

Current legislations in nutrition and issues requiring global harmonisation

I. Vintila^{1*}, V.Y. Waisundara² and H.L.M. Lelieveld³

¹University Dunarea de Jos, Domneasca Street 47, 800008 Galati, Romania; ²Australian College of Business and Technology – Kandy Campus, Peradeniya Road, 2000 Kandy, Sri Lanka; ³Global Harmonization Initiative, 18 Muthgasse, 1190 Vienna, Austria; vintilaiuliana@yahoo.com

Received: 4 August 2018 / Accepted: 12 February 2019

© 2019 Wageningen Academic Publishers

OPINION ARTICLE

Abstract

This article describes an overview of the current trends on international regulations on nutrition as well as global nutrition policies. We present recommendations for harmonisation of dietary guidelines, and nutrition and health claims starting with the societal needs driving this perspective. These recommendations also are proposed within the framework of objectives and actions by the Nutrition Working Group of the Global Harmonization Initiative (GHI). In all reviews to date, reports and critical point of views, the common conclusion is that harmonisation is the key to improving global legislation, which would benefit consumers, food quality and fair trade. The differences existing between global regulations regarding the main nutrition issues and the gap existing for the Nutrient Reference Value (NRV), daily energy value and intake, have made global harmonisation a vital initiative. Harmonised criteria checklists for food nutrition and health claims are proposed in this article, within the framework of general principle of harmonisation. These are strictly based on proven relationship(s) between food compounds and beneficial effects on nutrition or health.

Keywords: food security, legislation, standards, nutrition, harmonisation

1. Introduction

Nutrition and health claims are voluntary statements validated by food producers in support of food quality and food integrity, where these are primarily applicable to packaging and advertisements. An important segment of foodstuffs available on the global market claims to promote health and wellness. Nutrition claims state that a food or food component has direct and scientifically proved nutritional benefits related to correct nutrition principles, e.g. 'source of vitamin/minerals/fibre', 'high fibre' and 'low fat', etc. A health claim comprises a statement about a positive correlation between food/food component and health (e.g. 'regular consumption contributes to normal immune function'). It would generally refer to a relationship between food composition and promoting health rather than to prevent some particular disease (i.e. reduces cholesterol and risk of cardiovascular disease rather than prevents heart attacks).

The European Union (EU) adopted Regulation No. 1924/2006 regarding nutrition and health claims for foods, which represent the basis of EU-wide harmonisation of legislation. According to this Regulation, there are two types of health claims:

- functional claims based on generally accepted scientific data or based on newly developed scientific data;
- reduction of disease risk claims and claims for growth and development of children (EC, 2006a).

All food categories must meet specific requirements in order to have an assignment of nutrition or health claims. The 'Passclaim' (ILSI, 2018) process includes criteria for scientific substantiation of a health claim, as follows:

1. characterisation of the food or (active) food component;
2. scientific data and weighing of evidence;
3. claims primary based on human intervention studies;
4. biologically and technically valid markers, if the endpoint cannot be measured.

One of the key objectives of Regulation EC No. 1924 was to ensure that any claim is clear and substantiated through 'scientific assessment of the highest possible standard' with a reasonable effect on the condition of food for normal consumption, as part of a daily balanced diet. The final goal is to achieve a high level of consumer confidence, develop a fair and free common EU market of safe foods, increase food security of integrity, and ensure fair commercial competition (EC, 2006a). The EC Regulation No. 1047/2012, published in November 2012, added a new 'no added sodium/salt' claim to this list and amended the conditions of use for 'reduced [name of the nutrient]' claims (EC, 2012a).

The online 'Register of Nutrition and Health Claims' (<http://ec.europa.eu/nuhclaims>) includes more than 222 authorised health claims as well as more than 1,600 rejected claims and reasons for their exclusion. Food products with claims must comply with the provisions of nutritional labelling EC No. 1169/2011, which came into effect from 13th December 2014 and introduced mandatory declaration of energy as well as amounts of fat, saturates, carbohydrates, sugars, protein and salt expressed per 100 grams or per 100 millilitres, in the same matrix. The salt content must be expressed as salt, not sodium. Additionally, the nutrition declaration may be given as 'per portion' and expressed as a percentage of dietary reference intakes (EC, 2011).

In 2011 and 2012, the World Health Organization (WHO) published the e-library of Evidence in Nutrition (e-ELENA) and the Global database on the Implementation of Nutrition Action on the global scale (GINA). The last updated document, The Global Nutrition Policy Review (WHO, 2018), was decided by a Pre-Codex Committee on Nutrition and Food for Special Dietary Uses, Global Databases on Body Mass Index and Global Databases on Child Malnutrition (WHO, 2012). The European Safety Authority (EFSA) published the Dietary Reference Value (DRV) Summary Report in 2017, based on the opinion of EFSA Panel on Nutrition, Dietary Food and Allergies (EFSA, 2018).

