SECTION 3: Global and country (and relevant regional) nutrition labelling regulatory regimes

Global nutrition labelling regulatory regime

Food fortification

The WHO recommends large-scale food fortification as a powerful evidence-informed and cost-effective intervention to fight vitamin and mineral deficiency, including iodine deficiency disorders, anaemia and iron deficiency, among others. Recommendations in all settings include:

- Universal salt iodisation
- Fortification of maize flour, corn meal, wheat flour and rice with vitamins and minerals.

Globally, mandatory regulations are most often applied to the fortification of food with micronutrients such as iodine, iron, vitamin A and folic acid. Of these, salt iodisation is the most widely implemented form of LSFF globally.

The *Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods CAC/GL 9-1987*[7] states that authorities should determine whether fortification should be mandatory or voluntary based on public health needs; and that where there is a demonstrated public health need, national and/or regional authorities should regulate the mandatory fortification of staple foods in sufficient amounts to meet that need, with consideration of cost-effectiveness. Further, provisions may be made in policy to identify the food(s), nutrients, and the minimum and maximum amount of nutrients that should be present in foods, and to monitor the population's intake of nutrients to assess impact.

Compliance with nutrition labelling requirements is part of the quality assurance process for fortified foods.

Responsibilities and regulatory governance for nutrition labelling

Global guidance on the regulation of nutrition labelling comes primarily from international standards, guidelines and related texts produced by Codex, a joint intergovernmental body of the Food and Agricultural Organization of the United Nations (FAO) and the WHO Food Standards Programme. Codex's work has dual and potentially competing objectives of protecting consumer health and facilitating fair food trade.

Although Codex guidelines and standards are technically voluntary for member states, Codex guidance has a high degree of influence on national nutrition labelling policies, with countries often adopting Codex guidance directly into national law. Codex is also recognised by the World Trade Organisation (WTO) as a standard-setting body for food. Codex recommendations are used as a reference point for interpreting WTO agreements and informing the arbitration of trade disputes related to food. For example, national policy measures or regulations that are 'based on' international standards such as those set by Codex are presumed not to create unnecessary obstacles to trade in a WTO context, which promotes harmonisation. WTO members wishing to apply stricter standards than those set by Codex may be required to scientifically justify those measures.

While Codex provides the terms of international standards on nutrition labelling, guidance on best practice regulatory governance processes for nutrition labelling comes from authoritative documents issued by the WHO, the FAO, and supplementary work from non-governmental organisations such as the World Cancer Research Fund (WCRF). These documents emphasise the importance of government leadership in developing evidence-informed regulations, and in appropriately funding and authorising implementation, monitoring and enforcement activities. They also emphasise the importance of adhering to principles of good governance, such as transparency and accountability, throughout the policy cycle so that information is provided to the public, and that opportunities for consultation are provided during the development, operation and reform of regulations.

International standards on nutrition labelling

- *Codex Alimentarius Guidelines on Nutrition Labelling CXG 2-1985*[8] (adopted 1985, last amended 2021) provides requirements for the nutrient declaration and supplementary nutrition information, including specific guidelines on front-of-pack nutrition labelling in Annex 2, updated 2021.
- *Codex Alimentarius General Standard for the Labelling of Prepackaged Foods CXS 1-1985*[9] (adopted 1985, last amended 2018) general requirements that food labels not be false, misleading or deceptive, and sets out several requirements around labelling and branding foods that are not specific to nutrition labelling.
- *Codex Alimentarius General Guidelines on Claims CAC/GL 1-1979*[10] (adopted 1979, last amended 2009) sets out general requirements for all food claims (i.e., cannot be false, misleading or deceptive) and should be read in conjunction with the Codex Guidelines for the use of Nutrition and Health Claims (below).
- *Codex Alimentarius Guidelines for use of Nutrition and Health Claims CAC/GL 23-1997*[11] (adopted 1985, last amended 2013) provides definitions of, and conditions for, making nutrition and health claims.

- *Codex Alimentarius General Principles for the Addition of Essential Nutrients to Foods CAC/GL 9-1987*[7] (adopted 1987, last amended 2015) provides guidance for national or regional authorities developing regulations on the rational and safe addition of essential nutrients of foods. For labelling, the Codex principles require that the labelling of fortified foods must not mislead or deceive the consumer about the nutritional merit of the food.

