Model Provisions for Food and Drinks Legislation

This document contains around 700 model provisions. The purpose of the model provisions is to offer policy-makers and drafters as many choices as possible as to the potential policy and regulatory elements on the subject in question, without prejudging any decision. The model provisions will, of course, need to be adapted to the legal and policy context in which they are used. In particular, obligations and powers may need to be assigned to authorities and persons other than those set out in the model provisions. The model provisions are intended solely as a source of inspiration and a checklist, without any claim to validity.

Many, if not most, of the elements suggested by the various large language models are supported by real legislative examples. However, it would have been extremely cumbersome to keep track of these references at the stage of the final document. If necessary, we can make available an interim working document in which most of the references are still visible.

The model provisions were primarily drafted by one large language model, Mistral Le Chat, with input from several large language models during the references collection and ideation phase. They have undergone light editing and annotation. Nonetheless, the model provisions may contain errors, and some provisions may overlap.. For example, a particular power or obligation may appear in a specific context and in a more general chapter of the document. Where such a power or obligation has been selected in a general context, it may obviously be superfluous in the specific contexts.

The model provisions do not constitute a single, integrated, or internally consistent document. To avoid prejudging any decisions, we have deliberately left some variations.

At times, Mistral Le Chat was overly prescriptive in suggesting " must " where " may " would be more appropriate in many jurisdictions. We have corrected this in numerous cases, though not exhaustively. Conversely, there are also occasions where Mistral Le Chat suggested “may” when “must” would be more suitable.

To make use of the model provisions effectively, the following four steps are recommended:
- Select the provisions deemed relevant;
- Adapt them to the relevant context;
- Merge and reorganise them as necessary;
- Complement them, namely with certain provisions of the Cross-sectoral Standard Provisions.

For questions regarding this version of the model provisions, or to request or contribute to further sets, please do not hesitate to contact us.

Content

Generalities

Interpretation Rules

This Act must be interpreted in the light of its objectives. Interpretations must be adopted so as to best achieve these objectives, while avoiding impracticable interpretations or disproportionate burdens.

N.B.: Please select further interpretation rules from Chapter A. of the Cross-sectoral Standard Provisions.

Objectives and Scope

This Act aims to ensure the safety of Products, as defined in this Act, and to render these Products healthier.

Application

This Act applies to Products, as defined in this Act, which are marketed or intended to be marketed within the national territory, regardless of their place of origin. This Act also applies to natural and legal persons who manufacture, handle, or commercialise such Products, or who contribute to these activities, irrespective of their location.

N.B.: Get further inspiration from Chapter A. of the Cross-sectoral Standard Provisions.

Definitions

For the purposes of this Act, the following terms shall have the meanings ascribed to them below. These definitions are non-exhaustive and must be interpreted broadly to advance the objectives of this Act:

1. **"Additive"** means any substance that is not normally consumed as a food by itself and not normally used as a typical ingredient in food, whether or not it has nutritive value, and whose intentional addition to food for a technological purpose (including organoleptic purposes) results in such substance or its by-Products becoming a component of the foods. This definition excludes contaminants.

2. **"Adulterated food"** means any food: (a) that bears or contains any poisonous or deleterious substance which may render it injurious to health; (b) that consists in whole or in part, of any filthy, putrid, or decomposed substance, or is otherwise unfit for human consumption; (c) that has been prepared, packed, or held under unsanitary conditions; (d) to which any substance has been added or mixed or packed so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; (e) from which any valuable constituent has been wholly or in part omitted or removed.

3. **"Adulteration"** means the deliberate or negligent alteration of a Product in a manner that compromises its quality or safety, including through dilution, substitution, or mislabeling.

4. **"Alcohol"** means ethyl alcohol (ethanol) that is consumed in beverages and is produced either by fermentation or distillation. For the purposes of this Act, any beverage containing more than 0.5% by volume of alcohol is considered an alcoholic beverage.

5. **"Allergen"** means a substance capable of causing an allergic reaction in sensitive individuals, including but not limited to: peanuts, tree nuts, soy, gluten-containing grains, milk, eggs, fish, crustaceans, mollusks, mustard, sesame, and sulfites.

6. **"Artificial sweetener"** means any non-nutritive or low-calorie sweetening substance used as a sugar substitute that provides fewer or no calories when added to food or beverages, including but not limited to aspartame, acesulfame potassium, saccharin, sucralose, neotame, advantame, and steviol glycosides.

7. **"Calories"** means a unit of measurement of energy derived from food when metabolised in the human body, with one calorie equivalent to the amount of heat required to raise the temperature of one gram of water by one degree Celsius at atmospheric pressure.

8. **"Chewing item"** means any product intended to be chewed but not necessarily swallowed, including, but not limited to, chewing gum, medicinal lozenges, betel nut preparations, and similar Products that may release substances into the oral cavity during the chewing process.

9. **"Commercialising"** means the act of marketing, selling, or distributing food, drinks, or semi-fluid items for profit or other commercial purposes.

10. **"Contaminant"** means any biological, chemical, or physical agent present in a Product that poses a risk to health or violates safety standards, whether introduced during the production, manufacture, processing, preparation, treatment, packing, packaging, transport, or storage of such food or feed, or as a result of environmental contamination.

11. **"Critical Control Point"** means a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

12. **"Drink"** means any liquid or semi-liquid substance intended for human consumption, including: (a) water, whether naturally occurring, processed, or packaged; (b) beverages prepared from plant materials, including fruit and vegetable juices, coffee, tea, and plant-based milk substitutes; (c) beverages of animal origin, including milk and fermented milk Products; (d) carbonated and non-carbonated soft drinks; (e) alcoholic and non-alcoholic beverages; (f) infusions, broths, and liquid dietary supplements; (g) nutritional beverages, dietary supplements in liquid form, and sports or energy drinks; (h) any other liquid preparations intended for human consumption. (i) Excludes liquids administered intravenously or for medical purposes under clinical supervision.

13. **"Establishment"** means any premises where food is manufactured, prepared, processed, stored, or sold, including farms, factories, warehouses, distribution centers, retail stores, restaurants, and other food service establishments.

14. **"Exporter"** means any entity removing Products from the national territory, irrespective of ownership.

15. **"Food"** means any substance or product, whether processed, partially processed, or unprocessed, intended to be, or reasonably expected to be, ingested by humans. "Food" includes: (a) any substance used in the manufacture, preparation, or treatment of food; (b) drink, chewing gum, and any substance, including water, intentionally incorporated into food during its manufacture, preparation, or treatment; (c) dietary supplements, formulated supplementary foods, and special

dietary foods; (d) infant formula and follow-on formula; (e) any substance used as an ingredient, additive, or processing aid; (f) traditional, ethnic, religious, organic, and novel foods. (g) solid, semi-solid, or liquid items, including water intentionally incorporated into food during production; (h) dietary supplements, novel foods, and genetically modified foods; (i) substances used in the manufacturing, preparation, or treatment of food, including additives, vitamins, and minerals. "Food" does not include: (a) medicinal Products as defined by relevant pharmaceutical regulations; (b) narcotic or psychotropic substances as defined by relevant drug control regulations; (c) residues and contaminants; (d) live animals unless they are prepared for placing on the market for human consumption; (e) plants prior to harvesting; (f) tobacco and tobacco Products; (g) cosmetics; (h) feed intended for animals.

16. **"Food business"** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing, and distribution of food.

17. **"Food business operator"** means the natural or legal person responsible for ensuring that the requirements of food law are met within the food business under their control.

18. **"Food contact material"** means any material or article intended to come into contact with food, including: (a) packaging materials; (b) containers for transporting food; (c) machinery for processing food; (d) utensils and equipment for food preparation; (e) surfaces, coatings, and adhesives that may come into contact with food.

19. **"Food hygiene"** means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of food.

20. **"Food safety"** means the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use, and that it is free from biological, chemical, or physical hazards that could cause harm and complies with maximum residue limits for pesticides, veterinary drugs, and contaminants under applicable safety standards.

21. **"Foodborne illness"** means any illness resulting from the consumption of contaminated food, drinks, or semi-fluid items.

22. **"Fortification"** means the intentional addition of nutrients to a Product to address public health deficiencies (e.g., iodized salt, vitamin D-enriched milk).

23. **"Fortified food"** means food to which one or more essential nutrients have been added, whether or not they are normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

24. **"Genetically modified food"** means food containing, consisting of, or produced from genetically modified organisms.

25. **"Genetically modified organism" (GMO)** means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

26. **"Good Manufacturing Practices (GMP)"** means standards and procedures for ensuring that Products are consistently produced and controlled according to quality standards.

27. **"HACCP (Hazard Analysis and Critical Control Point)"** means a systematic approach to identifying, evaluating, and controlling food safety hazards which identifies, evaluates, and controls hazards which are significant for food safety.