The Codex General Guidelines on Claims CAC/GL 1-1979 (Rev. 1-1991) define, as fundamental principle, the fact that 'no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect' (FAO, 1991). The common legislation beside the existing gaps in the nutrition labelling were reviewed extensively in a recently published review (Kasapila and Shaarani, 2016) and the main issues regarding international legislation on nutrition and health claims were described by De Boer and Bast (2015), based on the inventory of 28 legislation jurisdictions.

In all international reviews, reports and critical point of views, the common conclusion is that harmonisation is the

key to improving global legislation, which would benefit consumers, food quality and fair trade. This article reports the state of international nutrition regulations (Section 2), the Global Harmonization Initiative (GHI) nutrition policy (Section 3), and GHI recommendations for nutrition legislation harmonisation (Section 4). The harmonisation of the global nutrition regulations is the genuine objective of the GHI Working Group (WG) in Nutrition. The first step is to investigate the current state of art on this aspect and to define specific harmonisation policies.

2. An overview of the current state of international nutrition regulations

EU regulation for nutrition labelling, health and nutrition claims

EU Member States (EU-MS) proceed under national ratification of EU legislation, regulations and directives, as a basis of harmonisation in Europe. EU Regulation (EC) No.178/2002 sets out the general principles and requirements for harmonised food law in the European Union (EC, 2002). In practice, there is variation and differences between EU-MS in interpreting EU legislation that affects the internal and international food trade.

The European Commission (EC) website hosts the community register of authorised and rejected health claims (EC, 2006c). The EFSA undertakes scientific evaluation of claims, on behalf of the EC and EU-MS. The panel on Dietetic Products, Nutrition and Allergies (NDA) deals with dietetic products, nutrition and food allergies, and is responsible for verifying scientific evidence submitted for a claim – some of which are in use, some of which are proposed by applicants (food manufacturers). This offers an opinion based on the evidence presented, which may lead to authorisation or exclusion by the EC. This process helps to ensure that nutrition and health claims are meaningful and accurate, giving protection to the consumer from false claims and enabling healthy choices.

Claims under Article 13.5 are those based on newly developed scientific evidence and/or for which protection of proprietary data is requested. For these health claims, authorisation is investigated on a case-by-case basis following submission of a scientific dossier to EFSA. General function claims under Article 13.1 refer to the role of a nutrient or substance in growth, development and function, psychological and behavioural functions, slimming and weight control, and satiety or reduction of available energy from the diet. EFSA finalised the evaluation of general functional health claims by the end of June 2011 and published 341 opinions on 2,758 health claims. An updated list of 4,637 claims was published in May 2010, after the EC examined more than 44,000 claims from EU-MS (EFSA, 2018).

The EC and EU-MS agreed that half the general functional health claims could be eligible for further assessment by EFSA including those related to micro-organisms (probiotics), which the NDA Panel considered initially as insufficiently characterised, as well as claims found to have initially lacked evidence to establish a cause-and-effect relationship between consumption and the claimed effect. Ninety-one claims (74 for micro-organisms, 17 with ‘insufficient evidence’) had been submitted to EFSA for assessment by December 2012. The first opinions related to these additional assessments were published in June 2012.

The EU legislation regarding nutrition labelling, nutrition and health claims include:

- Regulation EC 178/2002 General Food Law (EC, 2002);
- EU Council Regulation 1169/2011 (EC, 2011);
- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 regarding the approximation of the laws of the EU-MS relating to the labelling, presentation and advertising of foodstuffs (EC, 2000);
- The EC No. 1170/2009 of 30 November amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (EC, 2009);

The EC No. 432/2012 establishing a 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, and amended by EC No. 1048/2012 (EC, 2012b,c).

The EC No. 1169/2011 establishes new horizontal food labelling requirements and amends Regulation 1924/2006 on nutrition and health claims and EC No. 1925/2006 on fortified foods; it repeals Directive 87/250/EEC on the indication of alcohol strength, Directive 90/496/EEC on nutrition labelling, Directive 1999/10/EC on derogations, Directive 2000/13/EC on food labelling (EC, 2011). The new food labelling rules apply from the 13th December 2014 onwards, except for the mandatory nutrition declaration, which applies from the 13th December 2016 onwards, and Part B of Annex VI (specific requirements concerning the designation of minced meat), which came into effect from 1st January 2014. Nutrition declarations provided on a voluntary basis must comply with these rules from 13th December 2014 onwards.

