 regarding the EU quality schemes for

agricultural products and foodstuffs (EC, 2012a). The aim is to protect the unique character of foodstuffs, which is linked to their geographical area of provenance and to the genuine traditional knowledge applied to their production methods and recipes. The regulation introduces two new quality terms—Mountain Products and Product of Island Farming and provides clarification of the terminology used. According to this regulation:

- "**Traditional**" means "proven usage on the domestic market for a period that allows transmission between generations; this period is to be at least 30 years."
- "**Specific character**" of a product represents "the characteristic production attributes which distinguish a product clearly from other similar products of the same category."
- "**Designation of origin**" identifies a product: "(a) originating in a specific place, region or, in exceptional cases, a country; (b) whose quality or characteristics are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors; and (c) the production steps of which all take place in the defined geographical area."
- "**Geographical indication**" identifies a product: "(a) originating in a specific place, region or country; (b) whose given quality, reputation or other characteristic is essentially attributable to its geographical origin; and (c) at least one of the production steps of which take place in the defined geographical area."
- "**Traditional speciality guaranteed**" describes a product that: "(a) results from a mode of production, processing or composition corresponding to traditional practice for that product or foodstuff; or (b) is produced from raw materials or ingredients that are those traditionally used."
- **Mountain Products** are products of which: "(a) both the raw materials and the feedstuffs for farm animals come essentially from mountain areas; and (b) in the case of processed products, the processing also takes place in mountain areas."
- **Product of Island Farming** is a product prepared with raw materials that come from islands and for which "processing must also take place on islands in cases where this substantially affects the particular characteristics of the final product" (EC, 2012a).

The success of the implementation of quality schemes by the Balkan countries is illustrated by the number of traditional foods registered at EU level (EC, 2020a). An analysis of the current situation of applications for quality schemes in the Balkan region reveals several issues that affect validation of agricultural products and foodstuffs as traditional products.

First of all, the regulatory and evaluation institutions need to be more effective in the information process and much more supportive of applications for product registration under the EU quality schemes. For example, in Romania the Ministry of Agriculture and Rural Development and the regional quality assurance agencies

disseminate information regarding the certification process within professional bodies (e.g., Romanian Meat Association, Romanian Milk Association, etc.) through official meetings, conferences, etc., but this information is less reached by the small agricultural producers. Moreover, the bureaucratic process of applying to EU quality schemes is very heavy, incomprehensible, and inaccessible to the smallholder producer. "To register the name of a product, EU producers or producer groups need to lay down the product's specifications and link to the geographical area, if applicable. The application is sent to national authorities for scrutiny and then forwarded to the European Commission, who will examine the request" (EC, n.d.a).

The application for registration under the quality schemes involves two stages. In the first stage, the individual producer or group of producers recognize(s) the special characteristics of the product(s) and decide(s) to obtain protected status, by submitting an application to the competent national authorities. The national authorities will assist producers prepare the documentation to clearly describe the product specifications and submit the necessary forms. The applicants need to send to the EU authorities the following documents: (1) the list of national competent authorities—food sector; (2) PDO, PGI—Single Document (Annex I of EU Regulation 668/2014); (3) TSG—Product specification of a Traditional Speciality Guaranteed (Annex II of EU regulation 668/2014); (4) Application for approval of an amendment to the product specification of PDO/PGI which is not minor (Annex V of EU regulation 668/2014); (5) Application for approval of a minor amendment (Annex VII of EU regulation 668/2014); and (6) Privacy statement—registers of geographical indications. In the second stage, the application is submitted to the EC for product registration (EC, n.d.a, n.d.b). Then, the EC has a maximum of 12 and 6 months for examining the applications for spirit drinks and agro-food products, respectively, and to decide if the product will receive protected status under the requested quality scheme. No deadline is applied in case of wines (EC, n.d.a). There are product applications from 2012 whose registration is still not finalized, situation which discourages national authorities for creating new applications (EC, 2020a). The national authorities, the EU and non-EU producers, and the EC have the possibility to oppose or cancel the registration of a product, which can be done within 3 months from the moment the product is registered. The registration of a product name can be canceled "when compliance with the product specifications are no longer ensured" or "when no registered product name (as PDO, PGI, or TSG) has been put on the market for seven consecutive years." If no agreement is reached between the party opposing the registration and the producer(s) registering the product, then the EC makes the final decision (EC, n.d.a).

