Policy and regulatory determinants of nutrition labelling to support large-scale food fortification

An examination of 11 geographies

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Note that all efforts were made to find the most up-to-date versions of policies and legislation and to correctly interpret these. However, the authors are not practising lawyers in the countries whose laws were examined and were limited to information available in English, and/or the use of Google Translate where translated versions of documents were unavailable.

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Abbreviations (and detail as applicable)

ASEAN	Association of Southeast Asian Nations. Member States: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.
COMESA	Common Market for Eastern and Southern Africa. Member States: The Republic of Burundi, Union of the Comoros, Democratic Republic of the Congo, Republic of Djibouti, Arab Republic of Egypt, Kingdom of Eswatini, State of Eritrea, Federal Democratic Republic of Ethiopia, Republic of Kenya, Republic of Seychelles, Federal Republic of Somalia, Republic of The Sudan, Republic of Tunisia, Republic of Uganda, Republic of Zambia, and the Republic of Zimbabwe.
DRIs	Daily Reference Intakes
EAC	East African Community. Partner States: Republic of Kenya, Democratic Republic of the Congo, Republic of Burundi, Republic of Rwanda, Republic of South Sudan, Republic of Uganda and United Republic of Tanzania.
EAS	East African Standard
ECOWAS	Economic Community of West African States. Member States: Benin, Burkina Faso, Cabo Verde, Côte D'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo.
EU	The European Union
FAO	Food and Agricultural Organization of the United Nations
FOP	Front-of-pack
FOPNL	Front-of-pack nutrition label/labelling
GDA	Guideline Daily Amount
LSFF	Large-scale food fortification
NCD(s)	Non-communicable disease(s)
NRVs	Nutrient Reference Values
RDA	Recommended Dietary Allowance
SNI	Supplementary Nutrition Information
USA	United States of America
WHO	World Health Organization

Survey and interviewee respondents

Country	Survey	Semi-structured Interview
Ethiopia	1 regulator, 1 industry	2 regulator, 1 government
Kenya	1 industry/technical advisor	2 regulators, 1 industry/technical advisor
The Philippines	2 regulator, 1 research & advocacy	2 government, 1 research & advocacy
South Africa	1 industry	2 industry
Vietnam	2 government	1 regulator

*Government refers to departments such as a Department of Health or national nutrition institutes, that may provide evidence for policy development but do not directly regulate it.

Executive Summary

Malnutrition in all its forms – including nutritional deficiencies – is a leading cause of death and disability globally.[1] Food fortification is a proven and cost-effective intervention for addressing nutritional deficiencies.[2] Large-scale food fortification (LSFF) is the practice of adding minerals or vitamins to commonly consumed foods i.e., staple foods such as salt, flours, oil, and rice during industrial processing to increase their nutritional value and deliver potential health benefits to populations.[3]

Nutrition labelling has the potential to help achieve public health goals by improving the transparency around food product contents, including the contents of fortified foods. This information can be used by consumers to better understand their food's nutritional quality, by manufacturers as an incentive to improve products' nutritional attributes, and by governments and researchers to monitor the contents of the food supply. Requirements to provide standardised nutrition information on food packaging can also help to establish a level playing field for manufacturers. As a development intervention, consumers can be considered the primary beneficiaries of LSFF.

Scope:

The George Institute for Global Health was commissioned by the Bill and Melinda Gates Foundation to:

- develop a conceptual framework that outlines best-practice nutrition labelling regulation to support effective LSFF;
- examine how nutrition labelling requirements act as a barrier or an enabler to LSFF programmes in 11 geographies worldwide (nine study geographies and two comparator geographies). The term 'geography' in this context refers to both a country and a region such as the European Union;
- recommend how regulations in the nine study geographies could be reformed to accelerate LSFF with maximum public health impact, and with broader potential applicability to geographies with similar geographical, legal, and political contexts; and
- develop country-specific fact sheets aimed at assisting industry compliance with existing regulations.

This report details whether fortification with specific micronutrients is mandatory (e.g., of staple foods like rice and wheat) or voluntary (e.g., of non-staple foods like fruit juices) in a country. It doesn't detail further requirements set out in fortification regulations or general food labelling regulations that were out-of-scope for this work. These include requirements for ingredient lists, manufacturer details, use by dates, for imported fortified foods, for foods sold in open markets, or requirements for analysis of fortified foods and their micronutrient content. See further ***Structure and navigation of the report***.

This report and accompanying country-specific fact sheets are intended to support LSFF implementation partners (public and private sectors, multilaterals, and civil society) to develop, implement, monitor and enforce nutrition labelling regulations to promote the effectiveness of LSFF.

Methods:

To identify key characteristics of best-practice nutrition labelling regulation, we adapted Reeve and Magnusson's existing framework for analysing and improving the performance of public health law, which they previously used to examine food advertising to children.[4] This framework allows the examination of specific 'domains' relevant to regulatory effectiveness. Our adapted framework consolidates these 'domains' into two: Regulatory Form and Substance, which includes the regulations' form and substantive terms and conditions; and Regulatory Governance, which includes the processes by which regulation is developed, administered, monitored, evaluated and enforced.

We examined current international, regional, and national regulatory instruments via a desk review across 11 geographies, using the framework to extract relevant data. Nine study jurisdictions (*Ethiopia, *Kenya, Indonesia, Nigeria, Pakistan, *the Philippines, *South Africa, Thailand and *Vietnam) were selected because of their potential to accelerate LSFF activity and impact – accounting for factors such as malnutrition rates, existing LSFF programmes, and industry capacity for LSFF. The other two jurisdictions (the United States (US) and the European Union (EU)) were selected as international comparators. This mix of jurisdictions includes different geographical, legal, and political contexts and was chosen to generate findings with potential applicability to a wide range of other national settings. We searched a range of academic databases for peer-reviewed literature (e.g., PubMed, Embase, SCOPUS, and Web of Science), policy and/or normative guidance databases and websites (e.g., Global database on the Implementation of Nutrition Action (GINA), FAOLEX database, Food and Agricultural Import Regulations and Standards database of the Foreign Agricultural Service of the United States Department of Agriculture, and World Cancer Research Fund International (WCRF) Nourishing database), and conducted Google Advanced searches of government websites, alongside snowball searching from these sources and discussions with some country experts.

Following the desk review, nine qualitative surveys and 12 semi-structured interviews were undertaken in addition to a regulatory review in the geographies marked with an asterisk (*) above and in the headings in Section 3 of this report (see detail on survey and interview respondents in Report Details). These surveys and interviews allowed us to gain further insights into how different geographies' regulations were developed and/or are applied in practice.

Results from the desk review and qualitative follow-ups were synthesised to generate recommendations on overall best practices and highlight opportunities for stepwise reform in each geography, recognising relevant resource constraints.

Best practice:

Best practice nutrition labelling to support LSFF includes:

- ***Nutrient declarations*** – should be mandatory on all pre-packaged foods, including fortified foods, and list a minimum set of nutrients and added micronutrients where recommended intakes are established and/or are of nutritional importance in a country.
- ***Nutrition and health claims*** – should be voluntary but are useful to signpost mandatorily fortified foods and their potential nutrition and health benefits. Prioritising standardised claims may increase the efficiency of regulatory governance and support consumer understanding and use. This can apply to voluntarily fortified foods in some cases.
- ***Supplementary nutrition information*** – it should be voluntary or mandatory to use a standard fortification logo(s) to visually signal mandatorily fortified foods at a glance. This can apply to voluntarily fortified foods in some cases.
- ***Regulatory governance*** – from drafting regulatory rules to enforcement is also critical. Governance should also ensure that processes are aligned and coordinated with other activities in the food regulatory system (e.g., food safety audits and enforcement activities), with clear roles and responsibilities across government bodies involved in all elements of food regulation in a geography.

Findings and recommendations:

In the nine study geographies, we found that:

- Just over half of the study geographies and one province of Pakistan mandate the use of ***nutrient declarations*** across nearly all pre-packaged foods and require the inclusion of vitamins and minerals, provided they meet minimum levels.

Recommendation: Rectifying this regulatory gap is the highest priority where gaps exist.

- All geographies permit ***voluntary nutrition and health claims,*** including nutrient claims for vitamins and minerals where the vitamin or mineral in a food meets specified levels. Some geographies also have more specific claims for fortified foods, others have very little regulation of claims.

Recommendation: Prioritising standardised claims for mandatorily fortified foods (e.g., 'iodised for better health' based on food containing a required level of a micronutrient) may increase the efficiency of regulatory governance and support consumer understanding and use of fortified foods. This can be considered for voluntarily fortified foods in certain circumstances *(see further The interaction of nutrition labelling and LSFF).*

- ***Fortification logos*** were identified in four countries and recent fortification legislation in three provinces of Pakistan mandates the use of fortification logos to be established by relevant provincial food authorities. A fortification logo may also be included in Ethiopia's new fortification standards.

Recommendation: Alongside or instead of standardised claims for fortified foods, the voluntary or mandatory application of a standard fortification logo or logos to visually signal that specific products are fortified may be useful to consider in geographies that do not currently have such logos. Priority should be given to logos for mandatorily fortified foods, and logos can be considered for voluntarily fortified foods in certain circumstances *(see further The interaction of nutrition labelling and LSFF).*

- Regulatory governance:
  - Most countries operate ***pre- and post-market surveillance systems*** for food products, including labelling. Pre-market approval or licensing can act as pre-emptive enforcement – this essentially requires manufacturers to obtain a licence from a regulator prior to placing a product on the market – with the regulator only approving that licence after examining the product and its labelling. Post-market approval can include auditing and sampling products in the market, and/or renewal of a licence.
  - Where the ***regulatory authority*** for food labelling sits within the government will determine the structure of nutrition labelling regulations.
  - Some countries' nutrition labelling regulations also closely interact with ***regional standards,*** but others do not.
  - In a number of the geographies in which we conducted surveys and interviews, we learned that what happens in practice may not be what is written in relevant laws and regulations.

Recommendation: In looking to strengthen labelling regulations, stakeholders must consider their local context (e.g., the nutrition, health and political context, and the available human and financial resources) to prioritise investment. Assuming there are limited resources and budget for nutrition labelling regulation – we recommend a risk-based approach that considers country priorities and available resources to maximise effectiveness.

Conclusions and future work:

Accurate and informative nutrition labelling, that can be easily understood and interpreted by consumers, and not mislead them, is clearly important across the entire food system, including for fortified foods. Nutrition labelling of fortified foods benefits industry by helping to communicate and market nutrient qualities of foods, with standardised labelling also helping to create a level playing field and demonstrate fortification in line with government regulations. For governments, such labelling helps it to communicate the benefits and quality of fortified foods to the population and aids monitoring and enforcement of food quality and safety standards.

This report shows that there is opportunity across most all study jurisdictions to strengthen nutrition labelling to support LSFF to bring it more into line with best practice. But these opportunities for strengthening must be considered in light of a geography's context and broader LSFF and food quality and safety regimes, which were not examined in detail in this report. Future work could thus examine these nexuses, and the extent to which nutrition labelling (beyond nutrient declarations) should be prioritised for fortified foods, particularly when mandatory fortification in a geography is highly effective and covers the field across an entire food category, as well as how these parts of the food regulatory system are most efficiently and effectively regulated in practice.

Future work could also explore broader global trends in nutrition labelling and LSFF and examples of best practice through examining additional geographies. This could result in a global repository of permitted and 'best practice' standardized nutrition and health claims and logos, and consider the utility of comparative claims and the importance of consumer education, advocacy and social marketing to support LSFF. Deeper geography-specific analysis could also examine a population's knowledge, understanding and use of nutrition labelling to support LSFF.

Structure and navigation of the report

In ***section one, the report introduces the three key types of nutrition labelling:*** nutrition declarations; nutrition and health claims; and supplementary nutrition information (SNI), including fortification logos (see page 9, Figure 1 for reference). This section discusses the overall aims of nutrition labelling and how it is used by different stakeholders. It also covers the distinction between mandatory fortification and voluntary fortification, to set the scene for how nutrition labelling regulations are relevant to both types of policies. Finally, section one introduces a theory of change that sets out our hypothesis for how nutrition labelling regulations can act as a barrier and/or enabler to LSFF programmes.

In ***section two, the report introduces a conceptual framework for analysing and improving the performance of nutrition labelling regulations to support LSFF programmes.*** This framework is used to present overall findings on best practice nutrition labelling across two 'domains', based on our analysis of nutrition labelling regulatory regimes at the global level and in the two comparator geographies. The domain of ***Regulatory Form and Substance*** covers issues such as whether a regulation is mandatory or voluntary, what its regulatory objectives are, and its operative or key terms and conditions. The domain of ***Regulatory Governance*** covers information on regulatory processes, namely how a regulation can best be designed or drafted, and how it should be administered, monitored, evaluated and enforced to promote maximum public health impact. Section two also provides traffic light reporting of the study geographies' current fortification regimes, nutrition labelling regulations, regulatory governance archetype (i.e., does pre- and/or post-market surveillance exist and what does this involve?), and recommendations to strengthen nutrition labelling to support LSFF.

Section three of the report uses the conceptual framework to provide global and geographic (and relevant regional) level details on current nutrition labelling regulations.

Each geography is covered in a specific chapter that outlines:

- *Food fortification context* – summarising a geography's mandatory and/or voluntary food fortification environment and relevant details found in the nutrition planning and strategy documents that we reviewed.
- *Responsibilities and regulatory governance for nutrition labelling* – summarising which organisation has oversight and responsibility for food labelling regulations, and findings on the processes of regulatory design and drafting of nutrition labelling, administration, monitoring, evaluation, and enforcement.
- *Structure of nutrition labelling laws* – setting out the key regulations relevant to a country's nutrition labelling regulatory regime, alongside any key regional documents.
- *Policy context and objectives* – detailing any broader contextual factors relevant to nutrition labelling that we identified in our review and to what extent nutrition labelling regulations are aligned with other nutrition and health policies in the geography, including policies to address both under and over-nutrition.
- *Nutrition labels* – summarising the regulation of nutrient declarations, nutrition, and health claims and SNI.
- *Information limitations* – acknowledging any gaps in the available literature.
- *Recommendations to reform nutrition labelling regulations to accelerate LSFF* – based on our understanding of the best practices to emerge through this work.

For each geography, we also include a detailed table that analyses the three types of nutrition labelling regulations using our conceptual framework. In addition, a standalone fact sheet for each study geography can be separately accessed on The George Institute's website landing page for this project.

Finally, ***Annexure 1*** provides the ***framework for analysing and improving the performance of nutrition labelling regulations*** which can be used by stakeholders to analyse additional geographies' nutrition labelling regulations. ***Annexure 2*** provides an example fact sheet outlining ***Nutrition labelling for fortified foods in Nigeria*** to assist industry to comply with existing nutrition labelling regulations relevant to fortified foods. ***Annexure 3*** provides a ***template fact sheet that can be used to detail nutrition labelling requirements for fortified foods in a geography*** using Annexure 2 as a guide.

Country-level stakeholders can use the geography-specific analysis in section three and the summary of best practices in section two to help guide national conversations about areas where regulation could be reformed or strengthened. This is in addition to the quick-reference fact sheets for each study geography, which are aimed at aiding country-level understanding of and compliance with nutrition labelling regulations for fortified foods – in particular the fortification industry, for example, fortified flour millers.

Other stakeholders seeking an overall understanding may be interested in section two of the report and the overview of food fortification and labelling regulations at the beginning of each jurisdiction chapter.

SECTION 1: Labelling, fortification, and a theory of change

Introducing the types of nutrition labelling

Nutrition labelling has the potential to contribute to achieving public health objectives by providing nutritional information to consumers on a food package to help them to make informed, healthy and nutritious food choices. Nutrition labelling can also be used as a marketing tool by industry (e.g., food manufacturers) to highlight the favourable qualities of their products. Third, nutrition labelling is essential for governments to monitor the contents of the food supply. Governments can also use nutrition labelling as a public health tool to influence consumer choices and encourage the food industry to improve the quality of its products.

For this project, we have defined 'nutrition labelling regulations' as encompassing regulatory and policy action in three key areas: nutrient declarations, nutrition and health claims, and SNI, particularly in the form of food fortification logos.

Figure 1: Nutrient declarations, supplementary nutrition information and nutrition and health claims

Additional examples of fortification logos (or SNI):

Kenya's fortification mark of quality, Nigeria's fortification logo, and South Africa's fortification logo.

Nutrient declarations

Nutrient declarations provide a standardised statement or listing of the nutrient content of food, typically provided on the back or side of a pack.

At least 80% of countries in the World Health Organization's (WHO) regions of the Americas, Europe and Western Pacific had implemented nutrient declarations, but less than 50% of countries in Africa and Southeast Asia had done so by 2017. (Source: WHO Global Nutrition Review)

At a global level, the Codex Alimentarius Commission (Codex) provides guidelines on how nutrient declarations should be implemented, but there remain differences in national practice. Declarations are mainly mandatory in the Americas and Europe but are more likely to be voluntary in Africa and Southeast Asia. (Source: WHO Global Nutrition Review) There are differences in the nutrients that are required to be listed, the required manner of presentation, and the processes for calculating quantities of nutrients between geographies.

Nutrition and health claims

Nutrition and health claims come in a range of forms, each with specific regulatory requirements.

A nutrition claim is any representation that states, suggests or implies that a food has particular nutritional properties, e.g., 'Good source of Vitamin K'.

A nutrient comparative claim compares the nutrient levels and/or energy value of two or more foods, e.g., 'Reduced fat compared to regular milk'.

A health claim is any representation that states, suggests, or implies that a relationship exists between a food (or a constituent of that food) and health. It is important that nutrition and health claims are consistent with national nutrition and health policy, and that health claims are supported by sufficient scientific evidence.

Many countries have measures to regulate or guide nutrition and health claims. Eligibility to display claims may be based on predefined lists of foods and beverages or use nutrient-based criteria.

At a global level, Codex sets out conditions for making nutrition and health claims.

Many countries also specify instances where claims are not allowed, such as on products for infants and young children, or alcoholic beverages.

Supplementary nutrition information (SNI)

SNI aims to increase a consumer's understanding of the nutritional value of their food and to assist in interpreting the nutrient declaration. Use of interpretive elements such as pictures, words, colours and/or symbols can support use of SNI, especially in populations with a high rate of illiteracy or little nutrition knowledge.

One form of SNI is front-of-pack nutrition labelling (FOPNL). FOPNL uses graphics or logos to summarise the healthiness (or un-healthiness) of the food overall. By 2022, at least 44 countries had adopted some form of FOPNL to address diet-related non-communicable diseases associated with unhealthy diets. (Source: WHO Nutrition Labelling Policy Brief 2022)

In the context of this project's focus on LSFF, we will build on existing literature on best practice FOPNL regulation but will focus on visual logos or cues to specifically identify fortified foods.

The interdependence of nutrition labelling requirements

Importantly, the three types of nutrition labels are sometimes interdependent, and will ideally be implemented as part of a comprehensive approach to reinforce and support one another as illustrated in Figure 1. Specifically, a nutrient declaration could sit alone on a food packet. However, if a nutrition or health claim and/or SNI like a fortification logo is on a food packet, a nutrient declaration should always be included. This is because the nutrient declaration supports implementation and enforcement of food fortification logos and claims. In addition, food fortification logos, other SNI and nutrition and health claims assist consumers' interpretation and understanding of the nutrition declaration, by highlighting key nutrients in a product and in the case of health claims, the health benefit. Sometimes, as in the case of South Africa, a claim can also be incorporated into a logo (e.g., *'Fortified for better health'*).

The interaction of nutrition labelling and LSFF

Before we consider how nutrition labelling regulations interact with LSFF programmes and our recommendations for labelling fortified foods, it is useful to consider the aims and key differentiators between mandatory and voluntary fortification. Both types of fortification can form part of a single geography's fortification regime simultaneously, and the decision as to which to implement in a given circumstance involves consideration of a range of factors such as the population affected by the deficiency, the degree of centralisation of an industry producing a fortified food and other fortification or nutrition programming in a country.[5]

Mandatory fortification is when ***governments legally require food producers to fortify specific food or categories of food with specific micronutrients*** (vitamins and minerals) or fortificants. At a global level, regulations requiring mandatory fortification of food most commonly require staple foods (e.g., wheat flour and salt) to be fortified with micronutrients such as iodine, iron, vitamin A and folic acid. This is because evidence of the deficiencies is more widely available and thus more likely to address a public health problem.[5]

Voluntary fortification is when a ***food manufacturer voluntarily decides to fortify a particular food(s) with micronutrients*** in response to permission granted by governments in food law (including standards), or under special circumstances, is encouraged by a government to do so, to increase their brand value. Government oversight of any voluntary fortification regime remains important.[5]

Further detail on the differences between mandatory and voluntary fortification can be found on the WHO's website here.

The following theory of change (Figure 2) sets out our (the authors') findings and recommendations for how nutrition labelling regulations can act as a barrier and/or enabler to LSFF programmes based on our review of legislation and in focus geographies our qualitative interviews with experts. We note that this review did not involve testing consumer responses to labelling types.

Figure 2 recommends that nutrient declarations should be mandatory across all foods, including fortified foods, regardless of whether those foods have been subject to mandatory or voluntary fortification. However, we distinguish between our recommendations for nutrition and health claims and fortification logos where voluntary fortification does not meet specified criteria and is essentially not as beneficial for public health. The relevant criteria include that voluntary fortification is government driven, applies only to 'healthy' foods aligned to public health regulations and policies (i.e., avoids acting as a health 'halo' on otherwise unhealthy foods), and is supported by adequate regulatory oversight by government to not detract from any mandatory fortification in a geography. An example of this difference in recommendations can be seen in our recommendations for Vietnam outlined briefly in Figure 7 and in detail in Section 3, due to voluntary fortification of foods where deficiencies are not deemed a public health problem.

Figure 2: Theory of Change

Author recommendations for nutrition labelling regulations (Inputs) for *both* mandatory and voluntary fortified foods unless specified and provided a food is fortified in line with standards and/or regulations	Outputs			Outcomes	Goal
	Consumers	**Industry**	**Government**		
NUTRIENT DECLARATION • **Mandatory** on **all pre-packaged foods** (with some exceptions, e.g., spices) including all fortified foods. • **Mandatory** to list a **minimum standardised set of key nutrients**. Added vitamins and minerals can also be declared where of nutritional importance in the country and/or if recommended intakes are established. • Manufacturers may provide additional information on the percentage of the daily recommended intake that these vitamins and minerals provide.	• Inform consumers about the nutrient quantity in a food to enable informed purchasing/ consumption choices. • Not mislead or deceive consumers re nutritional merit of food.	• Uses to communicate nutrient quantity in a food, to substantiate the use of claims and/or logos, and to demonstrate conformity with other food standards.	• Enables authorities to monitor and enforce food quality and safety standards (e.g., allows assessment of foods to ensure they meet required standards including to qualify for fortification claims or logos, and to ensure foods in the market are safe for consumption).	**Consumers** buy and consume more mandatory (and as relevant voluntary) fortified food products. **Industry** sells more mandatory (and as relevant voluntary) fortified food products. **Government**'s mandatory (and as relevant voluntary) food fortification program is supported by effective nutrition labelling to maximise public health outcomes.	Alongside other efforts to decrease micronutrient deficiencies, such as food fortification regulations and standards – ***Nutrition labelling contributes to reducing micronutrient deficiencies in the general population or a target group.*** *If sustained over time, this reduction should result in improved health of the population or target group.*

NUTRITION AND HEALTH CLAIMS
• **Voluntary** to make, but useful to signpost mandatorily fortified foods and their potential nutrition and health benefits. **Prioritizing standardised claims** may increase the efficiency of regulatory governance and support consumer understanding and use.
This also applies to ***voluntarily fortified foods*** but only where:
  • Fortification is government-driven due to the potential lower public health benefit of voluntarily fortified foods;
  • Fortified foods are 'healthy' and aligned to public health regulations and policies to reduce the burden of diet-related disease (i.e., to avoid a health 'halo' on unhealthy foods); and
  • Supported by adequate regulatory oversight that does not compromise mandatory fortification.
• **Prohibit certain claims** to ensure that consumers are not misled (e.g., by implying that a food can prevent or cure disease).
• ***Where regulatory capacity is sufficient***, set out a process to apply for and substantiate other claims and/or increase standardized claims available.
	• Increase consumer understanding:
	  • Of the presence and/or health benefits of added micronutrients in a fortified food.
	  • That where a standardised claim has been used, that a food has been fortified in line with government regulations as part of a mandatory fortification program.
	• Increase consumer demand for fortified foods.
		• Uses to market the nutritional qualities of its products, particularly for voluntarily fortified foods.
		• Standardised claims can simplify compliance for small and large manufacturers – creating a 'level playing field'.
			• Communicates benefits and quality of fortified foods to the population or a target group, although consumers who do not have high nutrition literacy may not find claims helpful.
			• Standardised claims may support efficient monitoring and enforcement (vs claims that must be applied for with each use) and reduce the potential for misleading or fraudulent claims. Also, health claims should be straightforward to make given the required rationale for fortifying foods with specific micronutrients.	

SUPPLEMENTARY NUTRITION INFORMATION • **Voluntary or mandatory application of a standard fortification logo(s)** to visually signal mandatorily fortified foods at a glance. This also applies to ***voluntarily fortified foods*** where the criteria specified for voluntarily fortified foods under *Nutrition and Health Claims* above is met. • Logo implementation should be accompanied by consumer education.	• Increase consumer recognition at a glance that a food has been fortified in line with government regulations as part of a mandatory food fortification program, particularly for multi-fortified foods. • Increase consumer demand for a fortified food.	• Use increases the marketability of a food and at a glance visibility of fortified status, particularly for: multi-fortified food where multiple claims take up valuable package space; and for voluntarily fortified foods. • Standardised logos may simplify compliance for small and large manufacturers – creating 'level playing field'.	• Simple to communicate benefits and quality of fortified foods to the population or a target group, particularly if food is multi-fortified where multiple claims could be confusing to consumers. • Use of visual logos may be particularly useful in promoting public health objectives of fortification programs in settings with low literacy. • Standardised logos may enhance compliance and support efficient monitoring and enforcement.	

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SECTION 2: Conceptual framework for best-practice nutrition labelling and overall analysis

A conceptual framework for best practice nutrition labelling

To develop a conceptual framework for best-practice nutrition labelling regulations in the context of LSFF, we adapted and applied Reeve and Magnusson's framework for analysing and improving the performance of public health law.[4] The full conceptual framework is provided in the Annexure and can be used as a tool for examining nutrition labelling regulations in additional geographies. For this report, we used the conceptual framework to extract data on key components of nutrition labelling regulations at global and geographic levels. In the tables below, we summarise our findings on best practices for each nutrition labelling type (see page 9, Figure 1 for reference), and for regulatory governance processes. Best practices are based on our analysis of nutrition labelling regulatory regimes at the global level and in the two comparator geographies.

Figure 3: Nutrient declaration: conceptual framework for best practice in the context of LSFF

For an example of a nutrient declaration see page 9, Figure 1 for reference.

Nutrient declarations	Suggested best practice
Regulatory framework The regulatory framework is appropriate to the geography's legal context (i.e., provides sufficient authority and oversight of labelling).	• Requirements for the nutrient declaration may be included as part of an overarching Food Act/Law (e.g., often covering the regulation of food and drugs) or be detailed in subsidiary regulations. • The requirement to display a nutrient declaration should be mandatory for all pre-packaged foods with limited exemptions, e.g., on foods that don't make a significant contribution to nutrition such as plain tea or spices, and on small packages.
Regulatory objective(s) There are clear, measurable objectives against which the success of regulation can be assessed.	• To provide consumers with a suitable profile and quantity of the nutrients contained in the food that are considered to be of nutritional importance to enable consumers to make informed choices.

Operative terms and conditions
Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objective.
	• The following nutrients are mandatory to include in the standardised panel:
	  • Energy value, protein, carbohydrate, total sugars, fat, saturated fat, sodium.
	  • Any other nutrient for which a nutrition or health claim is made.
	  • Any other nutrient considered to be relevant for good nutrition, as required by the national context, national legislation or national dietary guidelines e.g., these could include iron in countries where iron deficiency is a common concern.
	• Nutrients should be declared in a specific order as specified by authorities and displayed consistently across food products.
	• Energy value should be expressed in kJ or kcal, and protein, carbohydrate and fat in g per 100g or per 100mL, or per package if a single portion package. This information may also be given per serving or per portion as quantified on the label (i.e., per 25g, where one serving is 25g).
	• In addition to the mandatory nutrients, vitamins and minerals may be listed where both: 1) recommended intakes for vitamins and minerals have been established (by the country, or by Codex) and/or which are of nutritional importance in the country; and 2) such vitamins and minerals are present in amounts that are more than 5% of the reference intake set by a government (or Codex, where not set by a government) per 100g or 100mL.
	• Display specifications for the nutrient declaration should promote visibility, legibility and salience:
	  • This could include a specified tabular format or a linear display where there is insufficient space for a table.
	  • Regulation can specify font type, style and minimum size to promote legibility.
	  • Regulation can require a sufficient contrast between the text and background colours.

Policy coherence: The nutrient declaration is an enabler of other nutrition labelling policies (nutrition and health claims and SNI) and can act as a monitoring and enforcement tool for those policies by flagging to authorities the presence and amount of different nutrients in food. The nutrient declaration can support LSFF programs by requiring vitamins and minerals that are the focus of LSFF in a country to be quantified in the declaration, allowing consumers to compare foods based on the presence or absence of such vitamins and minerals.

Figure 4: Nutrition and health claims: conceptual framework for best practice in the context of LSFF

For an example of a nutrition claim and a health claim see page 9, Figure 1 for reference.

Nutrition and health claims	Suggested best practice
Regulatory framework The regulatory framework is appropriate to the geography's legal context (i.e., provides sufficient authority and oversight of labelling).	• Requirements for making nutrition and health claims may appear in an overarching Food Act/Law or subsidiary regulations. • The use of nutrition and health claims should be voluntary and only given in addition to a nutrient declaration. • Certain claims are prohibited (e.g., claims that a food will provide an adequate source of all essential nutrients except where standards permit and claims about the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease or disorder).
Regulatory objective(s) There are clear, measurable objectives against which the success of regulation can be assessed.	• Ensure a high level of consumer protection and information. • Facilitate choice by providing clear information to make it easier for consumers to choose healthful diets (including fortified foods as part of this diet).

Operative terms and conditions
Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objective.
	• Must be supported with a nutrition declaration, which should include a statement of the quantity of the nutrient or ingredient that is the subject of the claim.
	• Must not be misleading or deceptive on the nutritional merit of foods and may be prohibited on some foods (e.g., should generally be prohibited on foods for infants and young children).
	• **Nutrition claims s**hould be permitted if they relate to energy, protein, carbohydrate, sugar, fat, fibre, and sodium. They may also be permitted for vitamins and minerals for which reference intakes have been set. Where specific, such as 'low in' or 'high in', nutrition claims can be guided by national regulations that incorporate nutrient reference intakes, or where these do not exist, by the table included in Codex Guidelines for the Use of Nutrition and Health Claims.
	• **Health claims:**
	  • Should have clear conditions to qualify to be able to make a specific claim, with authorities having the ability to prohibit claims on foods that contain nutrients or constituents in amounts that increase the risk of disease or adverse health-related conditions (i.e., restrict claims on unhealthy foods).
	  • Should be substantiated by sound scientific evidence, with the claim re-evaluated once new evidence becomes available.
	  • Should be accepted by, or be acceptable to, the competent authorities of the countries where the product is sold.
	  • Should also include additional information on the label, including a declaration of the quantity of the nutrient or constituent in the nutrient declaration; the target group (if appropriate); a statement on how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources where appropriate; advice to vulnerable groups (if appropriate) on how to use the food or the need to avoid the food; information on maximum safe intake of the food where necessary; information on how the food fits within the context of the total diet; and a statement on the importance of maintaining a healthy diet.
	• **Prioritising standardised fortification claims** may increase the efficiency of regulatory governance and support consumer understanding and use of fortified foods. Such standardised claims should be prioritised for mandatorily fortified foods over voluntarily fortified foods except where conditions are met.
	  • Health claims may be more persuasive than nutrition claims, but there is insufficient evidence to recommend any particular claim type to support food fortification. Testing of which claim is most useful and well understood by consumers in a geography will help maximise the potential public health impact of the claim. Note that health claims should be straightforward to substantiate, given the presumption that mandatory fortification is based on sufficient evidence of the health benefit. Voluntary fortification may be harder to substantiate as it may not be based on the same level of evidence as the health benefit.
	  • Three claim types are typically used:
	  • High-level health claims (e.g., *'Iron contributes to normal formation of red blood cells and haemoglobin', 'Zinc contributes to normal fertility and reproduction').*
	  • Generic health claims (e.g., '*iodised for better health*').
	  • Nutrition claims that mention fortification (e.g., '*iodised edible salt*' or '*fortified [or enriched] with iron and vitamin A*').

Policy coherence: Nutrition claims should be consistent with and support national nutrition policies. Health claims should be consistent with national health policies, including nutrition policies, and support such policies where applicable e.g., countries can set standards for the overall healthiness of products eligible to make nutrition and/or health claims to avoid such claims providing a 'health halo' on unhealthy foods.

Figure 5: Food fortification logos: conceptual framework for best practice in the context of LSFF

For an example of a fortification logo see page 9, Figure 1 for reference.

Food fortification logos (a form of SNI)	Suggested best practice
Regulatory framework The regulatory framework is appropriate to the geography's legal context (i.e., provides sufficient authority and oversight of labelling).	• Could be mandatory (i.e., through government legislation contained within the Food Act or subsidiary regulations) or voluntary (i.e., be outlined in government-issued policy guidelines). • Should generally be given in addition to a nutrient declaration.
Regulatory objective(s) There are clear, measurable objectives against which the success of regulation can be assessed.	• Increase consumer understanding of the nutritional value of their food (including fortified foods), and to assist in interpreting the nutrient declaration. • Allow appropriate comparison between similar foods to inform consumer choices. • May also incentivize re/formulation of products by industry to meet or avoid label conditions (e.g., to be able to include a fortification logo on a product label or to avoid having to place a high sugar, salt, or fat logo (or similar) on a product).

Operative terms and conditions
Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objective.
	• To meet the needs of a country, targeted consumers within that country, and to aid consumer understanding, the format of SNI, including food fortification logos, can vary from one country to another, or even within a country for different targeted groups (e.g., consumer testing of logos is often required). At the same time, standardized formats that promote consistent information are recommended.
	  • Standardised logos should be prioritised for mandatorily fortified foods over voluntarily fortified foods except where conditions are met.
	  • There may be a trade-off between the simplicity of a single logo that consumers find easy to recognize, understand and use, versus offering a variety of food-specific or nutrient-specific graphics that provide more detail but may also be more complicated to understand and resource-intensive to regulate. Consumer testing is often required.
	  • A claim could also be incorporated into a logo as it is in South Africa (e.g., *'Fortified for better health').*
	• The use of interpretive elements such as pictures, words, colours and/or symbols to signify that a product meets relevant fortification standards can be useful to support use, especially in populations with a high rate of illiteracy or little nutrition knowledge.
	• Incorporating elements that signal that the label is government-endorsed can increase consumer trust.
	• There must be clear guidance on which foods are eligible to display the logo, e.g., the scope of products eligible and the nutritional criteria those products must meet to display the logo.
	• The logo should be displayed in a way that promotes visibility and salience to consumers e.g., the logo could be required to be displayed in a uniform position such as the top right-hand corner on the front of a pack, meet minimum size requirements, and meet colour or contrast requirements.
	• SNI should be accompanied by consumer education to increase consumer understanding and use of the information.

Policy coherence: The fortification logo can be supported by nutrient declarations. Regulators can set standards for the overall healthiness of products eligible to use the food fortification logo to ensure that it does not provide a 'health halo' on otherwise unhealthy foods.

Figure 6: Regulatory governance: conceptual framework for best practice in the context of LSFF

Regulatory governance for nutrition labelling	Suggested best practice
Drafting regulatory rules and scheme design Transparency and accountability mechanisms are incorporated into regulatory regimes from their inception, including when developing substantive regulatory rules.	• Governments retain ultimate responsibility and authority for setting regulatory objectives and scope, and for setting the terms of regulation with appropriate independent expert input. • Governments can lead a stakeholder engagement process to develop robust regulation, including through processes of public consultation which can improve the feasibility and acceptability of the regulations developed. • Information about regulatory development should be transparent and easily accessible (e.g., submissions to public consultation should be released, meetings of committees should be public and/or with minutes published). • Conflicts of interest and industry interference are potential barriers to the development of evidence-based policies and must be carefully managed. • Harmonization (e.g., with Codex or regional standards) can facilitate trade, but countries retain policy space to develop regulations to protect public health even where these regulations exceed the level of protection provided in Codex standards.
Administration Administration by a government or independent body that monitors and enforces compliance and publicly disseminates information on the performance of regulation to facilitate external scrutiny.	• Responsibility can be granted to an independent statutory authority (e.g., a food standards agency) or government body (e.g., ministry of health). • The administrative body must be provided with the requisite authority and resources to conduct monitoring and enforcement activities and publicise how regulation is performing. • Implementation of nutrition labelling regulations should be accompanied by consumer education to increase use.
Monitoring Monitoring informs continuous improvement of regulation through the collection of baseline data, setting of process and outcome indicators and timeframes for measuring regulatory success, and ongoing data collection.	• Pre-market and post-market (e.g., via renewal) approval or licensing may act as a means to collect data on label use and compliance by industry. • Monitoring nutrition labelling regulation could also collect data on consumer understanding and use (particularly of claims and SNI such as fortification logos), product purchases (e.g., of foods carrying a fortification logo), population dietary intakes (e.g., of vitamins and minerals included in LSFF programmes), nutrient composition of foods and reformulation by industry. • Monitoring may be conducted by the government and/or another independent body with the requisite authority and resources.
Evaluation Structured, regular review of evaluation can ensure it is meeting its objectives. A review framework set down during regulatory development can include baseline data and performance indicators and timeframes to evaluate the effectiveness of the regulation.	• Evaluation of nutrition labelling regulations should be carried out by the government and/or an independent body or research group with the authority to assess the achievement of the regulatory objectives, using a transparent framework and sufficient data to assess whether performance indicators have been met within specified timeframes.
Enforcement A wide range of enforcement options are available, including incentives to encourage and reward high levels of compliance, 'soft' enforcement measures such as persuasion and more punitive measures for instances of serious or persistent non-compliance. Publication of enforcement decisions enhances transparency and allows the development of 'precedent' for users.	• Pre-market approval or licensing may act as a kind of 'pre-emptive' enforcement, where manufacturers must provide packaging with proposed nutrition labelling elements for approval before they can be sold in the market. • Post-market approval can include auditing and sampling of products in the market, or the renewal of the initial approval or license granted; a risk-based approach can be used to conduct targeted sampling. • The administrative body or other designated authority possesses a range of sanctions proportionate to the offence to act as a deterrent, which could include positive or negative publicity, written requests to manufacturers for action or amendment, withdrawal of the right to use (positive) labels such as a claim or logo, and fines or legal action. • Enforcement should be government-led and involve qualified personnel with sufficient resources to conduct their activities.

Policy coherence: Good governance of nutrition labelling regulations should ensure that processes are aligned with other activities in the food regulatory system (e.g., with food safety audits and enforcement activities). There is a need for coordination and clear roles and responsibilities across government bodies involved in all elements of food regulation in a geography.

Nutrition labelling: current practice and overall recommendations to support LSFF across nine study geographies

Here we detail trends in current nutrition labelling regulatory practice across the nine study geographies, noting how this practice may act as a barrier or enabler to LSFF. We highlight opportunities for different stakeholders to strengthen nutrition labelling regulations to support LSFF as recommendations, drawing upon ***Figure 2: Theory of Change.*** This analysis is presented at a glance in ***Figure 7: Traffic light reporting*** and is detailed for each country in section three of the report. Some geographies we reviewed – Ethiopia, Indonesia, some provinces of Pakistan, and South Africa – are at various stages in the regulatory reform cycle, having for example, issued draft laws or just promulgated laws but have not yet specified lower-level regulatory documents that provide detail on what is required by nutrition labelling. We have summarised this in the analysis below, and more detail sits in each country chapter.

Trends in current nutrition labelling practice of relevance to LSFF

- Just over half of the study geographies and one province of Pakistan mandate the use of nutrient declarations across nearly all pre-packaged foods and require the inclusion of vitamins and minerals in this declaration, provided they meet minimum levels, in line with best practice. Ethiopia's new fortification standards may mandate them on fortified foods. In Pakistan, nutrient declarations are voluntary in all provinces except Punjab. Thailand's regulations look to cover the field, but there are possible gaps depending on how its laws are interpreted. In Vietnam, declarations are voluntary, but a draft circular making them mandatory may become law soon.

Recommendation: Filling this regulatory gap should be the highest priority where gaps exist, as nutrient declarations promote transparency in the food supply for the purposes of monitoring compliance. Nutrient declarations are also a necessary precursor to the use of nutrition and health claims and SNI on foods.

- Similarly, all geographies permit ***voluntary nutrition and health claims,*** including nutrient claims for vitamins and minerals where the vitamin or mineral in a food meets specified levels, in line with best practice. Some geographies also have claims of fortified, enriched, or supplemented which in some cases must follow a generic statement. For example, in Punjab in Pakistan, a claim must be written as ***"This food is (state which enriched, fortified, vitaminised, supplemented, or strengthened) with (state the vitamins or minerals or both and their amount in units per the regulation)".*** Only two geographies (South Africa and Nigeria) have standard fortification claims that link to health benefits. For example, in Nigeria, food labels that contain sufficient calcium or phosphorous must state that it "Contains calcium and/or phosphorous that is a factor in the normal development and maintenance of bones and teeth especially in children". In South Africa, broader claims such as such as ***"fortified for better health"*** exist. Other geographies such as various provinces in Pakistan and Ethiopia have very little regulation of claims.

Recommendation: Prioritising standardised claims for mandatorily fortified foods (e.g., 'iodised for better health' based on food containing a required level of a micronutrient) may increase the efficiency of regulatory governance and support consumer understanding and use of fortified foods. This can also be considered for voluntarily fortified foods in certain circumstances.

- *Fortification logos* were identified in four geographies (Kenya, Nigeria, the Philippines and South Africa) and recent fortification legislation in three provinces of Pakistan mandates fortification logos to be established by relevant provincial food authorities. A fortification logo may also be included in Ethiopia's new fortification standards. Several geographies had FOPNL for foods high in salt, sugar, fats and sodium to address over-nutrition. No regulation of *SNI* was identified in Vietnam and some provinces of Pakistan. Some geographies also have a national standard mark that demonstrates general compliance with relevant food standards, including labelling standards.

Recommendation: Alongside or instead of standardised claims for fortified foods, voluntary or mandatory application of a standard fortification logo or logos to visually signal that specific products are fortified may be useful to consider in geographies that do not currently have such logos. Priority should be given to logos for mandatorily fortified foods as this signals government endorsement of a healthier food choice in line with public health objectives, although they may apply to voluntarily fortified foods in some circumstances. If logos are considered for voluntarily fortified foods, governments could consider differentiating such logos from those for mandatorily fortified foods (e.g., the Philippines uses a Diamond Sangkap Pinoy Seal for mandatorily fortified foods and a rectangular Sangkap Pinoy Seal for other foods fortified with iron, vitamin A and iodine).