The EU documents for harmonisation of nutrition legislation regarding the DRV are as follows:

- Opinion of EFSA NDS, 2010 (EFSA, 2010);
- The EFSA DRV Summary Report, 2017 (EFSA, 2017);
- EFSA databases on food consumption and food composition (EFSA, undated a,b);
- EURRECA project results (EURRECA, 2012);

- EU population nutrient reference intake (Roe *et al.*, 2013).

United States Food and Drug Administration regulations on nutrition labelling, health and nutrition claims

The regulations for general use include (FDA, 2018):

- Code of Federal Regulations (CFR): Title 21 – Food and Drugs – Part 101 – Food Labelling (FDA, 2019);
- Guidelines for Determining Metric Equivalents of Household Measures (FDA, 1993);
- Food Labelling: trans fatty acids in nutrition labelling, nutrient content claims, and health claims; small entity compliance guide (August 20, 2003) (FDA, 2003b);
- Retail Labelling: a labelling guide for restaurants and other retail establishments selling away-from-home foods (April 2008) (FDA, 2008c);
- A Food Labelling Guide (October 2009) (FDA, 2009a);
- Guidance for Industry: ingredients declared as evaporated cane juice; draft guidance (October 2009) (FDA, 2009b).

The regulations for nutrition labelling include:

- Small Business Nutrition Labelling Exemption (October 1, 2004; Updated May 7, 2007) (FDA, 2007c);
- FDA Nutrition Labelling Manual – a guide for developing and using databases (March 1998) (FDA, 1998a).

The regulations for nutrition claims include:

- Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (July 1998) (FDA, 1998b);
- Structure/Function Claims: small entity compliance guide (January 9, 2002) (FDA, 2002);
- Dear Manufacturer Letter Regarding Food Labelling (January 2007) (FDA, 2007a);
- Nutrient Content Claims: Dear Manufacturer Letter Regarding Sugar Free Claims (September 2007) (FDA, 2007b);
- Dear Manufacturer Letter Regarding Front-of-Package Symbols (December 2008) (FDA, 2008a);
- Nutrient Content Definitions: Food Labelling; Nutrient Content Claims; Definition for ‘High Potency’ and Definition for ‘Antioxidant’ for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods Small Entity Compliance Guide (July 2008) (FDA, 2008b);
- Letter Regarding Point of Purchase Food Labelling (October 2009) (FDA, 2009e).

The regulations for health claims include:

- Interim Procedures for Qualified Health Claims in the Labelling of Conventional Human Food and Human Dietary Supplements (July 10, 2003) (FDA, 2003a);
- FDA’s Implementation of ‘Qualified Health Claims’: Questions and Answers (May 12, 2006) (FDA, 2006);
- Evidence-Based Review System for the Scientific Evaluation of Health Claims (January 2009) (FDA, 2009c);

- Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999) (FDA, 1999);
- Food Labelling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis (May 2009) (FDA, 2009d).

Australia and New Zealand regulation for nutrition labelling, health and nutrition claims

The Standard 1.2.7 (Australian Standard, 1991) regulating the nutritional-content and health claims on food labels, as well as in advertisements became law in Australia and New Zealand on 18th January 2013. Food businesses were required to comply with the new standard from 18 January 2016. General health claims will be allowed on the basis of more than 200 pre-approved food-health relationships. The self-substantiation of a food-health relationship will be possible in accordance with detailed requirements set out in the Standard 1.2.7. Health claims will only be permitted for foods that meet nutrient profiling scoring criteria, i.e. health claims will not be allowed on foods high in saturated fat, sugar or salt.

Concerning the issues of global DRV and NRV harmonisation, there are Food and Agricultural Organization of the United Nations (FAO, undated), World Health Organisation of the United Nations (WHO) (Allen *et al.*, 2006) and the US Institute of Medicine (IOM) (Otten *et al.*, 2006) recommendations for the reference values. However, there is still a lack of updated reviews about global NRV differences.

3. A consensus policy

The following are some policies which are recommended to be taken into account for the purpose of agreement in legislation.

Policy 1: general basis of international nutrition regulation documents

The following regulatory systems could be accounted for when coming to a global consensus concerning nutrition:

- *Europe*: EC No. 1924/2006 amended by EC No. 1047/2012, EC No. 432/ 2012 amended by EC No. 1048/2012, EU Council Directive 90/496/EC amended by EC No. 1169/2011, EC No. 178/2002.
- *United States*: FDA regulation about Qualified Health Claims 2003 (FDA, 2003a) and Food Nutrition Labelling (FDA, 2009a), Food and Agricultural Import Regulations and Standards (FAIRS) (GAIN E70048) (USDA, 2012).
- *Canada*: Health Canada provides the legislation and guidelines related to Food and Nutrition, including Nutrition Labelling Regulations (published on January 1, 2003). Health Canada administers many pieces of

legislation and develops and enforces regulations under this legislation that have a direct impact on the health throughout nutrition and safety (Health Canada, 2018).

