

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 regulations⁴ 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<p>Key terms and conditions around the display of the nutrient declaration may include:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.
Regulatory objective(s)	There are clear, measurable objectives against which the success of regulation can be assessed.
Operative terms and conditions	Key terms and conditions are clearly defined; regulatory rules are sufficiently expansive to achieve the regulatory objectives.
Policy coherence	Regulation is framed within comprehensive policies to promote healthier diets, and aligned with other national health and nutrition policies. ¹⁹¹
SNI, PARTICULARLY FORTIFICATION LOGOS	
Regulatory framework	The regulatory framework is appropriate to the jurisdiction's legal context.
Regulatory objective(s)	There are clear, measurable objectives against which the success of regulation can be assessed.
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
Policy coherence	Regulation is framed within comprehensive policies to promote healthier diets, and aligned with other national health and nutrition policies. ¹⁹¹

<ul style="list-style-type: none"> 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)? 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)? 	<ul style="list-style-type: none"> 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)?
<p>Key terms and conditions around the use and display of the nutrition and health claims may include:</p> <ul style="list-style-type: none"> 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)? 	<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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? 	<ul style="list-style-type: none"> 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)?
<ul style="list-style-type: none"> 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)? 	<ul style="list-style-type: none"> 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)?
<p>Key terms and conditions around the use and display of the SNI in the regulation may include:</p> <ul style="list-style-type: none"> 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)? 	<ul style="list-style-type: none"> 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)?
<ul style="list-style-type: none"> 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? 	<ul style="list-style-type: none"> 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)?

Domain Three: Regulatory Governance	
Drafting regulatory rules and scheme design	<p>Transparency and accountability mechanisms are incorporated into regulatory regimes from their inception, including when developing substantive regulatory rules and in determining scheme design.</p> <p>Processes of development may be slightly different for the different types of nutrition labelling regulations, however, general areas of enquiry include:</p> <ul style="list-style-type: none"> • 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	<p>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</p> <p>Administering bodies and roles may be slightly different for the different types of nutrition labelling regulations however, general areas of enquiry include:</p> <ul style="list-style-type: none"> • 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	<p>Monitoring informs continuous improvement through the collection of baseline data, setting of process and outcome indicators and timeframes for achievement, and ongoing data collection.</p> <p>Monitoring activities may be slightly different for the different types of nutrition labelling regulations however, general areas of enquiry include:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>Review or evaluation of different nutrition labelling types may vary, but broad questions to ask include:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>Enforcement of nutrition labelling requirements may vary by label type, but broad questions to ask include:</p> <ul style="list-style-type: none"> • 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

4. Reeve B, Magnusson R. Regulation of food advertising to children in six jurisdictions: a framework for analyzing and improving the performance of regulatory instruments. *Arizona journal of international and comparative law*. 2018;35(1):71.

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