Policy context and objectives

The WHO recommends that policies and implementation programmes for fortification consider an alignment with policies for the reduction of diet-related non-communicable diseases. Such is the case for salt iodisation, which builds on sodium consumption and as a result, needs to consider strategies to reduce the intake of sodium.[5]

The most recent guidance from the WHO on best practice policies for the reduction of diet-related non-communicable diseases is contained in the updated Appendix 3 of the WHO Global NCD Action Plan 2013-2020. In the area of nutrition labelling, it includes a recommendation that countries implement FOPNL as part of comprehensive nutrition labelling policies for facilitating consumers' understanding and choice of food for healthy diets. It also includes reformulation policies for healthier food and beverages e.g., the setting of targets to reduce saturated fats, free sugars, and sodium.[12]

In the context of LSFF, these principles suggest that the labelling of fortified products should be consistent with other national policies, i.e., that nutrition, health claims or fortification logos do not act as a marketing technique for products whose consumption would otherwise be discouraged by FOPNL or other policies to promote healthier diets.

Nutrition labels (global guidance)

Nutrient declarations should be mandatory on all pre-packaged food, with certain foods exempted (e.g., small packages, and foods that don't make a significant contribution to nutrition such as tea and spices). The requirement for nutrient declarations on all pre-packaged foods updates an earlier version of the Codex standard which required nutrient declarations only on the subset of pre-packaged foods that used nutrition or health claims. Nutrient declarations should quantify a standard panel of nutrients (energy value, carbohydrate (i.e., total /dietary carbohydrate excluding dietary fibre), total sugars, fat, saturated fat, and sodium), any other nutrient for which a nutrition or health claim is made, and any other nutrient considered relevant for nutrition in a country as set out in national legislation. This last category of 'any other nutrient' is demonstrated in some countries that require specific vitamins and minerals to be declared and may be relevant to fortified products. Nutrient declarations should be made in a standard form (usually a table), with nutrients appearing in a standardised order, using a standardised amount (usually per 100g/100mL), and with minimum font sizes and contrast to background colours to support legibility.

Nutrition and health claims are voluntary and only given in addition (not in place of) to a nutrient declaration. The Codex guidelines provide a list of certain claims that should be prohibited, such as claims that a certain food will prevent, treat or cure disease, and prohibit the use of nutrition and health claims on some categories of foods (e.g., foods for infants and young children).

(a) *Nutrition claims* (e.g., 'source of iron') should only be permitted if they relate to energy, protein, carbohydrate, fat (and components thereof), fibre, sodium, and vitamins and minerals for which Nutrient Reference Values (NRVs) have been established. They should also be consistent with and support national nutrition policies. In countries that have a national policy focus on LSFF, national authorities should ensure that an NRV has been set for any fortificants so that nutrition claims can be made that draw consumers' attention to the qualities of a fortified product. Codex provides a table of conditions for making nutrient content claims. Most relevant to LSFF are the criteria for claiming that a product is a 'source of' or 'high in' vitamins and minerals, e.g., Codex requires that a product contains 15% of the NRV in 100g of product to be a 'source of' that vitamin.

(b) *Health claims* require stricter regulation than nutrition claims as they suggest a relationship exists between a food or a constituent of a food and health. As such, they need to be supported by a sound and sufficient body of scientific evidence to substantiate their claim, provide truthful and non-misleading information to help consumers choose healthy diets, and be supported by consumer education. They should also be consistent with and support national health policies, including national nutrition policies. Foods that make health claims must also provide additional information on the label, e.g., about how to use the food to obtain the claimed health benefit.

Supplementary nutrition information aims to increase a consumer's understanding of the nutritional value of their food and help them interpret the nutrient declaration. The content of SNI will vary from country to country according to national policies and population needs. Several ways of presenting SNI may be suitable on food labels, e.g., forms of SNI include FOPNL and food fortification logos. The use of SNI should generally be optional and in addition (not in place of) to a nutrient declaration. SNI should be accompanied by consumer education programmes to increase consumer understanding and use of the information. There is an emerging body of work (from Codex and other normative bodies) to support government policymakers in developing FOPNL systems as a form of SNI, but there is far less specific guidance on food fortification logos. In this report we extract relevant information on FOPNL, noting that many similar principles would likely apply to government policymakers interested in developing, implementing, monitoring, and enforcing food fortification logos.