- We examined trends across how regulations are governed, or ***regulatory governance archetypes,*** (i.e., the surveillance system used by a regulator to administer, monitor and enforce nutrition labelling requirements, and the timing of such approvals and surveillance). Most (seven) geographies operate ***pre- and post-market surveillance systems*** for food products, including labelling. This occurs via both business and product licensing, and sometimes the pre-approval of food product advertisements. Surveillance is generally undertaken by the national standards body (e.g., Kenya Bureau of Standards or KEBS) and/or the national food and drug regulatory agency (e.g., the equivalent of the Food and Drug Regulatory Authority in the US). Vietnam operates a ***self-declaration pre-market surveillance system with post-market surveillance*** conducted by the relevant regulatory authorities. In Pakistan, this surveillance system is managed predominantly by provincial food authorities and except for fortified foods only operates at the food business level, not at a product level, in Sindh, Balochistan and Khyber Pakhtunkhwa. Based on available information, South Africa appears to operate a ***post-market surveillance system only.***

- Where a ***regulatory authority for food labelling*** sits – with a food and drug regulatory agency (as is often the case), a standards body, or with the Minister/Ministry of Health – can determine the ***structure of nutrition labelling regulations.*** For example, if regulatory authority largely sits with a standards body such as KEBS, most labelling regulations are found in Kenyan Standards that sit under the law establishing KEBS and its powers and functions.

- Some geographies' nutrition labelling regulations also closely interact with ***regional standards.*** This can be seen most clearly in Kenya, which must adopt East African Standards into national law without deviation within six months of a standard being declared by the East African Standards Committee. Many of Kenya's standards are East African Standards that have been adopted directly as Kenyan standards. The Economic Community of West African States (ECOWAS) has standards for labelling and fortification, but it is not mandatory for member states to adopt them. In contrast, while the Association for Southeast Asian Nations (ASEAN) member states must evaluate regulation to ensure it is compatible with ASEAN nutrition and food security policy, we found little by way of specific regional labelling regulation that influences ASEAN member states' national food labelling regulations. The same can be said for countries that are part of the Common Market for Eastern and Southern Africa (COMESA).

- We garnered far more detail on the regulatory governance for the geographies in which we conducted surveys and interviews. In these focus geographies, we learned that ***what happens in practice may not be what is written in relevant laws and regulations.*** In several geographies, respondents told us that additional funding, human resources, laboratory capacity and/or training may be needed for a nutrition labelling regulatory regime to be operating optimally. We also heard that regular and ongoing education is required to ensure that the public understands and uses nutrition labelling and that industry players, regardless of their size, understand and can comply with regulatory requirements.

Recommendation: This finding is consistent with our previous work in both low- and high-resource settings globally, for example, our work for the WHO South-East Asia Region on Monitoring and Enforcing Food Regulations in that region.[6] In looking to strengthen labelling regulations, it is critical that stakeholders consider their local context (e.g., nutrition, health, and political context, and the available human and financial resources) to prioritise investment. There may be trade-offs, for example, between improving the regulatory governance of existing regulations, and/or amending or developing new regulations to align with best practice. Assuming there are limited resources and budget for nutrition labelling regulation, we recommend a risk-based approach that considers country priorities and the available resources to maximise effectiveness.

Section references

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Figure 7: Traffic light reporting of study geographies' current fortification regimes, nutrition labelling regulations, regulatory governance archetype and recommendations to strengthen nutrition labelling to support LSFF

To see more detailed recommendations and recommendations on regulatory governance please refer to the recommendations under each study geography in section three of this report.

Country	Mandatory fortification	Voluntary fortification	Nutrient declaration	Nutrition and health claims	SNI (e.g., fortification logo)	Regulatory Governance Archetype for labelling	Recommendations to strengthen nutrition labelling to support LSFF to be considered in country context (excl. governance)
Ethiopia*	Wheat flour, edible oils and salt.	Unclear but the Ethiopian Food and Drug Authority can require fortification / adopt fortification standards.	**Voluntary nutrient declaration** but **fortified foods must include a statement stipulating the vitamin or mineral used in fortification** (unclear if this is required in an ingredient list or declaration). *We understand new fortification standards will shortly mandate nutrient declarations on fortified foods, but we were unable to access full versions.*	**Voluntary nutrition and health claims**, but not highly regulated (e.g., no requirement for a food to contain a minimum amount of a nutrient to make a claim). Some claims are prohibited (e.g., cannot imply a food can prevent or treat disease). **No standard fortification claims**, but a mandatorily fortified food must be labelled as "**fortified**".	**No fortification logo** but any **information or pictorial device** may be displayed, provided it does not conflict with mandatory requirements in the same standard or would mislead or deceive consumers. A **National Standard Mark** indicates a product is standard-compliant including re-labelling. *We understand a fortification logo is in development and that it may exist in the new fortification standards.*	**Pre- and post-market surveillance** The Ethiopian Food and Drug Authority conducts pre- and post-market surveillance by requiring all foods to be registered with the EFDA via a certificate of competency. The Institute for Ethiopian Standards permits use of the National Standard Mark on application.	**Nutrient declarations** should be made mandatory for all processed foods, including for fortified foods (this may be achieved via the new fortification standards). The declaration should mandate inclusion of fortificants where food is fortified in line with standards. **Voluntary but standardised fortification claims and/or voluntary or mandatory fortification logos** could be considered for mandatorily fortified foods. Broader **claims regulation** could also consider setting requirements for nutrition and health claims in line with best practice, e.g., for specific nutrients (or vitamins and minerals) and based on levels of nutrient reference intakes.
Indonesia	Wheat flour, salt, and palm oil.	None identified.	**Mandatory nutrient declaration for all processed foods including fortified foods**. **Vitamins and minerals** can be included if present in an amount ≥2% of the RDA, if a label includes statements that food contains vitamins and minerals or if required by legislation mandating fortification.	**Voluntary nutrition and health claims** (including 'source of' claims provided they meet a minimum RDI) are permitted only if they meet certain conditions. Some claims are prohibited. **No standard fortification claims** but **permits statements that a food has been fortified, enriched, or supplemented** provided they do not mislead (i.e., where the statement confers a commercial but not a consumer benefit).	**No fortification logo**, but an Indonesian National Standard (SNI) mark is mandatory on fortified foods (and several other foods) to demonstrate conformity with the SNI. A **'Healthier Choice' logo** can be used if foods meet nutrient profiling criteria.	**Pre- and post-market surveillance** Indonesia's National Agency of Drug and Food Control (BPOM) must approve all processed foods for trade (inclusive of labelling) via a pre- and post-market surveillance system that requires renewal.	**Voluntary standard fortification claims** and/or **voluntary or mandatory fortification logo(s)** could be considered for mandatorily fortified foods.
Kenya*	Wheat flour, dry-milled maize, salt, edible fats and oils.	Where no Kenyan fortification specifications exist, Codex specifications apply.	**Mandatory nutrient declaration for all pre-packaged foods** (with minor exceptions, e.g., foods of nutritional insignificance like spices and condiments) and foods on which a health or nutrition claim is made. **Vitamins or minerals** can be included if present in a minimum amount (e.g., ≥5% of NRV per 100g/ml).	**Voluntary nutrition and health claims** are permitted provided they meet conditions. Some claims are prohibited. **No standard fortification claim** but **permits nutrient claims for vitamins and minerals** if conditions are met (e.g., can only claim 'source of' where a vitamin is ≥15% of NRV per 100g).	**A voluntary fortification logo (Fortification Mark of Quality**) can be applied for and is allowed only if a food meets fortification standards. A **Standardization Mark** is required prior to placing a food on the market. A **Diamond Mark of Quality** and **Import Standardization Mark of Quality** are also available. **Voluntary SNI** can also be used if a food meets conditions. A **draft traffic-light FOPL** is under review.	**Pre- and post-market surveillance** The Kenya Bureau of Standards (KEBS) requires all businesses to register to obtain a Standardization Mark before food is placed on the market. The mark requires renewal, and KEBS encourages concurrent application for the fortification logo.	**Voluntary standard fortification claims** for mandatorily fortified foods could be considered to add to existing fortification logos and increase consumer understanding of the benefits of fortified foods. If **claims regulations** were updated, stipulations on health claims could be considered to improve regulations.
Nigeria	Salt, sugar, wheat and maize flour, vegetable oil, margarine and butter – along with others in regulations.	Several foods can be voluntarily fortified (e.g., enriched alimentary pasta can be voluntarily fortified *and must be fortified* with specific micronutrients)	**Mandatory nutrient declarations on all pre-packaged foods**. **Vitamins and minerals** can be included if they meet conditions (e.g., ≥5% of NRV / serve). **Mandatorily fortified foods must include the amount of vitamin and/or mineral** added to the food in the declaration.	**Voluntary nutrition and health claims** are permitted provided they meet conditions. Some claims are prohibited. This includes **voluntary nutrition claims for vitamins and minerals** (e.g., 'a source', 'excellent diet source') if a % NRV is met. **Mandatory standard fortification claims for calcium, phosphorus and/or iron** (e.g., that it is a factor in the maintenance of good health, or re calcium or phosphorous only that it is a factor in the normal development and maintenance of bones and teeth especially in children). Salt must be labelled as '**salt fortified with iron'** or other 'names'.	**Mandatory fortification logo** for foods mandatorily fortified with vitamin A and a **mandatory iodised salt logo** for iodised salt. A regional **'Enrichi' logo** is available for wheat flour and cooking oil fortified with vitamin A as part of an ECOWAS program. A priority of the National Multi-Sectoral Action Plan for the Prevention and Control of NCDs (2019) is to adopt standards for **FOPNL**.	**Pre- and post-market surveillance** All fortified, processed and any foods to be advertised (including labelling) in Nigeria must be registered with the National Agency for Food and Drug Administration and Control (NAFDAC), with renewal required.	Increased attention should be paid to the interaction of fortification and food labelling to **ensure that policies and regulations coherently address over- and under-nutrition**. At this time, given existing fortification logos and claims and government consideration of FOPNL, we **do not recommend additional fortification logos or claims be considered unless** care is taken to align and coordinate these policies to enhance consumer understanding/mitigate potential confusion (e.g., this may be improved through a consolidated logo for claims such as in South Africa). Further, if **claims regulations** were updated, stipulations on health claims could be considered to improve regulations.
Pakistan	Edible oil.	Unclear but standards exist for iodised salt, enriched wheat flour and selfraising flour.	**Voluntary nutrient declaration.** No requirements on inclusion of **vitamins or minerals.**	Little regulation of claims but imported products claiming to be a source of vitamins and minerals must be registered in Pakistan. **No standard fortification claims.**	**No regulation identified.**	**Pre- and post-market surveillance (at food business level in general but for specific fortified foods in Sindh, Balochistan, Khyber Pakhtunkhwa provinces)** Little nutrition labelling regulation was identified in Pakistan outside of Punjab. However, the federal government regulates and implements food safety standards for food imports. Provincial food authorities regulate and implement food safety standards for domestic food products via mandatory food business licensing systems that require renewal.	**Mandatory nutrient declarations (highest priority)** for all processed foods, including fortified foods, that mandate the inclusion of fortificants wherever fortified, in line with standards. To help consumers more easily identify fortified foods beyond a label stating that food is enriched, fortified or supplemented with vitamins or minerals, **voluntary standard fortification claims** and/or a **voluntary or mandatory fortification logo** could be considered for mandatorily fortified foods and should ideally be aligned nationwide (except where they already exist in Punjab, Sindh, Balochistan, Khyber Pakhtunkhwa). At least **setting basic requirements for general claims** (e.g., for nutrition claims such as 'source of') and **prohibitions on specific claims** (except where they exist in Punjab).
Sindh, Balochistan, Khyber Pakhtunkhwa provinces, Pakistan	Vanaspati Ghee or edible oil, what flour/maida, atta, fine atta and suji. Salt in Balochistan only.	-	**Mandatory labelling with minimum essential information** about the mandatorily fortified food as specified by the Food Authority. *This may mandate a nutrient declaration.*	**No regulation** identified but advertisements re mandatorily fortified food must protect the consumer from **false and misleading claims**.	**Mandatory fortification logo** to be displayed on the pack of a mandatorily fortified food as prescribed by the Food Authority.		
Punjab province, Pakistan	Vegetable fats and oils, wheat flour/maida and atta.	Several foods can be voluntarily fortified. Salt can be voluntarily iodised.	**Mandatory nutrient declarations** and must include quantities of **vitamins and minerals.**	**Voluntary nutrition claims that a food is enriched or fortified** (e.g., *'This food is (state which, enriched, fortified, vitaminized, supplemented or strengthened) with (state which, vitamins or minerals or both and their amount in units expressed per the regulation)'* provided it meets a minimum amount. Some claims are prohibited.	**No regulation** of nutrition labels was identified, but the mandatory **Punjab Food Authorized Logo** demonstrates that a food meets labelling and other food standards.		
Philippines*	Salt, rice, wheat flour, refined sugar, cooking oil and other staple foods as required by the National Nutrition Council and regulated.	Encourages fortification of foods widely consumed by at-risk groups, such as cereals and cereal-based products including snack foods and instant noodles.	**Mandatory nutrient declaration on packaged foods and fortified staple foods**. Key nutrients and **vitamins or minerals** added during fortification must be specified.	**Voluntary nutrition and health claims** permitted provided they meet conditions (e.g., 'source', 'high' if they meet specified %'s of NRV). Any claims not covered by regulations can be approved via application to the FDA. Some claims are prohibited. **Claims that a food is enriched/fortified with vitamins and/or minerals** can only be made when the amount of added vitamin and/or mineral accords with fortification guidelines and is in the declaration. **Iodised salt** must be declared on labels.	**Three Sangkap Pinoy Seal fortification logos** that can only be used on foods containing minimum amounts of fortificant(s): - Mandatory **Saktong Iodine sa Asin Seal logo** on iodised salt - **Diamond Sangkap Pinoy Seal** for staples covered by mandatory food fortification - Voluntary **Sangkap Pinoy Seal** for other foods fortified with iron, vitamin A and iodine [but see recommendation re coherence]. **Voluntary FOPNL** allowed outlining energy content in calories of a food.	**Pre- and post-market surveillance** All products must be registered with the Food and Drug Administration (FDA), which also involves a review of labelling. Use of Sangkap Pinoy Seals is subject to FDA approval, including for the mandatory iodised salt logo. Mandatory licences to operate food businesses sit alongside product and labelling regulation and oversight.	Increased attention should be paid to the interaction of fortification and food labelling to **ensure that policies and regulations coherently address over- and under-nutrition** - including use of the Voluntary Sangkap Pinoy Seal. If deemed useful to enhance consumer understanding of fortified food, additional specific **voluntary standard fortification claims** (including health claims) for mandatorily fortified foods could be considered to add to existing fortification logos and existing claims for fortified foods. This recommendation could be considered for voluntarily fortified foods in certain circumstances.

Country	Mandatory fortification	Voluntary fortification	Nutrient declaration	Nutrition and health claims	Regulatory Governance Archetype for labelling	Recommendations to strengthen nutrition labelling to support LSFF to be considered in country context (excl. governance)
South Africa*	Salt, wheat flour, wheat bread, maize meal and unsifted maize meal.	-	**Mandatory nutrient declaration where nutrition claims are made and for fortified foods and iodised salt.** Declarations are voluntary for all other foods. *Draft legislation would make nutrient declarations mandatory for nearly all food products, including mandatorily fortified foods.*	**Voluntary nutrition and health claims are** permitted provided they meet conditions (e.g., 'very high in', 'high in', 'course of' if vitamin or mineral meets specified %'s of NRV). Some claims are prohibited. **Standard fortification claims** for iodised salt, maize meal, wheat flour, and 'fortified for better health' provided food is fortified per regulations. *Draft legislation would impose new criteria for voluntary nutrition and health claims including use of a nutrient profiling model for South Africa to screen foods for claim eligibility.*	**Post-market surveillance** Administration of all food regulation is assigned by the Department of Health to local municipalities and food health inspectors at ports of entry.	If draft **labelling regulations** out for comment until end April 2023 are implemented, South Africa's labelling regulations would broadly cover the field from a nutrition perspective.
Thailand	Salt	Rice can be voluntarily biofortified.	**Mandatory nutrient declarations for certain categories of food** (include foods making a nutrition claim, foods that make use of nutritional values in promotions, foods that target a group of consumers and other foods which may be specified by the FDA). Must include in g/mg and RDI %: **vitamin A, B1 and B2, calcium, iron.**	**Voluntary health and nutrition claims** permitted if meet conditions similar to Codex and US FDA standards. E.g., 'excellent source of' claims allowed if meet a minimum RDI and nutrient function claims such as 'Vitamin B1 and vitamin B12 assist in function of nervous system' are subject to FDA approval. Some claims are prohibited. **Comparative claims of "...enriched, fortified"** can be claimed for vitamins and minerals (excluding sodium) when compared to a reference food if the nutrient content meets a specified level. Edible iodised salt must state: **'Iodized edible salt'.**	**Pre- and post-market surveillance** Manufacturers and importers must obtain a license (that requires renewal) from the FDA prior to food manufacturing or importing to ensure foods meet standards (including nutrition labelling). The FDA must also approve any food advertising.	To bring Thailand into alignment with Codex standards and best practice, **nutrient declarations** should be made mandatory for all processed foods with limited exceptions. It is unclear whether current regulations achieve this in practice. Thailand could consider a **mandatory salt iodisation logo** on foods. Prioritisation of this action may depend on the priority of salt iodisation to address iodine deficiency vs other nutrition interventions, given the additional regulatory burden to implement. Prioritisation may also account for current sodium intake levels that are being partly addressed by the sodium declaration as part of the Guideline Daily Amount style FOPNL.
Vietnam*	Edible salt and salt used in processed foods, wheat flour used in processed foods, specific vegetable oils.	Where deficiencies are not deemed a public health problem, voluntary addition of specific micronutrients is allowed.	**Nutrient declarations** are not required by current legislation in Vietnam. *A draft circular on nutrition labelling (including a mandatory nutrient declaration) was notified to the World Trade Organization in 2022 and is due to progress into law in 2023.*	**Voluntary nutrient content claims** permitted if conditions are met and advertisements (including labels) must be consistent with the effects of the product specified in the product declaration and must not use images of health facilities, physicians, pharmacists, health workers etc. Some claims are prohibited. **For voluntarily ("supplemented") fortified foods, nutrient content claims and health claims are permitted** if conditions are met (e.g., "source of" and "high in" claims if meet minimum RNI). Voluntarily fortified foods must be labelled as **"supplemented food"**, but **no standard fortification claims exist**.	**No regulation identified.**	Ideally, the proposed Circular that would introduce mandatory **nutrient declarations** should mandate inclusion of added vitamins and minerals. To help consumers more easily identify fortified foods beyond a label including the word 'fortified', voluntary, but standardised **fortification claims** and voluntary or mandatory **fortification logos** could be considered for mandatorily fortified foods. We do not extend this recommendation to relevant voluntarily fortified foods. If **claims regulations** were updated, stipulations on health claims could be considered to improve regulations beyond the existing regulation for voluntarily fortified or supplemented foods.
South Africa*	Salt, wheat flour, wheat bread, maize meal and unsifted maize meal.	-	**Official fortification logos are voluntary** provided food is fortified per regulations: 'iodated for better health', 'Fortified for Better Health,' 'Manufactured with fortified maize meal for better health', 'Manufactured with fortified wheat flour for better health'. *Draft legislation would create a new mandatory FOPNL for foods high in salt, sugar, saturated fat and/or containing artificial sweeteners.*	**Official fortification logos are voluntary** provided food is fortified per regulations: 'iodated for better health', 'Fortified for Better Health,' 'Manufactured with fortified maize meal for better health', 'Manufactured with fortified wheat flour for better health'. *Draft legislation would create a new mandatory FOPNL for foods high in salt, sugar, saturated fat and/or containing artificial sweeteners.*	**Post-market surveillance** Administration of all food regulation is assigned by the Department of Health to local municipalities and food health inspectors at ports of entry.	If draft **labelling regulations** out for comment until end April 2023 are implemented, South Africa's labelling regulations would broadly cover the field from a nutrition perspective.
Thailand	Salt	Rice can be voluntarily biofortified.	**Mandatory nutrient declarations for certain categories of food** (include foods making a nutrition claim, foods that make use of nutritional values in promotions, foods that target a group of consumers and other foods which may be specified by the FDA). Must include in g/mg and RDI %: **vitamin A, B1 and B2, calcium, iron.**	**Voluntary health and nutrition claims** permitted if meet conditions similar to Codex and US FDA standards. E.g., 'excellent source of' claims allowed if meet a minimum RDI and nutrient function claims such as 'Vitamin B1 and vitamin B12 assist in function of nervous system' are subject to FDA approval. Some claims are prohibited. **Comparative claims of "...enriched, fortified"** can be claimed for vitamins and minerals (excluding sodium) when compared to a reference food if the nutrient content meets a specified level. Edible iodised salt must state: **'Iodized edible salt'.**	**Pre- and post-market surveillance** Manufacturers and importers must obtain a license (that requires renewal) from the FDA prior to food manufacturing or importing to ensure foods meet standards (including nutrition labelling). The FDA must also approve any food advertising.	To bring Thailand into alignment with Codex standards and best practice, **nutrient declarations** should be made mandatory for all processed foods with limited exceptions. It is unclear whether current regulations achieve this in practice. Thailand could consider a **mandatory salt iodisation logo** on foods. Prioritisation of this action may depend on the priority of salt iodisation to address iodine deficiency vs other nutrition interventions, given the additional regulatory burden to implement. Prioritisation may also account for current sodium intake levels that are being partly addressed by the sodium declaration as part of the Guideline Daily Amount style FOPNL.
Vietnam*	Edible salt and salt used in processed foods, wheat flour used in processed foods, specific vegetable oils.	Where deficiencies are not deemed a public health problem, voluntary addition of specific micronutrients is allowed.	**Nutrient declarations** are not required by current legislation in Vietnam. *A draft circular on nutrition labelling (including a mandatory nutrient declaration) was notified to the World Trade Organization in 2022 and is due to progress into law in 2023.*	**Voluntary nutrient content claims** permitted if conditions are met and advertisements (including labels) must be consistent with the effects of the product specified in the product declaration and must not use images of health facilities, physicians, pharmacists, health workers etc. Some claims are prohibited. **For voluntarily ("supplemented") fortified foods, nutrient content claims and health claims are permitted** if conditions are met (e.g., "source of" and "high in" claims if meet minimum RNI). Voluntarily fortified foods must be labelled as **"supplemented food"**, but **no standard fortification claims exist**.	**No regulation identified.**	Ideally, the proposed Circular that would introduce mandatory **nutrient declarations** should mandate inclusion of added vitamins and minerals. To help consumers more easily identify fortified foods beyond a label including the word 'fortified', voluntary, but standardised **fortification claims** and voluntary or mandatory **fortification logos** could be considered for mandatorily fortified foods. We do not extend this recommendation to relevant voluntarily fortified foods. If **claims regulations** were updated, stipulations on health claims could be considered to improve regulations beyond the existing regulation for voluntarily fortified or supplemented foods.

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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Comparator jurisdiction: the European Union (EU)

Food fortification

EU Member States may fortify food under ***Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.***[21] This regulation specifies the form and amount of vitamins and minerals that can be added to foods and prohibits their addition to certain foods, such as unprocessed foods and alcoholic beverages (the list of foods with additions prohibited can change with advances in scientific evidence and foods' nutritional value).

In practice, each EU Member State takes a national approach to fortification. For example, there is mandatory fortification of wheat flour in several EU Member States including Uzbekistan and Kazakhstan,[22] and voluntary salt fortification in several Member States including Greece, Germany and France.[23]

A European Community Register on the addition of vitamins and minerals and of certain other substances to foods is maintained by the European Commission (the Commission).

Responsibilities and regulatory governance for nutrition labelling

The Commission has overall oversight of and largely regulates food law in the EU, except for some elements that are left to Member States such as regulation of their national competent authorities, and FOPNL as outlined further below. Nutrition labelling laws are harmonised across the EU, except for FOPNL, with harmonisation currently being pursued. The European Food Safety Authority (EFSA) provides independent scientific advice and scientific and technical support to the Commission regarding the EU's legislation and policies in all fields that impact food safety. The EFSA also communicates on food safety risks. Member States monitor and enforce food law through their national competent authorities (e.g., Ministries of Health in Austria, Cyprus and Croatia, the Norwegian Food Safety Authority, and the Danish Veterinary and Food Administration).[24] ***Pre-market surveillance*** occurs in some Member States that require their competent authority to be notified of a food to which vitamins and minerals have been added before it is placed on the market.[25] Member States' competent authorities are also responsible for conducting ***post-market surveillance*** regularly, on a risk basis and with appropriate frequency, considering factors such as suspected non-compliance or where information indicates consumers might be misled.[26]

Regulatory governance – or the process of developing, implementing and evaluating nutrition labelling laws – is clear and transparent. For example, the development of food law (defined broadly) requires open and transparent public consultation and consideration of international standards. Member States must also engage with the Commission and other Member States if they deem it necessary to adopt new food information legislation. Clear processes and responsibilities are defined to monitor and enforce nutrition labelling laws. For example, Member States must set penalties that are effective, proportionate and dissuasive. The evaluation of existing regulations or new regulatory proposals is common and is often required by regulations.

Structure of nutrition labelling laws

The EU's nutrition labelling regulatory regime is structured as follows:

- *Regulation No 178/2002 laying down general principles and requirements of food law and procedures for food safety,*[27] including prohibiting labelling, advertising and presentation of foods misleading consumers. It also establishes the EFSA, its governance and functions.
- *Regulation No 2017/625 on official controls and activities to ensure food law application*[26] sets out, among other things, responsibilities for the implementation of food law by Member States' national competent authorities and related requirements.
- *Regulation No 1169/2011 on the provision of food information to consumers*[28] mandates nutrition declarations, requirements for FOPNL and other requirements for food labelling e.g., mandatory particulars such as ingredient lists, and that requirements for such particulars must be in the required font size (≥1.2 mm, smaller for smaller packages) and in a language easily understood by consumers of Member State/s where a food is marketed. The regulation also prohibits misleading labelling.
- *Regulation No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods*[21] sets out requirements for nutrient declarations and nutrition claims in fortified foods and prohibits businesses from misleading or deceiving consumers as to foods' nutritional merits and from stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients.
- *Regulation No 1924/2006 on nutrition and health claims made on foods*[29] sets out requirements for such claims and nutrient declarations where a claim is made on a food. Additional regulations to assist in the regulation's implementation (e.g., regarding applications for claims) are linked to this:

  - *Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006*[30]
  - *Regulation No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006*[31]
- *Regulation No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations)*[32] that are traditionally used to indicate a class of food that could imply an effect on human health (i.e., a health claim).

Under EU law, regulations and decisions are automatically binding across the EU on their date of application – creating harmonisation across the EU. Sometimes, changes are required to national legislation, and as outlined above, such regulations and decisions can require implementation by national agencies or regulators.[33]

Policy context and objectives

The EU's regulatory framework sets out clear and intersecting regulatory objectives offering a high level of protection to consumers and their health by facilitating informed choice, the free movement of food, and the promotion of high-quality products, among other elements. There are also clear links to promoting healthier diets, such as mandatory nutrition information to assist public health policies' nutrition actions, which could involve scientific recommendations for nutrition education for the public,[28] and the need for nutrient profiles and conditions for nutrition and health claims to accord with the role and importance of food (or food categories) in the general population's or certain risk groups' diets.[29]

Nutrition labels

Nutrient declarations are mandatory for most pre-packaged foods. The declaration must provide the energy value and the amounts of fat, saturates, carbohydrates, sugars, protein, and salt, and be presented in a legible tabular format. The content of the mandatory nutrient declaration may be supplemented voluntarily with an indication of the amounts of additional components, including vitamins and minerals. All information must be expressed per 100g or 100mL and may also be expressed per portion or serve.

Nutrition and/or health claims are voluntary, but they must meet conditions. For example, generally accepted scientific evidence must have established that a nutrient on which a claim is based has a beneficial effect, the nutrient must be in the correct quantity to produce the effect, and the average consumer must be able to understand the claimed benefit. Some claims are prohibited. Further, the label on which any health claim appears must also include a statement indicating the importance of a varied and balanced diet and a healthy lifestyle. The EU has an online Register of Nutrition and Health Claims, including rejected claims and the rationale for rejection, and lists permitted health claims here.

Supplementary nutrition information: No standalone fortification logo was identified, but foods with added vitamins and minerals can bear a statement indicating their addition, provided they meet the conditions for a nutrition and/or health claim. ***FOPNL*** is voluntary. As of October 2021, Denmark, Sweden, France, Belgium, Spain, The Netherlands, Luxembourg, and Germany had adopted additional FOPNL schemes. The EU committed to propose harmonised mandatory FOPNL by Q4 2022, as specified in the ***Farm to Fork Strategy For a fair, healthy and environmentally-friendly food system***[34] to enable consumers to make health-conscious food choices, although is yet to eventuate.[35]

Table 2 – European Union – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient declarations are mandatory for: - Processed foods.[28] - Foods with added vitamins and minerals, therefore including all fortified food.[21] - Where a nutrition and/or health claim is made, except generic advertising.[29] • Nutrient declarations are not mandatory on non-pre-packaged foods, where nutrition information is not a determining factor for purchasing (e.g. tea and herbs), where packaging is too small unless stipulated, unprocessed foods, alcoholic beverages, and supplements.[28]	• Nutrition and/or health claims are voluntary, but certain claims are restricted (e.g., that health could be affected by not consuming the food).[29]	FOPNL is voluntary.[28]
Regulatory objective(s)	• High-level protection of consumer health and interests (including from fraud) by enabling consumers to make informed choices and safely use food, taking into consideration health, economic, environmental, social and ethical considerations.[27, 28] • Food information law aims to achieve free movement of food, taking into account the need to protect producers' legitimate interests and promote the production of quality products, as relevant.[28] • Enable consumers to evaluate the nutritional quality of food to which vitamins and minerals are added, and not mislead or deceive.[21]	• Ensure a high level of consumer protection and information[26, 29, 32] and facilitate choice.[29] • Ensure fair trade practices.[26] • Provide clear information to make it easier for consumers to choose healthy and sustainable diets, and reduce health-related costs.[34] • Not mislead or deceive the consumer as to a food's nutritional merit that may result from the addition of these nutrients.[21]	• The most important elements of a nutrition declaration can be repeated in the principal field of vision, to help consumers easily see essential nutrition information when purchasing foods.[28] See also Nutrition Declaration.[28] • FOPNL policy objectives are typically to[1] provide more information to consumers to inform healthier food choices and[2] encourage food business operators to reformulate products towards healthier options.[36] FOP labelling is increasingly seen as a tool to support strategies to prevent obesity and other diet-related NCDs.[37]
Operative terms and conditions	Nutrition declaration[28] must be/have: • Per 100 g/ml - In addition, pre-packaged food with individual portions can be declared per portion or consumption units that are easily recognisable by consumers, provided they are quantified on the label and near declaration (but some foods only need to express energy per portion/ consumption unit alone, such as drained weight of canned goods). The European Commission will develop rules per portion or unit of consumption to provide a uniform basis of comparison. • Simple and easily understood, in a clear format, specified order, and in a tabular format with numbers aligned (linear if no space). • In the same field of vision (e.g., a single side of a pack, or the back of a pack). • (a) Energy value (in the principal field of vision, using a specified font size), (b) Amount of fat, saturates, carbohydrate, sugars, protein and salt (as relevant, a statement indicating salt content is exclusively due to naturally occurring sodium can appear near the declaration). - Can also include: (a) monounsaturates; (b) polyunsaturates; (c) polyols; (d) starch; (e) fibre; (f) any vitamins or minerals in defined significant amounts (DRIs) and be expressed as a % of the DRIs; trans fats. - Energy value and nutrients can be expressed as a % of DRIs and include: 'Reference intake of an average adult (8,400 kJ/ 2,000 kcal)' near the declaration. - Where there is a negligible energy or nutrient amount, information on those elements can be replaced with "contains negligible amounts of ..." near the declaration. • Meet criteria e.g., based on relevant scientific data, where provided voluntarily. Foods with added vitamins and minerals[21] must include a declaration as specified above, inclusive of the total amounts of vitamins and minerals added.[28] Products on which a nutrition and/or health claim is made[29] must include a declaration as specified above.[28] The declaration must also declare (as specified) the amount of nutrient on which a nutrition and/or health claim is made where it is a nutrient required to be declared, but where it is not a nutrient required to be declared, the amount/s of a substance(s) on which a nutrition or health claim relates must be stated (as specified) in the same field of vision as the declaration, with appropriate units of measurement for the substance. Mandatory particulars on food must be easily visible, clearly legible and where appropriate, indelible. Text font size must be ≥1.2mm, or for containers <80cm^2, font size must be ≥0.9mm.[28]	Nutrition and Health claims:[29] • Shall not be false, ambiguous or misleading; give rise to doubt about the safety or nutritional adequacy of other foods; encourage or condone excess food consumption; state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general (some exceptions);[21] refer to changes in bodily functions which could give rise to or exploit consumer fears. • Are only permitted if the nutrient or other substance on which a claim is made: - Is shown to have a beneficial nutritional or physiological effect, through its presence, absence, or reduced content, as established by generally accepted scientific evidence; is/is not present in the final product in a quantity that will produce the claimed effect; and is in a quantity that can reasonably be expected to be consumed. - Is in a form that the body can use. - Complies with set conditions listed in the Regulation's Annex. - If an average consumer is expected to understand the claim's beneficial effects. - Refers to food ready for consumption per manufacturer instructions. Nutrition claims:[29] • Of reductions in fat, saturated fatty acids, trans-fatty acids, sugars and salt/ sodium are allowed without reference to a nutrient profile for the nutrient/s for which the claim is made, provided they comply with the specified conditions (listed in Regulations, e.g., Low-Fat, Fat-Free). • Are allowed, where a single nutrient exceeds the nutrient profile provided that a statement about the nutrients appears near to, on the same side, and with the same prominence as the claim. Comparative claims must comply with several conditions, including that such claims are only made between foods in the same category.[29] Health claims are prohibited unless they comply with specifications, including that labelling (or advertising if no label exists) must include:[29] • A statement indicating the importance of a varied and balanced diet and a healthy lifestyle. • The quantity of food and pattern of consumption to obtain a claimed effect. • Where appropriate, a statement addressed to persons who should avoid using food. • A warning for products likely to present a health risk if consumed in excess. • A reference to the general, non-specific benefits of the nutrient or food for overall good health or health-related well-being. Foods to which vitamins and minerals have been added[21] may bear a statement indicating their addition provided they meet the above conditions.	• Energy value and nutrient amounts (e.g., of fat, saturates, carbohydrate, sugars, protein, and salt) can be expressed in other forms, such as graphical forms or symbols, in addition to words or numbers, provided requirements are met. These include that they are based on sound and scientifically valid consumer research and do not mislead consumers; their development is a result of consultation with a wide range of stakeholder groups, and they are objective and non-discriminatory.[28] - Member States may recommend to food business operators the use of one or more additional forms of expression or presentation of the nutrition declaration that they consider best fulfils the above requirements and will provide the Commission with the details of such additional forms of expression and presentation.

Regulatory governance	
Drafting regulatory rules and scheme design	• Under Regulation No 178/2002 laying down general principles and requirements of food law and procedures for food safety[27] during preparation, evaluation and revision of food law (defined as "the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at EU or national level; it covers any stage of production, processing and distribution of food..."), open and transparent public consultation, directly or via representative bodies, is required, except where urgency does not allow it (although no specific time limit is provided). Further, international standards (such as Codex) must be taken into consideration even when completion is imminent. Exceptions exist, such as where standards would be ineffective to fulfil the legitimate objectives of food law, or where there is a scientific justification. The Community and Member States must also contribute to and promote the development of international technical standards for food and promote consistency between international standards and food law while ensuring the level of protection in the Community is not reduced. • As an example of the regulatory development process: – The Farm to Fork Strategy included commitments to propose a harmonised mandatory FOPNL involving broad consultation, impact assessment, and work on principles, requirements, and food system actors' responsibilities.[34] – Regulation No 1924/2006 on nutrition and health claims on foods set a requirement for the Commission to establish nutrient profiles for foods to comply with to be able to make nutrition or health claims. This requirement included the need to take into account relevant scientific developments and to consult with interested parties (in particular, food business operators and consumer groups).[29] • Regulation No 1169/2011 on provision of food information to consumers requires Member States that deem it necessary to adopt new food information legislation to notify the Commission and the other Member States of the regulation envisaged and its rationale in advance of adoption. If useful, the Commission can consult the Standing Committee on the Food Chain and Animal Health about such legislation and if it does, it must ensure the process is transparent for all stakeholders.[28] This same law requires the Commission to establish appropriate transitional periods for the application of new measures, during which foods bearing non-compliant labels can be placed and sold on the market until exhausted.[28]
Administration	• Regulation No 178/2002 laying down general principles and requirements of food law and procedures for food safety [27] establishes the independent European Food Safety Authority (EFSA) with a budget from the Community to provide scientific advice and technical support for the Community's legislation and policies in all fields that impact food safety. The EFSA is required to carry out its activities with a high level of transparency (e.g., making scientific opinions and minutes of all committees available to the public). • Regulation 2017/625 setting out responsibilities for implementation of food and feed law by competent authorities in Member States[26] specifies a range of obligations for competent authorities. These include ensuring appropriate procedures and arrangements are in place for effective and high-quality administration of regulations, adequate laboratory capacity for analysis, adequate legal power to monitor and enforce regulations, and sufficiently qualified staff. • Regulation No 353/2008 establishing implementing rules for applications for authorisation of health claims requires Member States' competent authorities to verify the validity of health claim applications before making them available to the EFSA for assessment.[31] • Under Regulation No 1924/2006 on nutrition and health claims made on foods,[29] all requirements to apply for a health claim from the EFSA (not already approved) are outlined, including that each health claim application must cover a single claimed effect and the type of health claim. Member States' competent authorities can request food business operators produce all relevant information to establish regulatory compliance (i.e., scientific substantiation justifying claim use) and the EFSA can accept claims based on generally accepted scientific evidence. Member States can also require manufacturers/people placing such foods on the market to notify the competent authority of the food being placed on the market and provide a model label. Further: – Regulation No 907/2013 setting the rules for applications concerning the use of generic descriptors (health claims)[32] specifies that applications for use of generic descriptors must be submitted in the required form with particulars such as supporting data to a Member State's national competent authority which must forward the application to other Member States and the Commission. The competent authority must assess the application for a generic descriptor and send it to the Commission for approval along with comments from other Member States. – Applications relating to disease risk reduction claims and claims referring to children's development and health must be sent to competent authorities which send the applications to the EFSA for its opinion. The EFSA's opinion must factor in whether a claim is understandable and meaningful to an average consumer and can be made public and shared with the Commission and Member States. The Commission makes the ultimate decision on whether a claim is accepted.[29] – Health claims other than those referring to disease risk reduction and children's development and health can be either from a permitted Community register of allowed health and nutrition claims or if not on the permitted list, can be applied for by submitting an application to a competent authority for scientific assessment and shared with the Commission and Member States for information. The EFSA issues an opinion on the claim, and the Commission decides whether to approve the claim application.[29] • Under Regulation 1169/2011 on the provision of food information to consumers [28] food business operator responsibilities are set out, including that they are responsible for the presence and accuracy of food information required by law. • The Commission, assisted by the Standing Committee on the Food Chain and Animal Health, facilitates and organises the exchange of information between Member States, itself and stakeholders regarding the use of any additional forms of expression or presentation of the nutrient declaration.[28]
Monitoring	• Under Regulation No 178/2002 laying down general principles and requirements of food law and procedures for food safety, Member States must monitor and verify that the food law requirements are met by food business operators at all stages of production, processing and distribution; and maintain a system of official controls and activities, including public communication, on food safety and risk, food safety surveillance and other monitoring activities.[27] • Under Regulation 2017/625 on official controls to ensure the application of food law among other things,[26] Member States must designate a national competent authority. The competent authority must perform official controls regularly on a risk basis (including border controls) and in accordance with documented procedures, keep written records of controls, and collect fees for activities – with specified methods for sampling and analyses. Food business operators must give competent authorities access to premises and information. • Regulation No 1925/2006 on addition of vitamins and minerals and of certain other substances to foods facilitates efficient monitoring via Member States requiring that manufacturers or other relevant persons notify the competent authority of a food being placed on the market by providing a model product label and requiring information on product withdrawal.[21] A similar notification process to competent authorities is required to facilitate the efficient monitoring of foods bearing nutrition or health claims,[29] and for additional forms of expression of the nutrient declaration, including providing relevant justifications to fulfil regulatory requirements.[28]
Evaluation	• Under Regulation 2017/625 on official controls to ensure the application of food law among other things, the Commission performs controls and audits on Member States. Competent authorities carry out internal or external audits which are subject to independent scrutiny. Authorities must perform official controls with a high level of transparency and make relevant information about the organisation's performance, along with annual reports on its activities, publicly available at least once a year.[26] • Evaluation of regulations or proposals for regulations are common in the EU and are often required under regulations. For example: – Regulation No 1169/2011 on provision of food information to consumers requires a report to the European Parliament and Council on the use of additional forms of expression and presentation of the nutrient declaration (or FOPNL) and advice on further FOPNL harmonisation. The report outlined evidence and stakeholder views and proposed FOPNL harmonisation.[37] – Regulation No 1925/2006 on addition of vitamins and minerals and of certain other substances to foods required the Commission to submit by 2013, a report on the effects of regulation implementation (e.g., changes in the market for fortified foods, consumption, nutrient intakes) and any proposals for amendment to the European Parliament and Council. Member States were also required to provide information to the Commission for this purpose.[21] A similar requirement was set out for nutrition and health claims regulation,[29] including for consumers' understanding of claims, a proposal for amendments, and an evaluation of the impact of the regulation on dietary choices, and the potential impact on obesity and NCDs.
Enforcement	• Under Regulation No 178/2002 laying down general principles and requirements of food law and procedures for food safety,[27] Member States must enforce food law (defined above under Drafting regulatory rules and scheme design) at all stages of production, processing, and distribution. Member States shall also lay down the rules on measures and penalties applicable to food law infringements, which must be effective, proportionate and dissuasive. • Under Regulation 2017/625 on official controls to ensure the application of food law, among other things: – National competent authorities' enforcement action includes a period of investigation and intensified control of goods and operators where non-compliance is suspected. Competent authorities can take any action necessary to determine the origin and extent of non-compliance and establish operator responsibility. Appropriate enforcement measures must take into account the nature of non-compliance and past operator compliance (e.g., order label alteration, recall and destruction of goods). Authorities must provide the operator with its decision and reasons in writing, and inform them of any right to appeal, with all expenses to be borne by the relevant operator(s).[26] – For an infringement, Member States must lay down rules on penalties that are effective and proportionate (e.g., at least the economic advantage for the operator or a % of operator turnover) and notify the Commission of the rules. Member States must take all necessary measures to implement the rules and ensure competent authorities have effective mechanisms to enable reporting and follow-up of actual or potential infringements and protect the people reporting infringements.[26]

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Comparator jurisdiction: the United States (US)

Food fortification

In the US, fortification is mandatory for some foods as set out in standards of identity, to ensure the characteristics, ingredients and production processes of these foods are consistent with consumers' expectations. For example, margarine must be fortified with vitamin A and can optionally be fortified with vitamin D. Some other specific foods have a standard of identity for the enriched form of the product (e.g., enriched flour must contain specified levels of vitamins B1, B2, B3, iron, and folic acid) and a standard of identity for the unenriched or unfortified form of the product (e.g., flour).[38]

Responsibilities and regulatory governance for nutrition labelling

The US regulatory framework for food labelling provides clarity and transparency on regulatory governance. For example, the Food and Drug Administration (FDA) has primary responsibility for food labelling regulation including evaluating and reviewing regulations. Requirements are also in place to manage conflicts of interest, and regulatory development is informed by public consultation and considers the international Codex Alimentarius standards.