- *Australia and New Zealand*: Food Standards Australia New Zealand (Australian Standard, 1991) issues the Australia New Zealand Food Standards Code, with specific Nutrition, Health and Related Claims.
- *China*: USDA, GAIN Report-CH 8064 (USDA, 2008), Chinese specific label based on the GB7718-2011 and GB 28050-2011 (USDA, 2011),
- *Codex Alimentarius* general nutrition and health claims (CAC, 1997) and guidelines on nutrition labelling (CAC, 1985).
- *Japan*: Food Labelling Act (Act No.70/2013) regarding the purchasing foods, Act created in the benefit of the population in according with Food Sanitation Act (Act No. 233 of 1947), the Health Promotion Act (Act No. 103 of 2002), and the Act on Standardization of Agricultural and Forestry Products (Act No. 175 of 1950) (Japan, 1947, 1950, 2002, 2013).

Policy 2: Harmonised NRV, recommended dietary allowance (RDA) and the minimum values required bearing the conditions for a 'source of' and a 'high' claim

The differences existing between the Codex Alimentarius and EU regulation regarding the main nutrition issues and the gap existing for the NRV, daily energy value and intake (Tables 1-3), define the future global harmonisation actions.

Policy 3: Harmonised nutrition labelling guidelines

The GHI Harmonised Nutrition Labelling Guidelines will be based on the following international regulations:

- EC No. 1169 of the European Parliament and of the Council of 25th October 2011 on the provision of food information to consumers (EC, 2011);
- The Food Safety Authority of Ireland (FSAI) Statutory Instruments (SI) No. 461 on Nutrition labelling for foodstuffs (FSAI, 2002);
- The FSAI S.I. No. 483 on Labelling, Presentation and Advertising of Foodstuffs Regulations (FSAI, 2009).

Policy 4: Harmonised criteria for substantiating a nutrition and health claim

The general principles for the systematic review of the scientific evidence, in accordance with EFSA's recommendation (EFSA, 2018) and Australian Standard 1.2.7 Schedule 6 (Australian Standard, 1991) are proposed as follows:

- Nutrition and health claims based on current relevant scientific substantiation where the level of proof is sufficient to substantiate the claim and to prove the direct relationship with a specific health issue, as recognised by generally accepted research databases.

Table 1. Comparative basis of nutrient profile for the vitamins and minerals are listed with their nutrient reference values (NRVs) or recommended daily allowance (RDA) and the minimum values required bearing the conditions for a 'source of' and a 'high' claim.

Vitamin/Mineral	Standard/Regulation								
	CAC/GL 2-1985 (CAC, 1985)			Regulation EU 1169/2011 (EC, 2011)			Directive 90/496/EEC (EC, 1990)		
	NRV	claim: source of	claim: high	RDA	claim: source of	claim: high	RDA	claim: source of	claim: high'
Vitamin A	800 µg ¹	120 µg	240 µg	800 µg	120 µg	240 µg	800 µg	120 µg	240 µg
Vitamin D	5 µg	0.75 µg	1.5 µg	5 µg	0.75 µg	1.5 µg	5 µg	0.75 µg	1.5 µg
Vitamin E	–	–	–	12 mg	1.8 mg	3.6 mg	10 mg	1.5 mg	3.0 mg
Vitamin K	60 µg	9 µg	18 µg	75 µg	11.25 µg	22.5 µg	–	–	–
Vitamin C	60 mg	9 mg	18 mg	80 mg	12 mg	24 mg	60 mg	9 mg	18 mg
Thiamin	1.2 mg	0.18 mg	0.36 mg	1.1 mg	0.165 mg	0.33 mg	1.4 mg	0.21 mg	0.42 mg
Riboflavin	1.2 mg	0.18 mg	0.36 mg	1.4 mg	0.21 mg	0.42 mg	1.6 mg	0.24 mg	0.48 mg
Niacin	15 mg NE ²	2.25 mg	5 mg	16 mg	2.4 mg	4.8 mg	18 mg	2.7 mg	5.4 mg
Vitamin B6	1.6 mg	0.24 mg	0.48 mg	1.4 mg	0.21 mg	0.42 mg	2 mg	0.3 mg	0.6 mg
Folic acid/ Folate	400 µg DFE ²	60 µg	120 µg	200 µg	30 µg	60 µg	200 µg	30 µg	60 µg
Vitamin B12	2.4 µg	0.36 µg	0.72 µg	2.5 µg	0.38 µg	0.76 µg	1 µg	0.15 µg	0.30 µg
Biotin	30 µg	4.5 µg	9 µg	50 µg	7.5 µg	15 µg	0.15 mg	0.0225 mg	0.045 mg
Pantothenic acid	5 mg	0.75 mg	1.5 mg	6 mg	0.90 mg	1.8 mg	6 mg	0.90 mg	1.8 mg
Potassium	–	–	–	2,000 mg	300 mg	600 mg	–	–	–
Chloride	–	–	–	800 mg	120 mg	240 mg	–	–	–
Calcium	1000 mg	150 mg	300 mg	800 mg	120 mg	240 mg	800 mg	120 mg	240 mg
Phosphorus	–	–	–	700 mg	105 mg	210 mg	800 mg	120 mg	240 mg
Magnesium	300 mg	45 mg	90 mg	375 mg	56.25 mg	112.5 mg	300 mg	45 mg	90 mg
Iron	14 mg	0.6 mg	1.2 mg	14 mg	2.1 mg	4.2 mg	14 mg	2.1 mg	4.2 mg
Zinc	15 mg	2.25 mg	4.5 mg	10 mg	1.5 mg	3.0 mg	15 mg	2.25 mg	4.5 mg
Copper	NA ³	NA	NA	1 mg	0.15 mg	0.30 mg	–	–	–
Manganese	–	–	–	2 mg	0.30 mg	0.60 mg	–	–	–
Fluoride	–	–	–	3.5 mg	0.525 mg	1.05 mg	–	–	–
Selenium	NA	NA	NA	55 µg	8.25 µg	16.5 µg	–	–	–
Chromium	–	–	–	40 µg	6 µg	12 µg	–	–	–
Molybdenum	–	–	–	50 µg	7.5 µg	15 µg	–	–	–
Iodine	150 µg	22.5 µg	45 µg	150 µg	22.5 µg	45 µg	150 µg	22.5 µg	45 µg