Table 1 – GLOBAL – Summary of nutrition labelling regulations

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient declarations should be mandatory on all pre-packaged food, except where national circumstances would not support declarations.[8] • Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration.[13] • Certain foods may be exempted, e.g., on the basis of small packages, nutritional insignificance, or national circumstances.[8, 13]	• Nutrition and health claims should be voluntary and only given in addition to (not in place of) a nutrient declaration.[8, 14, 15] • Certain claims are prohibited (e.g., claims that a food will provide an adequate source of all essential nutrients except where standards/ regulations permit, claims about the suitability of a food for use in the prevention, alleviation, treatment, or cure of a disease/disorder, or claims that cannot be substantiated), and nutrition and health claims should generally be prohibited on foods for infants and young children.[10, 11]	• SNI can be mandatory or voluntary, in line with national regulation and should generally only be given in addition to (not in place of) a nutrient declaration.[8]
Regulatory objective(s)	• Provide consumers with a suitable profile and quantity of nutrients contained in the food and considered to be of nutritional importance. The information should convey an understanding of the quantity of nutrients contained in the product.[5, 8]	• Health claims should aid consumers in choosing healthful diets.[11]	• Increase consumer understanding of the nutritional value of food and assist in interpreting the nutrition declaration.[8] • Allow appropriate comparison between similar food products and inform consumer choice.[5] FOPNL: • Provide easy-to-understand additional information to help consumers make healthier choices, and to encourage healthier product re/ formulation.[16] • Facilitates a consumer's understanding of the nutritional value of a food and their choice of food, consistent with the national dietary guidance or health and nutrition policy of the country or region of implementation.[8]

	Nutrient declaration	Nutrition and health claims	SNI

Operative terms and conditions	• The following nutrients should be mandatory:
	  - Energy value, protein, carbohydrate (i.e., total /dietary carbohydrate excluding dietary fibre), total sugars, fat, saturated fat, and sodium;[13, 14]
	  - Any other nutrient for which a nutrition or health claim is made;[8]
	  - Any other nutrient considered to be relevant for good nutrition, as required by the national context, national legislation or national dietary guidelines. E.g., iron in countries where deficiency is a concern.[8]
	• Nutrients should be declared in a specific order developed by competent authorities and should be consistent across food products.
	• Energy value should be expressed in kJ and kcal, and protein, carbohydrate, and fat in g, per 100 g or per 100 ml, or per package if a single portion package. This information may also be given per serving or per portion as quantified on the label.[8]
	• Vitamins and minerals may be expressed in metric units and/or as a % of the Codex NRV where established, or a country's own NRVs (e.g., Daily Value in the US).[14]
	• Display specifications should promote visibility, legibility and salience:[8]
	  - Tabular format and numerical, or linear where insufficient space for a table.
	  - Font type, style and minimum font size should ensure legibility, with a significant contrast between text and background.
	General labelling[14] should be uncomplicated, prominent and legible, with sufficient contrast between the font and background, in a standard format, in an appropriate language for the target consumer, and accompanied by consumer education. Authorities should establish the font type, style, and minimum font size.
		Health and/or nutrition claims:
		• Must be supported by a nutrition declaration and should include a statement of the quantity of the nutrient or ingredient that is the subject of the claim;[11]
		• Should not be misleading or deceptive.[10]
		Nutrition claims should:
		• Only be permitted if they relate to energy, protein, carbohydrate, fat and components thereof, fibre, sodium, and vitamins and minerals for which NRVs have been established.[11]
		• Be consistent with and support national nutrition policy. Specific claims can be made according to the Table in the Codex Guidelines for use of Nutrition and Health Claims e.g., thresholds for making a 'low in' or 'high in' claim for specific nutrients.[11]
		Health claims should:
		• Have a clear regulatory framework for qualifying and/or disqualifying conditions to use a specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition.[11]
		• Be supported by sound scientific evidence to substantiate the claim, with the claim re-evaluated once new evidence becomes available.[11]
		• Use Codex recommendations on the scientific substantiation of health claims.[5]
		• Include additional information on the label:[11]
		  - A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.
		  - The target group, if appropriate.
		  - How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.
		  - If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food (e.g., if pregnant, avoid soft cheeses).
		  - Maximum safe intake of the food or constituent where necessary.
		  - How the food or food constituent fits within the context of the total diet.
		  - A statement on the importance of maintaining a healthy diet.
			• The content of supplementary nutrition information will vary from one country to another and within any country from one target population group to another according to the educational policy of the country and the needs of the target groups.[8]
			  - SNI, including pictorial or colour presentations, may be useful for target populations with a high rate of illiteracy or little nutrition knowledge.[8]
			FOPNL:
			• Must be supported by a nutrition declaration.[17]
			• Should take an interpretive format i.e., use words, colours and/or symbols to make judgments[16, 17, 18] and be understandable to all population subgroups.[17]
			• Only one FOPNL should be recommended by a country's government. However, if multiple FOPNL systems exist they should be complementary, not contradictory.[8] Should present information in a way that is easy to understand and use by consumers in the country or region of implementation.[8]
			• Should align with evidence-based national or regional dietary guidance, or in its absence, health and nutrition policies. Consideration should be given to the nutrients and/or food groups that are discouraged and/or encouraged by these documents.[8]
			• Should include valid scoring criteria and reference amount for included nutrients.[13, 16]
			• Scope (products and nutrients included and excluded) should be evidence-based and justified.[16]
			• FOPNL should be displayed in a way that promotes visibility and salience, e.g., on the front-of-pack, most visible to consumers.[15, 16]