While there is little by way of detail on administrative processes in legislation, the Secretary of Health and Human Services is required to carry out consumer education for nutrition labelling. The FDA produces a Regulatory Procedures Manual that outlines procedures used in labelling regulatory monitoring and enforcement, which is based on a ***post-market surveillance system***, following the ***FDA Modernization Act of 1997*** which eliminated the requirement for pre-market approval for most packaging. The FDA's Center for Food Safety and Applied Nutrition monitors the US food supply and diet and conducts research on food labelling in the US, including data on how consumers use and interpret nutrition labels.[39]

US state and local food authorities are authorised and responsible for enforcing nutrition labelling regulations in their jurisdiction and tiered penalty regimes are in place.

Structure of nutrition labelling laws

In the US, statutes (laws/acts) are continually 'codified' in the online United States Code (USC) by the Office of Law Revision Counsel. Regulations made by federal authorities (including the FDA) under the Code are compiled in the Code of Federal Regulations (CFR). In the summary below we refer to relevant statutes by their popular name and include the citation to their relevant location in the USC and/or CFR.

- ***Federal Food, Drug and Cosmetic Act (FD&C Act)*** 21 U.S.C §§ 301-392 (1983)[40] authorises the FDA to regulate and oversee the production, sale and distribution of foods, including by issuing and enforcing quality standards for foods and for food labelling and claims, inspecting food manufacturing and packaging facilities and recalling and seizing foods, and sets out offences for misbranded food, including food that bears false and misleading labelling. It also provides for national uniform nutrition labelling, preventing the states from establishing their own nutrition labelling regulations. In 1990, amendments to the Code passed under the 'Nutrition Labelling and Education Act' introduced requirements for nutrition labelling, including mandatory nutrient declarations (known as nutrition facts), and nutrition and health claims, as well as format and display specifications.[41] In 1997, amendments passed under the 'The FDA Modernization Act' added further requirements for nutrition and health claims, including processes for notification and approval to use. It also eliminated the requirement for pre-market approval for most product packaging.[42]
- Under the FD&C Act, the FDA has issued the following regulations on nutrition labelling:
  - ***21 CFR Ch. I Subch. B, Pt 101General provisions on food labelling***[43] set out detailed requirements for general food labelling (requiring a product name, ingredients list, and marketing authorisation number), nutrient declarations (termed nutrition facts), nutrition and health claims, and it prohibits false and misleading labelling. These regulations also incorporate amendments from the update of the nutrition facts panel in 2016, including offences for inaccurate declarations and requirements for manufacturers to retain records relating to their declarations.
- ***Fair Packaging and Labeling Act 15 U.S.C. § 1451 (1966)***[44] sets out general labelling requirements such as formatting and easily legible labelling, for a range of consumer products, and aims to protect consumers. With respect to food, the FDA is responsible for issuing and enforcing regulations under this law (the Federal Trade Commission administers consumer commodities outside the FDA's jurisdiction).

Policy context and objectives

The US regulation on nutrient declarations aims to assist consumers in healthy dietary practices. Beyond this, coherence with broader objectives may be implied from the FDA's Center for Food Safety and Applied Nutrition's monitoring of the US food supply and diet, and research on food labelling in the US (including how consumers use and interpret nutrition labels), and the requirement for the FDA to use science-based and data-driven decision making.

Nutrition labels

Nutrient facts (nutrient declarations) are mandatory for all packaged foods and must include specific vitamins and minerals as a % of the RDI, and other vitamins and minerals added as a nutrient supplement, or when a claim is made about them.

Nutrition and health claims are voluntary but must be from a pre-approved list and meet relevant conditions or be based on an authoritative statement from a relevant federal authority. The claims must accurately reflect that statement (and refer to the nutrient level in the statement) and the FDA's Center for Food Safety and Applied Nutrition must be notified about the claim. Qualified health claims can also be used on successful application to the FDA.

Supplementary nutrition information: No government regulation of SNI was found, but the FDA is currently conducting consumer research to develop a potential FOPNL scheme. Third-party FOPNL (FOPNL developed by NGOs or industry e.g., Smart Choices) are deemed to constitute a nutrient content claim, and they must comply with the relevant regulations for such claims.

Table 3 – USA – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrition facts labels are mandatory on packaged food.[40, 43]	• Nutrition and health claims are voluntary.[40, 43]	• At the time of writing, there is no government SNI. The FDA is conducting consumer research to develop a potential FOPNL scheme.
Regulatory objective(s)	• To assist consumers in maintaining healthy dietary practices.[45]	• None identified.	• None identified.
Operative terms and conditions	• Nutrient declarations must be accurate, truthful, and not misleading.[43] • The nutrition declaration shall contain information about the level of the following nutrients as grams and % daily energy per serving:[43] • Mandatory: total calories, calories from saturated fat, cholesterol, sodium, dietary fibre, total carbohydrate, total sugars, added sugar, protein, vitamin D.[43] • Voluntary: polyunsaturated fat, monounsaturated fat, potassium, soluble fibre, insoluble fibre, sugar alcohol, other carbohydrate, vitamins A and C. [43] • The declaration of vitamins and minerals as a % of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals when they are added as a nutrient supplement, or when a claim is made about them.[43] • The nutrient declaration must be in tabular format, with nutrients listed in no smaller than 8pt font, total fat, total carbohydrate, protein, sodium and cholesterol must be in bold; calories must be in bold and in 16pt font and the numerical value for calories must be in bond and 22pt font. Text in bold font is Helvetica Black, non-bolded is Helvetica Regular.[43]	Health claims, nutrient content claims, and structure/function claims are permitted but must be either: • From a preapproved list of claims (with conditions), or • Based on an authoritative statement from an appropriate federal authority (e.g., scientific body), in which case the FDA must be notified of the claim; and the claim must be an accurate reflection of the authoritative statement.[43, 46] For nutrient content claims, the authoritative statement must refer to a nutrient level.[43] Qualified health claims that are supported by scientific evidence, but do not meet the more rigorous "significant scientific agreement" standard required for an authorised health claim, can be used following a food manufacturer's successful application to the FDA. These claims must be accompanied by qualifying language to accurately communicate the level of scientific evidence supporting the claim to consumers.[42] Health claims cannot refer to a disease or related condition unless approved by the FDA based on significant scientific evidence.[43]	• Third-party front-of-pack labels (e.g. heart symbol) may constitute nutrient content or health claims and therefore need to comply with the relevant regulations for such claims.[43, 47]

Regulatory governance	
Drafting regulatory rules and scheme design	• Under amendments to the US Code passed in the Nutrition Labeling and Education Act of 1990, the Secretary of Health and Human Services is responsible for promulgating regulations under the Act.[40] In practice, the FDA carries out this task. • The process most often used by the FDA to issue rules and regulations is "notice and comment rulemaking", where the first public step is to issue a proposed rule explaining the FDA's intended requirements or actions and its scientific and policy reasons for doing so, and then asks for public comment. Comments are generally submitted via the Federal Government's electronic docket site. Alternatively, where more information is needed or the details of a regulatory path have not been set, the FDA may issue a request for comments or advance notice of proposed rulemaking. These notices ask for public comment on broad issues or questions and seek data or other information which is then used to formulate a policy to be put forth in a subsequent proposed rule. Once a proposed rule is issued and public comments have been received and reviewed, the FDA decides whether further action is needed – either in the form of ending the process, issuing a new proposed rule, or issuing a final rule, which then goes in the Federal Register. The final rule explains the regulatory requirements (the 'codified portion'), and the impact of the requirements on industry or the public and responds to the public comments made on the proposed rules. The 'codified portion' is also published under Title 21 of the Code of Federal Regulations.[48] For example, in the Final Rule published about the update of the Nutrition Facts Label, the FDA notes that it conducted significant stakeholder engagement and received ~300,000 comments during public consultation. In addition, consumer studies were conducted and made publicly available, and new scientific evidence was considered.[45] • Under 21 USC § 343-1 – National uniform nutrition labeling[40, 49] state regulation cannot require nutrition labelling that differs from federal labelling.[40]
Administration	• Under the FD&C Act [40] the FDA regulates and oversees the production, sale and distribution of foods, including by issuing and enforcing quality standards for foods, food labelling, and food claims, inspecting food manufacturing and packaging facilities, and recalling and seizing foods. • Under amendments to the FD&C Act passed in the FDA Modernization Act of 1997, nutrition and health claims based on authoritative statements must be notified to the Centre for Food Safety and Applied Nutrition before use, but the Act eliminated the requirement for pre-market approval for most packaging.[40, 46] • Under amendments to the FD&C Act passed in the Nutrition Labeling and Education Act of 1990, the Secretary of Health and Human Services is required to carry out consumer education for nutrition labelling.[40, 41] For example, the FDA carried out extensive consumer education after the 2016 update to the nutrition facts label.[45]
Monitoring	• Under the Final Rule issued by the FDA on the updated nutrition facts panel, manufacturers are required to make and keep records to verify the nutrient content of the product and the nutrient facts label.[45] • The FDA produces a Regulatory Procedures Manual for procedures used in labelling regulatory and enforcement matters. Under this manual, manufacturers must keep all information about labelling regulatory requirements on record and provide such information to inspectors on request.[50] • The FDA's Center for Food Safety and Applied Nutrition monitors the US' food supply and diet and conducts research on food labelling in the US, including data on how consumers use and interpret nutrition labels.[39]
Evaluation	• Under the FD&C Act,[40] the FDA retains responsibility for the evaluation and review of its regulations and reviews and updates regulations as required.[40]
Enforcement	• Under the FD&C Act [40] the FDA enforces food labelling and claims regulations and sets out offences for misbranded food, including food that bears false and misleading labelling. Relevant regulations made under the Act include: – 21 CFR Part 1: General Enforcement Provisions[51] non compliance may result in the removal of products from shelves or seizure, monetary fines, or criminal prosecution. – 21 CFR Part 101: Food Labeling[4] prohibits false and/or misleading labelling and trading food that does not comply with labelling regulations. Amendments to these regulations made at the time nutrition facts panel requirements were updated made inaccurate nutrition facts labelling constitute misbranding (an offence under the FD&C Act). • Under amendments to the FD&C Act passed in the Nutrition Labeling and Education Act of 1990, state and local food authorities are authorised and responsible for enforcing nutrition labelling regulations in their jurisdiction.[41] • Under amendments to the FD&C Act passed in the FDA Modernization Act of 1997, the FDA has a consumer complaint reporting mechanism for any FDA-regulated product.[42] • As specified in the Regulatory Procedures Manual, the FDA produces Compliance Program Manuals and Policy Guidelines, and Regulatory Procedures Manuals that instruct FDA personnel on the internal procedures and processes for enforcing and evaluating industry compliance with FDA-issued laws, and the consequences of non-compliance. Manuals are non-binding and alternative approaches can be used if appropriate. Under the Regulatory Procedures Manual, manufacturers are required to keep records related to regulatory compliance. The FDA has the authority to access these records, but cannot access records irrelevant to this purpose, such as sales or financial data. Where appropriate, the FDA may issue a warning letter to allow a business to take corrective action, such as relabelling products, before taking enforcement action.[50]

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Ethiopia

Food fortification

Under the *Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No.299/2013*,[52] the Ethiopian Food and Drug Authority (EFDA, formerly the Ethiopian Food, Medicine and Health Care Administration and Control) can order any food manufacturer to fortify food with specific vitamins and minerals and adopt standards for the fortification of foods with which all food establishments (manufacturers, importers, and sellers in Ethiopia) must comply.

In addition, the Institute for Ethiopian Standards (IES) can establish food standards[53] and has recently published standards for the mandatory fortification of wheat flour[54] (with zinc and vitamins B1, B2, B3, B6, B9 (folate), and B12) [only part of the Standard was available], and edible oils (that we understand mandates fortification of edible oils with vitamins A and D) (CES 310: 2022 Fortified Edible Oils - with Vitamin A and D – Specification) [unable to be accessed]. Ethiopia also mandates the fortification of salt with iodine.[23] Further, although it is dated, Ethiopia's ***National Nutrition Strategy, 2008***[55] recommended the expansion of food fortification, including that all salt be iodised and that there is adequate legal enforcement of food standards to ensure compliance.

Responsibilities and regulatory governance for nutrition labelling

The Federal Ministry of Health (MoH) leads the development of national and operational nutrition guidelines, monitoring, and evaluation.

The EFDA is responsible for establishing nutrition labelling regulations and must submit proposals to the MoH for government approval. It is ultimately responsible to the Ministry of Health. The EFDA is also responsible for ***pre- and post-market surveillance*** of nutrition labels, as well as appointing officers to enter and inspect premises to monitor, evaluate, and enforce labelling requirements (including the mandatory Ethiopian Standards issued by the IES). It does this by requiring all foods to be registered with the EFDA and all food businesses (e.g., manufacturers) to hold a certificate of competency. A dedicated e-service portal allows online applications for certificates of competence and related services.

The IES is responsible for developing Ethiopian Standards and/or recognising regional or international standards as Ethiopian Standards, including those for nutrition labelling and food fortification. It is also responsible for publicising, implementing, and monitoring such standards.

The Ministry of Industry and Trade is responsible for monitoring and enforcing labelling requirements on imported food.

Other various stakeholders are involved in the design and drafting of labelling regulations, including the Ethiopian Public Health Institute which conducts research such as national food and nutrition surveys, to inform standard and regulation setting, alongside academia and manufacturers. The benchmarking of similar countries' experiences and international standards are also considered. Other organisations are involved in the administration of nutrition labelling, including food and beverage institutes, the Private Business Association and Network (to promote and provide awareness training to its members' industries and lobby the government on policy issues), government, and private conformity assessment enterprises and companies (e.g., third party laboratories).

As a Member State of the Common Market for Eastern and Southern Africa (COMESA), Ethiopia also falls under the COMESA Authority's jurisdiction. Member States are required to apply uniform rules and procedures to formulate national standards and adopt African Regional Standards when available, or suitable international standards. [56] Specifically, Member States are required to create national legal frameworks for standardised pre-packing and labelling of goods traded in the COMESA.[56] No specific regulations were identified as flowing from COMESA requirements.

Structure of nutrition labelling laws

Ethiopia's nutrition labelling regulatory regime is structured as follows, noting that the Council of Ministers is the cabinet and executive body of the Government of Ethiopia.

- ***Definition of Organization, Powers and Duties of the Ethiopian Food and Drug Authority Council of Ministers Regulation No. 531/2023***[57] sets out the objectives, powers and duties of the EFDA, including the power to issue and enforce regulated products and enforce Ethiopian mandatory standards [Ethiopian Standards that are mandatory[58]]. Specifically, it can regulate health warnings, labelling, and the advertisement of foods, and can organise laboratories necessary to execute its functions.
- ***Ethiopian Standards Agency Establishment Council of Ministers' Regulation No.193/2010***[53] establishes the Ethiopian Standards Agency (which became the Institute of Ethiopian Standards (IES) in 2021), sets out its powers and functions and establishes the National Standard Mark.

- ***General Standard for Prepackaged Foods – Labelling (Compulsory Ethiopian Standard 73), 2013***[59] sets out general labelling requirements for pre-packaged foods (some of which are duplicative of those in the proclamation above). It also requires any label that places special emphasis on the presence of or low contents of an ingredient to declare that ingredient's percentage in the product on the label.
- ***Food and Medicine Administration Proclamation No.1112/2019***[60] sets out general labelling requirements for pre-packaged foods, including that labels must not be false, misleading or deceptive and that all foods must be registered with the EFDA or a regional health regulatory before being traded. It also includes a requirement for fortified foods to be fortified in line with applicable Ethiopian standards, labelled as 'fortified' (it is unclear if this is required in the ingredient list or as a declaration) and that they include a description of the type of fortificant.
  - ***Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No.299/2013***[52] requires labels on fortified food to include a phrase stipulating the vitamins or minerals with which the food has been fortified (in addition to the points on fortification above).

As a Member State of the COMESA, the following treaty and regional plans are also applicable to Ethiopia's labelling laws and/or fortification as indicated:

- The ***Treaty Establishing the COMESA adopted in 1993***[22] requires that Member States adopt a harmonised system and create national legal frameworks for the standardised labelling of goods traded in the Common Market and free trade area, although no such standardised COMESA-level labelling regulations were identified.
- The ***COMESA Medium Term Strategic Plan 2021-2025***[23] has broad applicability to nutrition labelling and fortification as it mandates that Member States develop common agriculture policies and it promotes the strengthening of food safety and technical standards and the coordination of nutrition promotion to access regional markets.
- The ***Regional Agricultural investment plan 2018-2022***[24] refers to supporting Member States to raise food literacy and implement nutrition interventions. It also details COMESA's intention to develop guidelines and products on high-impact nutrition interventions and references biofortification.

Policy context and objectives

No specific objectives were identified in regulations, but national food and nutrition surveys and international and similar geographies' regulations inform regulatory design and drafting in Ethiopia. This indicates that Ethiopia's labelling regulations seek to achieve good population-level nutrition. Nutrition labelling is also integrated into broader food safety and quality control regulation by both the EFDA and IES, but we found no evidence indicating how Ethiopia is seeking to ensure coherent nutrition labelling regulations to address both over- and under-nutrition.

Nutrition labels

Nutrient declarations are voluntary, but regulations do not include detail on what should be included in the declaration, aside from specifying that fortified foods must state the fortificant on the label (it is unclear if this should be in the ingredient list or nutrient declaration). It is also understood from one respondent that nutrient declarations will become mandatory for mandatorily fortified foods under new fortification regulations once the grace period for implementation ends.

Nutrition and health claims are voluntary (although there is little regulation of them aside from references to placing "emphasis" on an ingredient), however, claims cannot mislead or imply that a food can prevent or treat disease. Where a claim is made, the nutrient must be stated on the label (it is unclear if this must be included in a nutrient declaration or an ingredient list). Fortified foods must be labelled as 'fortified'.

Supplementary nutrition information: No specific SNI were found. However, any information or pictorial device may be displayed provided it does not conflict with mandatory labelling requirements in the ***General Standard for Prepackaged Foods – Labelling*** or mislead or deceive consumers. Further, there is a ***National Standard Mark*** which indicates that a product complies with relevant Ethiopian standards – including for labelling. The Mark is issued during the pre-market approval of a food and it can be mandated for certain products by the National Standardization Council.[53]

Standard Mark[59]

Recommendations to reform nutrition labelling regulations to enable LSFF

- ***Nutrient declarations*** should be made mandatory for all processed foods, including for fortified foods (this may be achieved via the new fortification standards). Similarly, and aligned with best practice, the declaration should mandate the inclusion of fortificants where food is fortified in line with required standards (e.g., that a food contains more than 5% of the reference intake set by the government or Codex per 100g/ml). Currently, the fortificant only needs to be included on the label via a 'statement' and it is unclear if this is required in the ingredient list or a declaration.
- To help consumers more easily identify fortified foods beyond a label including the word 'fortified', voluntary but standardised ***fortification claims*** and/or voluntary or mandatory ***fortification logos*** could be considered for mandatorily fortified foods. We do not extend this recommendation to voluntarily fortified foods given the additional regulatory burden this would impose and the limited public health significance of voluntarily fortified products.
- The ***regulation of broader claims*** could also consider setting requirements for nutrition and health claims in line with best practice, e.g., for specific nutrients (or vitamins and minerals) and based on levels of nutrient reference intakes.
- ***Regulatory governance*** appears to be strong – the EFDA and IES appear to have adequate powers, authority, and budget to administer regulations. Respondents also told us that to increase compliance further human resources and laboratory capacity, along with greater education for medium- and small-scale manufacturers in villages should be considered. In addition, the potential for conflicts of interest was raised by one respondent and should be adequately managed when developing regulations (in part, this would be via the 'one seat, one vote' process to agree standards). We also heard that the EFDA monitors and evaluates nutrition labelling in collaboration with Ethiopian county or city administrations via product registration, market surveys of all foods and post-market surveillance, in addition to submitting annual reports to parliament. The IES regularly reviews standards and must undertake research on the development, application and impacts of standards and related issues – however, we heard that no policy analysis of regulations has occurred. For any nutrition labelling reforms, building in required evaluation by independent organisations (including academia) should be considered.

Information sources and limitations

We undertook qualitative surveys and interviews in addition to a desktop regulatory review in Ethiopia. However, our inability to source the full versions of new fortification standards (CES 309 2022 Fortified Wheat Flour – specification and CES 310: 2022 Fortified Edible Oils- with Vitamin A and D – Specification) may impact the review and recommendations. Such information may sit outside of the regulatory documents reviewed or may have only been available in information published in a non-English language such as Amharic.

Table 4 – ETHIOPIA – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient declarations are voluntary.[59] • Nutrient declarations become mandatory for foods subject to mandatory fortification (e.g., edible oil, wheat flour) under new fortification standards when the grace period ends (understood to be June 2023) [ETH001-S].	• There is limited regulation on nutrition and health claims, but claims that place special emphasis on the presence of at least one valuable and/or characterising ingredient or where the description has the same effect, OR where labelling places emphasis on the low content of at least one ingredient require a declaration of the ingredient in the final product must be declared.[59] • Mandatory for fortified food to be labelled as 'fortified'.[52, 60] • Some claims on labels or advertisements are prohibited.[60]	• Voluntary pictorial device.[59] • A draft fortification logo is under development but is not yet approved. [ETH005-I, ETH001-I]
Regulatory objective(s)	• None identified.	• None identified.	• None identified.
Operative terms and conditions	• Labels must declare the percentage of an ingredient in a final product where labelling places special emphasis on the presence or low contents of that ingredient.[59] • General labelling for pre-packaged foods must be in Amharic or English language;[59, 60] be clear, prominent, indelible, and readily legible.[59]	• Content of the relevant nutrient must be stated on the label when a claim is made as above.[59] • Fortified foods must be labelled as 'fortified' along with a statement stipulating the vitamin or mineral used in fortification. (It is unclear if this is required in the ingredient list or a declaration.)[52, 60] • Claims (or any label information or advertisements[60]) cannot be false, misleading or deceptive[59] or imply that a food can prevent or treat disease[61] or in any way characterise the food as medicine.[60]	• Any information or pictorial device may be displayed in labelling provided it is neither in conflict with mandatory requirements in the same standard nor would mislead or deceive consumers in any way in respect of food.[59]
Regulatory governance			
Drafting regulatory rules and scheme design	• Under the Definition of Organization, Powers and Duties of the EFDA Regulation No. 531/2023[57] the EFDA has the power to initiate national standards, among other things and submit proposals on policy, strategy and law to the Ministry for Health – it can specifically regulate health warnings on food and labelling and advertisement of foods. It can also adopt and implement standards developed by the WHO, stringent regulatory authorities, or related international organisations, and regulate cross-regional advertisement of products. • Under the Food and Medicine Administration Proclamation No.1112/2019[60] the EFDA has the power and duties to initiate regulatory standards and implement standards for food safety, efficacy, and quality, and regulate cross-regional advertisements of products. Where no national standard exists, the EFDA can use acceptable Ethiopian standards adopted by international organisations to regulate food safety. • Under the Ethiopian Standards Agency Establishment Regulation No.193/2010[53] the IES must develop (through stakeholder involvement), approve and publicise Ethiopian standards, and establish national technical committees to develop Ethiopian standards and determine their working guidelines. The committees must be composed of different stakeholders consisting of educational institutions, research institutes (including the Ethiopian Public Health Institute [EPHI) [ETH001-S/I, ETH002-I]), government organisations, certification, inspection, and testing organisations, regulatory bodies, and consumer associations, for example.[59] The Regulations also establish the National Standardization Council made up of members from the government and other bodies, which approves standards. Standards are consensus-based reflecting the technical committee representatives' votes and comments from stakeholders.[59] We heard from respondents that: - The technical committee receives, reviews and discusses evidence in the drafting process. As each representative (including industry representative/s) receives one seat / one vote, technically conflicts of interest exist. [ETH002-I]. For example, the draft fortification logo (a national standard logo) was developed by the Technical Committee for Fortification. The committee drafted the regulation based on other countries' experiences. The draft was presented to an executive committee including higher officials and ministers for approval. The IES will then be responsible for enforcement. [ETH001-I] - In developing labelling standards, Ethiopia may use international standards, such as Codex, which are often adopted in full; other countries' or regional standards (African, US or EU) particularly those from neighbouring or similar countries, which are adapted to Ethiopia's context [ETH002-I, ETH005-I, ETH001-S]; country-specific evidence from EPHI, e.g., national food and nutrition surveys [ETH001-S]; research and technical documents. [ETH002-I]; and public consultation. [ETH002-I] - Once a regulation is drafted, a consultative workshop on the draft is conducted with stakeholders (e.g., millers' trade associations and iodised salt manufacturers), but comments from stakeholder engagement processes are usually not publicly available. [ETH001-I] • Under the Treaty Establishing the COMESA,[56] Member States are required to adopt a harmonised system and create national legal frameworks for the standardised pre-packing and labelling of goods traded on the common market – and cannot enact regulations that discriminate against like products of other Member States. Member States must also: establish national standards bodies; apply uniform rules and procedures to develop national standards; adopt African Regional Standards when available, or suitable international standards; and promote and enforce standards. More broadly, COMESA is governed by the Authority comprising Member States' Heads of State/Government whose decisions are binding on all Member States. Responsibility for monitoring, reviewing, and developing regulations sits with the Council of Ministers, which can make binding regulations and recommendations to the Authority. Technical committees, comprised of Member State representatives, are responsible for implementing the recommendations (including monitoring and review) and research and can consult with external stakeholders, including industry.		

Administration	• Under the Definition of Organization, Powers and Duties of the EFDA Regulation No. 531/2023[57] the EFDA has statutory authority to enforce and implement food safety and quality regulations (and thus nutrition labelling [ETH001-S, ETH005-I]). It has the power to issue market authorisation and certificates of competency, license products, take administrative measures and issue import permits; implement national standards; enforce mandatory standards; inspect, investigate relevant establishments and collect samples of EFDA-regulated products; educate the public on its functions and regulations [ETH005-I, ETH002-I]; establish a response system; undertake or order post-market surveillance and appropriate measures; establish and implement a modern regulatory system and regulatory information system; organise analysis laboratories; and collaborate with and support regional health regulators. The Government allocates the EFDA's budget. • Under the Food and Medicine Administration Proclamation No.1112/2019[60] the EFDA has the power to issue, renew, suspend or revoke a certificate of competence or market authorisation or other action of an importer, exporter, or manufacturer (among others), and evaluate and register foods as required under this or related regulations. The EFDA must also detain, seize or dispose of non-compliant products, inspect products and premises, undertake or order post-market surveillance to ensure food safety (and recover costs), appoint inspectors, and collect fees for health regulation. The EFDA or a regional health regulator can request third-party conformity assessments for the food safety of a food institution. All food and packing materials must comply with Ethiopian Standards. Further:[60] – All food manufacturers and all foods must register with the EFDA or a regional health regulatory body before commencing trade – and renew this in the time frame set by the EFDA. An EFDA-issued certificate of competency (a permit denoting that the facility and practice meet EFDA requirements [ETH001-I]) is required to manufacture, import or export food into Ethiopia, and the EFDA can order laboratory tests and/or evaluate good manufacturing processes as part of its assessment. Manufacturers must also meet certain obligations, e.g., continuous monitoring. – Respondents said that in general the EFDA regulates the '4 Ps': product, premises, practices, and professionals [ETH001-I] and works with other organisations to administer labelling, such as food and beverage institutes, the Private Business Association and Network (which promotes and provides awareness training to its members' industries and lobbies the government on policy issues), and conformity assessment companies/laboratories. [ETH004-S, ETH002-I] – Under the Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No.299/2013[52] food manufacturers are required to register to sell products in more than one regional state or for export. The EFDA issues a permit if a product is compliant with regulatory requirements, including via food safety and quality laboratory tests. The EFDA must undertake post-market surveillance and take action in the case of non-compliance. Food manufacturers/processors must cooperate with the EFDA during any post-market surveillance and must alert the EFDA of specific food-related issues. – One respondent noted [ETH001-I] that only highly perishable and other specific products (e.g., fortified foods, food supplements, dairy, meat, and infant foods) must be registered with the FDA after submitting detailed information about the product, including the manufacturer, a shelf-life study, and certificate of analysis. Other products only require importers or other food businesses to notify the EFDA of the product name, type and manufacture – and are thus only evaluated during post-market surveillance. • Under the Ethiopian Standards Agency Establishment Regulation No.193/2010 [53] the IES – whose budget is allocated by the government – must determine the national mark and its use; establish a national enquiry point and deliver services on standardisation, conformity assessments guidelines and technical regulations; develop and implement awareness-raising activities for consumers on standards; build industry capacity to comply with standards, work with institutions to ensure technical regulations are developed in line with world trade legal requirements; and charge fees for services rendered. – Food manufacturers are authorised to use the national standard mark on a product once they receive a permit from IES to demonstrate that the product complies with relevant standards. The mark can only be used on the product for which the permit was obtained, and permits must be displayed within the business premises. The IES must keep a public register of all persons authorised to use the mark. • Under the National Nutrition Strategy, the Ministry of Health should lead the development of national nutrition guidelines, their monitoring and evaluation and necessary laws for their implementation.[55] • Under the Treaty establishing COMESA,[56] documentation and related systems, quality assurance, specifications for inspection and testing of goods must be standardised. Under its Regional Agricultural investment plan 2018-2022[62] COMESA also conducts capacity-building programmes on customs and trade harmonisation.
Monitoring	• Under the Food and Medicine Administration Proclamation No.1112/2019[60] EFDA inspectors can enter and inspect establishments across the food supply chain, inspect foods, investigate or gather evidence when required, and take action as described in the Administration section above. We also heard that the EFDA monitors and evaluates nutrition labelling in collaboration with Ethiopian county or city administrations via product registration and market surveys of all foods and post-market surveillance. [ETH001-S,I] • See Ethiopian Standards Agency Establishment Regulation No.193/2010 [53] under Enforcement. • We also heard that the Ministry of Trade and Regional Integration can issue trade licenses and conduct monitoring of food imports which is similar to the EFDA's monitoring and license issue [ETH001-I]. • Under its Regional Agricultural investment plan 2018-2022, COMESA member states and secretariat monitor its strategic plan, supported by the monitoring and evaluation tools developed by COMESA, to promote the strengthening of regional coordination on nutrition promotion.[62]
Evaluation	• Under the Definition of Organization, Powers and Duties of the EFDA Regulation No. 531/2023 [57] the EFDA must submit performance and financial reports to the government. See also the EFDA's role in evaluation in Monitoring.[60] • Under the Ethiopian Standards Agency Establishment Regulation No.193/2010 [53] the IES must research the development, application and impacts of standards and related issues. Further, standards are continuously reviewed and are regularly updated to take into account the latest scientific and technological changes.[59] • We heard that standards are reviewed every five years, or on request [ETH002-I] but that no policy analysis of labelling regulations has been completed. [ETH005-I] • As above, under the EAC Standardisation, Quality Assurance, Metrology and Testing Act,[16] the EAS Committee reviews standardisation at national and EAC levels.

Enforcement	• Under the Definition of Organization, Powers and Duties of the EFDA Regulation No. 531/2023[57] the EFDA must establish and organise control and follow-up measures to prevent and control illegal activities concerning food labelling, and can issue warning letters, suspend or revoke certificates of competency or licences; impose fines or take other measures against violations of relevant regulations. • Under the Food and Medicine Administration Proclamation No.1112/2019,[60] misbranding or selling food in contravention of this proclamation or related regulations is prohibited. EFDA or regional health regulator inspectors can enter and inspect licensed institutions, take and test samples via laboratory examination, and take further legal action in some circumstances. Inspectors must observe the work procedures adopted by the EFDA or the regional health regulator. Once found, and depending on the type of violation of this proclamation or related laws, the EFDA can take administrative action (such as a warning letter or suspending a registration certificate, certificate of competence or other licence) and/or take a civil penalty, or pursue imprisonment where the violation is a crime. A complaint-handling organisation must also be established by the EFDA or regulator to handle complaints concerning administrative measures. – Under the Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No.299/2013[52] several prohibitions exist (e.g., selling food that is non-compliant with required standards or selling food without registration and a permit from the EFDA). The EFDA can seize food and order its destruction if it doesn't have market authorisation. – Under the Ethiopian Standards Agency Establishment Regulation No.193/2010[53] relevant federal and regional law enforcement bodies can: prohibit imports or exports subject to the mandatory national standard mark if they don't meet requirements (we heard that the Ministry of Trade and Regional Integration enforces labelling on food imports and the IES enforces the national standard logo (and fortification logo when implemented) [ETH005-I, ETH002-I]; undertake market surveillance and control measures to ensure products meet standards and authorise reintroduction to the market when products are seized due to non-conformity, and to engage with conformity assessment bodies to examine foods on the market and disclose their findings to the public via mass media. • We also heard from respondents that: – In general, laboratory and human resource capacity at the national level is good but is limited at sub-national levels for reasons including the complexity of identifying and taking corrective action on labelling. Industry compliance may be influenced by resourcing and capacity to follow standard production systems [ETH005]. More specifically, some medium and small-scale food manufacturers in villages are not fully aware of regulatory requirements (e.g., they may have a trade license but not a certificate of competency from the EFDA and for this reason may not fully meet labelling requirements). [ETH001-I] – Consumers can make complaints about nutrition labelling via a free complaint phone line. [ETH001-I] – Information on enforcement, post-market surveillance and administrative measures is not publicly available but may be presented during national meetings to stakeholders or the media [ETH005-I, ETH001-I], but safety issues such as public health hazards and product recalls, may be notified to the media. [ETH001-I, ETH002-I]

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Indonesia

Food fortification

Indonesia has mandatory fortification of wheat flour with iron, zinc, folic acid, and vitamins B1 and B2; salt with iodine; palm oil with vitamin A or provitamin A.[23] Rice can be voluntarily biofortified.[63] Some ASEAN guidelines also refer to fortification, as detailed under the ***Structure of nutrition labelling laws*** below.

Responsibilities and regulatory governance for nutrition labelling

The Indonesian National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan, or BPOM) regulates the safety and suitability of food and drugs for consumption by end-consumers. Its role is primarily to oversee, check, test, approve, register, and monitor consumer products, including food and beverages imported to, distributed and sold in the Indonesian market to ensure they meet minimum standards and requirements under Indonesian law. BPOM must approve all processed foods for trade (inclusive of labelling) via a ***pre- and post-market surveillance system*** that requires five-yearly re-registration and supervises information about sugar, salt, and fat contents in food and the health messages on such foods.

Responsibilities for other areas of labelling are spread among the Minister for Health (who supervises the implementation of labelling provisions and appoints officials to inspect these), Provincial Health Offices and Regency or Municipal Health Offices which supervise required labelling of fast foods based on their respective tasks and functions.

The government organises the monitoring, evaluation and control of the food control programme periodically; and relevant government institutions' inspectors conduct inspections, including of food packaging, and conduct investigations if inspections indicate a criminal offence has occurred. The government and local governments are also responsible for establishing a publicly available information system for food control monitoring and evaluation, although this isn't required to cover labelling.

Penalties are in place across the main labelling regulations and range from administrative sanctions to fines and imprisonment.

Structure of nutrition labelling laws

Indonesia's nutrition labelling regulatory regime is structured as follows:

- *Law No 18 of 2012 on Food*[64] sets out the requirements for general food labelling (e.g., product name, ingredients list) and for labelling processed food for trade. It prohibits trading food with non-compliant labelling and false and/or misleading labelling, along with establishing "a Government institution …to handle the food sector that is under and responsible to the President" which administers government affairs in the food sector.
  - *Regulations of the President of the Republic of Indonesia No. 80 of 2017 About Body that Supervises Drug and Food*[65] [translated on Google Translate] replaces earlier legislation on the same, and establishes BPOM which is responsible to the President through the Minister for Health. BPOM is tasked with supervising food and drugs in accordance with regulations. The regulations also specify BPOM's functions and powers.
- *Government Regulation No 69 of 1999 Food labels and Advertisements*[66] mandates nutrient declarations ("information on content of nutrition of food") on labels that include statements that the food contains vitamins, minerals and/or other added nutritional substances or if food is required to be fortified by legislation. It also allows health and nutrition claims, including fortification and enrichment statements, and sets out requirements for general food labelling, such as prohibiting false and/or misleading labelling and mandating the inclusion of ingredients and expiry dates. The labelling and advertisement provisions in this regulation do not apply to foods whose package is too small, foods that are sold in bulk or are directly sold and packaged before buyers in small numbers.
- *Regulation of Head of Drug and Food Control Agency of the Republic of Indonesia No 09955 of 2011 Concerning Processed Food Registration* (as amended by Regulation No. 42/2013 dated June 28, 2013)[67] sets out requirements to register processed foods (including labelling) and minimum requirements, such as nutrient content and an ingredients list.
- *Ministry of Health Regulation No. 30 of 2013 on the inclusion of sugar, salt, and fat contents as well as health message on processed foods and fast foods.*[68] The FAIRS Country report notes this Regulation was amended by BPOM Reg No 63/2015, but the regulation could not be located.[69]
- *Regulation of the Drug and Food Control Agency No 22 of 2019 About Nutritional Value Information on Processed Food Labels*[70] [translated on Google Translate] expands mandatory nutrient declarations to almost all processed foods and introduces the 'Healthier Choice' logo.

- *Several Ministry of Industry Regulations also govern Indonesian National Standards (SNI) for fortified wheat flour for foodstuff, salt for consumption and palm cooking oil that require use of an SNI mark to demonstrate conformity with the SNI.*[69] Several other foods also require use of the SNI mark such as bottled water, chocolate powder, instant coffee, biscuits, and several types of canned fish. Approval, product certification and issuing of a specific numbered SNI Mark, monitoring, and enforcement of these products is completed by an accredited institution approved by the Minister of Industry.[71] These regulations are not detailed in our analysis below aside from identifying the SNI mark, given this label is not a fortification logo.

As an ASEAN Member State, a set of non-binding regional guidelines, principles and standards are also applicable to Indonesia's food labelling laws and/or fortification as indicated, although we found little by way of specific regional labelling regulation that influences ASEAN Member States' national labelling regulations:

- *ASEAN Guidelines on Promoting Responsible Investment in Food, Agriculture and Forestry 2018*[72] propose considerations, including supporting food fortification, to improve nutrition security and promote the harmonisation of standards and regulations, while allowing national flexibility.
- *ASEAN Regional Guidelines on Food Security and Nutrition 2017*[73] serve as a reference guide to develop best practice policy that promotes nutrition and food security (including food fortification policies to address malnutrition and micronutrient deficiencies). Ultimately, the guidelines aim to build stronger cooperation and integration on food security and nutrition across the ASEAN region but they include few specifics on fortification.
- *ASEAN Principles and Guidelines for National Food Control Systems 2014*[74] is aligned with Codex principles and guidelines for National Food Control Systems CAC/GL 82-2013 and guide the development of food legislation that promotes food safety, including that national competent authority/ies should establish, implement, evaluate, and enforce evidence- and risk-based regulatory requirements.
- *ASEAN General Standards for the Labelling of Prepackaged Food 2016*[75] that adopt the Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985).

Policy context and objectives

The Law on Food states that food planning must "observe" food and nutrition consumption needs, population growth and distribution, and national and regional development plans, among other things. That law also requires that the central government and local governments establish a Food and Nutrition action plan every five years.[64] More broadly, regulatory objectives across Indonesia's labelling regulations aim to create fair and responsible food trade, increase knowledge and awareness of food nutrition, and facilitate consumer choice based on nutritional needs. As an ASEAN Member State, Indonesia must also evaluate new or existing regulation to ensure it is compatible with the ASEAN nutrition and food security policy.[73]

Nutrition labelling is also integrated into BPOM's overall food safety and quality control regulation. Further, there is evidence that Indonesia's nutrition labelling regulations seek to ensure coherence in addressing both over- and under-nutrition, e.g., both with statements around fortification and the Healthier Choice logo for products that meet nutrient profiling criteria, in addition to requirements for labelling fast food and some highly processed foods.

Nutrition labels

Nutrient declarations are now mandatory for processed foods and where the Healthier Choice ('Pilihan Lebih Sehat') logo is used, with few exceptions (e.g., tea and spices). Prior to updated regulations that broadly apply nutrient declarations, they were required in more limited circumstances (e.g., where nutrition claims were made, and in fortified foods which are required to be supplemented with vitamins and minerals). Vitamins and minerals can be listed only if present in an amount of at least 2% of the Recommended Dietary Allowance (RDA) and it also appears that they must be listed if a label includes statements that the food contains vitamins, minerals, or is required by legislation to be fortified.

Voluntary ***nutrition and health claims*** are permitted provided they meet conditions (with some claims prohibited). Statements that a food has been fortified, enriched, or supplemented are also permitted, but cannot mislead (i.e., where the statement confers a commercial but not a consumer benefit). Processed food and fast foods containing sugar, salt and/or fat must include a health message on the label that can be easily read by consumers: "Consuming more than 50 grams of sugar, 2,000 milligrams of sodium, or 67 grams of fat per person per day increases the risk of hypertension, stroke, diabetes, and heart attack". For fast foods, this message must also be promoted through leaflets, brochures, menu books, or other media.

Supplementary nutrition information: A FOPNL in the form of a voluntary Healthier Choice logo can be used if the food meets nutrient profiling criteria and has a nutrient declaration. No standalone fortification logo was identified, however a conformity mark otherwise termed an ***'SNI' mark*** must be added to several food products to demonstrate conformity of that food with Indonesian National Standards. This includes wheat flour for foodstuff, salt for consumption and palm cooking oil.[69]

Indonesia's Healthier Choice logo [76]

Indonesian National Standard conformity mark or 'SNI' logo [71]

Recommendations to reform nutrition labelling regulations to enable LSFF

- To help consumers more easily identify fortified foods beyond a label stating that food is enriched, fortified or supplemented with vitamins or minerals, ***voluntary standard fortification claims*** and/or a ***voluntary or mandatory fortification logo*** could be considered for mandatorily fortified food, in line with best practice. Broader claims regulation appears to contain some key elements of best practice regulation – noting that additional elements may sit in lower-level regulatory documents that were not identified in our review. For this reason, we do not make any specific recommendations for improving broader claims regulation based on our review.
- Based on our review and external analysis as below, Indonesia should consider ***improving the clarity of regulations*** and ***increasing capacity to improve regulatory enforcement.*** However, we note that current regulations provide a wide degree of flexibility in relation to who is responsible for what across government that may be common in Indonesia to prevent the invalidity of regulations if machinery of government changes take place. The United States Department of Agriculture's country report states that many Indonesian food regulations ***"are unclear and confusing, not enforced, or are enforced on a cursory basis in a haphazard manner."***[69] It notes that there may also be significant differences between the legislation as it appears on paper and what occurs in practice (globally, this is not uncommon). In addition, while pieces of legislation may use the term ***"in accordance with respective tasks or functions"*** it is often unclear what responsibilities are undertaken by which body for which regulatory processes (Regulatory Governance).
- To assist in ***monitoring and evaluation***, the central government and local governments could ensure that the food information system they are required to establish for monitoring and evaluation also extends to labelling.

Information sources and limitations

We only undertook a desktop regulatory review in Indonesia. Specific BPOM regulations that according to some reports[69, 77] apply to food labelling could not be located, i.e.: 13/2016 concerning processed food claims and advertisements; 31/2018 and 20/2021 concerning labelling of processed food; and 63/2015 (amending 30/2013) concerning health messages and content information on processed food.