28. **"Handler"** means any entity involved in storage, transport, distribution, or any activity involving the physical contact with food, drinks, or semi-fluid items, including: (a) warehousing operators; (b) delivery platforms and logistics providers; (c) those involved in preparation for sale.

29. **"Handling"** means the production, processing, manufacturing, preparation, treatment, packaging, storage, transportation, distribution, display, sale, serving, or delivery of food.

30. **"Hazard"** means a biological, chemical, physical, or radiological agent in, or condition of, food with the potential to cause an adverse health effect.

31. **"Health claim"** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health effects (e.g., "calcium supports bone health").

32. **"Healthy"** means a Product that may be classified as "healthy" only if it meets all the following criteria: (a) Contains ≤ [X]% of daily recommended limits for Key Health Parameters per serving; (b) Contains no artificial trans fats, synthetic dyes linked to hyperactivity in children, or microplastics; (c) Provides ≥ [Y]% of daily recommended vitamins, minerals, or fiber per serving (where applicable).

33. **"Healthy food"** means food, drinks, and semi-fluid items that are nutritious and contribute positively to the overall health and well-being of consumers.

34. **"Importer"** means any entity introducing Products into the national territory, irrespective of ownership.

35. **"Infant formula"** means a food intended for infants (0–12 months) as a partial or total replacement for breast milk.

36. **"Inner packaging"** means the immediate packaging material that comes into direct contact with the food, drink, or semi-fluid item, including but not limited to wrappers, bottles, cans, jars, cartons, films, plastic wrap, aluminum foil, and direct-contact containers.

37. **"Inspection"** means the examination of food or systems for control of food, raw materials, processing, and distribution, including in-process and finished product testing, to verify compliance with requirements.

38. **"Key health parameters"** means specific components or characteristics of a product that have a significant impact on human health. These include but are not limited to: (a) **Salt/sodium**: the total amount of sodium or sodium chloride present in a product, expressed either as sodium in milligrams or salt in grams; (b) **Calories**: the total energy value derived from carbohydrates, fats, proteins, and alcohol, expressed in kilocalories (kcal) or kilojoules (kJ); (c) **Saturated fat**: fatty acids without double bonds between the carbon atoms, including lauric, myristic, and palmitic acids, expressed in grams; (d) **Trans fat**: all industrially produced partially hydrogenated oils and naturally occurring trans fats in ruminant-derived Products, expressed in grams; (e) **Sugar**: all monosaccharides and disaccharides present in food, including both naturally occurring sugars (such as those in fruits, vegetables, and dairy Products) and added sugars (such as sucrose, fructose, glucose, corn syrup, and high-fructose corn syrup), expressed in grams; (f) **Added sugar**: sugars and syrups that are added to foods during processing or preparation, excluding sugars naturally present in fruits, vegetables, and dairy Products, expressed in grams; (g) **Alcohol**: ethyl alcohol content expressed in percentage by volume (% ABV) or mass; (h) **Artificial sweeteners**: non-nutritive or low-calorie sweetening substances used

as sugar substitutes, expressed in milligrams or as a percentage; (i) **Microplastics**: synthetic polymer particles ≤5mm in size, expressed in parts per million or per billion.

39. **"Label"** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, impressed on, or attached to a container of food.

40. **"Labelling"** means any written, printed, or graphic matter on packaging or accompanying a Product, including QR codes linking to digital information, as well as any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.

41. **"Legal person"** means an entity recognised by law as having legal rights and obligations, such as a corporation, partnership, or government agency.

42. **"Manufacturer"** means any natural or legal person who: (a) Produces, processes, or packages a Product; (b) Contracts third parties to perform these activities on their behalf.

43. **"Manufacturing"** means the process of producing food, drinks, or semi-fluid items from raw materials, including all stages of preparation, processing, and packaging.

44. **"Marketing"** means any activity promoting the sale or consumption of Products, including: (a) Advertising, sponsorship, or branding; (b) Digital campaigns, influencer endorsements, and in-store promotions.

45. **"Maximum Residue Limit (MRL)"** means the maximum concentration of a residue that is legally permitted or recognised as acceptable in or on a food or agricultural commodity.

46. **"Microplastics"** means synthetic polymer particles less than 5 millimeters in size that are insoluble in water and resistant to degradation, which may enter the food chain through various pathways including environmental contamination, food production processes, or packaging materials.

47. **"National territory"** means the geographical area over which the national government exercises jurisdiction, including land, airspace, and territorial waters.

48. **"Natural person"** means an individual human being, as opposed to a legal entity.

49. **"Novel food"** means a food or ingredient not historically consumed in the national territory, including: (a) food with a new or intentionally modified molecular structure; (b) food consisting of, isolated from, or produced from microorganisms, fungi, or algae; (c) food consisting of, isolated from, or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi, or algae; (d) food resulting from a production process not previously used for food production; (e) food containing or consisting of engineered nanomaterials; (f) vitamins, minerals, and other substances used in accordance with dietary supplement regulations, where a production process not previously used has been applied; (g) lab-grown meat; (h) insects or algae processed for human consumption.

50. **"Nutrition claim"** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and the content of protein, fat, and carbohydrates, as well as the content of vitamins and minerals (e.g., "low-fat," "high-fiber").

51. **"Nutritional information"** means data provided on the packaging or labeling of a product regarding its nutritional content, including key health parameters.

52. **"Operator"** means a natural or legal person responsible for ensuring that the requirements of this Act are met within the business under their control.

53. **"Outer packaging"** means the external packaging material that does not come into direct contact with the food, drink, or semi-fluid item, including but not limited to boxes, crates, cartons, and wrappings used for transport, display, or additional protection.

54. **"Packaging"** means any material or article intended to contain, protect, handle, deliver, preserve, transport, inform about and present Products that may come into contact with food.

55. **"Pathogen"** means a microorganism capable of causing disease or illness in humans, including bacteria, viruses, parasites, and fungi.

56. **"Pesticide residue"** means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide, including derivatives such as conversion Products, metabolites, reaction Products, and impurities considered to be of toxicological significance.

57. **"Premarket approval"** means the process of scientific evaluation and regulatory approval of a substance, process, or technology before it can be used in food production, processing, or packaging.

58. **"Processing aid"** means any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods, or their ingredients to fulfill a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product.

59. **"Product"** means food, drink, semi-fluid items intended for ingestion, or chewing items as defined in this Act, including their inner and outer packaging. This definition encompasses: (a) all items covered under "Food" and "Drink" (as defined above); (b) semi-fluid items (e.g., yogurts, purees, sauces); (c) chewing items (e.g., chewing gum, medicinal lozenges); (d) inner and outer packaging materials in direct or indirect contact with the product; (e) all such items regardless of their state of preparation, their compositional characteristics, their country of origin, and whether they are produced in an industrial, artisanal, or domestic setting.

60. **"Retailer"** means a person or entity selling Products directly to consumers, including online marketplaces.

61. **"Risk"** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

62. **"Risk analysis"** means a process consisting of three interconnected components: risk assessment, risk management, and risk communication.

63. **"Saturated fat"** means fatty acids with no double bonds between the carbon atoms, typically solid at room temperature, including lauric, myristic, and palmitic acids, which may increase the risk of cardiovascular disease when consumed in excessive amounts.

64. **"Semi-fluid item"** means any product that exhibits properties between those of a solid and a liquid, having some structural rigidity but able to flow under certain conditions, which is intended for human

consumption through ingestion, including but not limited to jellies, puddings, yogurts, purees, soft cheeses, sauces, honey, spreads, and similar food preparations.

65. **"Shelf life"** means the period during which a Product maintains its safety and quality under specified storage conditions, expressed as: (a) "Use by" (perishable items); (b) "Best before" (non-perishable items).

66. **"Sugar"** means all monosaccharides (such as glucose and fructose) and disaccharides (such as sucrose or table sugar) present in food, both naturally occurring and added during processing or preparation, including free sugars, added sugars, and intrinsic sugars from fruits, vegetables, and honey.

67. **"Supplement"** means a concentrated source of nutrients or substances sold in dose form (e.g., tablets, capsules) intended to supplement the normal diet that consists of concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form.

68. **"Trans fat"** means unsaturated fatty acids that contain at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration (meaning that the hydrogen atoms are on opposite sides of the double bond), including all industrially produced partially hydrogenated oils and naturally occurring trans fats in ruminant-derived Products.

69. **"Traceability"** means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

70. **"Ultra-processed food"** means formulations of ingredients, mostly of exclusive industrial use, typically created by a series of industrial techniques and processes, containing little or no whole foods and often including additives designed to make the final product palatable or more appealing.

71. **"Vulnerable populations"** means groups at heightened risk from unsafe or unhealthy Products, including: (a) Infants, children, pregnant or lactating individuals; (b) Elderly persons, immunocompromised individuals, or those with chronic diseases.

72. **"Wholesome"** means food that is fit for human consumption, clean, safe, and not adulterated.

N.B.: Select further definitions and connected rules from Chapter C. of the Cross-sectoral Standard Provisions.

