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.193/20I0[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]

Section references

23. Global Fortification Data Exchange. Food Fortification Dashboard (various countries) 2023 [Available from: https://fortificationdata.org/list-of-countries-for-the-food-fortification-dashboard/.
52. Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No. 299/2013., Regulation No.299/2013 (2013).
53. Ethiopian Standards Agency Establishment Council of Ministers Regulation No. 193/2010, No. 193/2010 (2011).
54. Fortified Wheat Flour- Specification, CES 309 (2022).
55. Ministry of Health of Ethiopia. National Nutrition Strategy Addis Ababa2008.
56. COMESA. Treaty establishing the Common Market for Eastern and Southern Africa. 1993.
57. Definition of Organization, Powers and Duties of the Ethiopian Food and Drug Authority Council of Ministers Regulation No. 531/2023 (2023).
58. Institute of Ethiopian Standards. About Standard Ethiopia: Institute of Ethiopian Standards; 2023 [Available from: https://www.ethiostandards.org/about-standard.
59. General Standard for Prepackaged Foods – Labelling CES 73 (2013).
60. Food and Medicine Administration Proclamation No. 1112/2019., Proclamation No. 1112/2019 (2019).
61. United States Department of Agriculture Foreign Agricultural Service. Ethiopia: FAIRS Country Report. 2021. Report No.: ET2021-0002.
62. COMESA Authority. Common Market for Eastern and Southern Africa MEDIUM TERM STRATEGIC PLAN 2021-2025. 2022.