Secondly, the regulatory authorities should note that the packaging and labeling of traditional food products lead to additional costs, which significantly increase the market price of the certified final product. As a result, the certified product becomes a noncompetitive niche product with a market status similar to that of organic products (i.e., good, but expensive). For these reasons, a significant number of traditional food

producers fail or renounce to register their products under the EU quality schemes. Instead, the semiindustrial and large mass food producers are extending their successful "gourmet" line with traditional-like products, well-packaged, although the product possesses less traditional attributes. The new generation does not recognize the quality specificities of traditional foods and, over time, the traditional characteristics may be lost if the regulatory institutions do not act to change the current paradigm (i.e., difficult application procedure and slow certification process).

18.2 A framework to determine whether the traditional Balkan foods meet international nutrition labeling requirements

The legislation on labeling requirements for traditional foods helps ensure the availability of food of adequate quality. This can be achieved using widely accepted standards and a globally recognized harmonization process that protects consumers' rights and facilitates the movement of foods between countries, without arbitrary legal constraints or unjustified inequities (Motarjemi, van Schothorst, & Kaferstein, 2001). In the Balkan countries, the nutrition and health claims made on foods, including traditional foods, are insufficiently investigated, despite a growing demand in recent years for these products. Within the EU project entitled FOCUS Balkans, the Western Balkan countries (e.g., Bosnia-Herzegovina, Croatia, Macedonia, Montenegro, Serbia, Slovenia) were subjected to a comprehensive assessment regarding consumer behavior related to traditional products among other food groups that are generally perceived to have positive nutritional characteristics (FOCUS, 2011). A lack of trust in food and nutrition claims associated with a strong conservative attitude regarding the authenticity of traditional foods were reported. Therefore the authors of the project have recommended the use of no more than one claim per food label, in order to avoid confusing the final consumer and to strengthen confidence in food labels (FOCUS, 2011).

For these reasons, the EU regulation should be applied correctly in the Balkan countries affiliated to the EU common market, especially in the case of nutrition labeling and claims, so as not to mislead and/or confuse the consumer and to guarantee the identity, quality, and conformity of all certified agro-foods and beverages (Djekic, Tomasevic, & Radomir, 2011). In the EU, Regulation No. 1169/2011 (EC, 2011) regarding the provision of food information (i.e., information on the identity, composition, and properties/characteristics of food) to consumers has become effective in December 2014 and mandatory in all member states after December 2016. According to this regulation, labeling represents "any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food" (EC, 2011). On January 30, 2020, the EC adopted a notice on the application of Article 26(3) from

Regulation (EU) No 1169/2011 with regard to the indication of the country of origin or place of provenance of the primary ingredient(s) of a food (EC, 2020b). For the Balkan countries, the compulsory food label requirements were set out in the following main EU Regulations:

- Article 9 of the EU Regulation 1169/2011 sets out the list of mandatory declarations on food and drink labels, including the Nutrition Declaration on:
  - Energy content: expressed in kilojoules (kJ) and kilocalories (kcal)
  - Nutrients content: fat, saturated fats, carbohydrates, sugars, proteins, and salt, expressed in grams (g), milligrams (mg), or micrograms (μg) per 100 g or 100 mL (EC, 2011).
- Part A of Annex XIII from the EU Regulation 1169/2011, which lists the legally authorized vitamins and minerals declared on the food label as a percentage of the daily reference intake (DRI) values per 100 mL or per 100 g (EC, 2011).
- Part B of Annex XIII from the EU Regulation 1169/2011, which lists the Reference Intakes for energy and selected nutrients, other than vitamins and minerals, per 100 mL or per 100 g (EC, 2011).
- Article 22 from the EU Regulation 1169/2011, which requires the indication of the quantity of a food ingredient or category of ingredients used in the preparation/manufacture of a food (EC, 2011).
- Annex V from the EU Regulation 1169/2011, which lists the foodstuffs that are exempted from the mandatory nutrition declaration (EC, 2011).
- Article 13 of the EU Regulation 1169/2011, which introduces a minimum font size of 1.2 mm for printing the mandatory information on food and drink labels (EC, 2011).
- Article 15 of the EU Regulation 1169/2011, which requires mandatory food information to be provided in "a language easily understood by the consumers of the Member States where the food is marketed" (EC, 2011).
- Article 34 of the EU Regulation 1169/2011, which states that the nutrition declaration must be presented, if space permits, in tabular format with the numbers aligned and, where space does not permit, in a linear format (EC, 2011).
- Annex to the Nutrition and Health Claims made on foods of the EU Regulation 1924/2006, which lists the EU authorized nutrition claims and the conditions for their application (EC, 2006c).
- EU Regulation 432/2012, which establishes the EU list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. Examples of permitted health claims are: "biotin contributes to normal energy-yielding metabolism," "calcium contributes to normal muscle function," "calcium is needed for the maintenance of normal bones," "reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels," or "meat or fish contributes to the improvement of iron absorption when eaten with other foods containing iron" (EC, 2012b).