Product and Manufacturing Requirements

Health Parameters and Nutrients

Objectives and Scope

1. The provisions of this section aim to: (a) Establish a regulatory framework for the management of health parameters and nutrients in food Products; (b) Empower the relevant Authority to monitor and

enforce standards related to health parameters and nutrients; (c) Improve population health outcomes through the optimisation of nutrient profiles in food Products; (d) Reduce the prevalence of diet-related non-communicable diseases by regulating potentially harmful substances.

2. These provisions apply to all Products, as defined in Section [X] of this Act, unless explicitly exempted.

General Principles for Health Parameters and Nutrients

1. All operators must ensure that Products manufactured, handled, or commercialised are in compliance with the limits established for key health parameters and nutrients.

2. The development and implementation of measures relating to health parameters and nutrients must be guided by the principles of proportionality, evidence-based decision making, and the precautionary principle.
3. Where international standards for health parameters and nutrients exist, they must be taken into consideration in the development of national standards, provided they meet or exceed the minimum requirements established in this Act.

4. Special attention must be given to Products intended for vulnerable populations, which must be subject to more stringent requirements regarding health parameters and nutrients, as specified in subsequent articles.

General Obligation to Optimise Key Health Parameters

1. All manufacturers, handlers, and retailers must take all reasonable measures to optimize the nutritional profile of their Products with respect to key health parameters.

2. "Optimisation" as referred to in paragraph 1 means: (a) Minimising the content of potentially harmful or excessive substances, while maintaining product functionality, safety, and consumer acceptability; (b) Maximising the content of beneficial nutrients, within the constraints of the product category, production methods, and shelf stability requirements; (c) Achieving a balanced nutritional profile appropriate to the product category and its intended use in the diet.

3. Manufacturers must: (a) Conduct regular reviews of their product formulations to identify opportunities for nutritional improvement; (b) Document optimization efforts, including reformulation attempts, technology limitations, and consumer acceptance studies; (c) Implement a continuous improvement strategy for the nutritional profile of their Products; (d) Submit an annual report to the Authority detailing optimisation activities and achievements.

4. The obligation to optimise must be progressive and take into account: (a) Technological feasibility; (b) Organoleptic impacts; (c) Food safety considerations; (d) Consumer acceptance; and (e) Economic viability.

5. The Authority must develop sector-specific guidelines for optimisation, taking into account the specific challenges and opportunities of different food categories.

Obligation to Minimise Potentially Harmful Substances

1. All manufacturers must take all reasonable measures to minimise the following potentially harmful substances in their Products: (a) Salt/sodium; (b) Free sugars and added sugars; (c) Saturated fats; (d) Trans fats; (e) Calories in energy-dense, nutrient-poor Products; (f) Artificial sweeteners; (g) Microplastics; (h) Any other substance designated by the Authority in accordance with Article … .

2. Without prejudice to more specific limits that may be established under Article … , manufacturers must: (a) Eliminate all artificial trans fats from their Products, with no more than 2g of trans fat per 100g of total fat permitted from ruminant sources; (b) Reduce sodium content by at least 20% below the industry average for the specific product category within 5 years of this Act coming into force; (c) Reduce added sugar content by at least 15% below the industry average for the specific product category within 5 years of this Act coming into force; (d) Reduce saturated fat content by at least 10% below the industry average for the specific product category within 5 years of this Act coming into force; (e) Take all reasonable steps to eliminate detectable microplastics from Products and their packaging; (f) Use artificial sweeteners only when necessary and at the lowest effective dose.

3. Manufacturers must maintain documentary evidence of their efforts to minimise these substances, including: (a) Baseline measurements of current levels; (b) Time-bound reduction targets; (c) Technological approaches employed; (d) Results of reduction efforts.

4. The Authority must publish guidelines for the substitution of potentially harmful ingredients with healthier alternatives, considering technological, safety, and sensory aspects.

Nutrient Density and Beneficial Nutrients

1. Manufacturers must strive to increase the nutrient density of their Products where appropriate by: (a) Increasing the content of essential nutrients such as vitamins, minerals, proteins, and dietary fiber; (b) Prioritizing whole food ingredients over refined ingredients where technologically feasible; (c) Ensuring that energy content is balanced with nutrient content.

2. When reducing potentially harmful substances as required under Article … , manufacturers must ensure that: (a) Reformulation does not lead to a decrease in beneficial nutrients; (b) Substitutes used are nutritionally advantageous in comparison to the replaced ingredients; (c) The overall nutritional profile of the Product is improved.

3. The Authority must, by virtue of … [1], create a Nutrient Density Scoring System that: (a) Evaluates the ratio of beneficial nutrients to calories; (b) Accounts for both nutrients to encourage and nutrients to limit; (c) Is tailored to specific product categories; (d) Can be communicated effectively to consumers.

Allergen Management and Minimisation

1. Manufacturers must implement a comprehensive allergen management system that: (a) Identifies all allergens present in their Products; (b) Prevents cross-contamination between allergen-containing and allergen-free Products; (c) Provides clear allergen information on product labels; (d) Regularly reviews product formulations to minimise the use of allergens affecting 5% or more of the population.

2. The following allergens, known to affect 5% or more of the population, must be subject to minimization efforts: (a) Cereals containing gluten; (b) Milk and dairy Products; (c) Eggs and egg

[1] Define the appropriate type of regulation.

Products; (d) Peanuts and Products thereof; (e) Tree nuts and Products thereof; (f) Soybeans and Products thereof; (g) Fish and Products thereof; (h) Crustaceans and Products thereof; (i) Any other allergen designated by the Authority based on epidemiological data.

3. Minimisation of allergens must involve: (a) Substituting allergenic ingredients with non-allergenic alternatives where technologically feasible; (b) Developing allergen-free versions of popular Products where commercially viable; (c) Using dedicated production lines for allergen-free Products where practicable; (d) Implementing cleaning validation procedures to verify the effectiveness of allergen removal.

4. Where allergens cannot be eliminated from a product, manufacturers must: (a) Implement the strictest controls to prevent cross-contamination; (b) Use clear, prominent allergen labeling exceeding minimum legal requirements; (c) Provide detailed information on allergen content and potential cross-contamination on company websites and consumer information services.

5. The Authority may/must maintain a public database of allergen prevalence and severity in the population and update the list of allergens subject to minimisation efforts every three years based on current epidemiological data.

Accountability and Reporting

1. Manufacturers must submit an annual Health Parameters Report to the Authority detailing: (a) Current levels of key health parameters in their Products; (b) Progress made in optimising health parameters compared to the previous year; (c) Challenges encountered in optimisation efforts; (d) Planned actions for the upcoming year; (e) Any analysis of the impact of reformulation on consumer acceptance.

2. The Authority must: (a) Review submitted reports within 60 days; (b) Provide feedback and recommendations to manufacturers; (c) Publish an anonymized industry-wide progress report annually; (d) Recognise manufacturers demonstrating exceptional progress; (e) Publish a list of manufacturers failing to meet minimum reduction targets.

3. Large manufacturers with annual revenue exceeding [threshold] must: (a) Conduct independent nutritional audits of their product portfolio every two years; (b) Establish an internal nutrition committee with qualified nutrition professionals; (c) Develop and implement a public health nutrition strategy; (d) Report publicly on their progress against key health parameters.

4. Small and medium manufacturers may apply for technical assistance from the Authority to meet their obligations under this Article.

Powers of the Government and of the Authority

General Powers of the Authority

1. The Authority has the power to: (a) Develop and implement regulations related to health parameters and nutrients; (b) Monitor compliance with the provisions of this Act; (c) Investigate potential violations; (d) Impose penalties for non-compliance; (e) Provide guidance to food business operators; (f) Conduct or commission research on health parameters and nutrients; (g) Collaborate with international bodies on matters related to health parameters and nutrients.

2. The Authority must publish an annual report on the state of health parameters and nutrients in the national food supply, including: (a) Progress in reducing potentially harmful substances; (b) Trends in nutrient levels across different food categories; (c) Compliance rates with established standards; (d) Recommendations for further action.

Power to Designate Additional Key Health Parameters

1. The Authority has the power to designate additional substances or nutrients as key health parameters through a transparent, science-based process.

2. In determining whether a substance or nutrient should be designated as a key health parameter, the Authority must consider: (a) Scientific evidence of significant public health impact; (b) Prevalence of the substance in the food supply; (c) Potential for practical and effective regulation; (d) International standards and practices; (e) Input from relevant stakeholders.

3. Before designating a new key health parameter, the Authority must: (a) Publish a comprehensive scientific review of the evidence; (b) Conduct a public consultation for a period of at least 90 days; (c) Consider all submissions received during the consultation period; (d) Publish a response to the submissions; (e) Issue a formal decision with detailed reasoning.

4. Where urgent action is required to protect public health, the Authority may, by virtue of … [2], provisionally designate a substance as a key health parameter for a period not exceeding 12 months while the process described in paragraph 3 is completed.