¹ For the declaration of β-carotene (provitamin A) the following conversion factor should be used: 1 µg retinol = 6 µg β-carotene.

² Niacin equivalents (NE): 1 mg niacin is equivalent to 60 mg tryptophan; dietary folate equivalents (DFE) = 1 µg food folate is equivalent to 0.6 µg folic acid added to food or as supplement.

³ NA = value to be established.

- Comparison of claims should be conducted only within the same food category, quantity (expressed as a percentage, fraction or an absolute amount) and conditions of use.
- Permitted nutrition claims are related to energy, protein, carbohydrate, fat, fibre, sodium, vitamins and minerals for which NRVs, in specific limited conditions.
- General or excessive claims, such as 'healthy food' or 'healthy diet' should be avoided to eliminate the mislead potential, particularly in promoting excessive/unbalanced consumption.

4. Proposed action plan

Given these perspectives, an action plan is suggested harmonising nutrition and health claims and nutrition labelling requirements, including conditions of use, to ensure proper functioning of international food markets and a high level of consumer protection, including food intended for use in foodservices units.

Table 2. Comparative daily energy value and nutrient reference values (NRVs) between Codex Alimentarius (CAC, 1985) and current EU Regulation (EC, 2011).

Compound	CAC/GL 2-1985	EU Regulation No. 1169/2011
Energy	8,370 kJ/2,000 kcal	8,400 kJ/ 2,000 kcal
Total fat	–	70 g
Saturates fat	20 g	20 g
Carbohydrate	–	260 g
Sugars	–	90 g
Protein	50 g	50 g
Salt	sodium 2,000 mg	6 g

Table 3. Comparative conversion factors for the calculation of daily food energy (CAC, 1985, EC, 2011).

Compound	CAC/GL 2-1985	EU Regulation No. 1169/2011
Carbohydrate (except polyols)	17 kJ/ g-4 kcal/g	17 kJ/g-4 kcal/g [√]
Polyols	– H ¹	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 [√]
Salatrim	– H	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 [√]
Fibre	– H	8 kJ/g-2 kcal/g
Erythritol	– H	0 kJ/g-0 kcal/g

¹ H = harmonisation required.

Action 1: Harmonisation in food nutrition labelling requirements

Harmonisation criteria checklist for the pool of permitted/ authorised food nutrition claims in the framework of harmonised regulations should be based strictly on proven relationship(s) between food compounds and beneficial effects on nutrition or health, and associated with:

- energy conversion factors;
- nutrient/substances bioavailability under specified conditions of use and in a consumable form;
- minimum values required meeting conditions for a 'source of' or 'high-in' claim (15% and 30%, respectively);
- nutrient/substances declaration per commercial unit as sold (units of expression and percentage RDA): presence/ absence/reduced content;
- nutrient/substances up to efficacious dose for the effect claimed (up to 15% of RDA) –comparative claim basis;

- conformity of declaration format: tabular or linear, language, type settings, position (field of vision) on the label.