Nonharmonized labeling regulations and standard requirements, including claims on origin, tradition, name, etc. represent an important barrier to trade. In case of nutrition labeling, in the USA the Food and Drug Administration (FDA) launched the new Nutrition Facts label in May 2016 for packaged foods to reflect latest scientific information, including the relationship between diet and chronic diseases (e.g., obesity, heart disease). The new label became mandatory in January 2020 for manufacturers with more than 10 million US dollars in annual food sales, and from 1st of January 2021 the small manufacturers with annual sales below 10 million US dollars have to comply, as well (FDA, 2020). In principle, the foundation of the USA and EU regulations on food labeling—including claims regarding tradition, origin, etc.—is based on Codex Alimentarius international food standards, guidelines, and code of practice (FAO/WHO, 2020). A comparison between nutrition and health regulations of the EU and Codex Alimentarius standards is presented in Tables 18.1–18.4.

Gaps have been identified between the nutrition labeling requirements in the Balkan member countries and international legislation on:

- Communication of nutrition information: according to Codex Alimentarius, the food label must indicate the number of servings per commercial unit, while the EU label regulation does not require the declaration of the number of servings per commercial unit (EC, 2011; FAO/WHO, 1985).
- Additives list and declaration: certain food additives authorized in the EU are not allowed in the USA (e.g., some color additives). Also, according to the EU legislation, the additive declaration on the food label is encoded with a three- or four-digits code identifying the food additive (i.e., the E number) (EC, 2008b), while in the USA additives must be referenced by their chemical names (FAO/WHO, 1995).
- The dietary reference values (DRVs) for the nutrients and energy: as seen from Tables 18.2–18.4, DRVs need to be harmonized (Vintila, Waisundara, & Lelieveld, 2019).

Nutrition labeling is applied to traditional foods, but there is not yet a database on the nutritional composition of every traditional Balkan food. In this regard, several EU projects were involved in assessing the nutritional profile of some traditional EU foods and eating patterns in the EU countries, such as:

- EPIC European Prospective Investigation into Cancer and Nutrition (IARC, 2020);
- Healthy Lifestyle in Europe by Nutrition in Adolescence Study (HELENA, 2020);
- European Food Information Resource network (EuroFIR, n.d.);
- European Union's Concerted Action on Nutrition and Health (EURONUT) (de Groot, van Staveren, & Hautvast, 1997).
- Eating out: Habits, Determinants, and Recommendations for Consumers and the European Catering Sector (HECTOR, 2013).

Table 18.1 Comparative analysis of food regulations regarding nutrition and health claims (EC, 2006c; FAO/WHO, 2013).

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
Nutrition claim regarding energy value		
Low energy	40 kcal (170 kJ) per 100 g (solids) 20 kcal (80 kJ) per 100 mL (liquids)	40 kcal (170 kJ) per 100 g (solids) 20 kcal (80 kJ) per 100 mL (liquids)
Energy-reduced	Reduced by at least 30%	–
Energy-free	Does not contain more than 4 kcal (17 kJ)/100 mL For table-top sweeteners, 0.4 kcal (1.7 kJ)/portion [equivalent sweetening properties to 6 g sucrose (approximately 1 teaspoon of sucrose)]	4 kcal per 100 mL (liquids)
Nutrition claim regarding fat content		
Low fat	No more than 3 g of fat per 100 g (solids) 1.5 g of fat per 100 mL (liquids) 1.8 g of fat per 100 mL (semi-skimmed milk)	3 g per 100 g (solids) 1.5 g per 100 mL (liquids)
Fat-free	No more than 0.5 g of fat per 100 g or 100 mL (claims expressed as "X% fat-free" are prohibited)	0.5 g per 100 g (solids) or 100 mL (liquids)
Low saturated fat	Sum of saturated fatty acids and trans-fatty acids it does not exceed 1.5 g per 100 g (solids) or 0.75 g per 100 mL (liquids), and in either case, the sum of saturated fatty acids and trans-fatty acids must not provide more than 10% of energy	Low cholesterol: 0.02 g per 100 g (solids) 0.01 g per 100 mL (liquids) Cholesterol-free: 0.005 g per 100 g (solids) 0.005 g per 100 mL (liquids) For both: Less than 1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 mL (liquids) and 10% of energy from saturated fat