5. For each newly designated key health parameter, the Authority must: (a) Establish baseline levels in the food supply; (b) Set initial targets for reduction or increase, as appropriate; (c) Develop implementation guidance for food business operators; (d) Establish a timeline for compliance; (e) Define appropriate monitoring mechanisms.

6. The Authority must review the list of key health parameters at least every five years to ensure it remains consistent with the latest scientific evidence.

Power to Set Minimum and Maximum Values

1. The Authority has the power to establish, by virtue of … [3], minimum and maximum values for key health parameters and nutrients by product category through regulations.

2. In establishing such values, the Authority must: (a) Base decisions on the best available scientific evidence; (b) Consider technological feasibility; (c) Take into account international standards and best practices; (d) Implement a phased approach when significant reformulation is required; (e) Consider the overall nutritional composition of foods within each category; (f) Account for the role of specific food categories in the typical diet.

3. The Authority must, by virtue of … [4], establish: (a) Maximum values for potentially harmful substances including but not limited to salt, saturated fats, trans fats, added sugars, and artificial sweeteners; (b) Minimum values for beneficial nutrients including but not limited to fiber, essential vitamins, and minerals for specific product categories where appropriate; (c) Product-category

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[2] Define the appropriate type of regulation.

[3] Define the appropriate type of regulation.

[4] Define the appropriate type of regulation.

specific values that recognise the inherent differences between food types.

4. For novel food categories or those not specifically covered by existing regulations, the Authority may, by virtue of … [5]: (a) Establish provisional values pending more detailed assessment; (b) Apply values from the most similar existing category as interim measures; (c) Require manufacturers to propose appropriate values with supporting scientific justification.

5. Values must be established through a transparent process involving: (a) Publication of proposed values; (b) A public consultation period of at least 60 days; (c) Expert committee review; (d) Publication of final values with detailed justification.

6. The Authority must review established values at least every five years, or more frequently when: (a) New scientific evidence becomes available; (b) Technological advances enable more ambitious targets; (c) Monitoring indicates values are not achieving the intended health outcomes.

7. The Authority must establish a technology innovation platform to: (a) Identify technological barriers to meeting established values; (b) Fund research into innovative solutions; (c) Facilitate knowledge transfer between academia and industry; (d) Accelerate the adoption of new technologies for improving nutritional profiles.

Power to Define Rules for Content Declaration

1. The Authority must, by virtue of … [6], establish comprehensive rules for the declaration of calorie and nutrient content on food labels, including: (a) Required nutrients to be declared; (b) Units of measurement; (c) Reference amounts; (d) Presentation format; (e) Prominence and placement; (f) Additional voluntary declarations.

2. The mandatory declaration must include at minimum: (a) Energy value (in both kilojoules and kilocalories); (b) Amounts of fat, saturates, carbohydrate, sugars, protein, and salt; (c) Percentage contribution to daily reference intake values; (d) Serving size and number of servings per package; (e) Any other nutrient determined by the Authority to be of significant public health importance.

3. The Authority must, by virtue of … [7], establish rules for: (a) Front-of-pack nutrition labelling systems; (b) Digital or extended information accessible via QR codes or similar technology; (c) Comparative nutrition claims; (d) Nutrient profiling models to determine eligibility for health and nutrition claims; (e) Presentation of information for low-literacy populations.

4. The Authority must develop specific rules for: (a) Small packages where space is limited; (b) Multi-component Products; (c) Non-prepacked foods; (d) Foods sold online or through vending machines; (e) Foods served in restaurants and other food service establishments.

5. The Authority must, by virtue of … [8], establish permitted tolerances for declared values, considering: (a) Natural variation in nutrient content; (b) Manufacturing variability; (c) Analytical uncertainty; (d) Stability over shelf life.

6. The Authority must require that declared values be substantiated by: (a) Laboratory analysis of representative samples; (b) Calculation from known or average values of ingredients; (c) Calculation

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[5] Define the appropriate type of regulation.
[6] Define the appropriate type of regulation.
[7] Define the appropriate type of regulation.
[8] Define the appropriate type of regulation.

from generally established and accepted data.

7. The Authority has the power to require the use of specific testing methodologies for verifying declared content.

Power to Mandate Food Fortification

1. The Authority has the power to mandate the fortification of specific food vehicles with essential nutrients when: (a) There is evidence of population-wide deficiency or inadequate intake of the nutrient; (b) The selected food vehicle is consumed by a significant proportion of the target population; (c) The fortification is technologically feasible and does not adversely affect the organoleptic properties of the food; (d) The cost-benefit analysis supports mandatory intervention; (e) The potential for excessive intake of the nutrient is minimal.

2. The Authority may, by virtue of … [9], mandate fortification of: (a) Staple foods such as flour, rice, maize, and other cereal Products; (b) Condiments and seasoning such as salt and cooking oil; (c) Processed foods with wide consumption patterns; (d) Foods specifically targeted to vulnerable populations; (e) Any other food category determined to be an appropriate vehicle.

3. The Authority must, by virtue of … [10], specify for each mandatory fortification program: (a) The specific nutrient(s) to be added; (b) The permitted forms of the nutrient(s); (c) The minimum and maximum levels of addition; (d) Quality assurance requirements; (e) Labelling requirements; (f) Implementation timeline; (g) Monitoring and enforcement mechanisms.

4. Without limiting paragraph 1, the Authority must consider mandatory fortification programs for: (a) Iodization of salt; (b) Fortification of flour with folic acid, iron, zinc, and B vitamins; (c) Fortification of cooking oil with vitamin A and vitamin D; (d) Fortification of dairy Products with vitamin D; (e) Fortification of appropriate food vehicles with essential minerals including calcium, zinc, and selenium based on population needs.

5. The Authority must, by virtue of … [11], establish a monitoring and evaluation system for all mandatory fortification programs that includes: (a) Regular market surveillance of fortified Products; (b) Assessment of nutrient intake levels in the population; (c) Biomarker studies to evaluate impact; (d) Economic analysis of program costs and benefits; (e) Ongoing review of program relevance.

6. The Authority must review each mandatory fortification program at least every five years to: (a) Assess continued need based on updated dietary intake and nutritional status data; (b) Evaluate compliance and technical challenges; (c) Consider any new evidence regarding safety or efficacy; (d) Make recommendations for program continuation, modification, or termination.

7. The Authority may/must, by virtue of … [12], establish exemption mechanisms for: (a) Traditional or artisanal Products where fortification would significantly alter the traditional character; (b) Organic Products subject to specific regulatory requirements; (c) Products targeting specific dietary needs incompatible with fortification; (d) Small-scale producers with production below defined thresholds.

Implementation and Compliance

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9 Define the appropriate type of regulation.

10 Define the appropriate type of regulation.

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12 Define the appropriate type of regulation.

Nutritional Risk Assessment

1. The Authority must, by virtue of … [13], develop and implement a Nutritional Risk Assessment Framework to: (a) Identify foods that pose significant risks due to their nutritional profile; (b) Classify Products according to their potential impact on public health; (c) Prioritize regulatory interventions based on population health impact; (d) Target monitoring and enforcement resources effectively.

2. The Nutritional Risk Assessment must consider: (a) Nutrient density relative to energy content; (b) Contribution of key health parameters to overall diet; (c) Consumption patterns and serving sizes; (d) Target consumer groups, with special attention to vulnerable populations; (e) Marketing and positioning of the product; (f) Potential for reformulation.

3. Based on the risk assessment, the Authority must, by virtue of … [14],: (a) Identify priority food categories for focused intervention; (b) Develop category-specific targets and timelines; (c) Allocate resources to high-impact areas; (d) Design tailored incentive and enforcement strategies.

Implementation Periods and Transitional Provisions

1. The provisions of this section must be implemented according to the following schedule: (a) General obligation to optimise key health parameters: Effective 12 months after promulgation; (b) Specific substance reduction targets: Phased implementation over 5 years; (c) Reporting requirements: Effective 18 months after promulgation; (d) New content declaration rules: Effective 24 months after promulgation; (e) Mandatory fortification programs: To be determined on a case-by-case basis.

2. Small and medium enterprises with fewer than [threshold] employees or annual turnover below [threshold] must be granted an additional 12 months for compliance with each provision.

3. The Authority must develop and publish detailed implementation guidelines within 6 months of the promulgation of this Act.

4. For Products with shelf life exceeding 18 months, special transitional provisions must apply to allow for the gradual replacement of existing stock.

Technical Assistance Program

1. The Authority must establish a Technical Assistance Program to support food business operators in meeting their obligations under this section, including: (a) Guidance documents and toolkits; (b) Training workshops and webinars; (c) One-on-one consultations for small and medium enterprises; (d) Digital compliance tools; (e) Laboratory testing subsidies for small producers.