Action 2: Global harmonisation of authorised food nutrition and health claims

1. nutrition claims;
2. health claims:
 - growth and development of body functions;
 - psychological and behavioural functions;
 - slimming or weight-control effects;
3. claims referring to child's development or reduction of disease risk claim.

The harmonisation checklist criteria design eligible to be used in the specific claim associated with:

- a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- scientific study of quantity and patterns of consumption, which demonstrate the impact of a claimed (beneficial) effect;
- statement addressing those who should avoid the substance concerned;
- warning of health risks caused by specified excessive consumption.

Action 3: Harmonisation criteria for special or individual authorised nutritional and health claims

The harmonisation checklist criteria design for eligibility to use the specific claim, based on new scientific evidence and/or including a request for the protection of proprietary data or referring to:

- reduction of a risk factor in the development of a disease;
- children's development and health.

In 2018, an updated process of harmonisation actions was proposed by the GHI Working Group in Nutrition, with the objective of Food Nutrition Regulation & Standards Global Harmonization within the Public Institutions (schools, universities, hospitals, etc.). It needs to be mentioned herein that the actions mentioned above are basically part of the consensus of the GHI WG in Nutrition and is a proposed operational model to be followed for other aspects concerning food legislation (GHI, 2018).

The operational objectives of the harmonisation process are as following:

1. Review of global food nutrition databases for public institutions regulations and standards development (schools and hospitals):
 - global food consumption databases;
 - global food compositions databases;
 - global nutrients reference value;
 - global anthropometry databases.

2. Review of food nutrition, menu planning and food services regulation and standards:
 - global nutrition regulations and dietary guidelines;
 - global nutrition labelling;
 - nutrient intake assessment;
 - public health nutrition menu planning (standard and fortified menus);
 - public care planning (food services standards).
3. Global harmonisation of nutrition planning and food service standards in public institutions:
 - harmonised NRV, nutrient intake value (NIV), daily reference value (DRV) and RDA;
 - harmonised of nutrition menu planning standards;
 - harmonised food services standards.

The expected outcomes in the following four years through the GHI WG in Nutrition are as follows:

- The GHI White Paper about Global Nutrition Food in Public Institutions.
- The harmonisation of global DRV, NRV, NIV and RDA.
- The harmonisation of menu planning and food services standards in public institutions.

5. Conclusions

It is recommended that all the international organisations and governments work together in order to maximise the harmonisation process in the following directions:

- Preparing a unitary and transparent register of harmonised permitted nutrition and health claims which is accessible for stakeholders.
- Guidelines for food claims for worldwide use, which benefit international business markets.
- Exclusive use of the harmonised list of permitted nutrition and health claims in global trade description act(s).
- Appropriate global advertising rules for foods with nutrition and health claims.
- Promote the communication and understanding of scientific research results to create a transparent and confidence link between validated methods quantifying food constituents, with proven health effects for the end-user, with regards to a healthy diet and lifestyle.
- Harmonisation of scientific reporting regarding study design, clinical practice, data analysis, statistical methods, results report, etc.
- Harmonisation of worldwide nutritional education and training.

References

Allen, L., De Benoist, B., Dary, O. and Hurrell, R. (eds.), 2006. Guidelines on food fortification with micronutrients. WHO, Geneva, Switzerland.

- Australian Standard, 1991. Australian Standard 1.2.7, Nutrition, health and related claims. New Zealand, Australia. Available at: <http://www.foodstandards.gov.au>
- Codex Alimentarius Commission (CAC), 1985 (revised in 2017). Guidelines on nutrition labelling, 6th session. The nutrient reference values for food labelling purposes in section 3.4.4, amended by the 20th session of the commission, 1993. CAC, Geneva, Switzerland.
- Codex Alimentarius Commission (CAC), 1997 (revised 2004). Guidelines for use of nutrition and health claims. FAO/WHO Food Standards Programme. July 14-18, 2014. CAC, Geneva, Switzerland.
- De Boer, A. and Bast, A., 2015. International legislation on nutrition and health claims. *Food Policy* 55: 61-70.
- European Commission (EC), 1990. Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling rules of foodstuffs. *Official Journal of the European Union* L 276: 44-46.
- European Commission (EC), 2000. Scientific committee on food intake levels for vitamins and minerals. Available at: <http://tinyurl.com/yyzkrv5r>
- European Commission (EC), 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *Official Journal of the European Union* L 31: 1-24.
- European Commission (EC), 2006a. Commission Regulation (EC) No.1924/2013 of 24 January 2013 on guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament. *Official Journal of the European Union* L63: 22-25.
- European Commission (EC), 2006b. 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. *Official Journal of the European Union* L404/26.
- European Commission (EC), 2006c. EU Register of Nutrition and Health Claims. Available at: <http://ec.europa.eu/nuhclaims>
- European Commission (EC), 2009. Commission Regulation (EC) 1170/2009. Lists of vitamins and minerals and their forms that can be added to foods, including food supplement. *Official Journal of the European Union* L314/36.
- European Commission (EC), 2011. Regulation (EU) No. 1169 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. *Official Journal of the European Union* L304/18.
- European Commission (EC), 2012a. Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims. *Official Journal of the European Union* L 310: 36-37.
- European Commission (EC), 2012b. Commission Regulation (EU) No. 432/2012 of 16 May 2012 establishing a 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. *Official Journal of the European Union* L 136: 1-40.
- European Commission (EC), 2012c. Commission Regulation (EU) No 1048/2012 of 8 November 2012 on the authorisation of a health claim made on foods and referring to the reduction of disease risk. *Official Journal of the European Union* L 310: 38-40.