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
Source of omega-3 fatty acids	At least 0.3 g alpha-linolenic acid per 100 g and per 100 kcal or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal	–
High omega-3 fatty acids	At least 0.6 g alpha-linolenic acid per 100 g and per 100 kcal or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal	–
High monounsaturated fat	At least 45% of the fatty acids present derive from monounsaturated fat, under the condition that monounsaturated fat provides more than 20% of energy of the product	–
High polyunsaturated fat	At least 45% of the fatty acids present derive from polyunsaturated fat, under the condition that polyunsaturated fat provides more than 20% of energy of the product	–
High unsaturated fat	At least 70% of the fatty acids present derive from unsaturated fat, under the condition that unsaturated fat provides more than 20% of energy of the product	–
Saturated fat-free	Sum of saturated fat and trans-fatty acids does not exceed 0.1 g of saturated fat per 100 g or 100 mL	–
Nutrition claim regarding sugar content		
Low sugars	No more than 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 mL for liquids	–
Sugars-free	No more than 0.5 g of sugars per 100 g or 100 mL	0.5 g per 100 g (solids) 0.5 g per 100 mL (liquids)
With no added sugars/ nonaddition of sugars	Does not contain any added mono- or disaccharides or any other food used for its sweetening properties.	Claims regarding the nonaddition of sugars to a food may be made

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
	If sugars are naturally present in the food, the following indication should also appear on the label: "Contains naturally occurring sugars"	provided the following conditions are met: (1) no sugars of any type have been added to the food; (2) contains no ingredients that contain sugars as an ingredient (e.g., jams, jellies, sweetened chocolate, sweetened fruit pieces, etc.); (3) contains no ingredients containing sugars that substitute for added sugars; and (4) the sugar content of the food has not been increased above the amount contributed by the ingredients by some other means (e.g., use of enzymes to hydrolyze starches to release sugars)
Nutrition claim regarding sodium/salts		
Low sodium/salt	No more than 0.12 g of sodium or 0.3 g of salt per 100 g or per 100 mL For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 mL	0.12 g per 100 g
Very low sodium/salt	No more than 0.04 g of sodium or 0.1 g of salt per 100 g or per 100 mL This claim shall not be used for natural mineral waters and other waters.	0.04 g per 100 g
No added sodium/salt[a]	A claim stating that sodium/salt has not been added to a food and any claim likely to have the same meaning for the consumer may only	Claims regarding the nonaddition of sodium salts to a food, including "no added salt," may be

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
	be made where the product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0.12 g sodium or the equivalent value for salt per 100 g or 100 mL.	made provided the following conditions are met: the food contains: (1) no added sodium salts, including but not limited to sodium chloride, sodium tripolyphosphate; (2) no ingredients that contain added sodium salts, including, but not limited to, Worcestershire sauce, pickles, pepperoni, soya sauce, salted fish, fish sauce; and (3) no ingredients that contain sodium salts that are used to substitute for added salt, including but not limited to seaweed.
Sodium-free/salt-free	No more than 0.005 g of sodium or 0.0125 g of salt per 100 g	A claim to the effect that a food is free of salt can be made provided the food meets the conditions for free of sodium listed: 0.005 g per 100 g
Nutrition claim regarding fiber content		
Source of fiber	At least 3 g of fiber per 100 g or at least 1.5 g of fiber per 100 kcal	3 g per 100 g or 1.5 g per 100 kcal or 10% of daily reference value per serving
High fiber	At least 6 g of fiber per 100 g or at least 3 g of fiber per 100 kcal	6 g per 100 g or 3 g per 100 kcal or 20% of daily reference value per serving