2. The Technical Assistance Program must prioritise: (a) Small and medium enterprises; (b) Traditional food producers; (c) Enterprises in underserved regions; (d) Producers of staple foods consumed by vulnerable populations.

3. The Authority may/must, in partnership with academic institutions, international organisations, and civil society, expand the reach and impact of the Technical Assistance Program.

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[13] Define the appropriate type of regulation.
[14] Define the appropriate type of regulation.

Incentives for Excellence

1. The Authority must, by virtue of … [15], establish a Recognition Program for food business operators demonstrating exceptional commitment to nutritional optimisation, including: (a) Annual Nutrition Innovation Awards; (b) Public recognition of industry leaders; (c) Preferential consideration in public procurement; (d) Use of official "Nutrition Excellence" logo; (e) Tax incentives for research and development in nutritional improvement.

2. The Authority may/must, by virtue of … [16], create a Nutrition Innovation Fund to: (a) Support research into novel ingredients and technologies; (b) Fund pilot projects for nutritional improvement; (c) Subsidise initial costs of significant reformulations; (d) Support consumer research on healthier alternatives.

Monitoring and Enforcement

1. The Authority must, by virtue of … [17], establish a comprehensive monitoring system to assess compliance with health parameter requirements, including: (a) Regular sampling and analysis of Products on the market; (b) Audit of manufacturer documentation and testing records; (c) Review of annual Health Parameters Reports; (d) Investigation of consumer and competitor complaints; (e) Cross-verification of declared values.

2. The Authority must develop a risk-based inspection program targeting: (a) High-risk product categories; (b) Products with previous compliance issues; (c) New market entrants; (d) Products targeting vulnerable populations.

3. In case of non-compliance, the Authority may: (a) Issue improvement notices specifying corrective actions and deadlines; (b) Require additional testing and verification; (c) Mandate modified labelling to accurately reflect content; (d) Impose fines proportionate to the severity of the violation and the size of the operation; (e) Order product recall in cases of significant public health concern; (f) Suspend or revoke operating licenses for repeated or severe violations.

4. The Authority must publish an annual compliance report detailing: (a) Overall compliance rates by product category; (b) Common areas of non-compliance; (c) Enforcement actions taken; (d) Improvements observed over time; (e) Recommendations for industry and policy makers.

International Cooperation

1. The Authority must actively participate in international standard-setting bodies related to nutrition and health parameters, including: (a) Codex Alimentarius Commission; (b) World Health Organization technical working groups; (c) Regional harmonization initiatives; (d) International research consortia on nutrition and food technology.

2. The Authority must work toward harmonization of health parameter requirements with major trading partners while maintaining or exceeding domestic health protection goals.

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[15] Define the appropriate type of regulation.
[16] Define the appropriate type of regulation.
[17] Define the appropriate type of regulation.

3. The Authority may/must share data, methodologies, and best practices with international counterparts to advance global nutrition improvement efforts.

Research and Evaluation

Research Mandate

1. The Authority may/must commission or conduct research on: (a) Health impacts of key parameters in the national population; (b) Technological innovation for healthier formulations; (c) Consumer behavior and acceptance of reformulated Products; (d) Economic impacts of nutrition optimisation measures; (e) Effectiveness of regulatory approaches in improving population health outcomes.

2. Research findings must be made publicly available and must inform the periodic review of standards and regulations.

Policy Review and Evaluation

1. The Authority must conduct a comprehensive review of the effectiveness of this section every five years, assessing: (a) Progress in optimising the nutritional profile of the food supply; (b) Changes in population dietary intake patterns; (c) Impact on relevant health indicators; (d) Economic impacts on the food industry; (e) Consumer acceptance and satisfaction; (f) Emerging nutritional challenges and opportunities.

2. Based on the review findings, the Authority must recommend amendments to this section as necessary to address evolving public health needs and scientific evidence.

3. An interim evaluation must be conducted after two years to identify early implementation challenges and opportunities for improvement.

Ingredient Restrictions

Objectives and Scope

1. The provisions of this section aim to ensure the safety of food Products by restricting or prohibiting ingredients, additives, and substances that may pose a risk to human health.

2. These provisions apply to all food, drinks, semi-liquid items intended for ingestion, and chewing items (hereinafter collectively referred to as "food Products") that are marketed or intended to be marketed on the national territory, regardless of their place of origin.

3. These provisions also apply to all natural and legal persons involved in the manufacturing, handling, or commercialisation of food Products, or contributing to such activities, irrespective of their location.

Prohibited Ingredients and Substances

1. The following ingredients and substances are prohibited in all food Products:

    a) Brominated vegetable oil

b) FD&C Red Dye #3 (Erythrosine)

c) Titanium dioxide (TiO2)

d) Potassium bromate

e) Propylparaben

f) Bisphenol A (BPA) in all materials that come into contact with food

g) Endocrine-disrupting chemicals in food packaging materials

h) Industrially produced trans fats exceeding 2% of total fat content in any food product

i) Partially hydrogenated oils.

2. The Authority must, by virtue of … [18], maintain and regularly update a comprehensive list of prohibited ingredients and substances, which must be publicly available on its official website.

3. Food Products containing any prohibited ingredient or substance may not be manufactured, imported, exported, distributed, sold, or otherwise placed on the market.

Allergen Management

1. The following substances known to cause allergies or intolerances must be clearly labelled on all food Products in accordance with the labeling requirements set forth in Section [X] of this Act:

a) Cereals containing gluten and Products thereof

b) Crustaceans and Products thereof

c) Eggs and Products thereof

d) Fish and Products thereof

e) Peanuts and Products thereof

f) Soybeans and Products thereof

g) Milk and Products thereof (including lactose)

h) Nuts and Products thereof

i) Celery and Products thereof

j) Mustard and Products thereof

k) Sesame seeds and Products thereof

l) Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter

m) Lupin and Products thereof

n) Molluscs and Products thereof

[18] Define the appropriate type of regulation.

2. The Authority has the power to:

   a) Add or remove substances from the list of allergens based on scientific evidence and risk assessment

   b) Establish thresholds for the presence of allergens in food Products

   c) Require specific handling procedures to prevent cross-contamination of allergens

   d) Conduct inspections to ensure compliance with allergen management requirements

3. Food business operators must:

   a) Implement practices to reduce or eliminate cross-contact of food with residues of major food allergens that are not intentional ingredients of the food

   b) Ensure that major food allergens are properly labelled on foods

   c) Maintain documentation of allergen control measures

Positive List of Food Additives

1. Only food additives included in the Positive List established by the Authority may be used in food Products.

2. The Positive List must specify:

   a) The approved food additives

   b) The food categories in which each additive may be used

   c) The maximum permitted levels for each additive in specific food categories

   d) Any specific conditions or restrictions for the use of each additive

3. Food additives may only be included in the Positive List if they:

   a) Do not, on the basis of available scientific evidence, present a hazard to consumer health at the level of use proposed

   b) Serve a technological need that cannot be achieved by other economically and technologically practicable means

   c) Do not mislead the consumer

4. Food additives may also serve one or more of the following purposes:

   a) Preserving the nutritional quality of the food

   b) Providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs

   c) Enhancing the keeping quality or stability of a food or improving its organoleptic properties

   d) Aiding in the manufacture, processing, preparation, treatment, packing, transport or storage of food

5. The Authority must review and update the Positive List at least once every five years based on new scientific evidence and technological developments.

Maximum Residue Limits

1. The Authority may/must, by virtue of … [19], establish maximum residue limits for:

   a) Pesticides in or on food Products

   b) Veterinary drugs in Products of animal origin

   c) Environmental contaminants in food Products

   d) Processing contaminants formed during food production

2. Maximum residue limits must be established based on:

   a) Scientific risk assessment

   b) Good Agricultural Practices (GAP)

   c) Good Manufacturing Practices (GMP)

   d) The principles of the Codex Alimentarius Commission

3. Food Products containing residues exceeding the established maximum limits may not be placed on the market.

Novel Foods and Ingredients

1. For the purposes of this section, "novel food" means food that was not used for human consumption to a significant degree within the national territory before [reference date], and that falls under at least one of the following categories:

   a) Food with a new or intentionally modified molecular structure

   b) Food consisting of, isolated from, or produced from microorganisms, fungi, or algae

   c) Food consisting of, isolated from, or produced from material of mineral origin

   d) Food consisting of, isolated from, or produced from plants or their parts, except when the food has a history of safe food use

   e) Food consisting of, isolated from, or produced from animals or their parts, except for foods obtained by traditional breeding practices and having a history of safe food use

   f) Food resulting from a production process not used for food production within the national territory before [reference date], which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism, or level of undesirable substances

   g) Food consisting of engineered nanomaterials

   h) Vitamins, minerals, and other substances used in accordance with specific provisions

[19] Define the appropriate type of regulation.

i) Food used exclusively in food supplements within the national territory before [reference date], where it is intended to be used in foods other than food supplements

2. Novel foods may only be placed on the market after:

   a) The food business operator has submitted a comprehensive application to the Authority

   b) The Authority has conducted a thorough safety assessment

   c) The Authority has granted authorization for the novel food

3. The following novel foods are subject to specific restrictions:

   a) Cannabidiol (CBD) and hemp-derived Products may only be used in food Products if:

   i. They contain no more than 0.2% tetrahydrocannabinol (THC)

   ii. They have been authorized by the Authority following a safety assessment

   iii. They comply with specific labelling requirements

   b) Genetically modified organisms (GMOs) and food produced from GMOs must be subject to the provisions set forth in Section [Y] of this Act.