Little detail was identified on regulatory drafting and design and evaluation, aside from establishing a food information system for evaluation and specifying responsibilities for evaluating processed food labelling. Such information may sit outside of the regulatory documents reviewed or may have only been available in information published in Indonesian.

Table 5 – INDONESIA – Summary of nutrition labelling regulations
Excludes draft regulations unless specified.

	Nutrient declaration		
Regulatory form and substance			**SNI**
Regulatory framework	• Nutrient declarations are mandatory: - On all processed food, [70, 68] except for powdered tea and coffee, tea bags, mineral bottled water, herbs, spices, seasoning, alcoholic beverages, and condiments. They cannot be listed on alcoholic beverage labels. - If a label includes statements that the food contains vitamins, minerals and/or other added nutritional substances or if food is required to be fortified by legislation ("supplementation with vitamins, minerals or other kinds of nutrition"), [66] - If the Healthier Choice logo is used.[70]		• Voluntary Healthier Choice logo.[70]
Regulatory objective(s)	• The creation of fair and responsible food trade; to provide society with true and illuminating information about the food they consume[66] and to increase knowledge and awareness re food safety, quality and nutrition.[64] • To reduce NCD risks (e.g., for hypertension, stroke, diabetes and heart attack) by improving consumer knowledge about sugar, salt and/or fat intake on processed foods and fast foods.[68, 78] • To provide information to the public to be able to choose processed food according to nutritional needs.[70]		• Per nutrient declaration: To provide information to the public to be able to choose processed food in accordance with the nutritional needs need to be included in the information nutritional value on processed food labels.[70]

	Nutrition and health claims	
Regulatory form and substance		
Regulatory framework	• Voluntary nutrition and health claims are permitted provided they meet conditions (e.g., health claims must be supported by scientific evidence).[66, 67] • Voluntary statements that a food has been fortified, enriched, or supplemented are permitted (they are "not prohibited").[66, 67] • Comparative claims[66, 67] – claims that a food functions as a medicine, or names, logos or identities of institutes conducting analyses of relevant food products[66, 67] – are prohibited.	
Regulatory objective(s)	• See "Regulatory objective" under Nutrient declaration.[66, 68]	

	Nutrient declaration	Nutrition and health claims	SNI
Operative terms and conditions	Requirements for nutrient declarations are set out in two regulations – one from 1999 mandating declarations where statements that the food contains vitamins and minerals etc. [66] and the other from 2019 mandating declarations on all processed foods [70] (both detailed above). The requirements in the 2019 regulation are detailed below, as these supplement and add to the requirements in the 1999 regulation which does not appear to be repealed. Nutrient declarations must list nutritional and non-nutritive content in a standardised table format – Information on Nutritional Value – and include:[66, 70] • Serving size; • Number of serves per package; • Nutrients listed by serving size, noting that for fortified processed food, only the nutrients that must be fortified must be listed per 100g or mL; • Type and amount of nutrient content: total energy, total fat, saturated fat, proteins, total carbohydrates, sugar, salt (sodium), dietary fibre if present in >0.5g per serve, cholesterol if present in >2mg per serve and/or claims re fats or fatty acids or cholesterol are made; • Vitamins and minerals can be listed only if they are present in an amount of at least 2% of the RDA [vitamins and minerals must be listed if the food falls under the 1999 regulations; [66]] • Some additional elements can be listed, but only if they meet conditions in the regulations, e.g., the energy content of fat does not need to be listed for processed food intended for infants and children up to three years, but if it is in included in such foods, it needs to comply with specifications in the regulations; • Type and amount of non-nutritive substance content; • Percentage of RDA per serve and footnote. Fast foods containing sugar, salt and/or fat for trade must include total sugar, total natrium and total fat contents on food labels based on an accredited laboratory's test results, and must be easily read by consumers. [68,78] Details on labels must be in Indonesian and should be easy to read. [66]	Fortification/enrichment/supplemented statements: • Cannot be false or misleading regarding benefits to consumers, e.g., due to consumption patterns vs only providing commercial benefits to producers (guidance notes that "not misleading" implies that even though the enrichment or fortification is done correctly, a statement of enrichment could mislead, e.g., due to the relevant food, or the consumption pattern, or if the enrichment brings no benefits to consumers, rather commercial benefits to producers).[66] • In advertisements are "not prohibited" provided the enrichment processing is done correctly. [66] Health claims: • Must be supported by scientific facts that can be accounted for; further provisions on the procedure and requirements will be stipulated by the Minister of Health.[66] • Processed food labels cannot make claims on several matters, including that it is healthy, can function as medicine or increase IQ; or include misleading or incorrect information or a picture of a health officer / a person acting as one.[67] Nutrition claims: if the volume of nutrition in the relevant food is at least 10% higher than the recommended daily nutrition adequacy volume in a dose for the food. [66] Any person stating a claim on a food label for trade is responsible for the truth of that claim, and certain processed food labels must also contain information about the allocation, application method and/or other information required concerning the food's effect on human health. [64] Processed food and fast foods containing sugar, salt and/or fat must include a health message on the label that can be easily and clearly read by consumers: "Consuming more than 50 grams of sugar, 2,000 milligrams of sodium, or 67 grams of fat per person per day increases the risk of hypertension, stroke, diabetes, and heart attack".[68] For fast foods, this message also needs to be promoted through leaflets, brochures, menu books, or other media.[68]	• The Healthier Choice logo may be used on the main section of the label if the product: meets nutrient profiling criteria for the food category; and includes Information on Nutritional Value or Nutrient declaration per the regulation. [70] • The logo format is prescribed (it is a circle with a tick symbol, has "Healthier Choices ' written on the top outside circle in capital letters, and the statement "Compared to Similar Products When Consumed in Reasonable [Amount]" at the bottom outside of the circle. Writing should be in, Arial font, with a white background, and the tick and writing in green. They should be logo-proportionate and legible. The size of the logo should not be >5% of the area of the main part of the label).[70]

Regulatory governance	
Drafting regulatory rules and scheme design	• The Law on Food[64] forms a government institution [...] to handle the food sector that is responsible to the President and that will be established by a Presidential Regulation. This government institution will administer government affairs in the food sector, which likely includes regulatory development. – The Regulations About Body that Supervises Drug and Food[65] establish BPOM to control drugs and food in the country, including to prepare national policies and develop norms, standards, procedures and criteria for food and drug control. • Under Regulation re Food labels and Advertisements, the Minister for Health can require certain processed foods to include other particulars connected with human health in labels or in relation to health claims.[66] • Under Regulation on inclusion of sugar, salt, and fat contents and a health message on processed and fast foods,[68] the obligation to include this information on food labels is staggered, based on processed food types by considering the risks of NCDs. Similarly, under Regulation about Nutritional Value Information on Processed Food Labels[70] implementation of the Healthier Choice logo is staggered based on a risk assessment. It is first being applied to ready-to-eat drinks and instant pasta and noodles. The same regulation provides a transitional period during which time processed food that has received a distribution permit prior to the enactment of this regulation can continue to be sold (it allows a 30-month grace period from enactment before labels need to comply). • Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States should provide clear and effective regulation that promotes food security and nutrition,[73] engage stakeholders in regulatory development to ensure transparency and that their views are considered,[74] and consider Codex standards, recommendations and guidelines.[74] All aspects of a national food control system should be transparent and open to public scrutiny while respecting legal requirements to protect confidential information.[74] Decisions should be evidence-based, and competent authorities and all officials should be free of improper or undue influence or conflict of interest.[74]
Administration	• Under the Law on Food,[64] in fulfilling food needs the central government and local governments are responsible for ...providing mentoring, eliminating policies that impact competitiveness and allocating budget; the government controls food labelling (for processed food by the drug and food control institution, and for fresh food by the government affairs institution in the food sector). Further, all food business operators must have marketing authorisation to trade foods in retail packaging (aside from foods produced by household industry) – but the authorisation process is in "the provisions of legislation". • The Regulations About Body that Supervises Drug and Food[65] stipulate that BPOM's food control responsibilities must be carried out in accordance with standards and regulations, including implementation and coordination of implementation of national policies; guidance and technical supervision; providing administrative support to all organisations involved in BPOM's activities; publishing product distribution permits and certificates and testing; monitoring and investigating; and applying administrative sanctions. A Deputy Field Supervisor for processed food is designated, along with one for field enforcement. BPOM's funding is also outlined. • Under Regulation Concerning Processed Food Registration,[67] all processed foods (with some exceptions) require a Registration Approval Letter from BPOM which is obtained after submitting a Registration Form (detailed in the Regulation) to the BPOM Head and Director, which includes the label design, and results of analysis of the finished product to which a claim relates and the scientific reference that supports a claim. The approval letter is valid for five years and may be extended through re-registration six months before expiry. If the registration application is rejected, a review can be requested. • Under Regulation re Food labels and Advertisements,[66] the Minister for Health supervises the implementation of labelling provisions and appoints officials to execute inspections. • Under Regulation of the Drug and Food Control Agency About Nutritional Value Information on Processed Food Labels[70] information included in the Nutrition declaration must be proven by nutrient analysis performed by government and/or other accredited laboratories, and be in accordance with defined tolerance limits (including for claims), with some exceptions such as micro/small enterprises. • Under Regulation on inclusion of sugar, salt, and fat contents and a health message on processed and fast foods,[68] the Minister for Health, Heads of Provincial Health Offices and Heads of Regency/Municipal Health Offices guide implementation (via advocacy and familiarisation, monitoring and evaluation, technical guidance and/or improving work and partnership networks) based on their respective tasks and functions, both to improve public knowledge on the risks of NCDs caused by fast and processed foods and to encourage producers of processed foods and fast foods to include information about their sugar, salt, and fat content. The Head of the Drug and Food Supervisory Board supervises the inclusion of information about sugar, salt, and fat contents and the health message. The Heads of Provincial Health Offices and of Regency/Municipal Offices supervise the inclusion of information about sugar, salt, and fat contents in fast foods based on their respective tasks and functions. The inclusion of information about the sugar, salt and fat contents must also be based on test results from an accredited laboratory. • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems, Member States' independent statutory bodies should retain authority for policy administration[73] and legislation should provide the authority with the power and mechanisms to: establish, monitor and enforce standards; implement regulations; perform activities to verify, investigate, and enforce regulatory compliance; and apply sanctions and/or penalties.[74]
Monitoring	• Under the Law 18 of 2012 on Food, the government organises the monitoring, evaluation and control of the Food Control programme for production processes or activity by Food Businesses Operators; and relevant government institutions' inspectors conduct inspections, which can involve opening and inspecting food packaging. If an inspection indicates that a criminal offence has occurred, an investigation is immediately performed. The central government and local government are responsible for establishing a food information system for monitoring and evaluation purposes (but this doesn't need to cover labelling), which must be publicly accessible.[64] – Under the Regulations About Body that Supervises Drug and Food,[65] BPOM must submit a report to the President on its implementation of functions periodically or as needed. • See Administration, including pre- and post-market surveillance via registration of processed foods.[68] • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems, Member States' national food control systems should be transparent and open to public scrutiny, while respecting the need to protect confidential information as appropriate.[74] To assess effectiveness and suitability to achieve objectives, the system should be subject to ongoing monitoring and review against documented criteria, and consider scientific evidence, and non-compliance.[74] Legislation and guidelines should also include provisions to monitor dietary consumption.[73]
Evaluation	• See Monitoring [64] and Administration.[68] • Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States' national food control systems should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is achieving its objectives.[74] Member States should also evaluate new or existing regulation to ensure it is compatible with their nutrition and food security policy[73]

Enforcement	• Under the Law on Food[64] sanctions for non-compliance with labelling laws include administrative sanctions, fines and imprisonment for up to two years.[64] • Violations of Regulation re Food labels and Advertisements[66] are subject to administrative sanctions (e.g., written warnings issued before other sanctions are imposed, and prohibitions on distributing food products for a period) through to fines and/or revoking production or business licences. Sanctions can be imposed by technical ministers in accordance with their areas of authority. • Violations of Regulation Concerning Processed Food Registration[67] are subject to administrative sanctions (e.g., written warnings, a temporary ban on circulation, suspended registration of processed foods, temporary suspension of activities or having registration approval revoked in specific circumstances). • Violations of Regulation on inclusion of sugar, salt, and fat contents and a health message on processed and fast foods[68] are subject to administrative sanctions that can be imposed by the Head of the Drug and Food Supervisory Board (and Heads of Regency/Municipal Offices with slightly different sanctions). • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' independent statutory bodies should retain enforcement authority,[73] be appropriately resourced and employ qualified personnel.[74] State authorities should establish, implement and enforce science- and risk-based regulatory requirements that encourage and promote positive food safety outcomes and establish and maintain arrangements with relevant organisations, such as officially recognised inspection, audit, certification and accreditation bodies.[74] Compliance and enforcement programmes should be designed to enable a competent authority to take corrective remedial action from education to sanctions, alongside maintaining public transparency.[74]

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Kenya

Food fortification

Mandatory fortification was introduced in Kenya first through salt iodisation in the early 1970's.[79] We learned through interview and survey responses that fortification regulations were subsequently expanded following a nationwide nutrition survey in 2000 showed that vitamin A and iron deficiencies were a major issue which prompted a Ministry of Health-led consultative process with industry and regulators and resulted in the updated regulations.

The Ministry of Public Health and Sanitation mandates food fortification in line with Kenyan standards and specifications (or where there are no Kenyan specifications, the specifications of the Codex Alimentarius Commission) in the ***Food, Drugs and Chemical Substances (Food Labelling, Additives and Standards) Regulations, 1978***. Kenya mandates that wheat flour and dry-milled maize products are fortified with vitamins A, B1, B2, B3, B6, B12, folic acid, iron and zinc; salt with iodine; and edible fats and oils with vitamin A.[80, 81]

Further, the ***Kenya National Food Fortification Strategic Plan 2018-2022***[82]seeks to improve LSFF in Kenya to address nutrient deficiencies, with a specific objective to increase the general population's awareness of fortified foods. ***The Kenya Nutrition Action Plan (KNAP) 2018 – 2022 Optimal Nutrition For All***[83] also notes that the fortification of wheat flour, maize flour, and edible oil and fats with essential micronutrients is important to address population deficiencies and references trends showing that the number of industries taking part in mandatory fortification has increased consistently during the last decade, but challenges remain in LSFF (such as the slow adoption of fortification by small and medium scale millers, poor standards compliance, inadequate human capital and infrastructure, and limited enforcement of the regulatory framework). The KNAP outlines a range of strategies and actions to improve LSFF, including strengthening regulatory monitoring and the evaluation of fortified foods to increase compliance with fortification standards, strengthening governance and coordination mechanisms for micronutrient programmes, and developing guidelines, training packages, and communication strategies.

As a member of the East African Community (EAC), the ***Sixth EAC Development Strategy (2021/22 – 2025/26)***[84] applies to Kenya, along with other EAC references below. This Strategy outlines broad strategic development objectives and priority areas for the EAC over a five-year period, including promoting the production of diversified foods and bio-fortification to improve food security and sustainability.

Kenya is also a Member State of the ***East, Central and Southern Africa Health Community*** which fosters regional cooperation for health. The Community's Strategy for Adolescent Nutrition Advocacy includes the fortification of staples as one intervention area and offers technical support to industry on food labelling as another.[85] No further links to the interaction of the Community with regulations in Kenya were identified.

Responsibilities and regulatory governance for nutrition labelling

Kenya's food labelling regulatory framework is largely set out in Kenyan Standards, is adopted by Kenya's National Standards Council, and is administered by the Kenya Bureau of Standards (KEBS), which is responsible for ensuring that levels of standards and regulations do not conflict. These standards are either developed in Kenya or through the EAC. Standards development in Kenya is a six-stage process that takes between six months and 18 months and involves a multisectoral Technical Committee that examines evidence, global shifts in standards and relevant national data (e.g., Demographic Health Surveys) and undertakes a thorough public consultation process before approval. A respondent described these standards as simplified versions of labelling requirements in legislation, with some minor exceptions (e.g., on-date marking) that industry is made aware of. Alternatively, a Kenyan Standard may be developed by Kenya or another EAC Partner State before moving through approval and declaration, before mandatory national-level adoption by all Partner States without deviation within six months of the declaration under the ***East African Community Standardisation, Quality Assurance, Metrology and Testing Act, 2006.***[86] Such standards borrow heavily from Codex guidelines, and in Kenya, most of such standards are prepared in accordance with KEBS procedures by the Labelling of Pre-packaged Foods Technical Committee. This committee includes representatives from KEBS, MOH, Kenya Industrial Research and Development Institute and other government departments, industry, and academia. We heard that as a result of the Constitution and other overarching laws mandating stakeholder engagement, regulatory development is "fairly transparent…open" and engages all stakeholders, including industry, which is viewed as positive and results in low levels of litigation. [KEN002-I]

In addition, KEBS is instrumental and active in the national Food Fortification Programme via its Project Implementation Unit and helps to develop the legal notice for mandatory food fortification that refers to Kenyan standards. [KEN002-I]

Administration, monitoring and enforcement of labelling is conducted predominantly by KEBS through ***pre- and post-market surveillance*** via its Quality Assurance and Market Surveillance Units and inspectors at ports of entry. For example, KEBS requires all manufacturers and businesses to register and obtain a Standardization Mark before they

place any food product on the market. The Standardization Mark requires a food product to be fully compliant with relevant specifications and labelling standards and must be renewed and audited for compliance every two years. The Fortification Mark of Quality (or fortification logo) is also administered by KEBS under a Memorandum of Understanding with the Ministry of Health. Like the Standardization Mark, to obtain the fortification logo, a business must apply to KEBS (usually via a concurrent application for both marks) to obtain a two-year approval to use the logo, which is only granted after KEBS samples the product and examines its labelling, and process and quality controls to ensure the product fully complies with applicable standards.

In addition, KEBS works with Kenya's Competition Authority to conduct market surveillance and enforce standards and with municipal councils that have enforcement powers under the Food, Drugs and Chemical Substances Act. While we heard from interviews and surveys that resources for local-level enforcement of standards could be improved, we also heard that KEBS is a well-resourced agency that tries to work with industry to ensure the correct interpretation of standards. KEBS has clearly prescribed penalty regimes ranging from licence withdrawal to fines and taking manufacturers to court (the latter is understood to be within the Competition Authority's purview, but no evidence of this occurring was identified in the review).

KEBS reviews its standards every four years to ensure they are up to date with new information and/or evidence. The East African Standards Committee is similarly required by law to review standardisation at national and EAC levels.

Structure of nutrition labelling laws

Kenya's nutrition labelling regulatory regime is structured as follows:

- *Food, Drugs and Chemical Substances Act (FDCSA) 1965*[87] sets out offences for false and misleading labelling and establishes the Minister for Health's powers to make regulations relating to food and other related powers and functions.
  - *Food, Drugs and Chemical Substances (General) Regulations, 1978*[88] set out general labelling requirements (e.g., they must be in English in addition to any other language), alongside other requirements for foods to be exported out of Kenya.
  - *Food, Drugs and Chemical Substances (Food Labelling, Additives and Standards) Regulations*[89] and amendments[81, 80] set out requirements for general food labelling (e.g., brand/trade name, expiry date) and mandatory food fortification, along with standards for various foods (e.g., cheese, milk).
  - *Food, Drugs and Chemical Substances (Food Hygiene) Regulations, 1978*[90] sets out requirements to obtain a licence to sell, prepare, package, store, or display food that will be sold.
- *Standards Act, 1973*[91] establishes KEBS and the National Standards Council and mandates the KEBS Mark of Quality.
  - *KS EAS 38: 2014 Labelling of pre-packaged foods – General requirements*[92] adopts East African Standard (EAS) 38 as a Kenya Standard. It sets out general labelling requirements (e.g., labels must be clear, prominently displayed and must include elements such as ingredients and net contents), offences for false and misleading labelling, and establishes KEBS' certification marks (Standardization Mark, Diamond Mark of Quality and Import Standardization Mark) that indicate products comply with Kenya's standards.
  - *KS EAS 803: 2014 Nutrition labelling – Requirements*[93] adopts East African Standard 803 as a Kenya Standard and sets out requirements for nutrient declarations and other SNI.
  - *KS EAS 804: 2014 Claims – General requirements*[94] adopts East African Standard 804 as a Kenya Standard and sets out general requirements for nutrition and health claims.
  - *KS EAS 805: 2014 Use of nutrition and health claims – Requirements*[95] adopts East African Standard 805 as a Kenya Standard and sets out additional requirements for nutrition and health claims, including a pre-approved list of claims.
  - *Draft Kenya Standard 2955:2022 Front of pack nutrition labelling – Requirements*[96] sets out voluntary FOPNL for most pre-packaged foods with some exceptions such as foods for infants and young children.

In addition to the above East African Standards that have been adopted by Kenya, as an ***EAC*** Partner State, Kenya is bound by the first-listed Act below. Various regional strategies to be implemented by Partner States and that are relevant to Kenya's labelling laws and/or fortification are:

- *East African Community Standardisation, Quality Assurance, Metrology and Testing Act, 2006*[86] establishes the EAS Committee and its representation from Partner States, including from national quality system institutions, and national manufacturing, trading and consumer organisations. The Committee is tasked with harmonising national and EAC standards with international standards to reduce costs, enhance compliance, develop trade opportunities, and protect and improve the health and safety of consumers. Within six months of the declaration of an EAS, Partner States must adopt the standard as a national standard without deviation.
- *The East African Community Food and Nutrition Security Action Plan (2019-2023)*[97] while not specifically addressing labelling, includes actions to harmonise the EAC standard for food fortification and complete an EAC food fortification manual, which may impact labelling. The Action Plan provides guidance and a framework for implementing nutrition policy in member states. Actions include developing and enforcing policies, regulations, and laws on food safety and standards for the region, noting that Partner States have existing fortification legislation that requires harmonising.
- *Draft (for public review) East African Standard 803: 2022 Nutrition labelling – Requirements*[98] is a proposed update to the current standard and is based on Codex Guidelines on Nutrition labelling (CAC/GL 2-1985 as amended in 2013). It includes more detail on SNI, including that SNI on labels may include front-of-pack warning labelling information represented by colour codes.

These East African Standards and related strategies also apply to other East African Community Partner States – the Democratic Republic of the Congo, the Republic of Burundi, the Republic of Rwanda, the Republic of South Sudan, the Republic of Uganda, and the United Republic of Tanzania.

We also heard from a respondent that ***African Regional Standards*** exist to facilitate trade in the African Economic Community (including on labelling of pre-packaged foods), and while there is no mandatory obligation to adopt such standards, it is encouraged and Kenya is moving towards adopting the standards. Given the status of these standards (i.e., their voluntary nature and that Kenya is yet to adopt them) they are out of scope for this review.

As a Member State of the ***Common Market for Eastern and Southern Africa (COMESA),*** the following treaty and regional plans are also applicable to Kenya's labelling laws and/or fortification as indicated:

- *Treaty Establishing the COMESA adopted 1993*[22] requires that Member States adopt a harmonised system and create national legal frameworks for the standardised labelling of goods that are traded in the Common Market and free trade area, although no such standardised COMESA-level labelling regulations were identified in the review.
- *COMESA Medium Term Strategic Plan 2021-2025*[23] has broad applicability to nutrition labelling and fortification as it mandates that Member States develop a common agriculture policy and promote the strengthening of food safety and technical standards and the coordination of nutrition promotion to access regional markets.
- *Regional Agricultural investment plan 2018-2022*[24] refers to supporting Member States to improve food literacy and implement nutrition interventions and details COMESA's intention to develop guidelines and products on high-impact nutrition interventions with references to biofortification.

Policy context and objectives

There is policy coherence both in the development of standards and the integration with East African Standards (via examining national data), the objectives of regulations (one objective is to provide consumers with information on nutrition content to benefit public health) and specific standards (such as the Kenyan Standard for Nutrition and Health Claims, which states that health claims should be consistent with and support national health and nutrition policy.[95]

Kenya's *Nutrition Action Plan (KNAP) 2018 – 2022 Optimal Nutrition For All*[83] *and the Kenya National Food Fortification Strategic Plan 2018-2022*[82] include actions to increase the population's level of awareness of fortified foods, improve large-scale food fortification, and develop legislation on the labelling and marketing of foods. In the introduction to the draft FOPNL standard, reference is made to Kenya experiencing a triple burden of malnutrition, with undernutrition, overnutrition, and micronutrient deficiencies across the population. It is establishing the FOPNL standard to help consumers make informed healthy choices on pre-packaged products. The consumption of unhealthy foods has continued due to consumers' "inadequate capacity" to interpret current nutrition labels, among other things. The FOPNL standard would also prohibit other endorsements on the label beyond marks for safety and quality if the product exceeds thresholds for fat, sugar, saturated fats, and/or sodium.[96]

We also heard from a respondent that discussions across government occur about the intersection of food fortification and policies to address over-nutrition, however improving consumer awareness of fortified foods is the current focus and addressing the "healthiness" of fortification vehicles is a future challenge.

Nutrition labelling is also integrated into KEBS' broader food safety and quality control regulation through its standardisation marks which take into consideration compliance with food labelling.

Nutrition labels

In general, we heard from respondents that few consumers read nutrition labels unless they want to learn about a new product as they are unaware of their usefulness. Respondents recommended greater consumer education to help consumers understand labelling. An effective consumer awareness campaign on the importance of fortification was conducted when mandatory fortification was introduced by the Ministry of Health. The campaign has not been repeated, so as with general labelling, consumers generally don't recognise the logo or understand its link with improved nutrient content.[82] We also heard that industry competition drives the use of the fortification logo so that the producers are not at a disadvantage.

Nutrient declarations are mandatory for all pre-packaged foods (aside from where national circumstances do not support declarations such as for foods of nutritional insignificance like spices or small packaging) and foods on which a health or nutrition claim is made. Vitamins and minerals can be included in a declaration if they are present in a minimum amount, and they are of nutritional importance in Kenya.

Nutrition and health claims are voluntary, but must meet conditions, including that claims a food has an increased nutritive value due to the addition of vitamins, can only be made if the addition is based on nutritional considerations according to Codex General Principles for the Addition of Essential Nutrients to Foods and it conforms with the relevant Kenyan Standard East African Standard (KS EAS). Some claims are prohibited, e.g., a claim that the food is suitable to use in the prevention or treatment of disease.

Supplementary nutrition information: A ***fortification logo (Fortification Mark of Quality*** or 'Kuboresha Afya') is voluntary and may be used following an application to KEBS (although one respondent indicated that it is mandatory for flour and edible oils). Three other Marks of Quality are administered by KEBS: a ***Standardization Mark***, an ***Import Standardization Mark of Quality*** and a ***Diamond Mark of Quality*** (their logos are below).[99] Other SNI are also permitted but must meet conditions if they are used, and a respondent stated that a draft regulation for a voluntary traffic-light FOPNL is under review and is expected to become law, with consumer testing taking place. [KEN002-I]

Recommendations to reform nutrition labelling regulations to enable LSFF

- A ***voluntary standard fortification claim*** for mandatorily fortified foods could be considered to add to existing fortification logos and increase consumer understanding of the benefits of fortified foods such as indicating why the fortified food is beneficial for an individual's health.
- If ***claims regulations*** were updated, stipulations on health claims could be considered to improve regulations (e.g., including additional information on labels where appropriate, such as target group, how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources where appropriate, and the importance of maintaining a healthy diet).
- ***Regulatory governance*** overall appears strong through KEBS' standards development process, its interaction with EAS, its authority and budget, pre- and post-market surveillance, and cooperation with the MoH in administering the Fortification Mark of Quality. Most labelling standards are based on EAC standards which are regularly reviewed by the EAS Committee, although we found no guidelines for monitoring and evaluating at the EAC level in general. However, there appears to be room for ongoing education and awareness-raising around standards for consumers, to increase uptake of fortified foods, and industry, to increase compliance with standards, both of which we understand from respondents are underway. This was highlighted as being particularly necessary for voluntarily fortified foods to increase their demand.

Fortification Mark of Quality (fortification logo)

Standardization Mark

Import Standardization Mark of Qualitye

Diamond Mark of Quality

Draft FOPNL nutrition logo (if all four nutrients are present in a product)[96]

Information sources and limitations

We undertook qualitative surveys and interviews in addition to a desktop regulatory review in Kenya. Based on these, information gaps only exist for guidelines for monitoring and evaluating and the transparency of evaluations. Such information may sit outside of the regulatory documents reviewed.

Table 6 – KENYA – Summary of nutrition labelling regulations
Excludes draft regulations unless specified.

	Nutrient declaration	SNI
Regulatory form and substance		
Regulatory framework	• Nutrient declarations are mandatory for all pre-packaged foods for which nutrition and health claims are made; and all other pre-packaged foods except where national circumstances would not support such declarations. Certain foods can be exempted, e.g., based on nutritional or dietary insignificance or small packaging.[93]	• The KEBS Standardization Mark is mandatory on all products manufactured in Kenya.[91] • The Import Mark of Quality is mandatory on all imported products.[91] • The Fortification Mark of Quality is voluntary.[100] • Voluntary SNI are permitted but mandatory conditions apply if SNI is used. SNI shall only be provided in addition to, and not in place of, the nutrient declaration.[55] • A draft voluntary traffic light FOPNL standard is being considered, under which a product that is carrying a front-of-pack nutrition symbol and exceeds the threshold of any of the total fat, sugar, saturated fats and/or sodium shall not carry any other form of endorsement except statutory marks/logos for safety and quality.[96]
Regulatory objective(s)	• Ensure effective nutrition labelling, that provides consumers with sufficient information on the nutrition content of the food, encourages the use of sound nutrition principles to benefit public health, and does not describe a product or present information about it that is in any way false, misleading, deceptive or insignificant in any manner.[93]	• The draft FOPNL focuses on providing consumers with a simplified version of the same information that is on a nutrition label.[96] • The content of SNI will vary from one target population group to another, according to the national health policy and guidelines, and nutrition labelling should not deliberately imply that a food that carries such labelling has any nutritional advantage over a food that is not so labelled.[95]
Nutrition and health claims		
Regulatory framework	• Voluntary nutrition and health claims are permitted, with mandatory conditions if either type of claim is made.[93,94] • Certain claims are prohibited such as claims that a food will provide an adequate source of all essential nutrients except where standards permit, or competent authorities have accepted the product to be an adequate source of all essential nutrients; and claims about the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease/ disorder.[94] • Health claims are only permitted in certain circumstances, e.g., based on current relevant scientific substantiation. Claims cannot be false or misleading.[94] • Conditional claims, that a food has obtained an increased or special nutritive value via the addition of nutrients, can only be made if the addition is based on nutritional considerations according to Codex General Principles for the Addition of Essential Nutrients to Foods[94]	
Regulatory objective(s)	• Ensure no nutritional claims are made without nutrition labelling[93] and that no food is described in a false, misleading or deceptive manner or is likely to create an erroneous impression regarding its character.[94]	

	Nutrient declaration	Nutrition and health claims	SNI
Operative terms and conditions	• Nutrient declarations must include [93] – energy value in kJ or kcal per 100g/ml; – amounts of protein, carbohydrate, fat, saturated fat, available carbohydrate (dietary carbohydrate excluding dietary fibre) in g per 100g/ml; – sodium in mg; – total sugars in g, written as "Carbohydrate ...g, of which sugar ...g"; – amount of any other nutrient for which a nutrition claim is made – in g/100g or % for carbohydrate, sugar, or starch; calories/100g for energy; mg/100g for sodium;[89] – amount of any other nutrient considered to be relevant for maintaining good nutritional status as required by legislation; – [where the amount and/or type of fatty acids or cholesterol is declared] a specified format is required declaring fatty acids and cholesterol. This information can be per serving, as quantified on the label, per package if the package is a single portion, or per portion provided the package states the number of portions per package.[93] • To be included in a declaration, vitamin or mineral content must be ≥5% of the NRV per 100g/ml and should be expressed in metric units and/or as a % of NRV per 100g/ml or per package if the package is a single portion. Further, only vitamins and minerals for which recommended intakes are established and/or are of nutritional importance in the country concerned can be declared.[93] • Nutrients must be declared in a specific order that is consistent across food products developed by competent authorities.[93]Protein and additional nutrients can also be expressed as a % of the NRV where established.[93] • The declaration should be in a numerical, tabular format, or linear format where there is insufficient space.[93] • The font type, style font size, and contrast should allow the nutrition information to be legible.[93] In general, labelling must be in English in addition to any other language. The English language type size must be equal to or greater than the type size for any other language used; labelling information must be clear, prominently displayed, and readily discernible.[88] KS EAS 38 duplicates much of this, noting that labelling must be in English and/or any other official language of the importing East African Partner State and small units with a surface area <10cm^2 are exempt from some label requirements.[92]	• Where a nutrition or health claim is made for the: – amount and/or type of carbohydrate, the amount of total sugars must be listed; – the dietary fibre content, the amount of dietary fibre must be listed; – the amount and/or type of fatty acids or the amount of cholesterol, amounts of saturated, monounsaturated, and polyunsaturated fatty acids and cholesterol must be listed, and the amount of trans fatty acid may be required.[95] • The only nutrition claims permitted are those for energy, protein, carbohydrate, fat, fibre, sodium, and vitamins and minerals that have a set NRV.[95] • Nutrient content claims must comply with conditions established in the standard (e.g., a claim of "source" of vitamins or minerals must be ≥15% of NRV per 100g[95] and low sodium claims must be≤10mg/serve or 20mg of the reasonable daily intake) [89] • Comparative claims are subject to conditions in the standard (e.g., foods compared must be different versions of the same or similar food).[95] • Where a consumer-ready food product carries a comparative or descriptive nutrient content claim, it must be supported by a nutritional breakdown of the specific attribute being described. For example, "This product is low in saturated fat, containing only three grams of saturated fat per 100 grams of total fat."[95]	• The KEBS Standardization Mark certifies that a product meets requirements under Kenya's Standards.[91] • The Import Mark of Quality certifies that an imported product meets the requirements of the relevant Kenya Standard or approved specification.[91] • The Fortification Mark of Quality is permitted upon application to KEBS, provided it meets all required fortification, labelling and other relevant standards [KEN002-I]] e.g., an applicant must have a valid Standardization Mark or Diamond Mark of Quality (indicating excellence in product manufacturing and quality) for the food vehicle. [100, 101] • Voluntary SNI if used:[93] – Can only be provided in addition to a nutrient declaration. – Should be accompanied by consumer education programmes to increase consumer understanding and use of information. – Must be consistent with national health policy guidelines, and general and claims-related standards, and should be developed in consultation with the relevant authority. – May include food group symbols and other pictorial or colour presentations for target populations with high illiteracy levels and/or little knowledge of nutrition.

Regulatory governance	
Drafting regulatory rules and scheme design	• Under the Food, Drugs and Chemical Substances Act[87] the Minister for Health may make food labelling regulations among other areas covered by the Act, following consultation with the Public Health (Standards) Board which includes representatives from the Ministry of Health, other government agencies, industry and municipal councils. • Under the Standards Act,[91] KEBS develops standards and standardisation marks. The National Standards Council (KEBS' Board of Management) can formulate policy and guide KEBS and endorse or amend standards via publication in the Gazette. The relevant Minister sets the date from which all products must comply with a standard. – To develop a standard, KEBS sets up multisectoral Technical Committees, including one for labelling [KEN001-I], which include representatives from the Ministry of Health who are subject matter experts and conduct research to identify policy gaps, the Ministry of Agriculture, research institutes, the food industry, and civil society [KEN001-I/S]. [92-96] – Standardisation is a six-stage process that takes between six months and 18 months [KEN002-1] and follows the International Organization for Standardization's good standardisation principles which cover Transparency, Impartiality, Consensus, and Effectiveness). The standardisation process involves: 1. Proposal; 2. Drafting, where a technical committee examines new evidence, national data (e.g., Demographic Health Surveys), market events and outputs, such as those from the European Food Safety Agency, to determine whether to adopt an East African Standard [KEN001-S, KEN001-I, KEN002-1] or to amend or develop a Kenyan standard and agree a draft; 3. Public review; 4. Balloting, where the WTO is notified within 60 days and the standard is circulated for public consultation via the KEBS website. The Technical Committee reviews and responds to all comments [KEN001-I] before voting on the standard, which can only be voted down on scientific grounds. [KEN002-1]; 5. Approval; and 6. Publication after Council approval. • Under the EAC Standardisation, Quality Assurance, Metrology and Testing Act,[16] the EAS Committee (with representatives from Partner States' standards bodies, the private sector, and consumer organisations [84]) undertakes, monitors and reviews standardisation at national and EAC levels, and must establish procedures to develop and approve harmonised EAS that borrow heavily from Codex guidelines [KEN001-S, KEN001-I]. Within six months of an EAS declaration, Partner States must adopt, without deviation, the EAS as a national standard and withdraw any existing national standard with a similar scope. Partner States lead EAS drafting if requested. [KEN001-I] • Under the Treaty Establishing the COMESA,[56] Member States are required to adopt a harmonised system and create national legal frameworks for the standardised pre-packing and labelling of goods traded in the common market, and cannot enact regulations that discriminate against similar products of other Member States. Member States must also: establish national standards bodies; apply uniform rules and procedures to develop national standards; adopt African Regional Standards when available, or suitable international standards; and promote and enforce standards. More broadly, COMESA is governed by the Authority comprising Member States' Heads of State or Government, whose decisions are binding on all Member States. Responsibility for monitoring, reviewing and developing regulations sits with the Council of Ministers, which can make binding regulations and recommendations to the Authority. Technical committees, composed of Member State representatives, are responsible for implementing regulations (including monitoring and review) and conducting research and can consult with external stakeholders, including industry.

Administration	• Under the Food, Drugs and Chemical Substances (Food Hygiene) Regulations,[90] a licence is required to sell, prepare, package, store or display food that is for sale and is valid until 31 December from the date of issue. A municipal council's health authority grants the licence upon fee payment and if it is satisfied the food complies with regulations. • Under the Standards Act[91] KEBS is responsible for implementing standards and standardisation marks (including the KEBS Mark of Quality[13]), promotion and education of standardisation, and the provision of testing facilities. All food manufacturers must apply to KEBS to receive a permit to use the standardisation mark on a food product label before any food is placed on the market. KEBS grants the permit if the product complies with all relevant standards and specifications, including for labelling (e.g., test quantities to ensure it meets the RDA (13)) [KEN002-I, KEN001-I]. The licence must be renewed and audited every two years. [KEN001-I] KEBS may cancel or suspend this permit if the manufacturer fails to comply with its conditions. Manufacturers must provide samples or information about the food to a municipal council when requested in writing. KEBS' funding is specified and includes funds received under the Act or from Parliament. – KEBS also administers the Fortification Mark of Quality under an MoU with the Ministry of Health which remains involved in application review. It is valid for two years, so KEBS encourages concurrent application for both marks. [KEN002-I] On application for the Fortification Mark of Quality, KEBS samples the product, tests fortification parameters at accredited laboratories and grants the mark if the product is fully compliant with all applicable standards, including labelling and process and quality controls. KEBS quality assurance officers also carry out an industrial inspection and discuss and agree on a scheme for supervision and control. If non-conformities are identified on inspection, manufacturers must undertake corrective action and inform KEBS.[100] • Under Standard 803: 2014 Nutrition labelling,[93] SNI should be accompanied by consumer education in addition to KEBS' promotion and education role specified under the Standards Act above. From respondents, we heard that: – While the Ministry of Health conducted an effective consumer awareness campaign on fortification when mandatory fortification was introduced, it has not been repeated, and "consumers do not generally recognise the [fortification] logo or associate it with improved nutrient content".[83] Further, for mandatorily fortified foods, consumer awareness of fortification labelling is seen as unnecessary as there is no need to separately identify fortified foods. [KEN002-I, KEN001-I] For voluntarily fortified foods, the nutrient declaration is important as it provides evidence of fortification. [KEN001-I] – In general, nutrition labelling is not well understood by consumers and industry, and industry does not always comply with regulations. For instance, some companies duplicate what others do, by using the same non-compliant label printers, or millers without realising they don't comply. KEBS works with the Ministry of Education to increase the awareness of nutrition labelling among consumers and industry and expects that understanding will increase soon via nutrition curriculum at schools. This education needs to be maintained particularly for voluntary fortification, so that consumers associate it with healthier or more nutritious food, look for the fortification logo, and increase demand. Further, KEBS trains industry on labelling requirements (leading to significant improvements in fortified and general food labelling) and allows industry to exhaust sales of non-compliant packages when they admit to errors especially as it is expensive to destroy food. [KEN002-I] • The EAC Standardisation, Quality Assurance, Metrology and Testing Act,[16] sets out the responsibility for arranging the public review of draft EAS through National Standards bodies (with comments incorporated before standards are finalised),[93] responding to EAS enquiries, identifying training needs and areas for capacity building, preparing budgets and publicising EAS. Partner States are also required to liaise with regional and international standards organisations (including the African Regional Standards Organization), promote and facilitate the use of standards, and can establish or designate test laboratories to provide scientific or technical services (such as a laboratory and the Partner State is then obliged to ensure it has adequate and competent staff). • Under the Treaty establishing COMESA,[56] documentation and related systems, quality assurance, and specifications for inspection and testing of goods must be standardised. Under its Regional Agricultural investment plan 2018-2022,[62] COMESA also conducts capacity building programmes on customs and trade harmonisation.
Monitoring	• Under the Food, Drugs and Chemical Substances Act,[87] authorised officers can enter and inspect premises, products and documentation, and sample, seize, or detain food products to assess their compliance with the Act. Municipal councils are also required to exercise powers to safeguard food including procuring samples for analysis. • Under the Standards Act[91] the relevant Minister can appoint inspectors who can enter premises, inspect, sample, require documentation, and seize and detain products for testing in relation to standardised products. More specifically, we heard from respondents that KEBS is well-budgeted with sufficient resources to enable their work (although one respondent indicated that resources for evaluation at local/village levels could be improved [KEN001-I]), including for monitoring and enforcement as follows [KEN002-I]: – Quality Assurance Unit – work with industry to ensure continuous improvement, inspect facilities, and issue corrective actions. – Market Surveillance Unit – sample foods from all retailers and open markets to assess compliance with standards, conduct analysis in government laboratories, confirm label accuracy [KEN001-I], provide market intelligence feedback (such as difficulties with compliance), and enforce the industry use of the fortification logo post-market (with Ministry of Health public health officers enforcing the fortification logo at the market level). Market surveillance and enforcement are also done in cooperation with the Competition Authority. [KEN001-I] – Quality Inspectors – operate at points of entry such as ports and airports to ensure imported products comply with standards. • Under its Regional Agricultural investment plan 2018-2022, COMESA Member States and Secretariat monitor its strategic plan, supported by monitoring and evaluation tools developed by COMESA which include promoting strengthening of regional coordination on nutrition promotion.[62] Data gaps: limited information identified on guidelines.
Evaluation	• Under the Standards Act[91] the National Standards Council must submit an annual report on its activities to the relevant Minister each year which must be tabled in parliament. • The KS EAS must be "reviewed regularly" and suggestions to improve published standards can be addressed to KEBS' Managing Director.[92]. We also heard from respondents that Kenyan Standards must be reviewed by KEBS every four years, taking into account new evidence and information. [KEN001-S, KEN001-S] • As above, under the EAC Standardisation, Quality Assurance, Metrology and Testing Act,[16], the EAS Committee reviews standardisation at national and EAC levels. Data gaps: limited information identified on transparency.
Enforcement	• Under the Food, Drugs and Chemical Substances Act,[87] offences include selling, advertising or packaging any food in contravention of any regulations under the Act (e.g., selling a food without a licence, or one that does not comply with labelling standards, or has misleading or deceptive labelling). Unless specific penalties are provided, on conviction, offences are subject to fines and/or imprisonment through to licence cancellation, and items related to the offence can be ordered to be forfeited. • Under the Standards Act,[91] KEBS enforces standards and can cancel or suspend a permit for use of the standardisation mark if a product is non-compliant and in some circumstances, order the destruction of goods that do not meet standards after testing. Offences under the Act, such as using a standardisation mark when a product doesn't meet relevant standards may result in a fine and/or imprisonment on conviction, and KEBS can prohibit the further sale of offending goods and confiscate them. Respondents also outlined that: – Enforcement results and challenges are shared at KEBS' and the Ministry of Health's quarterly forums with researchers to problem solve and improve compliance. [KEN002-I] – KEBS investigates and consults with manufacturers about any consumer complaint it receives, with decisions and corrective action applied on a case-by-case basis. [KEN002-I] While complaints and outcomes are not generally publicly available, a complainant may be briefed on the outcome [KEN002-I] and a press release is issued when a product is withdrawn due to food safety risks. [KEN001-I] Complaints about KEBS' standards are registered with the ombudsman (e.g., about those nutritive sweeteners approved under a Kenyan standard but not approved in the EU) and KEBS seeks scientific advice from authorities such as the WHO) on these types of complaints. [KEN002-I] – Non-compliant labelling and fortification is usually the result of misinterpretation for which KEBS takes corrective, rather than punitive action.[KEN002-I]

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Nigeria

Food fortification

The ***Food Grade (Table or Cooking) Salt Regulations 2021***[102] mandate that all food-grade salt as an ingredient of food for direct use by consumers, in manufacture or as a carrier of food additives must be fortified with iodine at a level specified by the National Agency for Food and Drug Administration and Control (NAFDAC).