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
Nutrition claim regarding protein profile		
Source of protein	At least 12% of the energy value of the food is provided by protein	10% of NRV (Nutrient Reference Value) per 100 g (solids) 5% of NRV per 100 mL (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) 10% of NRV per serving
High protein	At least 20% of the energy value of the food is provided by protein	2 times the values for "source of protein"
Nutrition claim regarding vitamins and/or minerals		
Source of (name of vitamin/s) and/or (name of mineral(s))	At least a significant amount as defined in the Annex to Directive 90/496/EEC (EC, 2011) or An amount provided for by derogations granted according to Article 6 of Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. (Note: the derogations referred to here have not been agreed yet)	15% of NRV per 100 g (solids) 7.5% of NRV per 100 mL (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) 15% of NRV per serving
High (name of vitamin/s) and/or (name of mineral(s))	At least twice the value of "source of (name of vitamin/s) and/or (name of mineral/s)"	Twice the value for "source"
Nutrition claim regarding nutrients or other substance		
Contains (name of the nutrient or other substance)	A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, OR any claim likely to have the same meaning for the consumer, may only be made where the product	–

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
	complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim "source of" shall apply.	
Increased (name of nutrient)	Meets the conditions for the claim "source of" and the increase in content is at least 30% compared to a similar product	For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source." For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.
Reduced (name of nutrient)	Where the reduction in content is at least 30% compared to a similar product, except for micronutrients (vitamins and minerals), where a 10% difference in the reference values as set in Directive 90/496/EEC (EC, 2011) shall be acceptable, and for sodium, or the equivalent value for salt, where a 25% difference shall be acceptable. [a]The claim "reduced saturated fat," and any claim likely to have the same meaning for the consumer,	Low in, reduced in, or free of the constituent in the case where reduced consumption is recommended. Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high," "low," "reduced," and "free."

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
	may only be made: (1) if the sum of saturated fatty acids and of trans-fatty acids in the product bearing the claim is at least 30% less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and (2) if the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product. The claim "reduced sugars," and any claim likely to have the same meaning for the consumer, may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product.	For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source." For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.
Light/lite	Conditions as those set for the term "reduced"; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food "light" or "lite"	Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food." For comparative claims about energy or macronutrients and

(*Continued*)

Table 18.1 (Continued)

Nutrition claim	EU regulation 1924/2006 (as amended)[a]	Codex Alimentarius CAC/GL 23–1997
		sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source." For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.
Naturally/natural	Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term "naturally/natural" may be used as a prefix to the claim.	The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fiber, sodium and vitamins and minerals for which NRVs.

[a]Amended by Commission Regulation (EU) No 1047/ 2012.

- Sustainable exploitation of bioactive components from the Black Sea Area traditional foods (BaSeFood, 2017).

Some prestigious global organizations, such as the International Network of Food Data Systems (INFOODS), have also helped to improve the availability of food composition data by developing databases (e.g., Food Composition Database for

Table 18.2 Comparative analysis of food legislation regarding vitamins and minerals listed with their nutrient reference values (NRVs) or recommended dietary allowance (RDA), and their minimum values required to meet the conditions for a "*source of*" and a "*high*" claim (EC, 1990, 2008a; FAO/WHO, 1985).