Powers of the Authority

1. The Authority has the power to:

   a) Ban additional ingredients, additives, and substances based on scientific evidence indicating potential risks to human health

   b) Establish and update the Negative List of prohibited ingredients, additives, and substances

   c) Establish and update the Positive List of permitted ingredients, additives, and substances, including their maximum usage limits

   d) Require pre-market approval[20] for new ingredients, additives, and substances before they can be used in food Products

   e) Conduct risk assessments of ingredients, additives, and substances used in food Products

   f) Establish specific requirements for the use of certain ingredients, additives, and substances

   g) Grant exemptions from prohibitions or restrictions in justified cases and under specific conditions

   h) Withdraw authorizations for ingredients, additives, and substances if new scientific evidence indicates potential risks to human health

   i) Establish transitional periods for the implementation of new restrictions or prohibitions

2. In exercising these powers, the Authority must:

   a) Base its decisions on scientific evidence and risk assessment

   b) Consider international standards and guidelines, particularly those of the Codex Alimentarius Commission12

[20] Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.

c) Apply the precautionary principle when scientific evidence is insufficient, inconclusive, or uncertain, and where there are indications of potential risks to human health

d) Consult with relevant stakeholders, including food business operators, consumer organizations, and scientific experts

e) Publish the scientific opinions and risk assessments that form the basis of its decisions

Obligations of Food Business Operators

1. Food business operators must:

a) Ensure that all ingredients, additives, and substances used in their food Products comply with the provisions of this Section

b) Maintain up-to-date records of all ingredients, additives, and substances used in their food Products

c) Verify the compliance of their suppliers with the provisions of this Section

d) Implement appropriate quality control measures to ensure compliance with the provisions of this Section

e) Notify the Authority of any new scientific or technical information that might affect the safety assessment of ingredients, additives, or substances used in their food Products

f) Withdraw from the market any food Products that do not comply with the provisions of this Section

g) Cooperate with the Authority in the implementation and enforcement of the provisions of this Section

Enforcement and Sanctions

1. The Authority must monitor compliance with the provisions of this Section through:

a) Regular inspections of food business operators' premises

b) Sampling and analysis of food Products

c) Audits of food business operators' quality control systems

d) Investigations of complaints and reported non-compliance

2. In case of non-compliance with the provisions of this Section, the Authority may impose one or more of the following sanctions:

a) Warning

b) Fine proportionate to the severity of the non-compliance and the size of the food business operator

c) Temporary or permanent prohibition of specific activities

d) Temporary or permanent closure of specific establishments

e) Withdrawal or recall of non-compliant food Products from the market

f) Suspension or revocation of authorizations, permits, or licenses

g) Publication of information on non-compliant food business operators and food Products

h) Criminal prosecution for serious or repeated non-compliance

3. The Authority must establish detailed guidelines for the application of sanctions, ensuring that they are effective, proportionate, and dissuasive.

Transitional Provisions

1. Food business operators shall have a transitional period of [X] months from the entry into force of this Section to comply with its provisions.

2. Food Products that were lawfully placed on the market before the entry into force of this Section may continue to be marketed until stocks are exhausted, but not longer than [Y] months after the entry into force of this Section.

3. The Authority may, by virtue of … [21], establish specific transitional periods for particular provisions of this Section, taking into account the time needed for food business operators to adapt their Products and processes.

Food Safety Standards and Requirements

General Food Safety Obligations

1. Food business operators must apply state-of-the-art food safety standards and guidelines in all their operations.

2. The standards,guidelines, and recommendations of the Codex Alimentarius Commission must be considered as the minimum baseline for food safety practices.

3. Food business operators must:

a) Ensure that food Products under their control satisfy the requirements of food law at all stages of production, processing, and distribution;

b) Verify that such requirements are met;

c) Implement a documented food safety management system based on HACCP principles, or an equivalent system recognised by the Authority;

d) Maintain records demonstrating compliance with food safety requirements for a minimum period of three years, or for the shelf life of the product plus six months, whichever is longer.

Food Safety Management Systems

1. Food business operators must implement, maintain, and continuously improve a documented food safety management system based on internationally recognised standards, including but not limited to:

[21] Define the appropriate type of regulation.

a) ISO 22000 (Food safety management systems - Requirements for any organization in the food chain);

b) FSSC 22000 (Food Safety System Certification);

c) Other equivalent standards recognised by the Authority.

2. The food safety management system must:

a) Identify and control food safety hazards;

b) Ensure effective communication throughout the food chain;

c) Ensure compliance with all applicable statutory and regulatory food safety requirements;

d) Be regularly evaluated and updated to reflect changes in operations, emerging hazards, or new scientific knowledge.

3. Food business operators must obtain certification of their food safety management system from an accredited[22] certification body at intervals determined by the Authority based on risk assessment.

Current Good Manufacturing Practices (CGMPs)

1. Food business operators engaged in manufacturing, processing, packing, or holding food must implement Current Good Manufacturing Practices (CGMPs) covering:

a) Personnel;

b) Buildings and facilities;

c) Equipment and utensils;

d) Production and process controls;

e) Warehousing and distribution.

2. Personnel CGMPs must include:

a) Disease control measures to prevent persons affected by illness or open lesions from contaminating food;

b) Cleanliness requirements including proper hand washing, protective clothing, and removal of jewelry;

c) Training in food protection principles;

d) Supervision to ensure compliance with hygiene requirements.

3. Buildings and facilities CGMPs must include:

a) Proper maintenance of grounds to prevent contamination;

b) Plant construction and design that facilitates maintenance and sanitary operations;
c) Sanitary operations for cleaning and sanitizing equipment and surfaces;
d) Pest control measures;

[22] Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.

e) Sanitary facilities and controls for water supply, plumbing, sewage disposal, toilet facilities, and hand-washing facilities.

4. Equipment and utensils CGMPs must include:

   a) Design, construction, and maintenance to facilitate cleaning and prevent contamination;

   b) Food-contact surfaces that are corrosion-resistant and non-toxic;

   c) Seams on food-contact surfaces that are smoothly bonded;
   d) Equipment installation and maintenance that allows for cleaning and inspection.

5. Production and process control CGMPs must include:

   a) Raw material inspection, storage, and handling;

   b) Manufacturing operations conducted under conditions that minimize the potential for growth of microorganisms or contamination;

   c) Chemical, microbial, or extraneous-material testing procedures;

   d) Packaging and labeling controls.

Employee Health and Hygiene

1. Food business operators must establish, implement, and maintain documented procedures for:

   a) Health screening of food handlers before employment and at regular intervals;

   b) Reporting of illness and symptoms that may affect food safety;

   c) Exclusion or restriction of food handlers with specific illnesses or symptoms;

   d) Reinstatement of excluded or restricted food handlers.

2. Food handlers must:

   a) Maintain a high degree of personal cleanliness;

   b) Wear clean, appropriate protective clothing;

   c) Wash hands thoroughly and at appropriate times;

   d) Cover cuts and wounds with waterproof dressings;

   e) Refrain from behaviors that could result in contamination of food, such as smoking, spitting, eating, or chewing in food handling areas;

   f) Remove jewelry and other objects that might fall into or contaminate food;

   g) Keep fingernails clean and trimmed.

3. Food business operators must provide:

   a) Adequate and conveniently located handwashing facilities;

   b) Sufficient supply of potable water at appropriate temperatures;

c) Soap and effective hand-drying devices;

d) Properly designed and maintained toilet facilities;

e) Adequate changing facilities for personnel.

4. Food business operators must ensure that all persons working in food handling areas:

a) Receive appropriate training in food hygiene, commensurate with their activities;

b) Are supervised and instructed in food hygiene matters;

c) Comply with all requirements of this Article.

Temperature Control Requirements

1. Food business operators must ensure that food Products requiring temperature control for safety are maintained at appropriate temperatures throughout the food chain.