The ***Food Fortification Regulations 2021***[103] mandate that sugar, wheat and maize flour, vegetable oil, and margarine and butter are fortified with vitamin A (to varying levels per kg); wheat flour, composite flour, maize flour, wheat semolina, and whole maize meal must be fortified with: vitamins A, B1, B2, B3, B6, B9, B12, iron and zinc. The Regulations also specify other foods to which vitamins, minerals, nutrients or other amino acids "may" be added, however, it lists both mandatory and voluntary fortification and applicable fortificants (e.g., enriched alimentary pasta must be fortified with thiamine, riboflavin, niacin, folic acid and iron, and can be voluntarily fortified with pantothenic acid, vitamin B6 and magnesium).

Further, the ***2016 National Plan of Action on Food and Nutrition***[104] contains fortification actions including to enforce food fortification standards in regulated food products and promote research on local food fortification. The private sector is also expected to collaborate with the government in supporting the food and nutrition programme including via fortification of certain identified foods with mandatory micronutrients. In the ***Agricultural Sector Food Security and Nutrition Strategy 2016 – 2025***[105] the Government of Nigeria has identified biofortification as a priority initiative to improve micronutrient deficiencies, mainstreaming nutrition into agriculture and specifying priority areas. The strategy highlights expanding biofortified staples to iron in beans, zinc rice, and vitamin A in plantain and bananas, among other staples, extending existing legislation on fortification to cover other important food staples, supporting multisectoral efforts to strengthen the food fortification regulatory environment and compliance, and comprehensive nutrition education on the benefits of consuming fortified foods as some priority areas.

Responsibilities and regulatory governance for nutrition labelling

NAFDAC, Advisory Council which comprises several government and industry representatives, is responsible for regulating and controlling food processes and labelling and advising the federal government on national policies on control and quality specifications of food. NAFDAC is also the Secretariat of Nigeria's National Food Safety Management Committee (NFSMC) which addresses challenges within Nigeria's Food Safety System such as the overlap of functions, poor co-ordination and communication among Nigeria's food regulators, and inadequate private sector and consumer association participation.[106]

Pre- and post-market surveillance occurs via the requirement to register all fortified foods, all processed foods (for sale, import, distribution, manufacture) and any foods to be advertised (which includes labelling) in Nigeria with NAFDAC, and registration must be renewed. NAFDAC has created an online portal for the registration of foods and other items (https://registration.nafdac.gov.ng/). NAFDAC is also responsible for enforcing food regulations. NAFDAC officers can enter premises and take samples and documentation, and there are tiered penalties for those who contravene the main Acts and their regulations, including in relation to fortified foods.

As a Member State of the Economic Community of West African States (ECOWAS), Nigeria is required to harmonise national policies with those of other ECOWAS Member States and is subject to a range of governance arrangements. However, it is unclear to what extent harmonisation has taken place or has been driven by ECOWAS, as only high-level actions, largely relating to fortification, were identified in ECOWAS regulatory and strategy documents as outlined further below.

Structure of nutrition labelling laws

Nigeria's nutrition labelling regulatory regime is structured as follows:

- *Food and Drugs Act of 2004*[107] prohibits false or misleading labelling and labelling that indicates a food has medicinal properties. The Act also sets out enforcement provisions and the Minister for Health's powers in relation to food and other substances covered by the Act and requires certification for imported foods.
- *National Agency for Food and Drug Administration and Control Act 2004* (NAFDAC Act)[108] establishes NAFDAC, its functions and powers, including to regulate and administer food labelling.
  - *Food Products Advertisement Regulations 2021*[109] require all food products that are manufactured, imported, distributed or sold in Nigeria to be registered with NAFDAC before advertisement (which includes labelling) and prohibits misleading or deceptive advertisements. The regulations also limit the nutrition and health claims that can be made in food advertisements.
  - *Processed Food Registration Regulations 2005*[110] require processed food products and labelling to be registered with NAFDAC and set out registration requirements.

- Food, Drug and Related Products (Registration) Act 2004[111] prohibits the manufacture, import, export, advertisement, sale, or distribution of food (and other products) in Nigeria unless they have been registered with NAFDAC. The Act also establishes the Food and Drug Registration Committee which advises NAFDAC on registration applications.
- *Regulations made under both the Food, Drugs and Related Products (Registration) Act and the NAFDAC Act:*
  - *Pre-Packaged Food (Labelling) Regulations, 2022*[112] set out the labelling requirements for all pre-packaged foods manufactured, imported, exported, sold or distributed in Nigeria, including general requirements (e.g., name of food and ingredients). The Regulations also mandate nutrient declarations and prohibit false and misleading labelling, non-compliant labelling, and medicinal claims. These regulations revoke the previous food labelling regulations and bottled water labelling regulations and apply to products fortified under the two fortification regulations outlined directly below.
  - *Food Fortification Regulations 2021*[103] alongside fortification requirements, set out requirements for the inclusion of vitamins and minerals in nutrient declarations and for nutrition and health claims and SNI for foods fortified with vitamin A. The regulations also require all fortified foods that are manufactured, imported, exported, distributed, advertised, sold or used in Nigeria to be registered with NAFDAC.
  - *Food Grade (Table or Cooking) Salt Regulations 2021*[102] along with iodisation requirements, set out labelling requirements for food grade salt, including an SNI and specific claims for iodised salt. The regulations also require all iodised salt manufactured, imported, exported, distributed, advertised, sold or used in Nigeria to be registered with NAFDAC.

As a Member State of the ***Economic Community of West African States (ECOWAS),*** Nigeria is bound by the Treaty and Decision below, with other strategy documents indicating areas of action for ECOWAS and its Member States as indicated:

- The ***1975 Treaty of the Economic Community of West African States***[113] establishes a common market and requires the harmonisation of national policies and standards and the promotion of regional integration.
- *ECOWAS 2025 Strategic Policy Framework – Summary*[114] will be translated into five-year programmes and states that agricultural policies should consider improving food quality and nutrition via food fortification. The Strategy also seeks to promote inclusive food value chains and integrate the regional market, including packaging.
- ***Regional Agriculture Investment Plan and Food Security and Nutrition 2016-20***[115] include actions to support Member States to promote nutrition and agricultural programmes, including food fortification and bio-fortification, via a range of mechanisms such as regulation and competitive funding. It also covers an action to streamline regional food and nutrition security governance mechanisms.
- In ***Decision A/Dec. 11/01/05 West African Agricultural Policy of the Economic Community of West African States (ECOWAP), 2005***[116] Member States have committed to harmonising national agricultural policies with regional policy, including food security. Through harmonisation, this may broadly include fortification, although fortification is not specifically mentioned.

ECOWAS also has an ECOWAS Standards Harmonisation Model (ECOSHAM) that defines a system to harmonise standards within ECOWAS. This system does not mandate harmonisation, rather after standards are approved, the standard text is "available to each [National Standards Body] for adoption and implementation within its system of national standards,"[117] although it is understood that Member States are expected to adopt and implement them domestically. ECOSHAM has a standard for the general labelling of packaged foods (ECOSTAN 50: 2015 – Labeling of prepackaged foodstuffs – that we were unable to locate) and is based on an ECOSTAND 47:2015 Standards for Enriched Soft Wheat Flour.[118] It applies to fortified wheat flour and thus may apply to other fortified foods in ECOWAS. Based on our review of Nigeria's regulatory environment, it appears Nigeria has not implemented ECOWAS standards for fortification and nutrition labelling even though such standards may align with Nigeria's existing regulatory environment.

Policy context and objectives

The ***2016 Nigeria National Plan of Action on Food and Nutrition***[104] provides a framework for coordinated action to address malnutrition in all its forms in Nigeria. It includes action on both LSFF and nutrition labelling. Fortifying staple foods during production and processing up to consumption level is listed within actions to 'improve food preparation and quality' and establishing standards for nutrition labelling and advertisement of all foods is included under actions to 'protect the consumer through improved food quality and safety'. The Plan guides the identification, design and implementation of intervention activities across different relevant sectors and provides a framework for monitoring and evaluation. In addition, the ***National Multi-Sectoral Action Plan for the Prevention and Control of NCDs (2019 – 2025)***[119] includes adopting standards for FOPNL as one of the actions identified to reduce the salt content of processed foods and references the use of labelling policies to reduce trans-fats in the food supply to promote healthy diets.

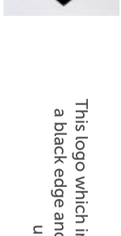
Beyond the above action plans, Nigeria's development of labelling regulations seeks to ensure a degree of coherence, for example, via prohibiting claims that describe food as 'healthy,' encourage or condone excessive food consumption, or disparage good dietary practices. However, we also identified potential challenges to policy coherence between LSFF and policies to address overnutrition. For example, mandatorily fortified foods include products such as sugar and margarine, and several foods that can be voluntarily fortified are likely to be foods high in sugars, fats and/or sodium (e.g., breakfast cereals, fruit nectars and fruit drinks, instant breakfasts, and condensed milk).

Nutrition labels

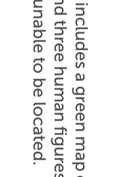
Nutrient declarations are mandatory on all pre-packaged foods unless NAFDAC makes exceptions for certain foods (e.g., single-ingredient foods, spices, and herbs). Mandatorily fortified foods must include the amount of vitamins and/or minerals added to the food in the nutrient declaration. Vitamins and minerals included in the nutrient declaration (for mandatorily fortified products or voluntarily for other products) must contain a minimum of 5% of the NRV for that vitamin or mineral per serving, with this percentage stated alongside the quantity contained.

Nutrition and health claims are largely voluntary but must meet certain conditions, including that they must be substantiated before approval (although it is unclear how based on the regulations). Nutrition claims on fortified foods are only allowed for vitamins and minerals (e.g., 'a source of') if they meet a percentage of an NRV. Some claims are prohibited, such as those that represent food as a treatment for or the prevention of disease. Specific claims are outlined for iodised salt, and some fortification claims for calcium, phosphorous and/or iron are mandatory.

Supplementary nutrition information: A fortification logo is required on foods mandatorily fortified with vitamin A (sugar, wheat and maize flour, vegetable oil and margarine and butter) and an ***iodised salt logo*** is required on mandatorily iodised salt. A ***regional 'Enrichi' logo*** is also available for use on wheat flour and cooking oil fortified with vitamin A as part of the 'Fortify West Africa' programme that ran throughout ECOWAS countries in conjunction with development partners between 2011 and 2017. Further, the 2019 Nigerian National Multi-Sectoral Action Plan for the Prevention and Control of NCDs lists the adoption of standards for ***FOPNL*** as a priority action to promote healthy diets.



Vitamin A fortification logo[120]



Iodised salt logo

Regional ECOWAS 'Enrichi' logo[121]

Recommendations to reform nutrition labelling regulations to enable LSFF

- Increased attention should be paid to the interaction of fortification and food labelling to ***ensure that policies and regulations coherently address over- and under-nutrition***. Specifically, while relevant regulations were only adopted in 2021, the government would ideally review foods that can be voluntarily fortified and/or, at the least limit claims that can be made on unhealthy voluntarily fortified foods to avoid health 'halo' effects on these products.
- At this time, given existing fortification logos and claims and the government's consideration of FOPNL, we ***do not recommend that additional fortification logos or claims be considered unless*** care is taken to align and coordinate these policies so that they enhance consumer understanding and mitigate potential confusion (e.g., this may be improved through a consolidated logo such as in South Africa).
  - If ***claims regulations*** were updated, stipulations on health claims could be considered to improve regulations such as including additional information on labels where appropriate, including a target group, how to use the food to obtain the claimed benefit and other lifestyle factors, other dietary sources where appropriate, and the importance of maintaining a healthy diet).
- ***Regulatory governance*** under NAFDAC covers most key elements (authority, funding, requirements to publish data from performance, promotion and pre- and post-market surveillance), but there was little public data on the processes of regulatory design and drafting, evaluation, and complaints handling to promote transparency. Further, although NAFDAC is required to educate consumers and industry (by promoting the standards) and monitor and enforce labelling, it remains important that these aspects of regulatory governance are adequately and sustainably prioritised and funded.

Information sources and limitations

We only undertook a desktop regulatory review in Nigeria. As part of this, we identified little detail on several aspects of regulatory governance, including processes for regulatory design and drafting, consumer education, guidelines for evaluation and enforcement transparency, and complaints handling. Such information may sit outside of the regulatory documents reviewed.

Table 7 – NIGERIA – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient declarations are mandatory for all pre-packaged foods (including fortified foods[103] and iodised salt)[102] although NAFDAC can in appropriate circumstances prescribe exceptions for some foods (e.g., single ingredient foods, spices and herbs, small units with a surface area <10cm^2, nutritionally insignificant foods and others as determined by NAFDAC).[112]	• Voluntary nutrition and health claims are permitted, and some claims are prohibited (e.g., medicinal claims) or have conditions.[103, 109, 112] • Specific mandatory claims for calcium, phosphorus and/or iron.[103] • Iodised salt claims (or names).	• Mandatory fortification logo on foods mandatorily fortified with Vitamin A and Iodised salt.[102, 103]
Regulatory objective(s)	• None identified.	• None identified.	• None identified.
Operative terms and conditions	• The nutrient declaration must be given per 100g/ml or per serving of a product and contain:[112] – energy value in kJ/kcal; – amount of fat, specifying saturated fat and trans-fat, carbohydrate specifying the quantity of sugar, and protein; – salt; and – the amount of any other nutrient for which a nutrition or health claim is made. • For products containing fats and oils, including emulsions alone or as part of processed foods, nutrient declarations must include:[112] – amount of type of fatty acids in grams or amount of cholesterol; amount of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids in grams and cholesterol in mg. • Vitamins and minerals must be expressed per 100g/ml and as a % of the NRV and can only be included in the declaration if they are present in an amount ≥5% of the NRV per 100g/ml as quantified on the label.[112] – For fortified foods, vitamins and minerals can only be declared where they meet the requirements of the Food Fortification Regulations, the vitamin or mineral is at least 5% of the NRV per serve, and is expressed as a % of the NRV per 100g/ml or per package if it only contains a single serve, plus as a % daily value on the product.[103] • Where labelling of food places special emphasis on the:[112] – presence of one or more ingredients, the presence of the ingredient by mass must be declared in the final product; – the low content of one or more ingredients, the % of the ingredient by mass in the final product. • Any statement on labels must be clear, prominent, and legible, and labelling must be in English and may include any other language.[112]	Food product claims: • Must be adequately substantiated before approval (e.g., 'natural', 'product of choice' claims). Labels must accurately interpret research findings, with any reference in a label (advertisement) to be verified by NAFDAC.[109] • Related to 'source', 'dietary source,' etc regarding energy and/or protein must meet specifications. [109] • Can only use the word 'nutritious' or similar if they meet conditions, including that they contain a range of nutrients including carbohydrates, fat, protein, vitamins and minerals (i.e., at least four vitamins and two minerals (excluding sodium) of an amount that meet criteria for claim as source). [109] Any nutrition claim must be justified expressly in the nutritional information (nutrient declaration) on the food label.[112] For fortified foods/food products:[103] • Nutrition content claims should comply with the conditions of the Food Fortification Regulations (e.g., Source of [Vitamin/Mineral] – at least 5% of NRV per 100g / 100ml / serving for claims of 'a source of' and increasing levels to claim 'a good source of' and 'excellent source of'). • Where fortified in line with the Food Fortification Regulations, advertising or labelling for a food must state: a) in the case of calcium or phosphorous, that it is a factor in the normal development and maintenance of bones and teeth, especially in infants and children; and b) in the case of calcium, phosphorous or iron, that it is a factor in the maintenance of good health. For iodised salt:[102] • The name of the label must be salt and include 'food grade' or 'table' or 'cooking'. Particulars must be included if cyanide salt is added. • When salt is used as a carrier for one or more nutrients and labelled as such for public health reasons, the name of the product shall be declared properly on the label as 'salt fluoridated', 'salt iodated', 'salt iodised', 'salt fortified with iron', 'salt fortified with vitamins', or as prescribed by the Agency, included in the ingredient list. • A salt cannot be represented as 'reduced in sodium' unless it contains ≤25% less sodium than regular table salt, labelled with the difference in the amount of sodium by %, fraction, or mg. Claims cannot: • Represent food as medicinal, such as having preventive, alleviative or curative effects of a disease, disorder or physiological condition[112, 107] or having 'guaranteed effectiveness'.[109] Similarly, fortified foods cannot specifically be sold or advertised among other things as a treatment, preventative or curative of diseases, disorders or abnormal physical states as specified in the regulations (e.g., Goitre, mental conditions).[103] • Describe food as 'healthy' or represent it in a way that implies the food will impact health;[109] • Encourage or condone excessive consumption of any food or disparage good dietary practice;[109] • Refer to medical or allied health professions unless the reference is scientifically proven .[109] Comparative claims must not mislead the public directly or indirectly and where a comparison is made it must be supported by scientific evidence, among other things.[109]	• Vitamin A fortification logo: A picture of an eye with an "A" at the centre of the eye. This logo is mandatory on sugar, wheat and maize flour, vegetable oil, and margarine and butter, which are subject to mandatory fortification.[103] • Iodised salt logo: Mandatory fortification of salt with iodine. The label of iodised salt must include the iodised salt logo of a green map of Nigeria with a black edge and three human figures in white.[102] • A priority of the National Multi-Sectoral Action Plan for the Prevention and Control of Non-Communicable Diseases (2019) is to adopt standards for FOPNL.[119]

Regulatory governance	
Drafting regulatory rules and scheme design	• Under the Food and Drugs Act, the Minister for Health may make regulations to carry out the purposes of this Act or any matter connected with it. The Minister can also establish a Food and Drug Advisory Council to assist and advise the Minister on preparing and reviewing regulations related to the Act.[107] • Under the NAFDAC Act, NAFDAC is responsible for the regulation and control of food processes and labelling. Its Governing Council advises the federal government on national policies for the control and quality of food and with the approval of the Minister for Health it can make relevant regulations.[108] • Under the Treaty of the Economic Community of West African States, the ECOWAS Authority (Heads of State and Government members) determines the general policy and guidelines for the community, oversees the functioning and implementation of community objectives and appoints delegates to the Council. The Council of Ministers is responsible for the functioning and development of the Community, can issue directives and make recommendations to the Authority, prepares and adopts rules of procedures, and approves work programmes and budgets. Technical Commissions are responsible for preparing Community programmes and projects, ensuring the harmonisation of projects and programmes, and other functions as required. Member states are required to harmonise national policies.[113]
Administration	• Under the NAFDAC Act[108] NAFDAC is responsible for regulation and control of food processes and labelling, including compiling, monitoring, and promoting standards and guidelines, advising the government, the private sector and others on regulatory and related matters, and publishing relevant data from the performance of its functions. NAFDAC's funding is outlined in the Act and includes revenue from its fees. • Under the following, food products and related elements must be registered with NAFDAC via an application, which NAFDAC must approve and is responsible for enforcing: – Food, Drug and Related Products (Registration) Act:[111] all processed food. If approved, a registration certificate is issued that is valid for five years and can be renewed. NAFDAC can publish registrations in the Gazette. The Act also establishes the Food and Drug Registration Committee which evaluates applications to register foods and food products, including their labelling, and advises NAFDAC on applications, including their withdrawal, suspension or cancellation. – Processed Food Registration Regulations:[110] all processed food products. Applications must include product samples and labelling, the original certificate of analysis, and evidence supporting any special labelling claims. NAFDAC can inspect an establishment as part of the registration process. If approved, a registration certificate is issued and must be produced by a manufacturer within 48 hours of NAFDAC's request. – Food Products Advertisement Regulations:[109] all advertisements (including labelling) for food products. If approved, the registration is valid for one year. – Food Fortification Regulations 2021:[103] all fortified foods. – Food Grade (Table or Cooking) Salt Regulations 2019:[102] all salt for human consumption. • The ECOWAS 2025 Strategic Policy Framework summary specifies that the implementation of development programmes is affected through the Regional Agency for Agriculture and Food (RAAF) which provides the administrative, technical and financial management of programmes and is responsible for their monitoring and evaluation.[114]
Monitoring	• See Administration re NAFDAC powers and functions, including monitoring. • The National Plan of Action on Food and Nutrition in Nigeria 2016[104] establishes a plan for monitoring and evaluation of its actions, coordinated by the Ministry of Budget and National Planning. • The ECOWAS 2025 Strategic Policy Framework specifies that the ECOWAS Commission monitors the implementation, results, and impact of all ECOWAS policies following an established framework, aiming to track information at national and regional levels, and ensure cohesion between national investment monitoring and control systems, and promote an open dialogue between stakeholders. Due to poor baseline and incomplete information systems with member states, it was difficult to evaluate the effectiveness of ECOWAS. National Steering Committees and regional actors are required to report on performance.[114]
Evaluation	• Under the NAFDAC Act,[108] NAFDAC must submit to the Minister for Health an annual report on its activities for the previous year and its audited accounts. • See above under the Food and Drugs Act,[107] the Minister can establish a Food and Drug Advisory Council to assist and advise on the preparation and review of regulations;[107] National Plan of Action on Food and Nutrition in Nigeria 2016.[104] • See Monitoring regarding evaluation under ECOWAS.
Enforcement	• Under the Food and Drugs Act[107] various misleading practices are prohibited (such as the contravention of standards) and: – NAFDAC's inspecting officers may enter premises used to manufacture, prepare, preserve, package, store, or sell food, and investigate premises, take samples and/or specimens, examine and copy documentation or records relevant to enforcement, and seize and detain products that do not comply with the regulations. – Any person who contravenes the Act, its regulations or any notice issued under them, is guilty of an offence and is liable on conviction to a fine and/or imprisonment. • Similarly, under the NAFDAC Act:[108] – NAFDAC officers can enter premises, inspect products and take samples. – Contravention of any provisions under the Act or its regulations on conviction results in penalties specified under the regulations, or if none are specified, under this Act. • Under the following Acts and/or regulations, contraventions on conviction result in financial penalties and/or imprisonment, and forfeiture of assets related to the offence: – Food, Drug and Related Products (Registration) Act[111] NAFDAC also has the power to suspend or cancel the registration of a food if, for example, the product does not meet the standards upon which it was registered. – Processed Food Registration Regulations[110] – Food Products Advertisement Regulations[109] For example, advertising a food without NAFDAC registration. – Food Grade (Table or Cooking) Salt Regulations[102] For example, manufacture, import, export, distribute, sell, or advertise any unregistered salt for human consumption. – Food Fortification Regulations[103] For example, selling or advertising any food labelled as fortified that is unregistered and/or not fortified in line with the regulations. – Pre-Packaged Food (Labelling) Regulations[112] For example, non-compliant food labelling and making a non-NAFDAC-authorised advertisement claim or professional association endorsement on a food product label contravenes the regulations.

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Pakistan

Food fortification

Pakistan's Standards and Quality Control Authority (PSQCA) has prescribed the mandatory fortification of edible oil with vitamin A via its Pakistan Standard Specification for Banaspati.[122] The PSQCA also has standards for Iodized Food Grade Salt (PS:1669-2008), Enriched Wheat Flour and Self-r[a]ising Wheat Flour (PS:4560-2000).[123]

The ***Punjab Pure Food Rules (2011)***[124] include levels of vitamins and minerals that must be in foods to state that a food is enriched, fortified, vitaminised, supplemented or strengthened. It also specifies which vitamins and minerals can be added to foods via a set of standards, such as fortified 'maida' and 'atta' (specific to wheat products) with one or more of iron, vitamin B1, B2, B3 and D3, and where nutrients are added to foods, the product must comply with the Codex Guidelines for Vitamins and Mineral Food Supplements (CAC/GL 55-2005). The subsequent ***Punjab Pure Food Regulations (2018)***[125] clarify the required fortification in the province (that was confirmed by a local consultant to have been promulgated).

Similar regulations were not located in other provinces, but Khyber Pakhtunkhwa's Food Safety Authority Act does specify that the authority can regulate food fortification. Recent fortification regulations across Sindh (2021), Balochistan (2021) and Khyber Pakhtunkhwa (2022) mandate the fortification of staple foods. News reporting in June 2023 states the provinces are yet to implement the respective regulations.[126] The reporting also flags that federal legislation has stalled and is yet to be tabled in the Assembly. No similar regulations were identified in Islamabad Capital Territory.[126]

A table detailing what is mandatorily vs voluntarily fortified across provinces is outlined below.

Fortification	Vegetable fats and oils	Wheat flour/maida and atta	Edible salt	Other
Pakistan (References as above)	Mandatory – vitamin Aw	Standard for Enriched Wheat Flour and Self-r[a]ising Wheat Flour	Standard for iodised food-grade salt	-
Punjab Punjab Pure Food Rules (2011)[124] Punjab Pure Food Regulations (2018)[125]	Mandatory (including margarines – vitamin A and D	Mandatory (including bread, rolls and buns) – iron, zinc, vitamin B12 and folic acid	Voluntary – iodine	Voluntary fortification of a range of products, e.g., vitamin C in vegetable and fruit juices
Sindh The Sindh Food Fortification Act, 2021[127]	Mandatory (specifically Vanaspati Ghee or Edible Oil) – vitamins A and D3	Mandatory (and Suji, Fine Atta) – iron, zinc, vitamin B12 and folic acid	-	-
Khyber Pakhtunkhwa The Khyber Pakhtunkhwa Food Fortification Act, 2022[128]	Mandatory (specifically Vanaspati Ghee or Edible Oil) – vitamins A and D3	Mandatory (and Suji, Fine Atta) – iron, zinc, vitamin B12 and folic acid	-	-
Balochistan The Balochistan Food Fortification Act, 2021[129]	Mandatory (specifically Vanaspati Ghee or Edible Oil) – vitamins A and D3	Mandatory (and Suji, Fine Atta) – iron, zinc, vitamin B12 and folic acid	Mandatory – iodine	-
Islamabad Capital Territory	-	-	-	-

Pakistan's Multisectoral Nutrition Strategy 2018-2025 also includes an intervention to improve food safety and quality, including through the public and private sectors working to improve foods' nutritional contents via improved regulation, monitoring and enforcement, to enable the fortification of salt, oil, flour and other foods.[130] The Strategy details key milestones in nutrition policy in Pakistan, including the 2011 introduction of wheat flour fortification with iron and folic acid at the federal level before devolution, and post-devolution, the provinces' development of policy guidance notes on nutrition and the adoption of multi/inter-sectoral nutrition strategies, alongside a 2017 launch of a Food Fortification Strategy that we were unable to locate.

Responsibilities and regulatory governance for nutrition labelling

The Pakistan federal government regulates and enforces food safety standards for food imports, while the provinces regulate food safety standards for domestic food products, even though provinces often adopt federal regulations.

Pakistan's labelling regulatory regime is largely governed at provincial levels and focuses on preventing false and misleading labelling and administrating ***pre- and post-market surveillance systems via provincial food business licensing systems.*** More specifically, across all provinces of Pakistan (Punjab, Islamabad Capital Territory, Khyber Pakhtunkhwa, Balochistan, Islamabad and Sindh), provincial food authorities formulate standards, procedures, processes and guidelines on food safety. All these food authorities operate food safety enforcement regimes, such as serving improvement notices and cancelling or suspending food operator licences, through to fines and imprisonment. New food fortification Acts in three provinces require ***food level (not food business level) pre- and post-market surveillance.***

Structure of nutrition labelling laws

Pakistan's nutrition labelling regulatory regime is structured as follows:

- The following acts establish provincial food authorities, their powers and functions, set out offences for false and misleading food labelling, and require food businesses to be licensed with the relevant authority:
  - *Punjab Food Authority Act 2011*[131]
- *Punjab Food Authority (Product Registration and Display of PFA logo) Regulations, 2017*[132] (out of scope for more in-depth review as not supplementary nutrition information) sets out the requirement for every manufacturer, trader, importer, exporter or wholesaler who intends to store, import, transport, export, manufacture, or sell food in Punjab to obtain a certificate of product registration to demonstrate compliance with food safety, quality, and labelling requirements. Once granted, the Punjab Food Authorized Logo must be used on the food product label after fee payment.
  - *Balochistan Food Authority Act (2014)*[133]
  - *Khyber Pakhtunkhwa Food Safety Authority Act (2014)*[134] in addition to the above, specifies that Khyber Pakhtunkhwa's Food Safety Authority can regulate food fortification.
  - *Sindh Food Authority Act (2016)*[135]
  - *Islamabad Capital Territory Food Safety Act (2021)*[136]
- *The Punjab Pure Food Rules (2011)*[124] set out general labelling requirements (e.g., all labelling statements must be legible and prominent, and the label must include the license number, batch or lot number, and date marking), including specific labelling and conditions for some fortified foods, alongside the use of nutrition claims, and the required food licensing with the Punjab Food Authority. Nutrient declarations are mandated only for infant formula.
  - *Punjab Pure Food Regulations (2018)*[125] prohibit false and misleading labelling and set out requirements for general labelling (e.g., statements must be clearly legible and prominent, in Urdu or English language), nutrient declarations, nutrition and health claims and prohibit some claims, e.g., that state or imply that the food is recommended, prescribed, or approved by medical practitioners. Fortification is also included as specified above. The use of a Punjab Food Authorized Logo is also mandated for all foods that are for sale, trade, import, export, and storage once a product is registered with the Punjab Food Authority after sampling and analysis.
- *The Khyber Pakhtunkhwa Food Fortification Act, 2022*[128] is almost identical to the Sindh Food Fortification Act (similar to mirror legislation in federations), save for referring to the appropriate Authority. We also note that the Act suggests businesses ***"may while advertising…provide true and accurate information",*** but we imagine this may be an issue of translation and that the regulations do not intend to make this an optional requirement.
- *The Balochistan Food Fortification Act, 2021*[129] is almost identical to the Sindh Food Fortification Act (similar to mirror legislation in federations), save for referring to the appropriate Authority. Other differences include that the Health Department 'may' conduct a provincial nutrition survey every five years and set timing for various reports to the Assembly.
- *The Sindh Food Fortification Act, 2021*[127] mandates the fortification of staple foods as above and applies to all such foods, including imports and exports and those used as ingredients in processed foods. It also specifies that all foods must be registered with the Sindh Food Authority and must include mandatory minimum information and a food fortification logo. The Food Authority can make further regulations about food labelling and advertising. The Act also provides powers for Food Safety Officers to inspect and investigate relevant sites and details enforcement action and a range of sanctions. It also covers the requirements for monitoring and evaluating fortification via nutrition surveys, annual reports to the Provincial Assembly, and evaluation reports to examine the efficacy of the Act and the Authority's implementation.

Policy context and objectives

Pakistan's overarching food regulations generally aim to ensure food safety and standards. ***Pakistan's Multi-sectoral Nutrition Strategy 2018-2025***[130] includes strategic objectives to regulate food labelling, inspection, and enforcement. Beyond this, we did not identify any documents that specifically identified how nutrition labelling policies in Pakistan were aligned with other health and nutrition policies.

Nutrition labels

Nutrient declarations are voluntary across most of Pakistan with no specific regulations found except in Punjab, where they are mandatory on all pre-packed food labels (with exceptions, such as meals served by caterers). Food Fortification Acts in ***Sindh, Balochistan***, and ***Khyber Pakhtunkhwa*** state that mandatorily fortified foods must be labelled with minimum essential information about the food as specified by the Food Authority. This may include a nutrient declaration.

Nutrition and health claims: Little regulation of nutrition and health claims was found outside of Punjab. However, imported products that claim to be a source of vitamins and minerals need to be registered across Pakistan, and as provinces generally adopt federal regulations, this registration requirement is also likely to apply in the provinces. Punjab only allows nutrition claims that a food is enriched or fortified where a statement of the contents is included and other criteria around the amounts of micronutrients, for example, are met. It prohibits therapeutic or prophylactic claims on foods. Pakistani authorities generally consider explicit or implied claims as largely promotional tools and have not required them to be based on scientific evidence.

Supplementary nutrition information: Sindh, Balochistan, and Khyber Pakhtunkhwa all require mandatorily fortified foods to contain fortification logos on the pack. Punjab also mandates its Punjab Food Authorized Logo on all foods, which demonstrates a food meets labelling and other required food standards but does not provide any nutrition information to consumers.[132]

Recommendations to reform nutrition labelling regulations to enable LSFF

- A programme of ***regulatory strengthening across provinces and nationally*** (to cover imported and domestically produced foods) that is based on best practice and provides consistency with deviations where appropriate, should include:
  - ***Mandatory nutrient declarations (highest priority)*** for all processed foods, including fortified foods. Aligned with best practice, the declaration should mandate the inclusion of fortificants where food is fortified in line with required standards. ***Note that it is possible that the fortification Acts in Sindh, Balochistan, and Khyber Pakhtunkhwa will mandate declarations on fortified foods.***
  - A ***voluntary standard fortification claim*** and/or a ***voluntary or mandatory fortification logo*** could be considered for mandatorily fortified foods and should ideally be aligned nationwide, to help consumers more easily identify fortified foods beyond a label stating that food is enriched, fortified or supplemented with vitamins or minerals. A decision on whether to prioritise a logo or standard claims may depend, for example, on levels of consumer literacy. A logo may be more easily understood but should be accompanied by consumer education to promote its use. ***Note that Punjab's regulations cover fortification claims, and the fortification acts in Sindh, Balochistan, and Khyber Pakhtunkhwa mandate fortification logos on fortified foods.***
  - At least ***setting basic requirements for general claims*** e.g., for nutrition claims such as 'source of' and ***prohibitions on specific claims. Note that Punjab's regulations generally cover these basic requirements for and prohibitions on claims.***

Ideally, regulations across Pakistan would be aligned so as not to create internal and/or external trade barriers that could impede fortification efforts. The fortification acts in Sindh, Balochistan, and Khyber Pakhtunkhwa appear to seek to achieve this.

- Any changes to labelling regulations, in particular with logos, should be accompanied by strong consumer education to ensure that labelling regulations are effective. Changes would also require that regulatory oversight be expanded to cover the product level, as they currently only cover the food business level. Further, any changes to labelling regulations should carefully consider the requisite increase in resources and systems necessary to enable and ensure compliance. A step-wise approach to implementation could prioritise the most critical labelling elements first.
- While some aspects of ***regulatory governance*** were outlined clearly in provincial food authority acts (such as the authority to regulate and licence food businesses, funding, annual reports to government and enforcement regimes and responsibilities), increasing publicly available information on some aspects of governance (see Information Limitations above and detail in the table below) could contribute to this regulatory strengthening.

Information sources and limitations

We only undertook a desktop regulatory review in Pakistan. Little detail was found on the process of regulatory design and drafting, and aspects of monitoring, evaluation (e.g., guidelines), and enforcement (e.g., transparency) aside from in those provinces with recent food fortification regulations. Such information may sit outside of the regulatory documents reviewed or may have only been available in information published in Urdu.

Table 8 – PAKISTAN – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient declarations are mandatory on all pre-packed food labels in Punjab Province (with exceptions, such as fruits and vegetables, and meals served by caterers).[125] • Nutrient declarations are voluntary in all other provinces.[137]	• Limited regulatory restrictions on nutrition or health claims[137] aside from provincial acts prohibiting false and misleading labelling. • Punjab Province has a voluntary fortification statement (provided conditions are met) and prohibits certain claims.[124, 125]	• Sindh,[127] Balochistan,[129] Khyber Pakhtunkhwa,[128] require mandatorily fortified foods to contain fortification logos on the pack.
Regulatory objective(s)	• None identified specific to labelling, but the Punjab Food Authority Act[131] aims to protect public health and provide for safety and standards of food. Other food safety authority acts also specify aims to provide for safety and standards of food for example in Sindh.[135]	• None identified	• To promote the nutritional status and health of residents of [the province].[127, 129 128,
Operative terms and conditions	Punjab Province: • Nutrient declarations must include the following information in the following order:[125] - energy value (kcal or kJ), protein, carbohydrates (g), and fat (g); - total quantity of each vitamin or mineral; - nutrients should be expressed per 100 g or 100 ml of food as sold, and per 100 ml of food ready to use when prepared according to the instructions on the label; - nutrients may also be declared per 100 kcal or kJ. • Information in declarations (including re-declarations for certain foods such as condensed milk) should be legible and the font should be ≥3mm in height, or ≥1mm if the package is <25cm^2.[124] Sindh Province,[127] Balochistan,[129] Khyber Pakhtunkhwa:[128] • Mandatorily fortified foods must be labelled with minimum essential information about the food as specified by the Authority. Similarly, advertisements must provide essential information. No detail about what constitutes 'essential information' is contained in the legislation but this may reasonably include a nutrient declaration.	• Imported products claiming to be a source of vitamins or minerals must be registered with the federal government before arrival, jointly in the name of the importer and manufacturer.[137,138] • Pakistani authorities consider claims (including implied claims) largely as promotional tools and do not require them to be based on scientific evidence.[137] Punjab Province[124] (noting that the Punjab Pure Food Regulations cover many of these same elements): • Any fruit or vegetable product claimed to be fortified with vitamin C shall contain ≥40 mg of ascorbic acid per 100 gm of product; • No food label can claim that the food is enriched, fortified, vitaminised, supplemented or strengthened or contain any statement that may or is likely to convey the meaning that the food is a source of ≥1 vitamins and/or minerals unless the specific food outlined in the legislation contains ≥ a specified amount of vitamin or mineral (e.g., 100 millilitres of wheat flour must contain ≥4,000 I.U. of vitamin A to claim that the wheat flour is fortified with vitamin A) – which does not exceed the recommended daily dose in Codex Guidelines for Vitamins and Mineral Food Supplements (CAC/GL 55-2005). - The claim must be written as: "This food is (state which: enriched, fortified, vitaminized, supplemented or strengthened) with (state the vitamins or minerals or both and their amount in units expressed per the regulation)." • Where a food is enriched with essential amino acid and/or essential fatty acid, a food label can claim: "This food is (state enriched or supplemented) with (state the amount in milligram) of (state whether essential amino acid, essential fatty acid or both)". • 'Source of energy' and 'source of protein' claims can be made, with conditions – e.g., that the label includes the quantity of food that can be consumed in one day.[125, 124] • The following are prohibited from being placed on food:[124,125] - claims for a therapeutic or prophylactic action or similar, unless specified in the Act; - statements or labelling that implies or suggests a food is recommended, prescribed or approved by medical practitioners; - words indicating quality, superiority, pure, or similar implications. Sindh Province,[127] Balochistan,[129] Khyber Pakhtunkhwa:[128] • Advertisements for mandatorily fortified foods must protect the consumer from false and misleading claims [see comment about the specific wording in Khyber Pakhtunkhwa under Structure of Nutrition Labelling Laws above].	Sindh Province,[127] Balochistan,[129] Khyber Pakhtunkhwa:[128] • An importer or a manufacturer shall display a fortification logo on the pack of a mandatorily fortified food as may be prescribed by the Authority.