Standard/legislation	CAC/GL 2–1985			Directive 2008/100/EC			Directive 90/496/EEC		
Vitamin/mineral	**NRV**	**Claim: *Source of***	**Claim: *High***	**RDA**	**Claim: *Source of***	**Claim: *High***	**RDA**	**Claim: *Source of***	**Claim: *High***
Vitamin A (μg[a])	800	120	240	800	120	240	800	120	240
Vitamin D (μg)	5	0.75	1.5	5	0.75	1.5	5	0.75	1.5
Vitamin E (mg)	–	–	–	12	1.8	3.6	10	1.5	3.0
Vitamin K (μg)	60	9	18	75	11.25	22.5	–	–	–
Vitamin C (mg)	60	9	18	80	12	24	60	9	18
Thiamin (mg)	1.2	0.18	0.36	1.1	0.16	0.33	1.4	0.21	0.42
Riboflavin (mg)	1.2	0.18	0.36	1.4	0.21	0.42	1.6	0.24	0.48
Niacin (mg NE[b])	15	2.25	5	16	2.4	4.8	18	2.7	5.4
Vitamin B6 (mg)	1.6	0.24	0.48	1.4	0.21	0.42	2	0.3	0.6
Folic acid/ folate (μg DFE[c])	400	60	120	200	30	60	200	30	60
Vitamin B12 (μg)	2.4	0.36	0.72	2.5	0.38	0.76	1	0.15	0.30
Biotin (μg)	30	4.5	9	50	7.5	15	15	22.5	45
Pantothenic acid (mg)	5	0.75	1.5	6	0.90	1.8	6	0.90	1.8
Potassium (mg)	–	–	–	2000	300	600	–	–	–
Chloride (mg)	–	–	–	800	120	240	–	–	–
Calcium (mg)	1000	150	300	800	120	240	800	120	240
Phosphorus (mg)	–	–	–	700	105	210	800	120	240
Magnesium (mg)	300	45	90	375	56.25	112.5	300	45	90
Iron (mg)	14	0.6	1.2	14	2.1	4.2	14	2.1	4.2
Zinc (mg)	15	2.25	4.5	10	1.5	3.0	15	2.25	4.5
Copper (mg)	NA[d]	NA	NA	1	0.15	0.30	–	–	–
Manganese (mg)	–	–	–	2	0.30	0.60	–	–	–
Fluoride (mg)	–	–	–	3.5	0.525	1.05	–	–	–
Selenium (μg)	NA	NA	NA	55	8.25	16.5	–	–	–
Chromium (μg)	–	–	–	40	6	12	–	–	–
Molybdenum (μg)	–	–	–	50	7.5	15	–	–	–
Iodine (μg)	150	22.5	45	150	22.5	45	150	22.5	45

[a]For the declaration of β-carotene (provitamin A) the following conversion factor should be used: 1 μg retinol = 6 μg β-Carotene.
[b]Niacin 1 mg niacin equivalents (NE) = 1 mg niacin 60 mg tryptophan.
[c]Folate 1 μg dietary folate equivalents (DFE) = 1 μg food folate 0.6 μg folic acid added to food or as supplement consumed with food; 0.5 μg folic acid as supplement taken on an empty stomach.
[d]NA—Value to be established.

Table 18.3 Comparative analysis of food legislation regarding reference intakes for energy and selected nutrients, other than vitamins and minerals (EC, 2011; FAO/WHO, 1985).

Compound	CAC/GL 2–1985	EU 1169/2011
Energy	8370 kJ/2000 kcal	8400 kJ/2000 kcal
Total fat	–	70 g
Saturates fat	20 g	20 g
Carbohydrate	–	260 g
Sugars	–	90 g
Protein	50 g	50 g
Salt	Sodium 2000 mg	6 g

Table 18.4 Comparative analysis of food regulations on conversion factors for calculating the energy value of food (EC, 2011; FAO/WHO, 1985).

Compound	CAC/GL 2–1985	EU 1169/2011
Carbohydrate (except polyols)	17 kJ/g–4 kcal/g	17 kJ/g–4 kcal/g
Polyols	[H][a]	10 kJ/g–2.4 kcal/g
Protein	17 kJ/g–4 kcal/g	17 kJ/g–4 kcal/g
Fat	9 kcal/g–37 kJ	37 kJ/g–9 kcal/g
Salatrims	[H][a]	25 kJ/g–6 kcal/g
Alcohol (ethanol)	29 kJ/g–7 kcal/g	29 kJ/g–7 kcal/g
Organic acid	13 kJ/g–3 kcal/g	13 kJ/g–3 kcal/g
Fiber	[H][a]	8 kJ/g–2 kcal/g
Erythritol	[H][a]	0 kJ/g–0 kcal/g

[a][H] Harmonization required.

Biodiversity), specific guidelines, and quality standards for products (including traditional foods). INFOODS regional data centers in Central and Eastern European countries (CEECFOODS) and European countries (EUROFOODS) were developed for technical assistance at EU level, including the Balkan countries. The Food and Agriculture Organization (FAO) and INFOODS issued guidelines and standards to improve quality and knowledge of food composition data (Charrondiere et al., 2016).

Traditional foods that are adapted for menus with religious restrictions (e.g., during Lent and religious periods specific to the liturgical year like Easter, Christmas, etc.) are also an important part of the national gastronomic heritage that must be preserved by certification recognized at EU/global level. Increased knowledge of the Balkan eating pattern during the specific fasting periods of the liturgical year, of food selection, and religious restrictions is crucial for the certification of such products as "traditional" and for their acceptance on the market. The producer must ensure compliance with religious requirements, in terms of consumer values and beliefs. For these reasons, specific

databases and guidelines, including checklists with forbidden ingredients, goods-in selection, recommended procedures of preparation, and cooking must be created for both producers and retailers, but also for quality assessors (Vintila, 2015).