Regulatory governance	
Drafting regulatory rules and scheme design	• Harmonisation of regulation (e.g., by adopting Codex standards) is encouraged and may be required under WTO agreements.[14] • The development and/or reform of nutrition labelling regulations can be supported by robust and independent evidence, advisory boards or expert committees, and stakeholder consultation. Public consultation can address challenges during development and implementation, and improve feasibility, acceptability, and transparency. Standards and procedures need to be written clearly so that they can be enforced.[13, 14, 19] • There is a need for transparency to make information about regulatory development easily accessible (e.g., releasing submissions to public consultation, public meetings and minutes of committees).[13, 14] • Labelling policy should be based on the needs of the consumers and producers in the country, considering potential long-term costs and benefits, including those to specific groups such as those with low nutrition literacy.[14] • COI and industry interference are potential barriers to the development and implementation of labelling policy and must be carefully managed in the development of regulation.[19] • FOPNL – The development of a FOPNL system should be government-led and country-specific. It should consider the needs of the population, literacy levels and communication barriers, food intake patterns, and economic, social, and cultural factors. Development should include clear policy objectives, needs assessment, development of nutrient-profiling scoring criteria, stakeholder engagement, public consultation, and pilot-testing. FOPNL systems should be aligned with existing food regulations and national nutrition and public health policies. Development should be evidence-based and transparent. Education campaigns should accompany implementation.[13, 16, 17, 19, 20]
Administration	• Governments are responsible for establishing and enforcing nutrition labelling regulations.[14] • Implementation should include engagement with stakeholders and key opinion leaders, and consumer education.[13, 14] • Responsibility may be shared for different parts of the monitoring, evaluation and enforcement of a policy (e.g., tasking national academia with evaluations, and health authorities with enforcement and monitoring of noncompliance), and adequate resources should be allocated.[19] • For SNI, including FOPNL, consumer education to increase consumer understanding and use of SNI should be undertaken during implementation, along with guidance documents for industry.[8, 16]
Monitoring	• Monitoring, evaluation and enforcement are key elements of nutrition labelling policies and require clear and transparent guidelines and structures. There may be shared responsibility for different parts of monitoring, evaluation and enforcement activities (e.g., tasking national academia with evaluations, and health authorities with enforcement and monitoring of noncompliance); baseline data should be collected to allow monitoring and enforcement, and adequate resources should be allocated.[13, 19] • FOPNL – Baseline data for impact and outcome evaluation should be collected before implementation. Monitoring and evaluation should be conducted by government agencies or independent groups without COI.[17] In addition, a framework for monitoring and evaluation should be developed with consideration for resourcing, technical capacity, and collection of baseline and follow-up data.[16]
Evaluation	• Evaluation should be government-led and/or carried out by an independent body or research group (e.g., auditor, consultant) with authority to assess achievement of the regulatory objectives using a transparent framework and sufficient data to assess whether performance indicators met in the specified timeframes[16, 17] • Evaluation should be proactive, rather than reactive. Clear and transparent guidelines and structures, and adequate resources are required to support proactive evaluation. [19] • Health claims should be re-evaluated periodically or in response to significant new evidence.[11]
Enforcement	• Clearly defined and resourced enforcement rules and procedures should include qualified personnel for monitoring compliance via labelling audits, random monitoring, and defined and escalating penalties for non-compliance.[14]

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