- European Food Safety Authority (EFSA), 2010. Scientific Opinion on lead in food. *EFSA Journal* 2010: 1570.
- European Food Safety Authority (EFSA), 2017. Overview on Dietary Reference Values for the EU population as derived by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Version 4. Available at: https://www.efsa.europa.eu/sites/default/files/assets/DRV_Summary_tables_jan_17.pdf
- European Food Safety Authority (EFSA), 2018. Panel on nutrition, novel foods and food allergens. Available at: <http://www.efsa.europa.eu/en/panels/nda.htm>
- European Food Safety Authority (EFSA), undated a. The EFSA Comprehensive European Food Consumption Database. Available at: <https://www.efsa.europa.eu/en/food-consumption/comprehensive-database>.
- European Food Safety Authority (EFSA), undated b. Food composition. Available at: <https://www.efsa.europa.eu/en/data/food-composition>.
- Food and Agriculture Organisation of the United Nations (FAO), 1979. Codex General Guidelines on Claims CAC/GL 1-1979 (Rev. 1-1991). Available at: <http://www.fao.org/docrep/005/y2770e/y2770e05.htm>
- Food and Agriculture Organisation of the United Nations (FAO), undated. Food-based dietary guidelines. Available at: <http://www.fao.org/nutrition/education/food-dietary-guidelines/en/>
- Food Labeling Act (FLA), 2013, Act No. 70. Japan. Available at: <http://tinyurl.com/y68ylyl7>.
- Food Safety Authority of Ireland (FSAI), 2002. S.I. No. 483 on labelling, presentation and advertising of foodstuffs regulations. Available at: <https://www.fsai.ie/uploadedFiles/SI483.2002.pdf>.
- Food Safety Authority of Ireland (FSAI), 2009. Statutory Instruments No. 461 on nutrition labelling for foodstuffs). Available at: <http://www.irishstatutebook.ie/eli/2009/si/461/made/en/print>.
- Global Harmonization Initiative (GHI), 2018. Available at: <https://www.globalharmonization.net/>.
- Health Canada, 2018. Available at: <https://www.canada.ca/en/health-canada.html>.
- International Life Science Institute (ILSI) Europe, 2018. PASSCLAIM: Process for the Assessment of Scientific Support for Claims on Foods – Final Results. Available at: <https://tinyurl.com/y5qdlflc>.
- International Life Sciences Institute (ILSI) Europe, 2012. EURRECA. Harmonising nutrient recommendations across Europe with special focus on vulnerable groups and consumer understanding. Available at: www.eurreca.org.
- Japan, 1947. Food Sanitation Act (Act No. 233 of February 24, 1947). Available at: <http://www.cas.go.jp/jp/seisaku/hourei/data/fsa.pdf>
- Japan, 1950. Act on Standardization and Proper Quality Labeling of Agricultural and Forestry Products. Available at: <http://www.japaneselawtranslation.go.jp/law/detail?id=1953&vm=04&re=02>
- Japan, 2002. Health Promotion Law 2002. Available at: <https://www.tobaccocontrolaws.org/files/live/Japan/Japan%20-%20Health%20Promotion%20Act.pdf>.
- Kasapila, W. and Sharaani, S.M., 2016. Legislation-impact and trends in nutrition labeling: a global overview. *Critical Reviews in Food Science and Nutrition* 56(1). DOI: <https://doi.org/10.1080/10408398.2012.710277>.
- Otten, J.J., Pitz Hellwig, J. and Meyers, L.D. (eds.), 2006. Dietary Reference Intakes DRI. The Essential Guide to Nutrient Requirements. National Academies Press, Washington, CD, USA.
- Roe, M.A., Bell, S., Oseredczuk, M., Christensen, T., Westenbrink, S., Pakkala, H., Presser, K. and Finglas, P.M., 2013. Updated food composition database for nutrient intake. *EFSA Supporting Publications* 10: 355E. doi: <https://10.2903/sp.efsa.2013.EN-355>
- United States Department of Agriculture (USDA), 2008. GAIN report China, Peoples Republic of food and agricultural import regulations and standards. Available at: <https://apps.fas.usda.gov/gainfiles/200808/146295566.pdf>.
- United States Department of Agriculture (USDA), 2011. Chinese specific label GB7718 GB 28050. Available at: <http://tinyurl.com/y3hdy7pv>.
- United States Department of Agriculture (USDA), 2012. Food and Agricultural Import Regulations and Standards – Narrative. FAIRS Country Report EU-27. GAIN Report Number E70048. Available at: https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Brussels%20USEU_EU-27_12-27-2012.pdf.
- United States Food and Drug Administration (FDA), 1993. Guidance for Industry: Guidelines for Determining Metric Equivalents of Household Measures. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063102.htm>.
- United States Food and Drug Administration (FDA), 1998a. Guidance for Industry: Nutrition Labeling Manual – A Guide for Developing and Using Data Bases. Available at: <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm063113.htm>.
- United States Food and Drug Administration (FDA), 1998b. Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm056975.htm>.
- United States Food and Drug Administration (FDA), 1999. Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard. Available at: <https://www.fda.gov/food/labelingnutrition/ucm2006876.htm>.
- United States Food and Drug Administration (FDA), 2002. Guidance for Industry: Structure/Function Claims; Small Entity Compliance Guide. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm>.
- United States Food and Drug Administration (FDA), 2003a. Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm>.
- United States Food and Drug Administration (FDA), 2003b. Guidance for Industry: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, Health Claims; Small Entity Compliance Guide. Available at: <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm053479.htm>.