The harmonization process on general and nutrition labeling in the Balkan countries is an important topic within the EU and also globally (Vintila et al., 2019). The global organizations involved in the nutrition legislation process—the European Union (EU), the United Nations (UN), Codex Alimentarius Commission (Codex), Food and Agriculture Organization (FAO), World Health Organization (WHO), and the World Trade Organization (WTO)—support the process of harmonizing global nutrition legislation. Despite this, cultural differences between countries represent a strong obstacle to the harmonization process (Bone & France, 2003). The authentic taste, texture, appearance, color etc., as well as the original methods of production, preservation, packaging, etc. are main attributes that form the identity of a traditional product. The harmonization process should lead to the identification of the common set of physicochemical and sensorial characteristics used by consumers to recognize traditional food products. These characteristics can be used as benchmarks when controlling the quality and safety of such foods.

The important mission of today's generation is to preserve the national food and gastronomic patrimony. The nation's best interest, and of its citizens, must be placed at the center of the legislation and of the harmonization process. As regards traditional products, the interest is to keep the knowledge of creating gastronomic products with the same quality characteristics (or, almost the same) as those consumed by our ancestors. For this reason, but also because we now trade agro-foods and beverages instead of consuming them in their area of origin and/or within the family that creates them, international bodies need to create fair standards of nutritional quality and safety.

18.3 Proposed strategies to harmonize nutrition and health claims regulations made on foods

Two indicators are proposed (Vintila, 2019) to assess the degree of harmonization of nutrition regulations and legislation across the world—(1) the ratio of similitude (k) as an indicator for legislative consistency, and (2) the gap index (g) as an indicator of the harmonization gap (inconsistency) between nutrition legislation from different jurisdictions. These indicators can be used to measure the similarities and differences between current global nutritional standards. The following are proposed:

1. The ratio of similitude (k) that can be calculated with Eq. (18.1):

$$k = \frac{L_{STAN1}}{L_{STAN2}} \tag{18.1}$$

where: k is ratio of similitude, L_{STAN1} is the absolute value of nutrients/energy for standard 1, while L_{STAN2} is for standard 2, with $L_{STAN1} \leq L_{STAN2}$.

The ratio of similitude measures the degree to which the two standards are harmonized. The k value is 1 for totally harmonized criteria/standards and varies between 0 and 1, depending on the similitude degree between the two compared standards.

2. The gap index (g) that can be calculated with Eq. (18.2):

$$g = |L_{STAN1} - L_{STAN2}| \tag{18.2}$$

where: g is the absolute inconsistency value.

The g value tends to 0 for totally harmonized criteria/standards.

Depending on the degree of harmonization (i.e., k and g values), specific recommendations are to be proposed and applied in order to improve the harmonization level, should a declaration of intent on harmonization be signed and adopted.

Also, a descriptive harmonization checklist (Vintila, 2019) for food nutrition and health claims is proposed as follows:

- Clear listing of the name of the nutrient/substance bearing a nutrition/health claim;
- Clear statement of the nutrient/substance absolute content per serving and commercial unit;
- Clear statement of the nutrient/substance content for bearing a "source of" or "high-in" claim (i.e., 0%–15% of DRV for "source of," above 15%–30% of DRV for "high-in" claim);
- Statement on product quality to be supported by scientific data for the claimed (beneficial) effect;
- Statement on recommended daily servings to achieve the claimed effect and support a varied and balanced diet, and a healthy lifestyle; and
- Warning statement about the health risks caused by excessive consumption (i.e., up to recommended daily intake).