Regulatory governance	
Drafting regulatory rules and scheme design	• In Pakistan, the federal government regulates food imports, while domestic food products and related food standards are regulated at the provincial level. Provinces often adopt federal regulations, but some have developed their own regulations.[137,138] • Punjab Province: The Punjab Food Authority is responsible for food regulation, monitoring, and enforcement, including the development or adoption of food standards, procedures, processes, guidelines, testing procedures, and enforcement systems. The Authority includes representatives of government departments, the food industry, consumers, and food scientists. The Authority may establish scientific panels including relevant experts and food industry representatives to make recommendations to the Authority on standards, and guidelines.[131] • Islamabad Capital Territory (ICT): The ICT Food Authority has the power to develop or adopt food standards, rules and regulations, procedures, processes, guidelines, testing procedures, and enforcement systems. The Authority includes representatives of government departments, food scientists, and industry.[136] • Khyber Pakhtunkhwa: – The Khyber Pakhtunkhwa Food Safety Authority is responsible for food regulation, monitoring, and enforcement, including the development or adoption of food standards, procedures, processes, guidelines, testing procedures, and enforcement systems. The Authority includes representatives of government departments, academia, the food industry, the Registered Farmers Association, and the Registered Consumers Association. Decisions are made by simple majority present and voting.[134] – The Khyber Pakhtunkhwa Food Fortification Act, 2022[128] allows the Food Authority to make any regulations to give effect to the Act including for the labelling and advertising of fortified foods. • Sindh Province: – The Sindh Food Authority is responsible for food regulation, monitoring, and enforcement, including the development or adoption of food standards, procedures, processes, guidelines, testing procedures, and enforcement systems. The Authority includes representatives of government departments, the food industry, one consumer representative, and one food scientist. Decisions are made by the majority present.[135] – The Sindh Food Fortification Act, 2021[127] allows the Food Authority to make any regulations to give effect to the Act, including for the labelling and advertising of fortified foods, after publishing draft regulations for comment, inviting and resolving objections and suggestions. • Balochistan Province: – The Balochistan Food Authority is responsible for food regulation, monitoring, and enforcement, including the development or adoption of food standards, procedures, processes, guidelines, testing procedures, and enforcement systems. The Authority includes representatives of government departments, the food industry, consumers, and food scientists. The Authority may establish scientific panels including relevant experts and food industry representatives to make recommendations to the Authority on standards and guidelines.[133] – The Balochistan Food Fortification Act, 2021[129] allows the Food Authority to make any regulations to give effect to the Act, including for the labelling and advertising of fortified foods.
Administration	• The federal Ministries of Food, Science, Health, and Industry are involved in food control at the federal level, and food authorities/departments do the same at a provincial level.[137,138] • Under provincial food authority Acts, the relevant provincial Food Authority may formulate standards, procedures, processes and guidelines about any aspect of food labelling in each province.[131,133-136] • Punjab Province: The Punjab Food Authority is responsible for implementing food rules and regulations, licensing, enforcement, and training programmes, promoting awareness of food safety and standards, collecting and analysing scientific and technical data, and providing scientific and technical support to the government in matters relating to food. Funding for the Food Authority is specified.[125] • ICT: The ICT Food Authority has the power to specify procedures and guidelines for sampling, accrediting, training, and promoting food safety standards. Fines and fees collected fund the ICT Food Authority's activities.[136] • Khyber Pakhtunkhwa Province: – The Khyber Pakhtunkhwa Food Safety Authority is responsible for implementing food rules and regulations, licensing, enforcement, and training programmes, promoting awareness of food safety and standards, collecting and analysing scientific and technical data, and providing scientific and technical support to the government in matters relating to food. Funding for the Food Authority is specified.[134] – The Khyber Pakhtunkhwa Food Fortification Act, 2022[128] mandates that all fortified foods be registered with the Food Authority and that manufacturers need to conduct quality assurance including on labelling. It also allows the Authority to issue detailed instructions to advertise fortified foods. The Authority can collect fees and fines under the Act for the Authority's Fund. • Sindh Province: – The Sindh Food Authority is responsible for implementing food rules and regulations, licensing, enforcement, and training programmes, promoting awareness of food safety and standards, collecting and analysing scientific and technical data, and providing scientific and technical support to the government in matters relating to food. Funding for the Food Authority is specified.[135] – The Sindh Food Fortification Act, 2021[127] mandates that all fortified foods be registered with the Food Authority, and that manufacturers need to conduct quality assurance including on labelling. It also allows the Authority to issue detailed instructions to advertise fortified foods. The Authority can collect fees and fines under the Act for the Authority's Fund. • Balochistan Province: – The Balochistan Food Authority is responsible for implementing food rules and regulations, licensing, and enforcement. Funding for the Food Authority is specified. [133] – The Balochistan Food Fortification Act, 2021 [129] mandates that all fortified foods be registered with the Food Authority and that manufacturers conduct quality assurance, including on labelling. It also allows the Authority to issue detailed instructions to advertise fortified foods. The Authority can collect fees and fines under the Act for the Authority's Fund.
Monitoring	• Punjab Province: Food businesses must be licensed by the Food Authority; licences must be renewed annually and displaced on premises in a prominent place. The Punjab Food Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[124,131] • ICT: Food businesses must be licensed by the ICT Food Authority.[136] • Khyber Pakhtunkhwa Province: – Food businesses must apply and obtain a licence which is valid for two years from the Food Safety Authority, subject to payment of fees. The Food Safety Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[134] – The Khyber Pakhtunkhwa Food Fortification Act, 2022[128] allows Food Safety Inspectors to inspect and investigate any site where fortified food is manufactured, stored, sold, transported, distributed, or located. They can also stop and search any vehicle used to transport fortified food. The Authority may also make mandatory electronic recordings of food inspections, sampling, and seizure. The Authority may establish or recognise food laboratories or mobile laboratories to analyse fortified food samples or equipment used for food fortification. In some cases, Food Safety Officers can be directed by a Court to have a sample tested by such laboratories. • Sindh Province: – The Food Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[135] – The Sindh Food Fortification Act, 2021[127] allows Food Safety Inspectors to inspect and investigate any site where fortified food is manufactured, stored, sold, transported, distributed, or located. They can also stop and search any vehicle used to transport fortified food. The Authority may also make mandatory electronic recordings of inspections, sampling and seizure. The Authority may establish or recognise food laboratories or mobile laboratories to analyse fortified food samples or equipment used for food fortification. In some cases, Food Safety Officers can be directed by a Court to have a sample tested by such laboratories. • Balochistan Province: – Food businesses require registration or a valid licence from the Food Authority to operate. A Food Safety Officer may issue an improvement notice and suspend or cancel a food operator's license if they fail to comply with the terms of this notice.[133] – The Balochistan Food Fortification Act, 2021[129] allows Food Safety Inspectors to inspect and investigate any site where fortified food is manufactured, stored, sold, transported, distributed, or located. They can also stop and search any vehicle used to transport fortified food. The Authority may also make mandatory electronic recordings of inspections, sampling and seizure. The Authority may establish or recognise food laboratories or mobile laboratories to analyse fortified food samples or equipment used for food fortification. In some cases, Food Safety Officers can be directed by a Court or the Authority to have a sample tested by such laboratories.
Evaluation	• Punjab Province: The Food Authority must submit annual reports on its previous and planned work and activities to the government which must be tabled in Parliament. The Authority must also submit three monthly reports to the government on performance, particularly regarding public health protection, food safety and standards, and related actions after which the government can issue directions to the Authority. The Auditor General of Pakistan must audit the Food Authority annually.[125,131] • ICT: The ICT Food Authority must submit annual reports on its previous and planned work and activities to the government which must be tabled in Parliament. The Auditor General of Pakistan must audit the ICT Food Authority annually.[136] • Khyber Pakhtunkhwa Province: – The Khyber Pakhtunkhwa Food Safety Authority must submit annual reports on its previous and planned work and activities to the government which must be tabled in Parliament. The Auditor General of Pakistan must audit the Food Safety Authority annually.[134] – The Khyber Pakhtunkhwa Food Fortification Act, 2022[128] The government may conduct a provincial nutrition survey of the status of specific micronutrients among Khyber Pakhtunkhwa residents every five years, with the Act detailing requirements, and it may conduct the first survey within three years of the Act's commencement. The Authority must also report annually to the government and Provincial Assembly on the implementation of food fortification regulation, including registration, compliance assessment, instances of violations, and enforcement actions. • Sindh Province: – The Sindh Food Authority must submit annual reports on its previous and planned work and activities to the government that must be tabled in Parliament. An auditor The Auditor General of Pakistan must audit the Sindh Food Authority annually [135] – The Sindh Food Fortification Act, 2021[127] The government may conduct a provincial nutrition survey of the status of specific micronutrients among Sindh residents every three to five years, with the Act detailing requirements, and may conduct the first survey within five years from the Act's commencement. The government sets the Authority's key performance indicators and can conduct annual monitoring and evaluation of the Authority to review the efficacy of the Act. The Authority must provide the monitoring agency access to all reports to allow for monitoring and evaluation, the reports for which must be submitted to the government. The Authority must also report annually to the Provincial Assembly on the implementation of food fortification regulation, including registration, compliance assessment, instances of violations and enforcement actions. The Assembly can refer the report to the relevant Standing Committee and can approve any of the committee's recommendations to improve fortification. • Balochistan Province: – The Balochistan Food Authority must submit annual reports on its previous and planned work and activities to the government which must be tabled in Parliament. An auditor must review the Authority's accounts and records annually.[133] – The Balochistan Food Fortification Act, 2021[129] The government may conduct a provincial nutrition survey of the status of specific micronutrients in residents every five years, with the Act detailing requirements. The government sets the Authority's key performance indicators and can conduct annual monitoring and evaluation of the Authority to review the efficacy of the Act. The Authority must provide the monitoring agency access to all reports to allow for monitoring and evaluation, the reports for which must be submitted to the government. The Authority must also report annually to the Provincial Assembly on the implementation of food fortification regulation, including registration, compliance assessment, instances of violations and enforcement actions.

Enforcement	• Provincial governments are responsible for the enforcement of domestic food products, while food imports are enforced at the federal level.[137,138] • Punjab Province: The Punjab Food Authority can appoint public analysts for testing and food inspectors/food safety officers, who have the power to enter and search any food premises, examine, sample or seize food products, examine or request any documents, identity card, business registration certificate, or licence from a food operator. Sampling methods are prescribed in the Punjab Pure Food Rules (2011). Complaints can be made in writing, which are investigated by food inspectors. Food inspectors may serve improvement notices for failure to comply with the provisions of the Punjab Food Authority Act. Failure to comply with the improvement notice may result in the Food Authority cancelling or suspending the food operator's licence or other action. False labelling offences may be subject to fines of 500,000 to 1 million Pakistani rupees and/or imprisonment of six months to 12 months. An order may be imposed to prohibit a food operator from conducting or operating a food business, or the use of equipment and premises. The Food Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[124, 131] Similar penalties are also set out in the Punjab Pure Food Regulations (2018).[125] • ICT: Food Authority officers have the authority to conduct enforcement activities. Food safety officers have the power to enter and search any food premises, examine, sample or seize food products, and examine or request any documents, identity card, business registration certificate, or licence from a food operator. Penalties are established for offences in ICT. False or misleading labelling may result in a fine of up to 500,000 Pakistani rupees and/or imprisonment of up to one year. Penalties are higher for subsequent offences and the licence of the food operator will be cancelled. If convicted, details of the offence may be published in newspapers.[136] • Khyber Pakhtunkhwa Province: – Food safety officers have the power to enter and search any food premises, examine, sample or seize food products, and examine or request any documents, identity cards, business registration certificates, or licences from food operators. A food safety officer may order prosecution, suspend or cancel a licence, impose a fine, issue an improvement notice, or order the recall of a product from the market. False labelling offences may be subject to fines of 100,000 to 1 million Pakistani rupees. An order may be imposed to prohibit a food operator from conducting or operating a food business, or the use of equipment and premises. The Food Safety Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[134] – The Khyber Pakhtunkhwa Food Fortification Act, 2022[128] allows food safety inspectors to seize fortified foods that contravene the Act, and seal premises for up to seven days. Where analysis shows that a food is not sufficiently fortified, a food safety officer must serve an improvement notice on the relevant person directing immediate remedy of the deficiency. The Authority can also order the withdrawal of a non-fortified food that is subject to mandatory fortification. If the person does not comply with an improvement notice or violates other provisions of the Act, penal action can be initiated against them, ranging from fines, suspension or cancellation of registration, and other penalties to remedy the issue (such as the destruction of food or directions for reprocessing food), to imprisonment where a person fails to apply for required registration, and other court-imposed sanctions. The Authority must make regulations to ensure fair enforcement procedures. • Sindh Province: – Food safety officers have the power to enter and search any food premises, examine, sample or seize food products, and examine or request any documents, identity cards, business registration certificates, or licences from food operators. A food safety officer may issue an improvement notice and suspend or cancel a food operator's license if they fail to comply with the terms of the notice. False labelling offences may be subject to fines of up to 1 million Pakistani rupees and/or imprisonment of up to six months. An order may be imposed to prohibit a food operator from conducting or operating a food business, or the use of equipment and premises. The Food Authority may refuse to issue or renew a licence if the business does not fulfil the requirements of the Act.[135] – The Sindh Food Fortification Act, 2021[127] allows food safety inspectors to seize fortified food that contravenes the Act, and seal premises for up to seven days. Where analysis shows that a food is not sufficiently fortified, a food safety officer must serve an improvement notice on the relevant person directing immediate remedy of the deficiency. The Authority can also order the withdrawal of a non-fortified food that is subject to mandatory fortification. If the person does not comply with an improvement notice or violates other provisions of the Act, penal action can be initiated against them, ranging from fines, suspension or cancellation of registration, and other penalties to remedy the issue (such as the destruction of food or directions for reprocessing food), to imprisonment where a person fails to apply for required registration, and other court-imposed sanctions. The Authority must make regulations to ensure fair enforcement procedures. • Balochistan Province: – The Food Authority can appoint public analysts for testing and food safety officers who have the power to enter and search any food premises, examine, sample or seize food products, examine or request any documents, identity cards, business registration certificates, or licences from food operators. A food safety officer may issue an improvement notice and suspend or cancel the food operator's license if they fail to comply with the terms of the notice. An order may be imposed to prohibit a food operator from conducting or operating a food business, or the use of equipment and premises, or the Authority can order the immediate withdrawal of a product from the market. False labelling offences may be subject to fines of up to 1 million Pakistani rupees or imprisonment for up to five years. Offences are higher for subsequent offences. If convicted, details of the offence may be published in newspapers.[133] – The Balochistan Food Fortification Act, 2021[129] allows food safety inspectors to seize fortified food that contravenes the Act, and seal premises for up to seven days. Where analysis shows that a food is not sufficiently fortified, a food safety officer must serve an improvement notice on the relevant person directing immediate remedy of the deficiency. The Authority can also order the withdrawal of a non-fortified food that is subject to mandatory fortification. If the person does not comply with an improvement notice or violates other provisions of the Act, penal action can be initiated against them, ranging from suspension or cancellation of registration, and other penalties to remedy the issue (such as the destruction of food or directions for reprocessing food), up to imprisonment where a person fails to apply for required registration, and other court-imposed sanctions. The Authority must make regulations to ensure fair enforcement procedures.

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The Philippines

Food fortification

The Philippine ***Food Fortification Act of 2000***[139] and its ***implementing rules and regulations***[140] establish the Philippine Food Fortification Program which includes mandatory and voluntary fortification to ***"promot[e]... optimal health and to compensate for the loss of nutrients due to processing and/or storage of food"***.[140] It applies to all imported or locally processed foods for consumption in the Philippines including food served at restaurants and food service establishments, with very few exceptions. The Act mandates fortification of staple foods (rice with iron; wheat flour with vitamin A and iron; refined sugar for human consumption with vitamin A; cooking oil for human consumption with vitamin A, except for export) and other staple foods as required by the National Nutrition Council based on nutrition survey results and promulgated through Department of Health (DoH)-issued regulations. The Act also encourages the voluntary fortification of processed foods or food products through the Sangkap Pinoy Seal Program which is based on the relevant standards for food fortification. For example, ***Administrative Order No. 4-A s. 1995 Guidelines on Micronutrient Fortification of Food, 1995***[141] sets out criteria for the fortification of staple foods (including meeting minimum levels of fortificants and being able to show at least 80% to 90% of the claimed fortification level if the food were to be tested at any point during its shelf-life). The Order also encourages the voluntary fortification of foods widely consumed by at-risk groups, such as cereals and cereal-based products, such as snack foods and instant noodles, with iron and B vitamins, and juices, flavoured drinks, and food gels with vitamin C.

The Philippine ***Act for Salt Iodization Nationwide (ASIN), 1995***[142] mandates that all producers and manufacturers of food-grade salt must iodise salt and use iodised salt in other processed food products, and all food outlets, restaurants, and stores are to only make iodised salt available to customers. An exemption from using iodised salt in food products can be sought under the ***Revised Implementing Rules and Regulations.***[143] However, we heard from respondents that National Nutrition Surveys conducted by the Food and Nutrition Research Institute have shown that industry is not meeting iodised salt regulations.

Responsibilities and regulatory governance for nutrition labelling

The main government bodies tasked with developing and enforcing food regulations for nutrition labelling are the DoH and its regulatory agency, the Philippines Food and Drug Administration (FDA). The FDA is responsible for the safety and quality of processed and pre-packaged foods, iodised salt, and fortified foods. The National Nutrition Council is the main policymaking and coordinating body on nutrition and also serves an advisory role on food fortification.[140] Other government agencies assist in monitoring and enforcement of regulations, including Local Government Units (LGUs) which are responsible for food safety in their jurisdictions, and other agencies linked to the food fortification programme (for example, the Bureau of Customs).

Food labelling and advertising regulatory development are informed by country-level evidence from the government's Food and Nutrition Research Institute. Codex standards, and a mandated public consultation process to promote harmonisation and consumer health, reduce trade barriers and ensure regulations are enforceable.[144] We heard from respondents that industry may be overrepresented in policy development via direct engagement with legislators.

Administration, monitoring and enforcement of nutrition labelling occurs through the FDA's (and LGU's) ***pre- and post-market product registration*** (which includes a label review). We heard from respondents that pre-market approval supports high compliance with nutrient declaration requirements. Post-market surveillance includes monitoring of products in the market, laboratory analysis of product samples, industry training, and consumer education programmes. An example of consumer education is the DoH and FDA's promotion of fortified food products through the Sangkap Pinoy Seal and other nutrition promotion programmes. At barangay levels (the smallest administrative division in the Philippines) village nutrition workers coordinate nutrition programmes, including fortification (including salt) seals.

Despite this regulatory governance, we heard in interviews and surveys that Filipino consumers tend not to use nutrition labelling and that general awareness of nutrition labelling, including the Sangkap Pinoy Seals, is poor. However, the awareness and use of nutrition labelling tend to be better in high socio-economic and educated groups and are lower in poorer, regional villages.

We also heard that industry, particularly smaller manufacturers, may not use Sangkap Pinoy Seals due to the associated costs (such as the cost of analysis of nutrients by accredited laboratories). Inspectors who monitor the programme are under-resourced and while new regulations often include a budget for human resources and capacity at the FDA, this may not be implemented. Scheduled, rather than surprise, inspections of manufacturing facilities also create an opportunity to mask non-compliance. Further, there are no limitations on ultra-processed foods being fortified and using the logo, which can create a perceived health 'halo' effect around otherwise unhealthy foods. Consumer education is needed to increase awareness of nutrition labelling, including the Sangkap Pinoy Seals. Education programmes could, for example, utilise barangay health and nutrition volunteers.

Structure of nutrition labelling laws

The Philippine's nutrition labelling regulatory regime is structured as follows:

- The ***Food, Drug and Cosmetics Act 1963*** (Republic Act No. 3720, last amended in 2009)[145] sets out general labelling requirements (including that mandatory labelling must be conspicuously placed so that it is likely to be read and understood), prohibits misbranding of food (e.g., false and misleading labelling) and establishes the FDA (previously the Bureau of Food and Drugs) and its functions, duties and powers.
  - ***Bureau Circular No. 2007-002*** sets out ***Guidelines in the use of Nutrition and Health Claims in Food***[144] by the FDA. The guidelines adopt the Codex Alimentarius Commission Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997, Rev. 1-2004) and are used to evaluate and make claims in food labelling and advertisements, ***in addition to, and insofar as it is consistent with existing relevant national laws and regulations.***
- The ***Food Safety Act of 2013***[146] sets out basic principles of food safety including requirements for general labelling, prohibitions on false or misleading labelling, and establishing science- and risk-based regulation. It establishes the DoH and Department of Agriculture (for primary agricultural products) as responsible for setting mandatory food and labelling standards.
  - ***Administrative Order 30 (2014) Labelling of prepackaged food products***[147] by the DoH sets out requirements for nutrition information on labels, including claims and nutrient declarations, prohibits specific claims, and includes general labelling requirements and offences for false and misleading labelling. Exemptions from the labelling provisions in specific circumstances can be sought.
- The ***Philippine Food Fortification Act of 2000***[139] establishes the Philippine Food Fortification Program with both mandatory and voluntary fortification, Sangkap Pinoy Seal programme logos and claims for fortified foods and requires nutrient facts labels on all processed food or food products with the micronutrient(s) added.
  - ***Administrative Order No. 4-A s. 1995 Guidelines on Micronutrient Fortification of Food, 1995***[141] sets out requirements for labelling fortified foods (including labelling foods as 'fortified') and criteria for the fortification of staple foods and establishes the FDA as responsible for enforcement.
  - ***Implementing rules and regulations for the Philippine Food Fortification Act of 2000***[140] sets out the requirements for meeting fortification specifications, and for monitoring, evaluating and enforcing the programme.
  - ***Administrative Order No. 82 s. 2003*** provides ***Guidelines on the Granting of Diamond Sangkap Pinoy Seal to the Manufacturers of Fortified Products***[148] sets out the terms of use of the Diamond Sangkap Pinoy Seal on fortified foods and related processes and offences.
- ***Act for Salt Iodization Nationwide (ASIN) 1995 (Republic Act 8172)***[142] mandates salt iodisation and required labelling, including the product name and fortificant listed, prohibits misleading labelling, and details requirements for manufacturers and to administer, monitor and enforce labelling.
  - ***Revised Implementing Rules and Regulations of Republic Act No. 8172 "An Act Promoting Salt Iodization Nationwide and for Related Purposes"***[143] sets out an offence for mislabelling salt and requires product labels to stipulate the use of iodised salt.
  - ***FDA Circular No. 2015-005 Guidelines on the Use of "Saktong Iodine sa Asin" Quality Seal***[149] introduced an iodine-specific Saktong Iodine sa Asin Quality Seal to increase the awareness and use of adequately iodised salt in households and point of purchase.
- ***FDA Circular No.2012-015 – Guidelines on Voluntary Declaration of the Front of Pack Labelling (Energy or Calorie Content) on the Labels of Processed Food Products***[150] establishes the FOPNL as part of the labelling system.

As an ASEAN Member State, a set of non-binding regional guidelines, principles and standards apply to the Philippines' labelling laws and/or fortification as indicated, although we found little by way of specific regional labelling regulation that influences ASEAN Member States' national labelling regulations.

- ***ASEAN Guidelines on Promoting Responsible investment in Food, Agriculture and Forestry 2018***[72] propose considerations including supporting food fortification to improve nutrition security and promote the harmonisation of standards and regulations while allowing national flexibility.
- ***ASEAN Regional Guidelines on Food Security and Nutrition 2017***[73] serve as a reference guide to develop best practice policy that promotes nutrition and food security (including food fortification policies to address malnutrition and micronutrient deficiencies). The guidelines aim to build stronger cooperation and integration on food security and nutrition across the ASEAN region but few specifics on fortification are included.

- ***ASEAN Principles and Guidelines for National Food Control Systems 2014***[74] is aligned with Codex principles and guidelines For National Food Control Systems CAC/GL 82-2013 and provides guidance on developing food legislation that promotes food safety, including that national competent authority/ies should establish, implement, evaluate, and enforce evidence- and risk-based regulatory requirements.
- ***ASEAN General Standards for the Labelling of Prepackaged Food 2016***[75] that adopt the Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985).

Policy context and objectives

We heard from respondents that the DoH identified diet and nutrition as a priority in its Health Promotion Framework Strategy 2019-2023 and advocated for FOPNL legislation [PHI002-S] and that food fortification and regulation is part of the Philippine Plan of Action for Nutrition [PHI004-I]. Aligned to this, respondents stated that the objectives of labelling regulation are to ensure food supply safety and quality and to promote healthier diets [PHI002-S] or ***"provide … an immediate way to make healthier choices"*** [PHI001-S]. This broadly aligns with the objectives of the ***Food Safety Act***[146] which include food safety and protecting health and consumer interests, and the objectives of nutrition labelling regulation which include providing information and education to facilitate choice.[147]

As an ASEAN Member State, the Philippines must evaluate new or existing regulation to ensure it is compatible with the ASEAN nutrition and food security policy.[73]

Nutrition labelling is also integrated into the FDA's broader food product and food business safety system through pre- and post-market surveillance, which incorporates a review of product labels. There is evidence that the Philippines' nutrition labelling regulations seek to address both over- and under-nutrition, by using both fortification logos and a voluntary FOPNL (even though this label could be improved based on best practice). However, there are also some potential tensions between these policies. For example, the Philippines mandates the fortification of sugar and encourages the fortification of unhealthy foods, such as cereals and snack foods like instant noodles, for which fortification claims can be made if they have been fortified in line with the regulations. Such policies may encourage the consumption of unhealthy foods that are associated with non-communicable diseases.

Nutrition labels

Nutrient declarations are mandatory on packaged foods and fortified staple foods (including foods that use the Sangkap Pinoy Seal as described below). Key nutrients as well as vitamins or minerals added during fortification must be specified.

Nutrition content claims, comparative claims, and health claims are voluntary. The FDA may approve any claims not covered by regulations if successfully substantiated through a submission to the FDA. Claims that a food product is enriched/fortified with vitamins and/or minerals can only be made when the amount of added vitamin and/or mineral accords with the level specified in the Food Fortification Guidelines and the nutrition information is included in the declaration. Iodised salt must also be declared on labels. Several claims are prohibited.

Supplementary nutrition information: There are ***three Sangkap Pinoy Seal fortification logos*** that can only be used on foods containing minimum amounts of fortificant(s): one for foods fortified with iron, vitamin A and iodine; one for salt fortified with iodine (introduced after the original logo to increase awareness and use of adequately-iodised salt in households and point of purchase as outlined above); and one (the diamond seal) for staple foods covered by mandatory food fortification. FDA approval must be sought to use the labels. The 'Saktong Iodine sa Asin' Seal logo is mandatory on iodised salt, while the use of Sangkap Pinoy Seal logos for other foods is voluntary. A ***voluntary FOPNL*** is also allowed to outline the energy content of a food product in calories.

Sample format for the Nutrition Facts Declaration[147]

Voluntary Diamond Sangkap Pinoy Seal for staples covered by mandatory food fortification[151]

Voluntary Sangkap Pinoy Seal for processed foods fortified voluntarily with iron, vitamin A and iodine[151]

Mandatory Saktong Iodine sa Asin Quality Seal for all salt products covered by mandatory food fortification[149]

Voluntary energy declaration FOPNL logo[150]

Recommendations to reform nutrition labelling regulations to enable LSFF

- Increased attention should be paid to the interaction of fortification and food labelling to ***ensure that policies and regulations coherently address over- and under-nutrition***. Specifically, the government should review the foods that can be voluntarily fortified and/or at least limit the use of claims and fortification logos to only foods that are healthy to avoid health 'halo' effects on otherwise unhealthy foods.
- If deemed useful to enhance consumer understanding (and mitigate potential confusion with existing claims and logos available), additional specific ***voluntary standard fortification claims*** for mandatorily fortified foods could be considered, to add to existing fortification logos and existing claims for fortified foods (to indicate why the fortified food is beneficial for an individual's health). This recommendation could be considered for voluntarily fortified foods where foods are deemed to be healthy and where sufficient regulatory capacity exists to adequately monitor and enforce additional labelling specifications.
- ***Regulatory governance*** overall appears strong through the DoH's regulatory development process, the National Nutrition Council's coordination role, and the FDA's pre- and post-market surveillance system, authority, budget, and enforcement regime, and the cooperation at barangay levels with village nutrition workers on salt iodisation and fortification. To improve the general awareness of nutrition labelling and the Sangkap Pinoy Seals in particular, adequate resources are required, especially at regional and village levels through barangay health and nutrition volunteers. Adequate resources are also required to improve the monitoring capacity of inspectors (e.g., to allow 'spot checks' rather than only pre-scheduled inspections) and compliance by smaller manufacturers.

Information sources and limitations

We undertook qualitative surveys and interviews in addition to a desktop regulatory review in the Philippines. From this, limited information was identified on guidelines and the structures and processes for evaluating labelling regulations. Such information may sit outside of the regulatory documents reviewed.

Table 9 – THE PHILIPPINES – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Nutrient facts/declaration labels are mandatory on packaged foods with some exceptions such as bottled water, and foods that contain insignificant amounts of all nutrients to be listed (e.g., coffee, spices, flavour extract).[147] They are also mandatory on fortified foods.[139]	• Nutrition content claims, comparative claims, and health claims are voluntary in accordance with Bureau Circular 2007-02 and are subject to Codex Standards CAC/GL 23-1997 and its revisions.[144] • Claims not covered by these regulations are allowed upon application with substantiation.[147] • Several specific types of claims are prohibited (claims as to the suitability of a food to prevent, treat or cure a disease or disorder or that a synthetic vitamin is superior to a natural vitamin,[147] and claims that a product is free from trans-fatty acids).[152, 153]	• Voluntary Sangkap Pinoy Seal Program (fortification logos) for use on mandatorily and voluntarily fortified foods.[139] • Mandatory Saktong Iodine sa Asin Quality Seal (logo) on all iodised salt.[149] • Voluntary energy declaration FOPNL.[150]
Regulatory objective(s)	• To inform the consumers about product contents, protect against misleading advertising and facilitate sound choices to acquire the knowledge necessary to be an informed consumer.[147]	• [Broad objectives from the Constitution to the Consumer Act are quoted, among others] To protect and promote the right to health and instil health consciousness among people; to enforce compulsory labelling and fair packaging to enable the consumer to obtain accurate information as to the nature, quality and quantity of the contents of consumer products and to facilitate comparison of the value of such products.[144]	• The Sangkap Pinoy Seal Program aims to encourage food manufacturers to fortify processed foods or food products with essential nutrients at DoH-approved levels by only allowing the seal if products pass defined criteria. The seal helps to guide consumers in selecting nutritious foods.[139] • Saktong Iodine sa Asin Quality Seal aims to "strengthen and revitalise the existing Diamond Sangkap Pinoy Seal used in iodised salt…increase awareness and use of adequately-iodised salt in households and point of purchase …[and] will serve as a guide to consumers in identifying and purchasing adequately-iodized salt".[149] • The energy declaration aims to renew consumer interest in and heighten consumer awareness of the energy content of food products.[150]

Operative terms and conditions	• Nutrition facts labels must be tabulated and must include:[147] – protein (g), total carbohydrates (g), dietary fibre (g) and sugar (g), total fat (g), saturated fat (g), trans fat (g), cholesterol (mg), sodium (mg), energy value or calories from fat (kcal); – vitamins or minerals added during fortification (Vitamin A, iron, and iodine) (in mg or microgram, or international units); – any nutrients for which a claim is made (specifically vitamins and minerals and/or other nutrients like fatty acids and linolenic acids for other products claimed to contain such). • All nutrients must be expressed per serve and can also be expressed as a % of the Recommended Energy and Nutrient Intake (RENI). Locally manufactured food products intended for local consumption must also indicate the corresponding RENI % in whole numbers. Where a nutrient is <2% RENI, state "contains less (or "<" symbol) 2% RENI" or refer to this statement via an asterisk (*).[147] • In addition to the above requirements, the nutrient declaration of fortified foods must comply with the below as relevant:[141] – Serving size must be by weight (solids) or volume (liquids) – If the food is not ready to eat and is (i) consumed after adding water/ edible liquid, the fortificant must be declared as % RENI per serve; (ii) used as an ingredient to prepare another food, the fortificant must be declared as % RENI per 100g of the packaged food. – When the food contains ≥40kcal per serve, the % RENI per 100 kcal can also be declared. • General labelling must be clear, prominently displayed, and readily discernible; should be in English and/or Filipino; small units with a surface area <10cm^2 are exempt from some labelling requirements.[147]	• The Philippines has adopted Codex Guidelines for Use of Nutrition and Health Claims, permitting voluntary claims subject to the terms of this standard:[144] – Nutrient content claims ('Source' or 'High') can be used for micronutrients if that nutrient is present in a specified % of an NRV (e.g., for 'High', the % of the NRV must be twice that required for a 'Source' claim).[11,144] – Claims cannot represent that a food is adequate or effective in the prevention, cure, mitigation or treatment of any disease or symptom of an illness, or that the food is an adequate source of all essential nutrients.[144] • Nutrition and health claims on food labels are required to comply with the relevant Codex standards and amendments. Claims not covered by these standards must be evaluated based on submitted substantiation.[147] • Fortified claims: – Shall only be made when the amount of added vitamin(s) and/or mineral(s) is in accordance with the level(s) specified in the Food Fortification Guidelines and/or Administrative Order No. 4-A s. 1995, and must retain 80%-90% of minimum levels if tested at any point during the product's shelf-life.[141 139] – Shall be based on the processed food as packaged and purchased by the consumer.[141] – 'Enriched', 'added with', 'supplemented with' and other similar terms are considered equivalent to fortified.[139] – The nutrition information shall appear on the Nutrition Facts (declaration).[141] – "IODIZED SALT" must be printed in bold capital letters and included on the label of iodised salt and any food using iodised salt as an ingredient.[143]	• Sangkap Pinoy Seal Program logos: – Sangkap Pinoy Seal: fortified with iron, vitamin A and iodine. – Saktong Iodine sa Asin Quality Seal: salt fortified with iodine. – Diamond Sangkap Pinoy Seal: staple foods covered by mandatory food fortification.[139] – Use of the seals requires approval by the Sangkap Pinoy Seal Program via the FDA and must contain minimum amounts of the fortificant. A nutrient declaration (Nutrition Facts) including the type and quantity of nutrients must be included on the label.[139,148] • Energy declaration FOPNL logo:[150] – Declaration should be at the lower right-hand portion of the principal display panel in a cylindrical shape with a white colour background. The border line of the cylindrical shapes and lines and fonts appearing inside the cylindrical shape shall be legible and the colour shall be in good contrast with the background. – The following is the only information that shall appear inside each of the cylindrical shapes: a. The statement 'Energy or Calories' in the cylindrical shape. b. The amount of energy inside the cylindrical shape is stated as: i) amount per serving of the food, ii) percentage of the calorie value based on RENI for energy.

Regulatory governance	
Drafting regulatory rules and scheme design	• Under the Food Safety Act of 2013 the DoH is responsible for developing regulations on processed and pre-packaged food labelling and advertising and provides guidance to LGUs.[146] In this regulatory development process: – Codex standards are often adopted to limit trade barriers, except when conflicting evidence or consumer protection requirements exist.[146] [PHI001-S] Country-specific research – often from the Food and Nutrition Research Institute – also carries great weight. [PHI002-I/S, PHI006-S] – Technical committees are formed and include representatives from government departments (e.g., the DoH, and Department of Finance), local government and independent experts. Industry stakeholders are excluded due to conflicts of interest, but they can seek to influence politicians and whether legislation passes via lobbying, for example. [PHI002-I] – For transparency, the DoH and other implementing agencies must conduct public consultation and disseminate relevant information during the preparation, evaluation and revision of food legislation unless urgency does not allow this.[146] During consultation, industry is engaged, improvements are recommended [PHI001-S] and agencies seek to ensure that any proposed regulations are enforceable. [PHI002-I, PHI006-S] – [PHI004-I] • Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States should provide clear and effective regulation that promotes food security and nutrition,[73] engage stakeholders in regulatory development to ensure transparency and that views are considered,[74] and consider Codex standards, recommendations and guidelines.[74] All aspects of a national food control system should be transparent and open to public scrutiny while respecting legal requirements to protect confidential information.[74] Decision making should be evidence-based, and competent authority(ies) and all officials should be free of improper or undue influence or conflict of interest.[74]
Administration	• Under the Food, Drug and Cosmetic Act 1963[145] the FDA must enforce laws relevant to food fortification and labelling, and establish food safety or efficacy standards and quality measures. The FDA is funded from fees and government appropriation. The FDA provides guidance to the food industry on regulations and ensures transparency via its Citizen Charter and website which enable stakeholders to communicate with the FDA and understand and view applications and public and industry announcements. [PHI001-S] • Under the Food Safety Act[146] the FDA is responsible for establishing a performance-based food safety control management system; inspection (required to be regular, with frequency depending on the risk level); licensing; registration; post-market monitoring; establishing and strengthening laboratories for food safety; certifying food safety inspectors; training food industry and government personnel (it trains enforcement officers through its Academy and holds nutrition labelling workshops to ensure industry compliance [PHI001-S]); and consumer education for processed and pre-packaged food and nutrition labelling requirements (to be developed in consultation with LGUs and the Department of Education, and carried out by the National Center for Health Promotion (NCHP)). The FDA and DoH may delegate official enforcement controls to LGUs, provide technical assistance, and implement capacity building programmes for LGUs. – Before any pre-packaged food product enters the market, businesses must obtain a License to Operate and a Certificate of Product Registration from the FDA which are only issued if the product is compliant with relevant standards and regulations, including for nutrition labelling. [PHI006-S, PHI001-S, PHI002-I] – Some resourcing limitations exist due to limited FDA human resources and capacity to implement regulation, and while regulations often include a budget for capacity building and implementation at the FDA, this is not always implemented. [PHI002-I] – Post-market surveillance focuses on the retail end of the supply chain via periodic inspections of manufacturers and retailers [PHI002,3-I] and sampling. [PHI001-S] • Under the Philippine Food Fortification Act (or related regulations as specified): – Under the Act's Implementing rules and regulations[140] the DoH (via the FDA) leads food fortification implementation and must monitor,[141] evaluate, and enforce processed and pre-packaged food regulations, including promoting the use of fortified foods through its Sangkap Pinoy Seal and related programmes. It can collect registration fees to fund food fortification efforts. Several government agencies and programmes support manufacturer compliance with the fortification programme through tax credits, preferential loan rates, and technology assistance, and such agencies are mandated to allocate a budget for such assistance. The FDA also conducts a final inspection of all fortified imported foods to ensure that they are compliant and registered with the FDA before their sale and distribution. – Food manufacturers must apply to the Sangkap Pinoy Seal Program at the FDA to use the logo.[139] Further, under Guidelines on the Granting of Diamond Sangkap Pinoy Seal [148] manufacturers must fortify their products according to fortification standards to use the Seal. Applications must include application forms, the FDA-issued Licence to Operate, results of product analysis of vitamin A, iron, and iodine from an accredited laboratory, and a sample of the label with the Seal. Application fees apply. The FDA conducts a plant inspection as part of the application process (except in some circumstances) and if a food is compliant,[140] issues a Letter of Diamond Sangkap Seal Award and Diamond Seal of Certificate of Acceptance, which is valid indefinitely and must be displayed at the manufacturer's site. • Under the Act for Salt Iodization Nationwide (ASIN)[142] (or related regulations as specified): – The FDA sets, enforces, and monitors compliance with mandatory salt iodisation, funded by government appropriations. LGUs monitor the salt sold in their jurisdiction for iodisation compliance (working in cooperation with the local law enforcement agencies[143] and keeping a list of all salt producers) and must allocate a budget for this purpose. The DoH must spearhead (in cooperation with LGUs and government agencies) public information on the benefits and rationale for iodised salt, provide training, and establish a system to monitor the quality of iodised salt in collaboration with other government agencies. – Salt manufacturers and producers must register with the FDA (or LGU delegates) and be issued with a License to Operate. The License to Operate is valid for one year and manufacturers must meet document and technical requirements and pay fees. If manually fortifying, a DoH-issued Certificate of Training is also required.[142] – Under Revised Implementing Rules and Regulations for the Act[143] the FDA and Department of Science and Technology must establish a salt iodisation database. – Under the Guidelines on the Use of "Saktong Iodine sa Asin" Quality Seal[149] all interested iodised salt importers, distributors, re-packers, and traders are required to submit applications with appropriate labels (including use of the new seal) to the FDA for approval before use. • Under the Guidelines on Voluntary Declaration of the Front of Pack Labelling[150] food manufacturers and distributors wishing to use the FOPNL must submit new or revised labels with the FOPNL energy declaration for their products to be granted FDA approval. • The National Nutrition Council (comprised of the DoH and nine other government agencies) is the highest national nutrition policy-making and coordinating body with three divisions involved in nutrition labelling and fortification. The Nutrition Policy and Planning division coordinates nutrition, food fortification, and salt iodisation programmes and develops the Philippine Plan of Action for Nutrition. The Nutrition Surveillance Division monitors and evaluates the nutrition programme and manages the early warning system on nutrition. The Nutrition Information and Education Division (NIED) conducts nationwide nutrition, labelling and fortification programme advocacy and capacity development. [PHI004-I] • Village nutrition workers (Barangay-level) also coordinate nutrition programmes at a local level, including on salt iodisation and the fortification seal. [PHI004-I] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems, Member States' independent statutory bodies retain authority for policy administration[73] and legislation should provide authorities with the power and mechanisms to: establish, monitor and enforce standards; implement regulations; perform activities to verify, investigate, and enforce regulatory compliance; and apply sanctions and/or penalties.[74]

Monitoring	• The Food Safety Act[146] establishes a Food Safety Regulation Coordinating Board in charge of continuously evaluating how effectively food safety regulations are enforced and how research and training programmes are implemented. It submits regular reports to Congressional Committees on Health, Agriculture and Food, and Trade and Industry. – Policies and procedures for official controls must be documented in a manual of operations to ensure consistency, quality and transparency. – Food inspectors must perform regular, uniform inspections of food premises to assess compliance with food standards. Food testing must be periodically carried out by accredited, qualified laboratories without conflicts of interest.[146] • Under the Philippine Food Fortification Act[139] the FDA must establish a quality assurance system and standard operating procedures to monitor implementation.[140] – Under the Act's Implementing rules and regulations[140] various other bodies assist in monitoring and reviewing the programme, including the Bureau of Customs for imported products, the National Food Authority for rice, and the Sugar Regulatory Administration for sugar. LGUs monitor mandatorily fortified foods in public markets, and retail and food service establishments, check the labelling of fortified products, including nutrient facts tables, and submit monitoring reports to the FDA. The food industry must also submit annual reports to the DoH on the production, distribution and marketing of fortified foods and concerns and recommendations.[139] – Under Guidelines on the Granting of Diamond Sangkap Pinoy Seal[148] the National Food Authority, Sugar Regulatory Administration and Philippine Coconut Authority assist the FDA in monitoring the compliance of all registered staple food manufacturers. • Under the Act Promoting Salt Iodization Nationwide:[142] – LGUs monitor the compliance of salt sold in markets in their jurisdiction and set the frequency of inspections.[143] Manufacturers must also conduct routine quality assurance. – The Salt Iodization Advisory Board (the National Nutrition Council) acts as the policy and coordinating body on salt iodisation efforts, monitors implementation and submits an annual report to Congress on the salt iodisation programme's process and recommendations for improvement. – Under the Act's Revised Implementing Rules and Regulations the Salt Iodization Advisory Board monitors and evaluates salt iodisation programmes.[143] • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' national food control systems should be transparent and open to public scrutiny, while respecting the need to protect confidential information as appropriate.[74] To assess the effectiveness and suitability to achieve objectives, the system should be subject to ongoing monitoring and review against documented criteria, and consider scientific evidence, and non-compliance.[74] Legislation and guidelines should also include provisions to monitor dietary consumption.[73]
Evaluation	• Under the Implementing rules and regulations for the Philippine Food Fortification Act[140] the National Nutrition Council conducts periodic reviews at least once every five years or on petition from an industry mandated to fortify food. Using data from the Food and Nutrition Research Institute and other nutrition surveillance systems, the Council determines if mandatory food fortification is still required.[140] [PHI002-I] • Through its monitoring and various reports to Congress, the FDA evaluates labelling regulations. [PHI002-I] However, it is understood that no Regulatory Impact Assessment for labelling regulation has been completed to date, nor has any assessment of labelling on consumer behaviour. [PHI001-S] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States' national food control systems should have the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the food control system is achieving its objectives.[74] Member States should also evaluate new or existing regulation to ensure it is compatible with nutrition and food security policy.[73]
Enforcement	• Under the Food, Drug, and Cosmetic Act, the Secretary of Health can issue rules and regulations to enforce provisions of the Act.[145] A range of prohibited acts (such as misbranding food) and penalties from fines and/or imprisonment are specified, and goods may be seized. To enforce the Act, the FDA can enter and inspect premises and sample products. Some enforcement data, including those companies deemed to be non-compliant with labelling regulations, is available on the FDA's website. [PHI002-I] – Sanctions under the Act for Salt Iodization Nationwide (ASIN)[142] and its related regulations[143] (including for misbranding or failure to obtain a Licence to Operate) cross-refer to the Food, Drug and Cosmetic Act enforcement regime (and other provisions of the Consumer Act), but the Act and its regulations specify some fines and allow licence revocation. The FDA and LGUs can impose and collect fines that accrue to the FDA for Act implementation. – Violations and sanctions under the Administrative Order 30 (2014) Labelling of prepackaged food products[147] render products misbranded and also cross-referenced to the Food, Drug and Cosmetic Act enforcement regime. • Under the Food Safety Act: – LGUs are responsible for the enforcement of food regulations and standards in their jurisdictions, including the proper labelling of pre-packaged foods.[146] – Non-compliant businesses may be subject to fines and suspension of appropriate authorisation for a month, with increasing penalties and the revocation or cancellation of a Certificate of Product Registration also possible.[146] – Under the Rules and regulations Governing the labeling of prepackaged Food Products, the FDA may seize misbranded foods or impose administrative sanctions such as suspension or revocation of a Licence to Operate, fines or written warning notices. Penalties for criminal offences can also apply.[154] • In relation to the Act Establishing the Philippine Food Fortification Program: – Under the Guidelines on Micronutrient Fortification of Food, 1995,[141] once processed food claiming fortification is deemed to be mislabelled, a notice and hearing occur after which the FDA can impose a range of administrative sanctions from ordering product recall to suspending or cancelling a product's registration. – Under the Guidelines on the Granting of Diamond Sangkap Pinoy Seal,[148] non-compliance may result in product recall, an order to correct labelling, inclusion in published lists of non-compliant manufacturers, administrative fines, and suspension or cancellation of a Licence to Operate or approval to use the Seal. • Respondents stated that clear and transparent guidelines and enforcement structures are used to enforce nutrition labelling regulations. [PHI001, 2-S] Citizens can also submit complaints to the FDA, which the FDA then investigates. [PHI002, 3-I]. However, information on monitoring, evaluation or enforcement is not always publicly available and access via freedom of information requests can be hindered by laws protecting commercial-in-confidence information. [PHI001-S, I] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' independent statutory bodies should retain enforcement authority,[73] be appropriately resourced and employ qualified personnel.[74] State authorities should establish, implement and enforce science- and risk-based regulatory requirements that encourage and promote positive food safety outcomes and establish and maintain arrangements with relevant organisations such as officially recognised inspection, audit, certification and accreditation bodies.[74] Compliance and enforcement programmes should be designed to enable a competent authority to take corrective remedial action, from education to sanctions, alongside maintaining public transparency.[74]

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South Africa

Food fortification

South Africa introduced a Food Fortification Programme in 2003 after a National Food Consumption Survey in 1999 found that one in two children aged between one and nine did not meet half of their daily requirements for specific nutrients.[155] The fortification regulations borne of the Program repeal regulations on the enrichment of maize meal which were promogulated in 1979.