- United States Food and Drug Administration (FDA), 2006. Guidance for Industry: FDA's Implementation of 'Qualified Health Claims': Questions and Answers; Final Guidance. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm053843.htm>.
- United States Food and Drug Administration (FDA), 2007a. Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053425.htm>.
- United States Food and Drug Administration (FDA), 2007b. Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Sugar Free Claims. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm053431.htm>
- United States Food and Drug Administration (FDA), 2007c. Small Business Nutrition Labelling Exemption. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053857.htm>.
- United States Food and Drug Administration (FDA), 2008a. Guidance for Industry: Dear Manufacturer Letter Regarding Front-of-Package Symbols. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120274.htm>.
- United States Food and Drug Administration (FDA), 2008b. Guidance for Industry: Nutrient Content Claims Definition for 'High Potency' and Definition for 'Antioxidant' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Small Entity Compliance Guide. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm063064.htm>.
- United States Food and Drug Administration (FDA), 2008c. Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part I. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053455.htm>.
- United States Food and Drug Administration (FDA), 2009a. A Food Labelling Guide – Guidance for industry. Available at: <https://www.fda.gov/downloads/food/guidance%20compliance/regulatoryinformation/%20guidancedocuments/foodlabelingnutrition/foodlabelingguide/ucm265446.pdf>.
- United States Food and Drug Administration (FDA), 2009b. Guidance for Industry: ingredients declared as evaporated cane juice; draft guidance. Available at: <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocuments/regulatoryinformation/ucm502679.pdf>.
- United States Food and Drug Administration (FDA), 2009c. Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm>.
- United States Food and Drug Administration (FDA), 2009d. Guidance for Industry: Health Claims on Calcium and Osteoporosis; and Calcium, Vitamin D, and Osteoporosis. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm152626.htm>.
- United States Food and Drug Administration (FDA), 2009e. Guidance for Industry: Letter Regarding Point of Purchase Food Labeling. Available at: <http://food-label-compliance.com/Sites/5/Downloads/FOP-Signposting-Nutrition-Label-Industry-Guidance-USFDA-102109.pdf>.
- United States Food and Drug Administration (FDA), 2018. Available at: <https://www.fda.gov>.
- United States Food and Drug Administration (FDA), 2019. Electronic Code of Federal Regulations. Title 21: Food and Drugs – Part 101 – Food labelling. Available at: <https://tinyurl.com/yxvwtw876>.
- World Health Organization (WHO), 2012. WHO Handbook for guideline development. WHO, Geneva, Switzerland.
- World Health Organization (WHO), 2018. Global Nutrition Policy Review 2016-2017: country progress in creating enabling policy environments for promoting healthy diets and nutrition. WHO, Geneva, Switzerland. Available at: <https://tinyurl.com/y272pdbl>.

