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]

	Nutrient declaration	Nutrition and health claims	SNI
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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