2. For refrigerated foods:

a) Cold storage facilities must maintain temperatures at or below 5°C (41°F)

b) Refrigerated display units must maintain temperatures at or below 5°C (41°F)

c) During transportation, temperatures must be maintained at or below 5°C (41°F)

3. For frozen foods:

a) Freezer storage facilities must maintain temperatures at or below -18°C (0°F)

b) Frozen display units must maintain temperatures at or below -18°C (0°F)

c) During transportation, temperatures must be maintained at or below -18°C (0°F)

4. For hot-held foods:

a) Hot-holding equipment must maintain temperatures at or above 63°C (145°F)

b) During transportation, hot foods must be maintained at or above 63°C (145°F)

5. Food business operators must:

a) Install temperature monitoring devices in all temperature-controlled storage areas

b) Regularly calibrate temperature monitoring devices

c) Maintain records of temperature monitoring

d) Establish and implement corrective actions for temperature deviations

e) Verify the effectiveness of temperature controls

6. The cooling of cooked foods must be conducted as follows:

a) Cooling from 60°C (140°F) to 21°C (70°F) within two hours

b) Cooling from 21°C (70°F) to 5°C (41°F) within an additional four hours

7. The thawing of frozen foods must be conducted:

   a) Under refrigeration at temperatures not exceeding 5°C (41°F)

   b) Under cold running water

   c) In a microwave oven, only if the food will be immediately transferred to conventional cooking

   d) As part of the cooking process

Allergen Management

1. Food business operators must develop and implement a comprehensive allergen management program that includes:

   a) Identification of allergenic ingredients in all raw materials and food Products

   b) Segregation of allergenic ingredients during storage and handling

   c) Prevention of cross-contact during manufacturing

   d) Proper cleaning of equipment between production runs

   e) Clear labeling of finished Products

   f) Training of personnel in allergen management

2. Food business operators must maintain documentation of:

   a) Allergen information for all raw materials

   b) Production scheduling to minimize cross-contact risks

   c) Cleaning validation studies demonstrating the effectiveness of allergen removal

   d) Verification activities to ensure the effectiveness of allergen controls

3. Food business operators must validate and verify their allergen management program through:

   a) Visual inspection of cleaning effectiveness

   b) Analytical testing for allergen residues where appropriate

   c) Review of production records

   d) Internal audits of allergen management practices

4. Food service establishments must:

   a) Maintain accurate information on the allergenic ingredients in all menu items

   b) Communicate allergen information to customers upon request

   c) Implement procedures to prevent cross-contact during food preparation

d) Train staff on food allergens and proper handling of allergy-related requests

Cleaning and Disinfection

1. Food business operators must develop, implement, and maintain documented cleaning and disinfection procedures for:

   a) Food contact surfaces

   b) Non-food contact surfaces

   c) Environmental surfaces

   d) Equipment and utensils

   e) Facilities and infrastructure

2. Cleaning and disinfection procedures must specify:

   a) Areas, equipment, and utensils to be cleaned and disinfected

   b) Responsibility for specific cleaning tasks

   c) Method and frequency of cleaning and disinfection

   d) Monitoring activities to verify effectiveness

   e) Corrective actions when deviations occur

3. Cleaning and disinfection chemicals must:

   a) Be approved for use in food establishments

   b) Be used according to manufacturer's instructions

   c) Be stored separately from food and food packaging materials

   d) Be clearly labeled

   e) Have safety data sheets available for reference

4. Food business operators must validate the effectiveness of cleaning and disinfection procedures through:

   a) Visual inspection

   b) ATP (adenosine triphosphate) testing or other rapid sanitation monitoring methods

   c) Microbiological sampling

   d) Environmental monitoring programs for high-risk operations

5. Records of cleaning and disinfection activities must be maintained, including:

   a) Date and time of cleaning and disinfection

   b) Person responsible for the cleaning and disinfection

c) Verification that cleaning and disinfection was properly performed

d) Results of effectiveness monitoring

e) Corrective actions taken when necessary

Pest Control

1. Food business operators must implement an integrated pest management program that includes:

   a) Prevention of pest entry through proper building maintenance

   b) Elimination of potential harborage areas

   c) Elimination of potential food sources

   d) Monitoring for pest activity

   e) Appropriate control measures when pests are detected

2. Preventive measures must include:

   a) Sealing of cracks, crevices, and other openings that could allow pest entry

   b) Installation and maintenance of screens on windows and other openings

   c) Installation of air curtains, plastic strips, or self-closing doors at exterior entrances

   d) Maintaining a clear space between walls and equipment

   e) Proper waste management to prevent attracting pests

3. Monitoring must include:

   a) Regular visual inspections of premises for signs of pest activity

   b) Installation and maintenance of pest monitoring devices

   c) Documentation of monitoring results

   d) Trend analysis to identify recurring problems

4. When chemical pest control measures are necessary:

   a) Only approved pesticides may be used

   b) Application must be performed by trained personnel or licensed pest control operators

   c) Food, equipment, utensils, and food-contact surfaces must be protected from contamination

   d) Detailed records of pesticide applications must be maintained

5. Food business operators must maintain documentation of:

   a) Pest control program details

   b) Pest sightings and activity

c) Corrective actions taken

d) Service reports from pest control operators

e) Maps showing the location of pest control devices

Use of Gases in Food Manufacturing

1. Food business operators using gases in food manufacturing, processing, packaging, or storage must ensure that:

   a) Only food-grade gases approved by the Authority are used

   b) Gases are stored and handled in a manner that prevents contamination

   c) Gas delivery systems are designed to prevent contamination of food Products

   d) Gas concentrations are monitored and controlled within specified parameters

2. Modified atmosphere packaging (MAP) must be conducted under conditions that:

   a) Control potential microbial hazards

   b) Maintain the safety and quality of the food product throughout its shelf life

   c) Include validation studies demonstrating safety

   d) Include appropriate labeling of MAP Products

3. Food business operators using gases as processing aids must:

   a) Validate that the use of gases does not result in unsafe residues

   b) Ensure that gas use complies with good manufacturing practices

   c) Maintain records of gas usage and monitoring

4. Cryogenic freezing using liquid nitrogen or carbon dioxide must be conducted:

   a) With equipment designed for food use

   b) Under conditions that prevent contamination

   c) With appropriate ventilation to prevent oxygen depletion hazards

   d) By trained personnel aware of safety hazards

Storage and Preservation Requirements

1. Food business operators must store and preserve food Products under conditions that:

   a) Protect against contamination

   b) Minimize deterioration

   c) Prevent damage to packaging

d) Maintain appropriate temperature and humidity

e) Prevent pest access and harborage

2. Storage facilities must:

a) Be designed and constructed to facilitate maintenance and cleaning

b) Provide adequate space for segregation of different types of food

c) Include monitoring devices for temperature and humidity where appropriate

d) Be secured against unauthorized access

3. Food Products must be stored:

a) Off the floor on pallets, racks, or shelves

b) Away from walls to allow inspection and cleaning

c) In a manner that allows proper air circulation

d) According to the principle of "first in, first out" (FIFO) or "first expired, first out" (FEFO)

e) Separately from non-food items, chemicals, and potential allergens

4. Preservation methods must:

a) Be validated as effective for the specific food product

b) Be applied consistently according to documented procedures

c) Include monitoring of critical parameters

d) Be supported by appropriate record-keeping

5. Food business operators must conduct regular inventory checks to:

a) Identify and remove expired Products

b) Verify proper rotation of stock

c) Inspect for signs of damage or deterioration

d) Verify proper storage conditions

Retail and Food Service Requirements

1. Retail and food service establishments must:

a) Implement food safety management systems appropriate to the nature and size of the business

b) Ensure proper temperature control of potentially hazardous foods

c) Prevent cross-contamination between raw and ready-to-eat foods

d) Manage allergens to prevent cross-contact

e) Maintain proper personal hygiene of food handlers

2. Temperature control in retail and food service must include:

   a) Cold holding of potentially hazardous foods at or below 5°C (41°F)

   b) Hot holding of potentially hazardous foods at or above 63°C (145°F)

   c) Cooking foods to minimum internal temperatures specified by the Authority

   d) Cooling cooked foods according to the time and temperature parameters specified in Article 15

   e) Regular monitoring and recording of temperatures

3. Cross-contamination prevention must include:

   a) Separation of raw and ready-to-eat foods during storage and preparation

   b) Use of separate equipment and utensils for raw and ready-to-eat foods

   c) Proper cleaning and sanitizing of food contact surfaces between uses

   d) Proper handwashing after handling raw foods

   e) Appropriate workflow to prevent contamination

4. Self-service areas must:

   a) Be supervised by food service personnel

   b) Be equipped with proper sneeze guards or other protective devices

   c) Provide clean and sanitized serving utensils

   d) Maintain proper food temperatures

   e) Be monitored for potential contamination

5. Food delivery and takeaway services must:

   a) Use containers that protect food from contamination

   b) Maintain appropriate temperatures during transportation

   c) Ensure vehicles used for transportation are clean and well-maintained

   d) Provide information on safe handling and reheating instructions to consumers

Requirements for Refill Shops and Sustainable Food Practices

1. Food business operators operating refill shops or implementing sustainable food practices must:

   a) Ensure that refill stations and dispensers are designed to prevent contamination

   b) Establish and implement enhanced cleaning and sanitizing procedures for refill equipment

