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.