Two regulations under South Africa's Foodstuffs, Cosmetics and Disinfectants Act (FCD Act) 1972[156] mandate fortification. The first are the FCD Act Regulations ***Relating to the Fortification of Certain Foodstuffs No. 504 of 2003***[157] (amended by No. 1206 of 2008[158]) which mandate the fortification of wheat flour, wheat bread, maize meal and unsifted maize meal with vitamins A, B1, B2, B3 and B6, folic acid, iron and zinc.[155] Second, the FCD Act ***Regulations Relating to Food Grade Salt No. 184 of 2007***[159] which mandate the iodisation of food-grade salt but which does not apply to low sodium salt.

Further, the ***National Food and Nutrition Security Plan for South Africa 2018-2023***[155] includes an intervention to fortify porridge for specific populations and notes that biofortification should be explored further in South Africa. The Plan also notes areas of 'good progress' including reductions in fatalities of severe acute malnutrition in young children, reduced vitamin A deficiency, lower anaemia and iron-deficiency anaemia, and a decrease in wasting and being underweight in young children.

Responsibilities and regulatory governance for nutrition labelling

In South Africa, the Minister for Health is responsible for regulating food, including labelling, and the process of nutrition labelling regulation design and drafting is regarded to be strong. Several divisions of the Department of Health (DoH) and other relevant departments are involved in the process of nutrition labelling, including the Department of Planning, Monitoring and Evaluation, which conducts socio-economic impact analyses of new labelling regulations and monitors and evaluates regulations once made. Scientific evidence informs regulation, in the form of local data (where available) and international best practices and standards. Further, all draft regulations are published for public comment and all stakeholders are engaged in the process.

Administration of all food regulation is assigned by the DoH to local municipalities and food health inspectors at ports of entry, an approach that can be problematic as some communities lack the resources to appropriately enforce regulations and rely on self-regulation,[160] making it essentially a ***post-market surveillance system.*** Evaluation is referred to in some strategic plans, and it is understood from a respondent that academia often monitors and evaluates the effectiveness of nutrition policy. Clear enforcement regimes are also laid out in labelling and fortification regulations, and the DoH can authorise officers to enter and inspect premises and sample products and enforce increasing penalties depending on the number of offences committed under the FCD Act.

More generally, survey and interview responses indicated that while nutrition labelling regulation is strong, its implementation, monitoring and evaluation are inadequate, and food labelling responsibilities are disjointed across government departments. For example, inspectors do not have the capacity and are not well trained to monitor labels, which is done at the retail or marketplace level, and inspectors' travel allowances are insufficient to allow travel to manufacturers or laboratories within large jurisdictions, making the inspection or testing of samples unfeasible. One respondent suggested that to be more effective, the monitoring of labels should take place at the production level instead of retail and market levels, which would add pre-market surveillance to the existing post-market surveillance.

It was noted by respondents that consumer awareness of food labelling is low, that consumers do not tend to read labels, and that their food choices are largely driven by product cost and taste. Consumer awareness of food fortification logos has also dropped from 'high' to 'low' since they were introduced (while not reported, we assume this is because of a reduction in consumer awareness campaigns that were conducted when the logos were introduced). This aligns with a 2017 report that showed that in two provinces, only 37% and 44% of respondents reported ever seeing South Africa's food fortification logo, and of those who saw the logo, nearly 80% and 65% reported positive attributes, and 57% and 42% noted that the logo influenced their decision to buy fortified food.[161]

Structure of nutrition labelling laws

South Africa's nutrition labelling regulatory regime is structured as follows:

- *FCD Act (as amended to 2009)*[156] sets out offences for false and misleading labelling and gives the Minister for Health the power to regulate food, including labelling.
- *FCD Act Regulations:*
  - *Relating to the Fortification of Certain Foodstuffs No. 504 of 2003*[157] (amended by No. 1206 of 2008[158]) sets out specific fortification claims and logos and requires detail in nutrient declarations on fortified foods in addition to mandating fortification as outlined above. Manufacturers or importers of food vehicles can seek exemption from labelling provisions.
  - *Relating to Food Grade Salt No. 184 of 2007*[159] sets out a salt-specific fortification claim and logo and requires detail in nutrient declarations on fortified foods, in addition to the naming of iodised food-grade salt. The Regulations also specify that salt be sampled to monitor compliance and set out requirements for batch analysis for quality control purposes. Exemption from labelling requirements can also be sought.
  - *Relating to the Labelling and Advertising of Foodstuffs No. 146 of 2010*[162] sets out the requirements for nutrient declarations, nutrition and health claims and general food labelling requirements (e.g., ingredient list, name of food, and label letter height and language/s). The Regulations also prohibit false and misleading labelling and apply to fortified foods in addition to the specific fortification and salt regulations above.
- *Guidelines Applicable to the Regulations Relating to the Labelling and Advertising of Foodstuffs (R.146 of 1 March 2010) for Compliance Purposes*[163]

Several draft regulations under the FCD Act related to labelling have also been published by the government for public comment but do not appear to have been promulgated yet:

- Draft: FCD Act Regulations Relating to the Labelling and Advertising of Foods: Amendment No. R. 429 of 2014[164] covered nutrient declarations, claims, and a FOPNL, along with the use of the fortification logo.
- Draft: FCD Act Regulations Relating to the Fortification of Certain Foodstuffs No. 217 of 2016[165] covered a fortification FOPNL, general fortification, and health claims.
- Draft for public comment by 30 April 2023: FCD Act Regulations Relating to the Labelling and Advertising of Foodstuffs No. R. 2986 31 January 2023[166] – details of this most recent regulation published in 2023) are below under Nutrition Labels.

Policy context and objectives

While regulations themselves do not specify clear objectives, an interviewee noted that the DoH ensures any labelling regulations align with NCD and broader food and nutrition security policies. The double burden of under- and over-nutrition is also acknowledged in ***South Africa's National Food and Nutrition Security Plan 2018-2023.***[155] This Plan acknowledges that "the complex interconnectivity [of food control] requires a collective effort in the development, implementation, and enforcement" and that effective food control requires food regulation, a policy and institutional framework, food inspection and monitoring, laboratory services and information, and should involve and inform all stakeholders.

There is also evidence that South Africa's nutrition labelling regulations seek to address both over- and under-nutrition as draft food labelling regulations would introduce FOPNL for unhealthy foods, adding to existing fortification logos.

Nutrition labels

Nutrient declarations are mandatory where nutrition claims are made and for fortified foods and iodised salt. Declarations are voluntary for all other foods.

Nutrition and health claims are voluntary (with conditions and some prohibited claims), along with fortification claims for iodised salt, maize meal, wheat flour, and foods that are "fortified for better health" provided the food is fortified per relevant regulations.

Supplementary nutrition information: Four official fortification logos are voluntary if foods are fortified in line with regulations: "Iodated for better health", "Fortified for Better Health", "Manufactured with fortified maize meal for better health", and "Manufactured with fortified wheat flour for better health".[158]

The government released draft food labelling regulations in April 2023 to update requirements for nutrient declarations (to be mandatory for nearly all products, including products that are mandatorily fortified), nutrition and health claims (imposing additional criteria for making voluntary nutrition and health claims, including the use of a nutrient profiling model to screen foods for eligibility), and enrichment of food (specifying what and how much of any vitamin or mineral nutrient can be added per serve, and that foods required to bear the FOPNL cannot be enriched). The draft legislation would also create a new mandatory front-of-pack warning label (FOPNL) for foods high in salt, sugar, saturated fat and/or containing artificial sweeteners. This would add to South Africa's official voluntary fortification logos for salt, maize meal, and wheat flour, and likely follows the commitment to investigate and establish an appropriate educational tool for front-of-pack labels (and meals in restaurants) in the Strategy for the Prevention and Control of Obesity in South Africa 2015-2020, which takes into consideration populations with low literacy.[167]

Recommendations to reform nutrition labelling regulations to enable LSFF

- If draft ***labelling regulations*** that are out for comment until the end of April 2023 are implemented, South Africa's labelling regulations would come into line with best practice – making them mandatory for nearly all pre-packaged foods.
- While ***regulatory governance*** appears to cover key aspects, such as authority, clear enforcement regimes, and responsibility for monitoring, in practice, several aspects of regulatory governance can be improved, for example, through ensuring adequate resources, training and capacity at all levels to implement, monitor, test products/samples, and enforce regulations. This could cover provinces, local municipalities and food health inspectors at ports that are assigned the administration role for all food labelling and who need to manage multiple competing priorities including administration of more time sensitive food safety administration. Pre-market approvals should also be considered (even if via a self-declaration process) rather than relying on post-market surveillance to ensure regulatory compliance – which would also assist in general monitoring and evaluation of regulations by providing better baseline data. The evaluation of regulations and the processes for evaluation (beyond this being the responsibility of the Department of Planning, Monitoring and Evaluation) could be clarified in publicly available documents. Clearer roles and responsibilities and/or improved coordination across departments could also improve regulatory effectiveness and efficiency. We also heard that penalties were insufficient to incentivise compliance, so reviewing penalty adequacy should be considered in updated regulations.

Information sources and limitations

We undertook qualitative surveys and interviews in addition to a desktop regulatory review in South Africa. From these, little detail was identified on several aspects of regulatory governance, including how conflicts of interest are managed during regulatory drafting and design, monitoring and resourcing, and the transparency of evaluation and enforcement. Such information may sit outside of the regulatory documents reviewed.

Table 10 – SOUTH AFRICA – Summary of nutrition labelling regulations
Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	• Mandatory where nutrition claims are made,[162] for foods that are mandatorily fortified[158] and for salt where the "Iodated for better health" claim and logo are used.[159] Voluntary for all other foods.[162]	• General nutrition and health claims are voluntary,[162] along with the following fortification claims that can be used if fortified in line with regulations: - "Iodated for better health"[159] - "Fortified for better health" on the label or advertising material[158] reserved only for food that is identified and fortified per the regulations[157] - "Manufactured with fortified maize meal for better health" and "Manufactured with fortified wheat flour for better health" may be used for foodstuffs other than food prepared with and containing at least 90% of one or more of the identified food vehicles as an ingredient, excluding water.[158]	• The official fortification logos ("Iodated for better health", "Fortified for Better Health", "Manufactured with fortified maize meal for better health", "Manufactured with fortified wheat flour for better health") are voluntary (if fortified per relevant regulations – see "Nutrition and health claims" column).
Regulatory objective(s)	• None identified	• None identified	• None identified
Operative terms and conditions	• Where included, it must contain:[162] - "Typical nutrition information" as the title and be presented in tabular format unless otherwise indicated, with the order of nutrients per the example in point 1 of the Annexure; - The mass or volume of a single serving; - Minimum mandatory nutrition information per single serving and per 100gm (solids) or ml (fluids) – with the option to include protein, vitamins and minerals for which a Nutrient Reference Value (NRV) exists in a separate column; - Appropriate measurement unit for energy (always "kilojoules" or "kJ") or nutrient value (per the regulations); - Where a mineral is added to a food, the elemental mineral can only be included in the nutrition information, and vitamins and minerals present naturally or added in amounts ≥5% of the NRV for individuals 4 years+. • Additional requirements for nutrient declarations are at s50 and Annexure 2.[162] • Label lettering must be a minimum size (generally 1mm), for fortified foods, the height of lower-case letters must be 1mm in height or bigger size in the case of woven propylene packaging.[157] • For food-grade salt[159] and food and foodstuff manufactured with fortified wheat flour or maize meal[158] the nutrition information must be printed in letters ≥1mm high for lowercase (bigger for polypropylene packaging), the fortification amount per serving (except for iodised salt) and per 100 gm must also be declared, with the declaration printed on the back or side panel of food vehicles or foodstuffs. • In general, labels must be in English and where possible one other official language of South Africa and visible. Unless stipulated otherwise, label information should be ≥1mm in height for lower-case letters. Smaller sizes apply to small packages.[162]	• Certain claims are prohibited (whether in words, logos, pictorials, e.g., implying a food has health-giving properties aside from regulated fortification logos)[164] and nutrient content claims and comparative claims must meet specified conditions, e.g., to claim to be a 'source of', 'high in' or 'very high in' a vitamin or mineral it must be present in varying minimum percentages of an NRV). Antioxidant claims are subject to approval.[162] • The claim "Iodated for better health" must be printed in a prominent position on the main panel in bold print against a contrasting or clear background on all packaging and be visible, easily legible and indelible.[159] • Nutrient content claims may be used in addition to the word 'fortified' on a label only where a micronutrient other than the specified fortificants is added to a food vehicle; provided the conditions of the specific nutrient content claim are met.[157]	• The format and design of the logos are specified in the respective regulations which provide that logos must be:[159 158] printed in a prominent position on the main panel in bold print against a contrasting or clear background on all packaging; clearly visible, easily legible and indelible; and ≥25 mm for paper and plastic packaging and ≥100 mm for woven polypropylene packaging; and be printed in monochrome or colours as specified.

Regulatory governance	
Drafting regulatory rules and scheme design	• Under the FCD Act, the Minister of Health signs off on food labelling regulations,[156] although various DoH divisions and other departments are involved in regulatory drafting. [SA002-I] [SA001-S] The DoH's Food Control Division conceptualises, drafts and acts as the custodian of food labelling regulations, and ensures alignment with other NCD and broader food and nutrition policies [SA001-I]; the Department of Nutrition informs and conceptualises the information and research underpinning food labelling regulations [SA002-I]; and the Department of Planning, Monitoring and Evaluation monitors and evaluates regulations once made [SA001-S], and conducts socio-economic impact analyses of new labelling regulations. • Regulations are informed by national level research if available or best practice (including other countries' experiences, normative guidance from the WHO, and Codex). [SA001-I, SA001-S] • All stakeholders are consulted and draft legislation is published for public comment for three months and the government notifies the WTO of the legislation. [SA001-S] For example, the process to establish mandatory fortification legislation commenced in 1998 and involved ensuring industry was willing and able to implement (for example, concerns about the changes in product stability and use of existing packaging) with legislation promulgated in 2003. [SA002-I]
Administration	• Under the FCD Act, the Minister for Health may prescribe powers of inspectors and a local authority can be given authorisation to enforce the Act in its jurisdiction.[156] Respondents also noted that: - Administration of all food regulation is assigned by the DoH to provinces and local municipalities and food health inspectors at ports of entry. This approach can be problematic as some communities lack the funding and resources to appropriately enforce regulations leaving large gaps and a reliance on self-regulation.[160] This view was confirmed by respondents who indicated that inspectors, who are also responsible for food safety and hygiene inspections and compliance within their jurisdictions, tend to be under-resourced, have limited budgets, and don't necessarily receive required training. For example, inspectors' travel allowances are insufficient to allow travel to manufacturers or laboratories within large jurisdictions, making inspection or testing of samples at these locations unfeasible. [SA001-I, SA002-I] - Responsibilities are viewed as disjointed across departments [SA001-S] and implementation, monitoring, and evaluating is viewed as inadequate. [SA001-I] • The Food Control Division acts as South Africa's National Contact Point for the joint FAO/WHO Codex Alimentarius Commission; International Food Safety Authorities Network (INFOSAN) and the European Union Rapid Alert System for Food and Feed (RASFF). • Under the Regulations re the Fortification of Certain Foodstuffs[157] any manufacturer or importer of food can seek exemption from labelling provisions by applying in writing to the Nutrition Directorate. Registration with the DoH is required for fortification mix manufacturers, importers and suppliers (with set requirements). Other requirements are specified for manufacturers, importers or sellers of foodstuffs identified as food vehicles such as keeping monthly records of the amount of fortification mixes and total production of food vehicles required to be fortified each month as indicated by the DoH. • Under the Regulations re Food Grade Salt[159] processors, packers or importers of food-grade salt products packed in quantities ≤ 250 g can apply in writing to the DoH to be exempted from iodisation requirements including sampling.
Monitoring	• See details under Administration re the FCD Act. • Respondents stated that inspectors do not have the capacity nor are they well trained to monitor labels at the retail/marketplace level [SA002-I] making monitoring ineffective as a method to ensure compliance since industry does not receive feedback on compliance. [SA002-I] It was suggested that monitoring should take place at production. [SA002-I] • Under the Regulations re Food Grade Salt, food grade, iodised salt is sampled for compliance monitoring purposes to ensure correct levels of iodisation at the processing and packaging point[159] in accordance with the Codex Standard for Food-Grade Salt (CX STAN 1 50-1 985).[168] • Under the Regulations re Labelling and Advertising of Foodstuffs:[162] - All information about the requirements of the Regulations Relating to the Labelling and Advertising of Foodstuffs must be kept on record by the manufacturer, importer, or seller who must be able to produce the documentation within two working days on request by an inspector or employee of the DoH, otherwise they commit an offence. - Information in the nutrient declaration that is required when a claim is made must be the real, typical values as determined by a reputable and accredited laboratory in accordance with the methods in the regulations, guidelines or Codex, and where not recommended, via an accredited method. • Under the Guidelines Applicable to the Regulations Relating to the Labelling and Advertising of Foodstuffs:[163] - Analysis is required to verify that a claim is specified – a manufacturer must establish an audit system for all quantitative nutritional claims to substantiate a claim within 12 months of a product being available for sale or any change in a product formulation, with claims verified by analysis for each nutrient every three years – and when not making a claim (nutritional information should be verified every three years for products with no claims and where nutrient information is not obtained from reputable international databases).
Evaluation	• A respondent stated that enforcement is inefficient due to low inspector knowledge and ability and because monitoring takes place at the retail/marketplace level; and that the monitoring and evaluation of the effectiveness of nutrition policies is often done by academia (for example, small salt intake studies) but in general, the evaluation of nutrition labelling is inadequate. [SA001-I/S] • The National Food and Nutrition Security Plan refers to an independent evaluation of nutrition interventions for children under five: "2.4.2.15 The evaluation compared South Africa against five countries that have made substantial progress towards enhanced food security and nutritional status – Brazil, Columbia, Malaysia, Malawi, and Mozambique. All five countries were found to have a fivefold competitive edge over South Africa, and had the following characteristics in common: (a) a single national leadership and governance structure for food security and nutrition; (b) a single national plan for food and nutrition security; (c) a single national budget for the implementation of food and nutrition security programmes; (d) a single national monitoring and evaluation system; (e) a single national set of indicators."[155]
Enforcement	• The FCD Act, details a clear enforcement regime with penalties for offences relating to labelling foodstuffs in a false and misleading manner. The regime allows, through the head (Director General) of the DoH, authorising various powers and duties to inspectors, including to enter and inspect premises and seize foodstuff that is suspected of contravening provisions under the Act (including regulations). A magistrate's court has the jurisdiction to impose any penalty provided under the Act and its regulations.[156] - Respondents indicated that complaints can be reported to district or municipality inspectors and that overall, enforcement tends to be greater on imported products at ports. [SA002-I] Laboratories face resourcing challenges such as a lack of consumables, which impact their ability to analyse samples. These resourcing issues (along with those concerning officers outlined under Administration, can result in enforcement taking a low priority. [SA001-I, SA002-I] Further, in general fines are small so they are not usually contested [SA002-I] and nutrition labelling is not well enforced. [SA001-S] • Under the Regulations re Fortification of Certain Foodstuffs, any person who uses the official fortification logo on labels or in advertisements for foods other than in accordance with the regulations is guilty of an offence.[157] • Under the Regulations re Food Grade Salt, any person who uses the official iodation health claim and logo on labels or in advertisements for salt other than in accordance with the regulations is guilty of an offence.[159] • Annual national fortification sweeps should also occur and are budgeted for. [SA002-I]

Section references

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Thailand

Food fortification

Thailand mandates that edible salt is iodised under its Notification of the Ministry of Public Health Re: Edible Salt 2011[169] except for specific foods, such as foods for people who need to restrict iodine consumption, electrolyte drinks, and foods that use less than 1% of salt as an ingredient or have less than 1% salt in a finished product, for example, rice can be voluntarily fortified with vitamins B1, B2 and B3.[170]

Responsibilities for regulatory governance for nutrition labelling

Thailand's food industry is governed by the Food Act of 1979, and subsequent laws stipulated by the Ministry of Public Health (MoPH). The Food Act authorises the MoPH's Food and Drug Administration (FDA) to implement and administer the Food Act. The Act also sets out the role of the Food Commission (which includes the Secretary General of the FDA and Permanent Secretary of the MoPH) in advising the Minister on regulations related to the Minister's powers (including food labelling), product withdrawal and appeals regarding licences, among other things.

Manufacturers and importers must obtain licenses from the FDA's Food Bureau before manufacturing and/or importing food into Thailand to ensure foods meet relevant standards. Product and nutrition labelling is reviewed as part of the licensing process to ensure compliance. Licences are valid until 31 December three years from their issue date. An extension can be sought before licence expiry, with a right to appeal if rejected. The FDA must also approve any proposed advertising of a food, ensuring a pre- and post-market surveillance system operates for foods in Thailand.

However, the Nutrition Promotion Foundation under the Institute of Nutrition of Mahidol University (INMU), or other relevant authorised agencies, conduct inspections and certifications required for the 'Healthier Choice' FOPNL. Of note, the INMU – the focal point for experts in food and nutrition – was established in 1977 to strengthen the National Food and Nutrition Act (the Food Act) under the public university's (Mahidol University) supervision, given its expertise in public health and medicine.

The FDA Inspection Division conducts post-market control of foods including compliance monitoring and surveillance to check that foods comply with national food safety and quality standards. This monitoring includes inspections of food factories and premises and the sampling of products for laboratory testing. Samples may be analysed for nutritional value and standard conformity. Technical guidance on appropriate food production, handling and storage processes may be given during the monitoring process. If violations occur, products can be recalled, and manufacturers can be prosecuted depending on the degree of violation. Detail on sanctions is outlined further in the ***Enforcement*** section of the table below.

Structure of nutrition labelling laws

Thailand's nutrition labelling regulatory regime is structured as follows:

- *The Food Act B.E. 2522 (1979)*[171] sets out the powers to regulate food labelling including to promulgate Ministerial Regulations for labelling and the FDA's requirements for food licensing. The Act also prohibits false and deceptive food labelling and advertisements.
- *Notifications of the MoPH:*
  - *No. 182 of B.E. 2541 (1998) and No. 219 of B.R. 2544 (2001) Re: Nutrition Labelling*[172] sets out requirements for nutrition labelling, including nutrient declarations (nutrition facts) and nutrition and health claims. Conditions for comparative nutrient claims of 'added, fortified, or enriched' are specified. Requirements are also included around process controls for the addition or mixing of iodine. ***Note that the Notification of the Ministry of Public Health (No. 219) B.E. 2544 (2001) Re: Nutrition Labelling (No. 2) is not included but specifies dual display of nutrition declaration if a product is sold subject to mixing with other ingredients or further processing pre-consumption.***
  - *No. 367 B.E. 2557 (2014) Re: Labelling of Pre-packaged Foods*[173] sets out general labelling requirements for pre-packaged foods (ingredients) excluding foods sold by food hawkers, or that are for sale in hotels etc., and prohibits false, misleading and/or deceptive labelling.
  - *Re: Edible Salt 2011*[169] mandates salt iodisation and required labelling of iodised salt. The Notification exempts edible salt from required labelling under the ***"Notification of the Ministry of Public Health, Re: Label"***, but the Notification does not specify any number or year making it unclear.
  - *No.373 B.E. 2559 (2016) Re: The Display of Nutrition Symbol on Food Label*[174] establishes the "Healthier Choice" nutrition logo.
  - *No. 394 B.E.2561 (2018) Re: Food products Required to bear Nutrition Labelling and Guideline Daily Amounts, GDAs Labelling*[175] establishes the FOPNL, required format of nutrition declaration (nutrition facts) and a consumption warning.

As an ASEAN Member State, a set of non-binding regional guidelines, principles and standards apply to Thailand's labelling laws and/or fortification as indicated, though we found little by way of specific regional labelling regulation that influences ASEAN Member States' national labelling regulations:

- *ASEAN Guidelines on Promoting Responsible investment in Food, Agriculture and Forestry 2018*[72] propose considerations including supporting food fortification to improve nutrition security and promote harmonisation of standards and regulations while allowing national flexibility.
- *ASEAN Regional Guidelines on Food Security and Nutrition 2017*[73] serve as a reference guide to develop best practice policy that promotes nutrition and food security (including food fortification policies to address malnutrition and micronutrient deficiencies). The guidelines aim to build stronger cooperation and integration on food security and nutrition across the ASEAN region but few specifics on fortification are included.
- *ASEAN Principles and Guidelines for National Food Control Systems 2014*[74] is aligned with Codex principles and guidelines For National Food Control Systems CAC/GL 82-2013 and guides on developing food legislation that promotes food safety, including that national competent authority/ies should establish, implement, evaluate, and enforce evidence- and risk-based regulatory requirements.
- *ASEAN General Standards for the Labelling of Prepackaged Food 2016*[75] that adopt the Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985).

Policy context and objectives

Thailand's National Plan of Action on Nutrition 2019 – 2023 focused on prioritising and solving malnutrition in all its forms including undernutrition and overweight and obesity. Current nutrition labelling initiatives such as the Guideline Daily Amount and Healthier Choice Logo on the front-of-pack reflect Thailand's focus on nutrition labelling initiatives to address the number of overweight people in the population and obesity. Logos focusing on over-nutrition appear to have been prioritised over fortification to address under-nutrition, with salt the only product that is mandatorily fortified and for which the specific "iodized edible salt" claim can be made. More broadly, Thailand's labelling regulations are focused on providing information and useful nutrition facts to people, and consumer protection.

As an ASEAN Member State, Thailand must also evaluate new or existing regulation to ensure it is compatible with the ASEAN nutrition and food security policy.[73]

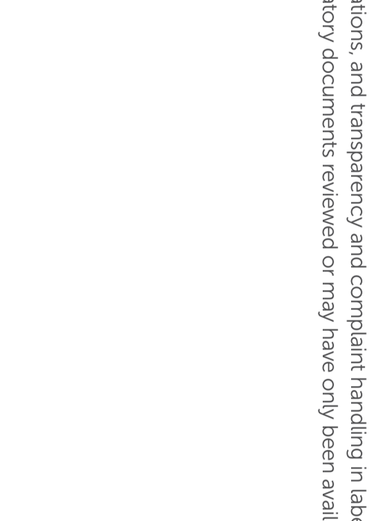
Nutrition labels

Nutrient declarations are mandatory for certain categories of food. These include foods with a specific nutritional claim, foods that use nutritional values in sales promotions, foods that target a group of consumers (e.g., students or the elderly), and other foods specified by the FDA. The FDA's specified foods are a range of specific food categories (snacks, chocolates, bakery products, and ready meals) which are required to display the mandatory 'Guideline Daily Amount' FOPNL, and consequently require a mandatory nutrient declaration to support this display.

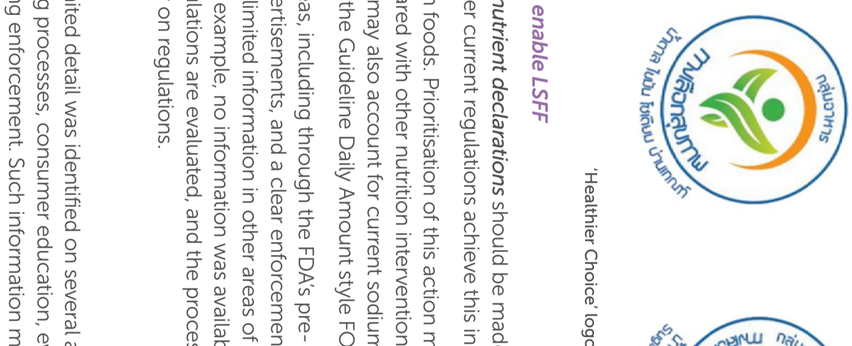
Nutrition and health claims: Nutrition claims are voluntary but are subject to conditions that are similar to Codex and US Food and Drug Administration standards. Nutrient function claims, which are claims about the function of a nutrient to the human body such as "Vitamin B1 and vitamin B12 assist in function of nervous system", are subject to FDA approval. Comparative claims of '...enriched, fortified' can be claimed for vitamins and minerals (excluding sodium), dietary fibre or protein only when the per 100g or mL of food when compared to the reference food: a) has a higher nutrient content; b) when the quantity difference is not less than 10% of Thai RDI for people aged six or over; and c) the reference food is displayed. Other health claims are not allowed on food products in Thailand.

Edible iodised salt must include the statement 'Iodized edible salt' displayed adjacent to the name of the food product. Products that contain non-iodised salt should include a statement 'for people who need to limit iodine consumption'.

Supplementary nutrition information: No standalone fortification logo was identified in the review, with the iodisation statement and enriched and fortified claims the only data linking nutrition labelling to fortification. A ***'Guideline Daily Amount' style FOPNL*** label is mandatory for specific food categories and voluntary for other foods. Foods bearing the Guideline Daily Amount label are also required to display the statement 'Consume less and exercise for better health'. There is also a voluntary ***'Healthier Choice' FOPNL*** that can be applied for where a product meets nutrition criteria (for energy, fat, sugar and sodium) and is considered a healthier choice within certain categories.



'Guideline Daily Amount' style FOPNL[175]



'Healthier Choice' logo[176]

Recommendations to reform nutrition labelling regulations to enable LSFF

- To align Thailand with Codex standards and best practices, ***nutrient declarations*** should be made mandatory for all processed foods with limited exceptions. It is unclear whether current regulations achieve this in practice.
- Thailand could consider a ***mandatory salt iodisation logo*** on foods. Prioritisation of this action may depend on the priority of salt iodisation to address iodine deficiency compared with other nutrition interventions, given the additional regulatory burden it will require to implement. Prioritisation may also account for current sodium intake levels that are being partly addressed by the sodium declaration as part of the Guideline Daily Amount style FOPNL.
- ***Regulatory governance*** appears strong across many key areas, including through the FDA's pre- and post-market surveillance of food products, the pre-approval of food advertisements, and a clear enforcement regime administered through the FDA's Competent Officers. However, we found limited information in other areas of regulatory governance – which would ideally be publicly available. For example, no information was available on consumer education for labelling, in particular for SNI, about how regulations are evaluated, and the process for regulatory drafting beyond the Food Commission advising the Minister on regulations.

Information sources and limitations

We only undertook a desktop regulatory review in Thailand. Limited detail was identified on several aspects of regulatory governance, including resourcing, regulatory design and drafting processes, consumer education, evaluation of existing regulations, and transparency and complaint handling in labelling enforcement. Such information may sit outside of the regulatory documents reviewed or may have only been available in information published in the Thai language.

Table 11 – THAILAND – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory framework	• Mandatory for foods: with a nutrition claim; that use food values in their promotion; which define consumer groups (e.g., elderly); foods notified by the FDA and approved by the Food Committee (but excludes food prescribed by the Ministry of Public Health re labelling such as infant food etc.); and processed foods that require the FOPNL logo.[172]	• Voluntary nutrition claims – nutrient content claims, comparative claims (including 'fortified') and nutrient function claims (e.g., "Vitamin B1 and vitamin B12 assist in function of nervous system").[172] • Voluntary health claims – 'healthy, healthful, healthiness, health'.[172] • Certain claims are prohibited.[172] • Mandatory salt iodisation statement and fortification statement for plant stanol/sterol.[172]	• We are unaware of a standalone fortification logo. • Mandatory 'Guideline Daily Amount'-style FOPNL logo for a range of processed foods; voluntary for other foods.[175] • Voluntary Nutrition Symbol (a "Healthier Choice" nutritional logo).[174]
Regulatory objective(s)	• To provide information and useful nutrition facts to people and to protect consumers.[172]	• To provide information and useful nutrition facts to people, and to protect consumers.[172]	• Guideline Daily Amount FOPNL to benefit consumers and support preventive measures to reduce nutritional problems.[175] • "Healthier Choice Logo" to assist consumers in decision making for balanced nutrition to prevent over-nutrition and NCDs.[174]
Operative terms and conditions	• Expressed in the required format (varies for container size, e.g., full-form, short-form and dual nutrition display box and number of nutrients) and colour with contrasting text for reading, text size proportional to box area, quantity per serve and per serve per container, expressed in RDIs and kCal, g or ml per the appendices or nutrition value per 100m/gm where no serving size can be determined. Reference serving sizes specified.[172] • Must include:[172] – total energy kcal and energy from fat kcal. – the quantity and % of RDI in g or mg for: total fat; saturated fat; cholesterol; protein; total carbohydrate; dietary fibre; sugar; sodium; vitamin A, B1 and B2; calcium, iron. – a second panel detailing energy demand for an individual of 2000 kcal per day, and the relevant nutrients they shall receive (e.g., fat, cholesterol). • Expressed in Thai, but a foreign language may be included and must conform to criteria and conditions (applies to nutrient and health claims).[172] • For processed foods requiring the FOPNL logo with GDAs:[175] the full format nutrition facts label or simplified format nutrition facts label is required; but where a nutrition claim is made, the full format facts label is required. • Cholesterol content must be displayed where >2mg per serve.[175] • General labelling requirements for pre-packaged foods:[173] must be in a prominent position, proportional (e.g., size requirements apply, not <2mm for product name, not <1mm for small labels and for texts re nutrients, nutrient values etc.) and readily legible; background label colour must contrast with the text colour for legibility.	• Nutrient content (e.g., 'low in', or 'source of'), comparative (e.g., 'less than or fewer' compared to a reference food), and nutrient function claims (e.g., reference to Thai RDIs for 6+ years) – are allowed but are subject to conditions. For example, comparative claims must specify the reference food and display the comparative nutrient or energy level increased or decreased to the reference food; nutrient function claims must be based on reliable scientific evidence; nutrient content and comparative claims must accord with specific conditions in the Notification.[172] – NB comparative claims of '...enriched, fortified' can be claimed for vitamins and minerals (excluding sodium), dietary fibre or protein provided that when compared to the reference food, per 100g or 100mL of food the nutrient content is higher and the difference of quantity is not less than 10% of the Thai RDI for 6+ years, and the reference food is displayed.[172] • Some claims are prohibited a nutrient function claim cannot be used if it leads consumers to think that consumption prevents or cures disease.[172] • Only foods that meet nutrient criteria can make claims such as 'low fat' or that express health such as 'healthy' e.g., per serve or 100 g/ml contain: sodium ≤360 mg; cholesterol ≤60 mg; and vitamin A, B1 or B2, protein, calcium, iron and dietary fibre ≥10% of the Thai RDI. • Edible iodised salt (as a food or ingredient) must be labelled with "Iodized edible salt" in Thai (but can also be in a foreign language) with letters of ≥5 mm height and legible attached with the food name, among other requirements. A similar fortification phrase exists for foods with added Phytosterols.[169] • Products that require the FOPNL logo must include "consume small amount and exercise for healthy condition" in bold, visible letters contrasting with the background and with the frame colour contrasting with the label colour.[175]	• Guideline Daily Amount (GDA) with summary indicators of energy (kCal), sugar (g), fat (g), sodium (mg), % of GDAs, and nutritional value and servings:[175] – Mandatory for e.g.: snacks; chocolate; bakery products; and semi – processed foods including noodles. Not required where such foods are sold directly to consumers. – GDAs shall be: Four figures of vertical cylindrical shape attached to display energy value, sugar, fat, and sodium content; cylinder frames must be black, dark blue or white, contrasting to the label background; the cylinder background must be white; each line in cylinders must be black or dark blue and in the same letter colour as that in cylinders; they must be displayed in a clear, prominent position at front side of label and be readily legible. – Must also display: % of GDAs; 'nutritional value per' (easily understood unit e.g., per cup/packet); 'should divide to eat...times' (the no. of serves if >1 serve per pack). – For some products, where the FOP is <65cm^2, a nutrient detective mobile application can be applied. • "Healthier Choice Logo" must comply with the format and technical requirement set by the Sub-Committee of Developing and Promoting the Use of Simplified Nutrition Symbol.[174]

Regulatory governance	
Drafting regulatory rules and scheme design	• Under the Food Act, the Minister of Public Health has specific powers concerning foods (such as prescribing controlled foods, and standards, and determining which foods require labels, the label text and conditions, including their display). The Food Commission has the power and duty to offer advice and opinions to the Minister on regulations related to the Minister's powers.[171] • Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States should provide clear and effective regulation that promotes food security and nutrition,[73] engage stakeholders in regulatory development to ensure transparency and that views are considered,[74] and consider Codex standards, recommendations and guidelines.[74] All aspects of a national food control system should be transparent and open to public scrutiny while respecting legal requirements to protect confidential information.[74] Decision making should be evidence-based, and competent authority/ies and all officials should be free of improper or undue influence or conflict of interest.[74]
Administration	• Under the Food Act the FDA issues licences for the importation of food, and for specific food products, to ensure compliance with Thai standards before they enter the market. The application and process are outlined in the regulations and include a review of a product's nutrition labelling. Licences are valid until 31 December three years from their date of issue, but extensions can be sought. The FDA must also pre-approve any food advertisement for quality, usefulness, or indication.[171] • Under the Notification re Nutrition Labelling[172] for food producers and importers that hold food registration licences and food labelling approvals under the Food Act B.E. 2522 are provided time to update their licences and approvals to accord with this Notification, and for labels printed pre-enforcement of this Notification to be used for at most one year from enforcement. • Under the Notification re Display of Nutrition Symbol on Food Label, food manufacturers, importers and distributors can only display the voluntary Healthier Choice nutrition symbol on a food label after it has been inspected and certified by The Nutrition Promotion Foundation under the Institute of Nutrition of Mahidol University, or other relevant agencies authorised under the National Food Committee.[174] • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems, Member States' independent statutory bodies should retain authority for policy administration[73] and legislation should provide the authority with the power and mechanisms to: establish, monitor and enforce standards; implement regulations; perform activities to verify, investigate, and enforce regulatory compliance; and apply sanctions and/or penalties.[74]
Monitoring	• Under the Food Act Competent Officers can enter premises to inspect and carry out other duties in connection with enforcing the Act (see Enforcement), and pre- and post-market authorisation via licences allows monitoring (see Administration).[171] • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' national food control systems should be transparent and open to public scrutiny, while respecting the need to protect confidential information.[74] To assess effectiveness and suitability to achieve objectives, the system should be subject to ongoing monitoring and review against documented criteria, and consider scientific evidence, and non-compliance.[74] Legislation and guidelines should also include provisions to monitor dietary consumption.[73]
Evaluation	• Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States' national food control systems should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is achieving its objectives.[74] Member States should also evaluate new or existing regulation to ensure it is compatible with nutrition and food security policy.[73]
Enforcement	• Under the Food Act:[171] – The FDA may order food producers, importers, or distributors to stop advertising if they do not have a licence or to stop producing, importing, distributing or advertising a food that the Food Commission deems does not have the usefulness or quality of indication advertised. – The FDA's Competent Officers have powers to enter and inspect premises and seize food and containers that do not accord with the Act for analysis. – Where a licensee violates the Act, ministerial regulations or notifications issued under the Act, the authority can suspend the licence pending judgment, and revoke the licence if final judgment is reached against the licensee. For example, if a licensee violates notifications for labelling they are subject to a fine of ≤30,000 Thai baht. If a licensee doesn't follow the orders of the Food Commission or obstructs a competent officer, they are liable to imprisonment of ≤1 month or a fine of ≤1,000 Thai baht or both. Penalties are also provided if FDA orders are not followed regarding halting advertising. • Under ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' independent statutory bodies should retain enforcement authority,[73] be appropriately resourced and employ qualified personnel.[74] State authorities should establish, implement and enforce science- and risk-based regulatory requirements that encourage and promote positive food safety outcomes and establish and maintain arrangements with relevant organisations such as officially recognised inspection, audit, certification and accreditation bodies.[74] Compliance and enforcement programmes should be designed to enable a competent authority to take corrective remedial action, from education to sanctions, while maintaining public transparency.[74]

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Vietnam

Food Fortification

The Government of Vietnam mandates the fortification of specific foods with specific micronutrients through the ***Law on Food Safety***[177] which requires food producers to comply with Government regulations on the fortification of micronutrients to address deficiencies that impact public health at a population level or in a particular target group.

- ***Decree 9/2016/ND-CP Regulating Fortification of Micronutrients in Food***[178] ***specifies that:***
  - Edible salts and salts used for food processing must be fortified with iodine;
  - Wheat flour used for food processing must be fortified with iron and zinc;
  - Vegetable oils that contain soy oil, palm oil, rapeseed oil, and peanut oil must be fortified with vitamin A, except for vegetable oils used for food processing.

All such fortified foods must also meet relevant national technical and/or food safety regulations.

Where deficiencies are not deemed a public health problem, the Government of Vietnam allows the voluntary addition of micronutrients to supplemented food ***("ordinary foods added with healthy micro-nutrients and elements, such as vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics and substances having other biological activities") via the Circular No. 43/2014/TT-BYT Providing for Management of Functional Foods.***[179]

A separate Circular provides a list of micronutrients that can be used in food fortification and supplementation, for example, specifying sources of vitamin A.[180]

While now dated, Vietnam's ***National Plan of Action on Nutrition for 2012-2015***, includes activities to enhance food fortification (such as making regulations on fortifying foods, strengthening production, trading, and control of food quality) and issuing regulations on food nutrition labelling (by reviewing global regulations, issuing standards and building capacity for developing nutrition labelling).[181] No subsequent nutrition strategy was identified, aside from the ***National Action Plan on Food Systems Transformation toward Transparency, Responsibility and Sustainability in Vietnam by 2030***,[182] which only focuses on country of origin labelling, not nutrition labelling or fortification.

Responsibilities for regulatory governance for nutrition labelling

The Ministry of Health (MoH) has overall responsibility for setting nutrition labelling regulations in Vietnam and for micronutrients[183] as part of its role in coordinating food safety. Current labelling regulations focus largely on basic labelling (such as ingredients and the product name) and prohibit misleading labelling. Regulatory development is underway on nutrient declarations.

