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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