The general principles proposed for the harmonization of legislative requirements are as follows:

- Assisting consumers in understanding claims in relation to their daily diet and the official dietary guidelines;
- Avoiding food discrimination, as well as illegal and unethical business practice by creating transparent comparative food claims [e.g., "energy reduced," "increased (name of the nutrient)," "light," and "reduced (name of the nutrient)"];
- Developing an effective quality control tool accepted internationally by food manufacturers, traders, other stakeholders, etc.;
- Providing food quality markers for nutrition and health claims based on scientific evidence;
- Encouraging international market exchange and increasing profits in different regions and continents by establishing common rules for legal communication in business and advertising;

- Endorsing good dietary practice and a healthy lifestyle, avoiding excessive consumption of any food type;
- Ensuring health claims are truthful, clear, reliable, and helpful to the consumer;
- Expanding the range of permitted health claims based on proven food-health relationship;
- Fostering innovation in the food industry and offering consumers a wider range of healthy food choices;
- Developing a standard and easily recognizable food label that provides accurate information to consumers and promotes the food product;
- Reducing the risk of misleading and deceptive claims about food by accurate labeling, declaration of authorized nutrition and health claims on the international market, and by providing scientifically-proven information on ingredients and products with respect to human health and well-being; and
- Supporting consumers in making healthy dietary choices by providing a clear and legal means of communication (Vintila et al., 2019).

Additionally, the tolerance limits for nutritional labeling declarations must be standardized, depending on nutrient type and food profile.

In the harmonization process, the first step is to assess the differences between national standards and EC directives in terms of nutrient and energy intakes, including energy DRI, recommended dietary allowance (RDA), and adequate intake (AI). Then, the next step is to harmonize the methods used in the assessment of the nutrient profile by applying guidelines developed in the work carried out in the EuroFIR_GAMA project (Castanheira, Saraiva, Rego, & Ollilainen, 2016). FAO/INFOODS has published three comprehensive guidelines, which can serve as tools for the control and harmonization of food, in general, and traditional food, in particular: (1) Guidelines for Food Matching (FAO/INFOODS, 2011a); (2) Guidelines for Checking Food Composition Data (FAO/INFOODS, 2011b); and (3) Guidelines for Converting Units, Denominators, and Expressions (Charrondiere et al., 2016). These guidelines are intended for food and beverage recipe calculation, selecting nutrient retention factors, food sampling, and the management of food composition databases. Sampling is crucial in case of traditional foods because the analyzed sample must be representative in terms of the origin, variety, and seasonality of ingredients, as well as in terms of the recipe, production techniques, preservation, portioning, etc. Those artisanal procedures or techniques that were genuinely used in ancient households should be considered for traditional food creations. Traditional foods containing spices or ingredients from another geographical area other than their true place of origin should not exist. The autochthonous animal breeds, and plant and crop varieties are of utmost importance when it comes to the quality of traditional products, such as meat or cheese. Their conservation has become a necessity for the modern agro-farms involved in the production of certified traditional foods (Dias & Mendes, 2018).

In this regard, the Association of Official Analytical Collaboration (AOAC) has established standard methods that can be used with confidence by various stakeholders, from industry and regulatory agencies to research and academic institutions, to analyze food integrity and safety.

Certification is considered an effective way to protect authentic artisanal products against foreign imitation and unfair competition. On the other hand, strict standardization and excessive guidance can obstruct the unique characteristics of those artisanal foods created in small quantities in small agro-farms and in rural households. The certification of traditional foods requires two main categories of information:

1. Historical and sociological information: historical period in which the food was initially produced and consumed, the geographical area of production and consumption, the characteristics of the local population; and
2. Cultural information: the etymology of the name of the food, a brief history of the recipe and its importance in the local diet, economy, religious and social life, the traditional characteristics, consumption patterns, evolution, and variations of the recipe (Dilis et al., 2013).

Combining nutrition and health claims with quality logos (e.g., PDO, PGI, TSG) could increase competitiveness of traditional foods on the market and support consumers with specific dietary needs.

18.4 Conclusions

Harmonization of law and regulations is the key to creating sustainable structures that can benefit all stakeholders, from the food industry and marketers to consumers. It is a practical tool for improving the safety and quality of foods (including their authenticity), as well as the overall health and satisfaction of consumers, while promoting fair international trade and reducing inequities in market access between countries due to noncompliance with international regulatory standards. Harmonization requires strong willingness, both politically and scientifically, a deep knowledge of similarities and differences in legislation, as well as sustained effort to achieve a science-based consensus, possibly requiring lengthy debates, negotiations, reformulations, and amendments to current legislation before a global agreement is reached. As regards the harmonization of global labeling legislation, it is necessary to move from the current description of policy gaps to an objective scientific assessment of the level of harmonization using harmonization assessment indicators, which have been introduced in this chapter.

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