Regulatory governance, in particular the administration and monitoring of food safety and labelling laws across the supply chain, is shared among different ministries largely depending on the type of food. Most processed food products and packaging sit under the jurisdictions of the MoH through the Vietnamese Food Administration (VFA) and the ***Ministry of Industry and Trade (MOIT, e.g., for retail marketing)***. Meat and poultry, bulk commodities, dairy products, fresh fruits, and tree nuts are under the ***Ministry for Agriculture and Rural Development's (MARD)*** jurisdiction.[177] Similarly, the MoH is responsible for fortified foods but has reassigned responsibility to MOIT for wheat flour and vegetable oils fortified with micronutrients and to MARD for iodised salt.[178] Provincial/ Municipal Health Services/ Departments organise local implementation (per the Elaboration of Some Articles of the Law on Food Safety[183] along with the Ministry of Science and Technology leading the implementation of general goods labelling[184]). For example, we heard that the MoH's Institute of Public Health's (IPH) experts in nutrition and labelling are responsible for the local implementation and monitoring of food safety regulations in 19 southern provinces of Vietnam. [VIE002-S] The complexity in coordination across this system is expressed well in a World Bank report, ***"Although MOH is responsible for overall food safety, it does not have authority to direct the management of other ministries and departments involved in food safety management. This leads to more or less independent activities on food safety control by each ministry and, therefore, no comprehensive food control management system in the country. The role of MOH in this regard becomes one of coordinating and collating different reports."***[185]

Regulatory development is multisectoral and involves the WHO and National Institute of Nutrition, and stakeholder and public engagement. ***Pre-market surveillance of foods*** is conducted through food-specific ***self-declarations, certificates of food safety and through registration of advertising (including labelling) contents***. Self-declarations and advertising registrations are both publicly available on regulator websites (e.g., some authorisation requirements can be undertaken on the National ATTP Public Service Registration System, which also allows consumers to search registered food advertisements).

A system of food safety inspections and a range of penalties are in place to enforce laws as part of the ***post-market surveillance system***.

Structure of nutrition labelling laws

Legislation in Vietnam cascades down from laws (enacted by Vietnam's National Assembly), then decrees (issued by the Government) and lastly circulars (issued by ministries). In this context, Vietnam's nutrition labelling regulatory regime is structured as follows:

- *Law on Food Safety, 2010*[177] is the umbrella law that guides food safety, food production and trading, food import and export, food advertisements and labelling, and food testing and analysis.
  - *Decree 15/2018/ND-CP Elaboration of Some Articles of the Law of Food Safety*[183] sets out registration and certification requirements for food manufacturers and sellers in Vietnam and food inspection processes, and limits some advertising (including label) content.
- *Law on Advertising, 2012*[186] sets out requirements for advertising (including printed) products in Vietnam, including requiring foods or food additives to be advertised to hold a certificate of registration of quality, hygiene, and safety or to notify the competent state body that standards are met. The law also bans some advertisements, including advertising products that would have a negative effect on the health or normal development of children.
  - *Decree No. 181/2013/ND-CP on Elaboration of Some Articles of the Law on Advertising*[187] sets out requirements for advertisements for foods and food additives, including that they state "This product is not a medicine and is not a substitute for medicines".

As these regulations are not critical to nutrition labelling, we have not included details of regulatory governance in the table below.

- *Decree No. 43/2017/ND-CP on Goods Labelling*[184] (as amended by *Decree No. 111/2021/ND-CP*[188]) sets out general labelling requirements such as the name of goods, ingredients, lettering height, labelling in Vietnamese, with the MoST the implementing department alongside People's Committees that manage and inspect goods labelling in their jurisdictions. Decree No. 111 also requires that nutritional composition and values are labelled according to MOH guidance for processed and pre-packaged foods.
- *Circular No. 43/2014/TT-BYT Providing for Management of Functional Foods*[179] sets out general requirements and requirements to make nutrition and health claims for supplemented foods such as voluntarily fortified foods.
- *Circular No. 34/2014 on detailed guidelines on labelling of packed foods, food additives, and food processing aids*[189] sets out general labelling requirements (including that ingredients are listed in ascending order of weight or weight proportion, the product name, and size of lettering), conditions for nutrient content claims, and proscribes misleading or deceptive labelling.
- *Draft Circular – Guidelines for nutrition labelling of foods G/TBT/N/VNM/219* sets out a mandatory nutrient declaration for food produced and imported into Vietnam. In May 2023, the MoH stated that it has accepted a range of comments on the draft (including those relating to nutrient reference values (NRVs) and mandatory requirements to label foods with percentages of NRVs) and will conduct further technical discussions with the government and industry to progress the draft.[180] It is anticipated that this new law will be passed in 2023 and come into force in 2024 and 2025.

As an ASEAN Member State, a set of non-binding regional guidelines, principles and standards apply to Vietnam's labelling laws and/or fortification as indicated, though we found little by way of specific regional labelling regulation that influences ASEAN Member States' national labelling regulations:

- *ASEAN Guidelines on Promoting Responsible investment in Food, Agriculture and Forestry 2018*[72] propose considerations including supporting food fortification to improve nutrition security and promote harmonisation of standards and regulations while allowing national flexibility.
- *ASEAN Regional Guidelines on Food Security and Nutrition 2017*[73] serve as a reference guide to develop best practice policy that promotes nutrition and food security (including food fortification policies to address malnutrition and micronutrient deficiencies). The guidelines aim to build stronger cooperation and integration on food security and nutrition across the ASEAN region but few specifics on fortification are included.
- *ASEAN Principles and Guidelines for National Food Control Systems 2014*[74] is aligned with Codex principles and guidelines for National Food Control Systems CAC/GL 82-2013 and guides on developing food legislation that promotes food safety, including that national competent authority/ies should establish, implement, evaluate, and enforce evidence- and risk-based regulatory requirements.
- *ASEAN General Standards for the Labelling of Prepackaged Food 2016*[75] that adopt the Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985).

Policy context and objectives

The Law on Food Safety outlines broad aims, including producing high-quality, safe food, fortifying food, prioritising consumer access to information on food safety, and the need to issue specific regulations on food labelling based on socioeconomic conditions.[177] The draft Circular to introduce mandatory nutrient declarations aims to ensure accuracy and make foods' nutritional value easy to understand for consumers. Regulatory development takes into consideration existing laws and national policies, trade agreements, international reference documents (from Codex and the WHO), data from national nutrition surveys, and the food industry's capacity to implement the policy, demonstrating the desire to create coherent regulations. Regulatory administration by way of self-declarations for most foods and post-market surveillance operates as a single system considering both food safety and labelling.

Separately we heard from respondents that promoting healthier diets is a priority in developing nutrition labelling regulations, such as draft back-of-pack labelling regulations.

Nutrition labels

Nutrient declarations are not required by current legislation in Vietnam. However, in April 2022 the Vietnamese government issued a draft circular on nutrition labelling and notified the WTO. The government has received comments on this draft from stakeholders and is due to progress the law through the parliamentary process in 2023.

Voluntary nutrient content claims are permitted provided conditions are met, and ***voluntary health and nutrition claims for supplementary foods*** (voluntarily fortified foods as explained above under Food Fortification) provided minimum contents based on RNI are met. Claims that foods cure or treat diseases are prohibited. There are no standardised fortification claims beyond voluntarily fortified food being labelled as 'supplemented food'.

However, one interviewee indicated that the government reviews health claims. This may relate to the requirements to register the advertisements for some foods, including product labels, with the government.

Supplementary nutrition information: No regulation specific to SNI was identified, including any standalone fortification logo or FOPNL system.

Recommendations to reform nutrition labelling regulations to enable LSFF

- Ideally, the proposed Circular that would introduce mandatory ***nutrient declarations*** should mandate the inclusion of added vitamins and minerals.
- To help consumers more easily identify fortified foods beyond a label including the word 'fortified', voluntary but standardised ***fortification claims*** and voluntary or mandatory ***fortification logos*** could be considered for mandatorily fortified foods. We do not extend this recommendation to relevant voluntarily fortified foods at this stage given the lower public health significance of fortification in these products, and the potential to distract from the upcoming regulatory focus on implementing mandatory nutrient declarations.
- If ***claims regulations*** were updated, stipulations on health claims could be considered to improve regulations beyond the existing regulation for voluntarily fortified or supplemented foods (for example, including additional information on labels where appropriate, such as target groups, how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources where appropriate, and the importance of maintaining a healthy diet).
- The process for drafting nutrition labelling regulations is comprehensive, including the use of evidence and public consultation. It appears that authority for administering regulation is complex – which may be necessary in the Vietnamese context – but requires high levels of coordination for effective operation. It is unclear what consumer education takes place, or how well-resourced nutrition labelling monitoring and enforcement is. We also heard that no evaluation of regulations is planned. These elements could be considered to strengthen regulation. Given Vietnam also relies on a self-declaration system for foods, monitoring via inspections and adequate training for inspectors is crucial to enforce compliance.

Information sources and limitations

We undertook qualitative surveys and interviews in addition to a desktop regulatory review in Vietnam. From these, limited information was identified on the evaluation of regulations and resourcing of regulatory governance. Such information may sit outside of the regulatory documents reviewed or may have only been available in information published in Vietnamese.

Table 12 – VIETNAM – Summary of nutrition labelling regulations

Excludes draft regulations unless specified.

	Nutrient declaration	Nutrition and health claims	SNI
Regulatory form and substance			
Regulatory framework	No current regulation requiring nutrient declarations. • However, organisations and individuals labelling nutrition information are encouraged to follow requirements recommended by the CODEX Alimentarius Committee.[189] • In April 2022, Vietnam notified the WTO of an updated draft Circular that stipulates the requirements for mandatory nutrient declarations for foods produced, traded and imported for circulation in Vietnam excluding table salt, unpackaged foods and other foods such as single-ingredient foods. It includes an implementation roadmap (with implementation in 2024 and 2025, depending on the type of food).[190]	• Some voluntary nutrient content claims are permitted, with conditions.[189] • Voluntary claims for supplementary foods (i.e., voluntarily fortified foods) with conditions (e.g., meet a minimum amount).[179] • Some claims are prohibited, such as those stating that functional food cannot be advertised as to cause confusion with medicines[187] nor state that it is a substitute for curative medicine.[5] Similarly, advertisements (including labels) for foods must state, "This product is not a medicine and is not a substitute for medicines" and be consistent with the effects of the product[183, 186] and not use images of health facilities and workers etc.[183]	None identified.
Regulatory objective(s)	The proposed principles of the draft Circular are: comply with goods and food labelling regulations (including those relating to food safety); ensure accuracy, not cause misunderstanding or confusion about the nutritional value of foods; ensure information on ingredients and nutritional values on food labels is easy to understand, read and identify, attached to product packaging and cannot be erased.[190]	None identified.	None identified.
Operative terms and conditions	The proposed nutrient declaration:[190] • Includes energy (in kcal or Kj), protein (g), carbohydrate (g), total sugars (g), fat (g), saturated fat (g), and sodium (mg); • Is represented per 100g or ml of food and as a % of the nutritional reference values (NRVs); • Does not apply to table salt, unpackaged foods, and other foods such as single-ingredient foods; • Should be presented in numbers and with adequate information per the form in the Circular; • If food is packaged with many servings, each serving must be recorded. General label requirements include that:[189] • The height of text on pre-packaged and other foods must be ≥1.2mm, save for smaller labels of <80cm^2 where text cannot be <0.9mm; • Text colour must contrast with the label's background colour; • Labelling is in Vietnamese covering all mandatory contents, noting that contents can also appear in a foreign language provided it is not larger than the Vietnamese text. Additional labelling (attached to the original labelling) can be used on food imported for consumption in Vietnam.	Nutrient content claims for general foods:[189] • 'Low' or 'no' claims may be used for calories, fat, saturated fat, cholesterol, sugar, or sodium, and 'source of' or 'high' may be used for claims for protein and fibre, provided conditions of the specific claim are met, e.g., 'Low in fat' must contain ≤3g per 100g (solid) or 1.5g per 100ml (liquid). • 'Source of' and 'high' claims may be made for vitamins and minerals, provided conditions of the specific claim are met, e.g., 'Source of' must contain ≥15% RNI per 100g. Nutrient content claims (for supplemented foods, e.g., added vitamins):[179] • [Name and content of the substance] can only be used on a label when the content of the substance is ≥10% of RNI for Vietnam – and based on each meal ration or 100g; • The maximum content of vitamins and minerals in foods calculated based on producers' RNI must not exceed the maximum intake limits of vitamins and minerals in the regulations. If Vietnam has no RNI and maximum intake limits, the provisions of Codex or relevant international organisations shall apply. Health claims (for supplemented foods):[179] • Can only be used on a label when the contents of such substances in foods reach ≥10% of RNI accompanied by scientific evidence; • For added ingredients where no RNI is available, health claims can be made only when accompanied by scientific evidence or the contents conform to recommended intakes in existing scientific documents; • Must be written clearly and consistently as suitable to users and intakes already announced. Supplemented food labels must include:[179] • Recommendations about risks, if any; • The phrase 'Supplemented foods' or the phrase stating the name of the foods per the technical regulation must be written in the main panel of the label; • Specific users suitable to response levels of recommended intakes, where available, or suitable to accompany scientific evidence on recommended intakes for ingredients for which no response levels are available.	None identified.

Regulatory governance	
Drafting regulatory rules and scheme design	• The MoH (VFA and Departments of Preventive Medicine and Legislation) has responsibility and authority for setting the nutrition labelling regulatory agenda, developing draft legislation, and co-developing the final legislation via a consultative cross-government board that excludes industry. The National Institute of Nutrition, MOIT, MARD, the WHO country office and Health Bridge Canada are involved in regulatory development [VIE001-S, VIE003-I] alongside public consultation on drafts until consensus from most stakeholders is reached, including via industry workshops. A final draft and report on industry and consumer behaviour and the effect of the new regulations on social and economic conditions is submitted to the Vice Minister of Health for approval, ahead of approval by the Minister for Health. [VIE003-I] • Regulatory development is also informed by existing laws and policies, trade agreements, regional considerations, normative guidance (Codex and WHO guidelines), other jurisdictions' experiences, data from national nutrition surveys, and food industry implementation capacity. [VIE003-I] Monitoring and evaluation processes are also considered during regulatory development. [VIE001-S, VIE003-S] • Under the draft Circular on Guidelines for nutrition labelling of foods a transition period would allow foods produced and labels printed before the date of the draft regulation to continue to be used until they expire.[190] • Under ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States should provide clear and effective regulation that promotes food security and nutrition,[73] engage stakeholders in regulatory development to ensure transparency and that views are considered,[74] and consider Codex standards, recommendations and guidelines.[74] All aspects of a national food control system should be transparent and open to public scrutiny while respecting legal requirements to protect confidential information.[74] Decision making should be evidence-based, and competent authority/ies and all officials should be free of improper or undue influence or conflict of interest.[74]
Administration	• Under Decree 15/2018/ND-CP Elaboration of Some Articles of the Law of Food Safety:[183] – Food suppliers wishing to sell pre-packaged processed foods in Vietnam (along with food additives and related food materials with exceptions, such as raw materials and dietary supplements, medical foods, foods for special dietary uses, for which separate requirements exist) must submit a food-specific self-declaration to the relevant regulatory authority in the relevant province to receive a certificate of production registration, which must be posted on the authority's website and the producer must post the certificate via mass media, or on its website or premises. – To obtain a certificate of production registration, every food manufacturer and seller (excluding micro-food processors and sellers of pre-packaged foods, which must meet requirements in the Law on Food Safety to obtain a certificate of food safety; or dietary supplement manufacturers that must satisfy separate criteria) must also obtain a certificate of food safety (we assume that this is also termed the regulation conformity declaration for which dossiers with food labels must be submitted per Circular Providing the management of functional foods, 2014). – Some foods require advertisement their contents to be registered before they can be advertised (e.g., dietary supplements and medical foods). – Food inspection processes for imported and exported foods are also specified, with some exceptions including for foods that have a certificate of registered product declaration.(9) These expand on requirements under the Law on Food Safety for importers to obtain a notice of satisfaction of import requirements for micronutrient-fortified foods, and a certificate of free sale or health certificate as prescribed by the government.[177] • Under the Circular Providing the management of functional foods 2014[179] the VFA has primary responsibility for implementation and coordinates implementation with functional agencies (MOIT and Ministry of Public Security). Provincial-level Health Departments examine and supervise and direct provincial-level Food Administrations and related units in examining and supervising producers and traders of functional foods in their localities. Before functional foods can be marketed, they need a regulation conformity declaration to be registered with the VFA. • Under the draft Circular on Guidelines for nutrition labelling of food [190] the Food Safety Authority assumes primary responsibility for implementation; the Institute of Nutrition has professional responsibility for publishing and updating nutritional reference values; MOIT and MARD organise implementation for foods under their management; and People's Committees organise implementation in their localities. • No training for officers engaged in design, administration, monitoring, enforcement of labelling regulations occurs. [VIE001-S] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems, Member States' independent statutory bodies should retain authority for policy administration[73] and legislation should provide the authority with the power and mechanisms to: establish, monitor and enforce standards; implement regulations; perform activities to verify, investigate, and enforce regulatory compliance; and apply sanctions and/or penalties.[74]
Monitoring	• Beyond details of approvals under Administration above, under the Law on Food Safety, food safety management agencies must conduct transparent, planned and unplanned food safety examinations, coordinating with relevant agencies and People's Committees, with decisions issued after receipt of inspection reports. Examination teams can request documents, take samples, and suspend food advertisements, and must report accurately and in a timely way to the food safety management agency. Expenses are paid by the agencies that decide on examination and testing, but when violations occur, expenses are refunded by violators, and those organisations that request the testing must pay for it.[177] Some foods are exempt from this process, such as those with a certificate of registered product declaration.[183] – Each department has specific inspectors, for example, the Department of Market Surveillance under the MoIT has the power to audit all products on the market, including food. [VIE003-I] Only food safety criteria are tested, not the fortificants in food, as it is a quality criterion, and some inspection outcomes are publicly available. [VIE003-I] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' national food control systems should be transparent and open to public scrutiny, while respecting the need to protect confidential information as appropriate.[74] To assess effectiveness and suitability to achieve objectives, the system should be subject to ongoing monitoring and review against documented criteria, and consider scientific evidence, and non-compliance.[74] Legislation and guidelines should also include provisions to monitor dietary consumption.[73]
Evaluation	• Ministries do not discuss measuring the impact of nutrition labelling during relevant regulatory development [VIE001-S, VIE003-S] and no evaluations are planned. [VIE003-I] • Under the ASEAN Regional Guidelines on Food Security and Nutrition and ASEAN Principles and Guidelines for National Food Control Systems Member States' national food control systems should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is achieving its objectives.[74] Member States should also evaluate new or existing regulation to ensure it is compatible with nutrition and food security policy.[73]

Enforcement	• Under the Law on Food Safety: – Foods that do not meet relevant technical regulations (including incorrect labelling) can be recalled and disposed of as 'unsafe' on request of competent agencies which decide on conditions and time limits for food recall and disposal, or if this should be done voluntarily by the producer/trader.[177] – Food producers and traders that violate the law on food safety (including labelling provisions) will, depending on the severity of the violation, be subject to administrative or penal liability. They will pay compensation and remedy the consequences if damages are caused. Administrative violations are specified by the government, but fines for violations are based on seven times the value of the violating food with any funds earned from violations confiscated.[177] • Under the Circular Providing the management of functional foods, 2014[179] functional foods can also be recalled in various circumstances, including if they are marketed without regulation conformity certificates, with recall reported to the VFA. • Under the ASEAN Regional Guidelines on Food Security and Nutrition and Principles and Guidelines for National Food Control Systems Member States' independent statutory bodies should retain enforcement authority,[73] be appropriately resourced and employ qualified personnel.[74] State authorities should establish, implement and enforce science- and risk-based regulatory requirements that encourage and promote positive food safety outcomes and establish and maintain arrangements with relevant organisations such as officially recognised inspection, audit, certification and accreditation bodies.[74] Compliance and enforcement programmes should be designed to enable a competent authority to take corrective remedial action from education to sanctions, alongside maintaining public transparency.[74]

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Annexure 1: Framework for analysing and improving the performance of nutrition labelling regulations

We adapted an existing framework for analysing and improving the performance of public health nutrition regulations[4] to identify relevant features of the three types of nutrition labelling regulation (nutrient declarations, nutrition and health claims, and SNI) in each jurisdiction. Earlier adaptations of this framework include Jones et al.'s application to the context of FOPNL. The framework was used to inform data extraction from the regulations retrieved in our search.

The framework provides for the examination of three 'domains' relevant to regulatory effectiveness. For this work, we combine the first two, 'Regulatory Form and Substance', to examine the form of regulation, and the substantive terms and conditions for each type of nutrition label, given the similarity and links between these two previously separated domains. The third domain, 'Regulatory Governance', examines the processes by which regulation is developed, administered, monitored, and enforced. Given the likely commonalities in regulatory processes in a jurisdiction, we consider features of regulatory governance for all three types of nutrition labelling together, while allowing space to specify findings that were unique to a particular type of nutrition label (for example, a process that was unique to the development of a food fortification logo).

Column one lists the components of the domains. Column two lists the high-level recommendation for best practice for each component, drawn from the original framework and based upon regulatory studies literature. Column three outlines key questions to ask when extracting data from relevant regulations to determine whether the regulation meets best practice recommendations.

Figure 8: A framework for analysing and improving the performance of nutrition labelling regulations

Component	Recommendation	Application (or questions to ask) in practice
Domains One and Two: Regulatory Form and Substance		
NUTRIENT DECLARATION		
Regulatory framework	The regulatory framework is appropriate to the jurisdiction's legal context.	• In what type of regulations are the requirements for the nutrient declaration contained (e.g., overarching Food Law or Act, subsidiary regulations, voluntary government-issued guidance)? • Is the requirement to display the nutrient declaration mandatory or voluntary?
Regulatory objective(s)	There are clear, measurable objectives against which the success of regulation can be assessed.	• What is the stated objective of the overall regulation and/or the section on nutrient declarations? E.g., to inform consumers of the nutritional content (profile and quantity) of food considered to be relevant for good nutrition, and/or to allow for comparisons between foods.
Operative terms and conditions	Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objectives.	Key terms and conditions around the display of the nutrient declaration may include: • On what foods is it required? Are there any exceptions (e.g., foods of nutritional insignificance or where packaging is too small)? • What nutrients must be listed in the declaration at a minimum? What additional nutrients may be listed voluntarily, and when (including vitamins and minerals that may be subject to LSFF programmes)? Are there requirements for the order of display of nutrients? • What units of measurement must be used to display information (e.g., per serve, per 100g/mL)? • Are there any other display specifications/requirements to enhance salience and visibility (e.g., format, minimum font size, contrast to the background colour, position on the pack, reference statements)? • Does the regulation specify how a nutrient declaration should be calculated (e.g., by analytic testing of foods, using recipes, using databases)? This also relates to Regulatory Governance - see further below.
Policy coherence	Regulation is framed within comprehensive policies to promote healthier diets and is aligned with other national health and nutrition policies.[191]	• Is the regulation aligned with other national health and nutrition policies and/or international guidance (e.g., are the nutrients required in the declaration aligned with the nutrients that are the focus of policies to address under- and over-nutrition)?

NUTRITION AND HEALTH CLAIMS		
Regulatory framework	The regulatory framework is appropriate to the jurisdiction's legal context.	• In what type of regulations are the requirements for nutrition and health claims contained (e.g., government-led statutory legislation such as an overarching Food Act, subsidiary regulations, or voluntary government-issued guidance documents)?
Regulatory objective(s)	There are clear, measurable objectives against which the success of regulation can be assessed.	• What is the stated objective of the regulation? Can this be measured to determine effectiveness (e.g., to support consumers in choosing healthful diets, or a high level of consumer protection and information)?
Operative terms and conditions	Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objectives.	Key terms and conditions around the use and display of the nutrition and health claims may include: • How are nutrition claims and/or health claims defined? • Do nutrition and health claims require the support of a nutrient declaration as a prerequisite for display? • On what products can nutrition and/or health claims be used? Are there categories of products on which nutrition and/or health claims are prohibited (e.g., on unhealthy products)? • With nutrition claims: Are there different types (i.e., nutrition content claims; nutrition comparative claims)? Are there qualifying and disqualifying criteria in regulations for levels of nutrients present in the product to make a claim (e.g., a % of an NRV per 100gm)? • With health claims: Are there different types specified (e.g., low level, high level, function claims, reduction in disease risk claims)? Are there qualifying and/or disqualifying criteria for making a claim (e.g., scientific standards for substantiating the claim)? Is there a pre-approved list of health claims or can a producer make their own provided there is sufficient substantiation? • Are there other requirements for display (e.g., legibility, size, position on the pack, accompanying statements about how to use the food, general requirements not to be misleading or deceptive)?
Policy coherence	Regulation is framed within comprehensive policies to promote healthier diets, and aligned with other national health and nutrition policies.[191]	• Does the nutrition and health claims regulation/policy align with and support other national health and nutrition policies (e.g., does the regulation facilitate making nutrition claims for any fortificants focused on in national policy, and does the regulation allow the making of health claims on unhealthy products)?
SNI, PARTICULARLY FORTIFICATION LOGOS		
Regulatory framework	The regulatory framework is appropriate to the jurisdiction's legal context.	• In what type of regulations are the requirements for the SNI contained (e.g., government-led statutory legislation or government-issued policy documents)? • Is the requirement to display SNI voluntary or mandatory?
Regulatory objective(s)	There are clear, measurable objectives against which the success of regulation can be assessed.	• What is the stated objective of the SNI? Is it something that can be measured to determine effectiveness (e.g., to guide consumers towards fortified foods, and/or stimulate fortification by industry)?
Operative terms and conditions	Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objectives.[4] The supplementary nutrition information format selected supports the regulatory objective(s), that is, can be understood and used by consumers to inform healthier choices.[191]	Key terms and conditions around the use and display of the SNI in the regulation may include: • What foods are eligible to display SNI? Are there any foods that are always ineligible to display SNI? • Are there specifications on what nutrient(s) and/or vitamins or minerals underpin SNI (e.g., the logo represents fortification with vitamin A, iron etc, and what level of these substances must the product contain to be eligible to carry the logo)? • Are there specifications for the graphic design of SNI and how it should be displayed on the pack (e.g., size, placement, colour)?
Policy coherence	Regulation is framed within comprehensive policies to promote healthier diets, and aligned with other national health and nutrition policies.[191]	• Does regulation align with and support other health and nutrition policies in the jurisdiction and/or international guidance (e.g. are there requirements that prevent unhealthy foods from displaying the fortification logo as a 'health halo'?) • If a country has both a fortification logo and an FOPNL logo, are there display requirements to ensure they complement rather than contradict each other?

Domain Three: Regulatory Governance		
Drafting regulatory rules and scheme design	Transparency and accountability mechanisms are incorporated into regulatory regimes from their inception, including when developing substantive regulatory rules and in determining scheme design.	Processes of development may be slightly different for the different types of nutrition labelling regulations, however, general areas of enquiry include: • Which body led the development of the regulation? • What stakeholders were involved and at what stage of development? Were public health and consumer organisations involved and/or consulted with? Did public consultation take place? Are relevant documents about this process publicly available? • Were food industry stakeholders involved and in what way? Are there safeguards in place to protect regulatory development from conflicts of interest? • Was there any testing of the proposed label to assess consumer understanding and use (for SNI and nutrition and/or health claims)? • Was robust and independent evidence used in the regulatory development, and if so, how?
Administration	Administration by a government or independent body which monitors and enforces compliance and publicly disseminates information on performance to facilitate external scrutiny and improve the regulation	Administering bodies and roles may be slightly different for the different types of nutrition labelling regulations however, general areas of enquiry include: • What body is tasked with administering the regulation and does it have the requisite authority and resources? • What are the activities of this body, and does it make information about these activities publicly available?
Monitoring	Monitoring informs continuous improvement through the collection of baseline data, setting of process and outcome indicators and timeframes for achievement, and ongoing data collection.	Monitoring activities may be slightly different for the different types of nutrition labelling regulations however, general areas of enquiry include: • Is there monitoring of the use of the nutrition label by consumers and/or industry? • Who conducts the monitoring? Is it a government and/or independent body (e.g., academic institute)? • Are there resources dedicated to monitoring (e.g., human and financial) and monitoring guidelines in place? • How often does monitoring occur and is it proactive rather than reactive? • Is there relevant data available to conduct monitoring? • Are the results of monitoring publicly available to facilitate improvements?
Evaluation	Structured, regular review ensures regulation meets its objectives. A review framework set during development includes baseline data and, performance indicators and timeframes to evaluate effectiveness.	Review or evaluation of different nutrition labelling types may vary, but broad questions to ask include: • What body is responsible for conducting a review/evaluation of the nutrition labelling regulation? • How will the effectiveness of the label be measured? • Are there timeframes for evaluation/review and is it proactive rather than reactive? • Is there relevant data available to conduct an evaluation? • Is information on evaluation activity publicly available?
Enforcement	A wide range of enforcement options are available, including incentives to encourage and reward high levels of compliance, 'soft' enforcement measures such as persuasion and more punitive measures for instances of serious or persistent non-compliance. Publication of decisions enhances transparency and allows the development of 'precedent' for users.	Enforcement of nutrition labelling requirements may vary by label type, but broad questions to ask include: • What body is responsible for enforcing the regulation? • Is there a process of pre-market approval to use the label? • What are the sanctions for not using a mandatory label? What are the sanctions for incorrectly using a voluntary label? Are sanctions effective and proportionate? • Is there a mechanism for stakeholders to make a complaint about label use? • How is enforcement conducted and is it proactive rather than reactive? Is there post-market surveillance? • How is enforcement funded? • Is information on enforcement activity publicly available?

Annexure references

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Annexure 2: Nutrition labelling for fortified foods in Nigeria (example fact sheet)

Nutrition labelling for fortified foods in Nigeria

The George Institute for Global Health

Mandatory fortification of sugar, vegetable oil, margarine and butter with vitamin A (varying levels per kg); wheat flour, composite flour, maize flour, wheat semolina and whole maize meal with vitamins A, B1, B2, B3, B6, B9, B12, iron and zinc; food-grade salt with iodine (except in certain cases). Other foods may be voluntarily fortified per Food Fortification Regulations, 2021.

1. TAKEAWAYS

Labels on fortified foods in Nigeria must include a nutrient declaration (section 3). Where foods are fortified in line with regulations, nutrition and health claims can be made (section 4) and/or a fortification logo can be displayed (section 5). On page 2, wheat flour is provided as a pictorial case study product (section 6) as well as a summary of key regulations (section 7) and links to further information (section 8)

2. GENERAL

- It is an offence to label food in a false or misleading manner (e.g., to include B12 in the food's ingredients list when no B12 is present) or to label food in a way that indicates it has medicinal properties.
- Labelling must be in English and may include any other language and must be clear, prominent, and legible.
- All fortified foods, all processed foods (for sale, import, distribution, manufacture, etc.) and any foods to be advertised (includes "labelling") in Nigeria must be registered with the National Agency for Food and Drug Control (NAFDAC), with registration renewal required. NAFDAC has created an online portal for registration of foods and other items (**https://registration.nafdac.gov.ng**).

3. NUTRIENT DECLARATION

Nutrient declarations are mandatory on all pre-packaged foods (incl. fortified foods and iodised salt) though NAFDAC can prescribe exceptions for some foods (e.g., single ingredient foods, spices and herbs, small units with a surface area <10cm2, nutritionally insignificant foods etc).

- Where a nutrient declaration is included on a label, it must:
- Be presented in a tabular (or table) format
- Express nutrition information in columns per serve or per 100g (solids) / 100mL (liquids)
- Include minimum mandatory nutrition information: energy (kJ/kcal); fat (g); saturated fat (g); trans-fat (g); carbohydrate (g); sugar (g); protein (g); salt (mg); and the amount of any other nutrient for which a nutrition or health claim is made.
- Express vitamins and minerals per 100g/ml and as a % Nutrient Reference Value (NRV) – but only if they are present in an amount ≥5% of the NRV per 100g/ml as quantified on the label.
  - **For fortified foods:** vitamins and minerals can only be declared where they meet the requirements of the Food Fortification Regulations; the vitamin or mineral must be present in ≥5% of the NRV per serve; and be expressed as a % NRV per 100g/ml or per package if it only contains a single serve, plus as a % daily value.
- *Products containing fats and oils, including emulsions alone or as part of processed foods:* cholesterol (g), monounsaturated fat (g), and polyunsaturated fat (g) should also be declared.

In addition, where labelling of food places special emphasis on the: a) presence of ≥1 ingredients, the mass must be declared in the final product; b) low content of ≥1 ingredients, the % of the ingredient must be declared.

4. NUTRITION AND HEALTH CLAIMS + FORTIFICATION CLAIMS

- You may include nutrition and health claims on the label if they meet conditions (e.g., health claims must be supported by evidence).
- If fortified foods are fortified in line with the Food Fortification Regulations:
  - Nutrition claims are allowed for vitamins and minerals if they meet a % of a NRV (e.g., "Source of [vitamin or mineral]" ≥5% of NRV per 100g/ml/serve, with increasing %'s of NRVs to claim, "A good source of" and "Excellent source of").
  - In advertising or labelling of the relevant food, the label must state a) calcium or phosphorous is a factor in the normal development and maintenance of bones and teeth, especially in infants and children; and b) calcium, phosphorous or iron is a factor in the maintenance of good health.
- When salt is fortified, it must be labelled as such. E.g., "salt fluoridated", "salt iodated", "salt iodized", "salt fortified with iron", "salt fortified with vitamins", or included in ingredient list. Further, salt cannot be represented as "Reduced in Sodium" unless it contains ≤25% less sodium than regular table salt and satisfies other conditions.
- Food product claims on labels must be: Adequately substantiated before approval (e.g., 'natural' claims) and accurately interpret research findings. Any reference in a label (advertisement) needs to be verified by NAFDAC. Terms like "source", "dietary source" etc re energy and/or protein must meet specifications. Terms such as "nutritious" must meet nutrient profiling criteria (i.e., at least four vitamins and two minerals excluding sodium of an amount that meet criteria for claim as source).
- Fortified foods cannot specifically be sold or advertised among other things as a treatment, preventative or curative of diseases, disorders or abnormal physical states as specified in the regulations (e.g., Goitre, mental conditions). Similar claims are prohibited for all foods.

5. FORTIFICATION LOGOS

You must include the Vitamin A fortification logo (below left) on sugar, wheat and maize flour, vegetable oil, margarine and butter, that are subject to mandatory fortification.

You must include the iodised salt logo on mandatorily iodised salt (below centre).

The regional 'Enrichi' logo (below right) can be used on wheat flour and cooking oil fortified with vitamin A as part of the 'Fortify West Africa' program that ran throughout ECOWAS countries in conjunction with development partners between 2011 and 2017.

The logo must be a specified format and size. E.g., printed in a prominent position on the main panel in bold print against a contrasting or clear background, and be clearly visible, legible and indelible.

6. PICTORIAL CASE STUDY PRODUCT – WHEAT FLOUR

This case study product only details the three nutrition label types outlined in this fact sheet –nutrient declaration, fortification claim and fortification logo – along with a product name. Figures used are provided as an example only and may not be accurate. Other details are required on food labels (e.g., ingredient list and weight) but not shown here.

7. MORE DETAIL ON THE LABELLING REGULATIONS

Food and Drugs Act of 2004 sets out enforcement provisions and the Minister for Health's stance in relation to food and other substances covered by the Act and requires certification for imported foods. The Act also prohibits false or misleading labelling and labelling that indicates food with medicinal properties.

National Agency for Food and Drug Administration and Control Act 2004 (NAFDAC Act) establishes NAFDAC, its functions and powers, including to regulate and administer food labelling.

Food Products Advertisement Regulations 2021 sets out requirements for registration of all food products manufactured, imported, distributed or sold in Nigeria with NAFDAC prior to advertisement (that includes labelling) and prohibits misleading or deceptive advertisements. The regulations also limit nutrition and health claims that can be made in food advertisements.

Processed Food Registration Regulations 2005 sets out requirements for processed food products and labelling to be registered with NAFDAC and sets out registration requirements.

Food, Drug and Related Products (Registration) Act 2004 prohibits manufacture, import, export, advertisement, sale or distribution of food (and other products) in Nigeria unless they have been registered with NAFDAC. The Act also establishes the Food and Drug Registration Committee that advises NAFDAC on applications for registration.

Regulations made under both the Food, Drugs and Related Products (Registration) Act and the NAFDAC Act:

Pre-Packaged Food (Labelling) Regulations, 2022 set out labelling requirements for all pre-packaged foods manufactured, imported, exported, sold or distributed in Nigeria, including general requirements (e.g., name of food, ingredients). The Regulations mandate nutrient declarations and prohibit false and misleading labelling, non-compliant labelling and medicinal claims. These regulations revoke the previous food labelling regulations and bottled water labelling regulation – and apply to products fortified under the two fortification regulations.

Food Fortification Regulations 2021 alongside mandatory fortification requirements, the Regulations specify via schedule, other foods to which vitamins, minerals, nutrients or other amino acids "may" be added, though the schedule lists both mandatory and voluntary fortification and applicable fortificants (e.g., enriched alimentary pasta must be fortified with thiamine, riboflavin, niacin, folic acid and iron, and can be voluntarily fortified with pantothenic acid, vitamin B6 and magnesium).

Requirements for inclusion of vitamins and minerals in nutrient declarations and for nutrition and health claims and SNI for foods fortified with vitamin A are set out. The regulations also require registration of all fortified foods manufactured, imported, exported, distributed, advertised, sold or used in Nigeria with NAFDAC.

Food Grade (Table or Cooking) Salt Regulations 2021 alongside iodisation requirements, set out labelling requirements for food grade salt, including a SNI and specific claims for iodised salt. The regulations also require registration of all iodised salt manufactured, imported, exported, distributed, advertised, sold or used in Nigeria with NAFDAC.

As a Member State of the **Economic Community of West African States (ECOWAS)**, Nigeria is bound by the **1975 Treaty of the Economic Community of West African States** that establishes a common market and requires the harmonisation of national policies and standards and promotion of regional integration. It is also bound by other decisions and ECOWAS strategies and plans apply to it. However, while these require harmonisation and seek to strengthen regional cooperation and coordination, no documents were identified that appeared to directly affect the regulatory environment described in this fact sheet.

8. REGULATORS, USEFUL CONTACTS AND WHERE TO GET MORE INFORMATION

The **National Agency for Food and Drug Administration** implements the regulations above. NAFDAC regulations can be searched at **https://www.nafdac.gov.ng/about-nafdac/nafdac-laws/.**

Government regulations can be searched at **http://www.nigeria-law.org/.**

The US Department of Agriculture's (USDA) Foreign Agricultural Service issues a Food and Agricultural Import Regulations and Standards Country Report for Nigeria on a regular basis. See their **Nigeria page** to access the latest report.

The Global Fortification Data Exchange's **Nigeria Fortification dashboard** provides more detail about food fortification in the country.

Annexure 3: Template fact sheet that can be used to detail nutrition labelling requirements for fortified foods in a geography

Nutrition labelling for fortified foods in <country>

Mandatory fortification of <insert foods and fortificants>.

Voluntary fortification of <insert foods and fortificants>.

1. Takeaways

Labels on fortified foods in <country> <e.g., must, may> include a nutrient declaration (section 3). Where foods are fortified in line with regulations, nutrition and health claims <e.g., can be made> (section 4) and a fortification logo <e.g., can be displayed> (section 5). On page 2, wheat flour is provided as a pictorial case study product (section 6) as well as a summary of key regulations (section 7) and links to further information (section 8).

2. General

- <insert details of general labelling requirements as dot points. E.g., It is an offence to label food in a false or misleading manner or to label food in a way that indicates it has medicinal properties. Labelling must be in English and may include any other language and must be clear, prominent, and legible. All fortified foods, all processed foods and any foods to be advertised (includes "labelling") must be registered with the regulatory agency, with registration renewal required.>

3. Nutrient Declaration

Nutrient declarations are <e.g., mandatory on all pre-packaged foods including fortified foods though the regulatory agency can prescribe exceptions for some foods (e.g., single ingredient foods, spices and herbs, small units with a surface area <10cm2, etc).>

Where a nutrient declaration is included on a label, it <e.g., must>: <insert key details as dot points, e.g.,

- Be presented in a tabular (or table) format
- Express nutrition information in columns per serve or per 100g (solids) / 100mL (liquids)
- Include minimum mandatory nutrition information: energy (kJ/kcal); fat (g); saturated fat (g); trans-fat (g); carbohydrate (g); sugar (g); protein (g); salt (mg); and the amount of any other nutrient for which a nutrition or health claim is made.
- Express vitamins and minerals per 100g/ml and as a % Nutrient Reference Value (NRV) – but only if they are present in an amount ≥5% of the NRV per 100g/ml as quantified on the label.>

<insert any other key details in regulations>

4. Nutrition and Health Claims + Fortification Claims

- You <e.g., may> include nutrition and health claims on the label if they meet conditions <insert example, e.g., health claims must be supported by evidence>.
- <insert any other key details in regulations, e.g., If fortified foods are fortified in line with the Food Fortification Regulations:
  - Nutrition claims are allowed for vitamins and minerals if they meet a % of a NRV (e.g., "Source of [vitamin or mineral]" ≥5% of NRV per 100g/ml/serve, with increasing %'s of NRVs to claim, "A good source of" and "Excellent source of").
- When salt is fortified, it must be labelled as such. E.g., "salt fluoridated", "salt iodated", "salt iodized", "salt fortified with iron", "salt fortified with vitamins", or included in ingredient list. Further, salt cannot be represented as "Reduced in Sodium" unless it contains ≤25% less sodium than regular table salt and satisfies other conditions.
- Food product claims on labels must be: Adequately substantiated before approval (e.g., 'natural' claims) and accurately interpret research findings. Any reference in a label (advertisement) needs to be verified by the regulatory agency.
- Fortified foods cannot specifically be sold or advertised among other things as a treatment, preventative or curative of diseases, disorders or abnormal physical states as specified in the regulations (e.g., Goitre, mental conditions). Similar claims are prohibited for all foods.>

<insert and label all fortification logos and other SNI that may be relevant to fortified food>

Nutrition labelling for fortified foods in <country>

Mandatory fortification of <insert foods and fortificants>.

Voluntary fortification of <insert foods and fortificants>.

6. Pictorial case study product – Wheat flour

This case study product only details the three nutrition label types outlined in this fact sheet – nutrient declaration, fortification claim and fortification logo – along with a product name. Figures used are provided as an example only and may not be accurate. Other details are required on food labels (e.g., ingredient list and weight) but not shown here.

7. More detail on the labelling regulations

<Insert labelling regulation title, include a hyperlink to where it can be found, and detail the key elements of the regulation, e.g., Food and Drugs Act of 2004 sets out enforcement provisions and the Minister for Health's stance in relation to food and other substances covered by the Act and requires certification for imported foods. The Act also prohibits false or misleading labelling and labelling that indicates food with medicinal properties.>

<Insert all relevant labelling regulations in the country per above instructions>

8. Regulators, useful contacts and where to get more information

<Insert details of the regulatory agency that is responsible for implementing labelling regulations and where any of its guidance or specific regulations can be searched, e.g., The National Agency for Food and Drug Administration implements the regulations above. NAFDAC regulations can be searched at https://www.nafdac.gov.ng/about-nafdac/nafdac-laws/.>

<Insert where all government regulations can be searched if regulations beyond those of the regulatory agency described above apply. E.g., Government regulations can be searched at http://www.nigeria-law.org/.>

The US Department of Agriculture's (USDA) Foreign Agricultural Service issues a Food and Agricultural Import Regulations and Standards Country Report for <insert country> on a regular basis. See their <hyperlink to country page, e.g., Nigeria page> to access the latest report.

The Global Fortification Data Exchange's <hyperlink to country dashboard, e.g., Nigeria Fortification dashboard> provides more detail about food fortification in the country.

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Policy and regulatory determinants of nutrition labelling to support large-scale food fortification

An examination of 11 geographies

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The George Institute for Global Health, UNSW Sydney for
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