   c) Provide clear instructions to consumers on proper refill practices

d) Implement allergen management procedures appropriate for refill operations

2. Refill containers provided by consumers must:

   a) Be visually inspected for cleanliness and integrity

   b) Be used only for the same type of food product previously contained, unless thoroughly cleaned

   c) Not be filled if they appear damaged, soiled, or otherwise unsuitable

3. Bulk food dispensers must:

   a) Be designed to protect food from contamination

   b) Be cleaned and sanitized at frequencies based on usage and type of food

   c) Be equipped with appropriate utensils for dispensing

   d) Include clear information on product identity, ingredients, and allergens

4. Food business operators implementing sustainable packaging must ensure that:

   a) Alternative packaging materials are suitable for food contact

   b) Reusable packaging is capable of being effectively cleaned and sanitized

   c) Biodegradable or compostable packaging does not introduce chemical hazards to food

   d) Packaging reduction measures do not compromise food safety

5. Food waste reduction practices must:

   a) Not compromise food safety requirements

   b) Include appropriate temperature controls for foods intended for donation

   c) Maintain traceability of food Products

   d) Include proper labeling of repackaged or repurposed foods

HACCP Requirements

1. Food business operators must implement and maintain procedures based on Hazard Analysis and Critical Control Points (HACCP) principles, including:

   a) Conducting a hazard analysis to identify potential biological, chemical, and physical hazards

   b) Determining Critical Control Points (CCPs) where control is essential

   c) Establishing critical limits for each CCP

   d) Implementing monitoring procedures for CCPs

   e) Establishing corrective actions when monitoring indicates a CCP is not under control

   f) Establishing verification procedures to confirm the HACCP system is working effectively

g) Establishing documentation and record-keeping procedures

2. The HACCP plan must:

   a) Be specific to each establishment and the Products processed therein

   b) Be developed by a multidisciplinary team with appropriate training

   c) Be based on scientific evidence

   d) Be reviewed and updated when changes occur in the process, equipment, or ingredients

   e) Be verified through internal audits at least annually

3. Food business operators must maintain the following HACCP records:

   a) The hazard analysis

   b) The HACCP plan

   c) CCP monitoring activities

   d) Corrective actions

   e) Verification procedures and results

   f) Modifications to the HACCP plan

4. Food business operators must ensure that personnel responsible for developing and maintaining the HACCP system receive adequate training in the application of HACCP principles.

Safe Disposal of Surplus Food

1. Food business operators must establish and implement procedures for the safe disposal of surplus food that:

   a) Prevent the risk of disease transmission

   b) Protect public health and the environment

   c) Comply with waste management regulations

   d) Maintain records of disposal

2. Surplus food of animal origin must be:

   a) Segregated from other waste

   b) Stored in leak-proof, covered containers

   c) Kept at appropriate temperatures to prevent decomposition

   d) Collected and disposed of by approved methods or contractors

3. Approved methods for disposal of surplus food of animal origin include:

   a) Rendering at approved facilities

b) Incineration at approved facilities

c) Anaerobic digestion at approved facilities

d) Other methods approved by the Authority

4. Food business operators must:

a) Maintain records of the quantity and type of surplus food disposed

b) Maintain records of the method and location of disposal

c) Ensure traceability of disposed food Products

d) Make records available to the Authority upon request

5. Food business operators must prioritize food waste hierarchy in the following order:

a) Prevention of surplus food generation

b) Redistribution for human consumption where safe and legal

c) Recycling as animal feed where permitted

d) Recovery through composting or energy generation

e) Disposal as a last resort

Bottled Water Requirements

1. Bottled water must:

a) Be obtained from an approved source

b) Be processed, packaged, and transported under sanitary conditions

c) Meet microbiological, chemical, physical, and radiological standards established by the Authority

d) Be labeled in accordance with requirements specified in Section [X] of this Act

2. The following types of bottled water must comply with specific compositional requirements:

a) Natural mineral water:

i. Must be obtained directly from natural or drilled sources from underground water-bearing strata

ii. Must be collected under conditions which guarantee the original microbiological purity

iii. Must have a consistent composition of minerals

iv. May not undergo any treatment other than those permitted by the Authority

b) Spring water:

i. Must be derived from an underground formation from which water flows naturally to the surface

ii. Must be collected at the spring or through a borehole tapping the underground formation

iii. Must have the same composition and properties as the water that flows naturally to the surface

c) Purified water:

i. Must be produced by distillation, deionization, reverse osmosis, or other suitable processes

ii. Must meet standards for chemical and microbiological purity established by the Authority

3. Bottled water producers must:

a) Implement a HACCP plan specific to bottled water production

b) Conduct source water monitoring at a frequency determined by the Authority

c) Conduct finished product testing for microbiological, chemical, and physical parameters

d) Maintain records of water quality testing

e) Implement recall procedures for non-compliant Products

4. Bottled water packaging must:

a) Be made from food-grade materials

b) Protect the organoleptic, chemical, and microbiological qualities of the water

c) Be free from substances that may migrate into the water

d) Be sealed to prevent contamination

5. The Authority may/must establish and regularly update:

a) Maximum limits for contaminants in bottled water

b) Microbiological criteria for bottled water

c) Sampling and analytical methods for bottled water testing

d) Labeling requirements specific to different types of bottled water

Enforcement and Compliance

1. The Authority must:

a) Conduct regular inspections of food establishments to verify compliance with the provisions of this Section

b) Collect and analyze samples to verify compliance with food safety standards

c) Review food safety management systems and associated documentation

d) Investigate consumer complaints related to food safety

e) Take appropriate enforcement actions in case of non-compliance

2. Food business operators must:

a) Grant the Authority access to establishments, records, and Products

b) Provide assistance necessary for the Authority to carry out its duties

c) Implement corrective actions for non-compliances identified during inspections

d) Notify the Authority of significant changes to facilities, processes, or Products

3. In case of non-compliance with the provisions of this Section, the Authority may impose one or more of the following measures:

   a) Written warning

   b) Order for corrective action within a specified timeframe

   c) Increased inspection frequency

   d) Temporary suspension of specific operations

   e) Product detention or seizure

   f) Mandatory recall of affected Products

   g) Monetary penalties proportionate to the severity of the non-compliance and the size of the business

   h) Suspension or revocation of operating permits or licenses

   i) Closure of the establishment

   j) Criminal prosecution for serious or repeated violations

4. The Authority must establish a risk-based inspection system that considers:

   a) The type of food and associated risks

   b) The intended consumer population

   c) The compliance history of the food business operator

   d) The effectiveness of the food safety management system

   e) The size and scope of operations

Food Contact Materials and Packaging

Prohibited Food Contact Materials

1. The following substances may not be used in food contact materials (FCMs):

   - Bisphenol A (BPA) and derivatives classified as carcinogenic, mutagenic, or toxic to reproduction
   - Other bisphenols (BPS, BPF, BPAF) with endocrine-disrupting properties
   - Ortho-phthalates including DEHP and DBP

- Per- and polyfluoroalkyl substances (PFAS)
- Brominated flame retardants
- Heavy metals exceeding established migration limits:
  - Lead: ≤0.01 mg/kg
  - Cadmium: ≤0.002 mg/kg
  - Mercury: ≤0.003 mg/kg
  - Arsenic: ≤0.01 mg/kg

2. The Authority must, by virtue of … [23], establish and maintain a comprehensive negative list of prohibited substances based on:
   - Scientific risk assessments from recognised bodies (WHO, FAO, Codex Alimentarius)1
   - International regulatory developments
   - Emerging scientific evidence on health impacts
3. The negative list must be reviewed and updated at minimum every three years.

Authorization Framework for Food Contact Materials

1. The Authority must, by virtue of … [24], establish and maintain a positive list of substances authorized for use in FCMs, specifying:
   - Substance identification parameters
   - Restrictions on use (maximum concentration limits)
   - Specific migration limits
   - Permitted food types for contact
   - Temperature and time restrictions
2. FCMs are presumed safe if they:
   - Contain only substances from the positive list
   - Comply with Good Manufacturing Practices under ISO 22000 and Codex Alimentarius standards5
   - Demonstrate no detectable migration of unauthorized substances above 0.01 mg/kg
   - Meet purity standards for food-grade materials
3. Authorization for new substances requires:
   - Comprehensive toxicological data

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[23] Define the appropriate type of regulation.
[24] Define the appropriate type of regulation.

- Migration testing under worst-case scenarios
- Technical function justification
- Analytical methods for enforcement

Chemical Safety Requirements

1. FCMs must:
    - Prevent migration of non-authorized substances into food
    - Ensure total migration does not exceed 60 mg/kg of food or 10 mg/dm² of material surface
    - Comply with substance-specific migration limits
    - Not release primary aromatic amines in detectable quantities
    - Not contain substances classified as carcinogenic, mutagenic, or toxic to reproduction
2. For non-regulated substances, manufacturers must conduct risk assessments considering:
    - Toxicological threshold of concern (TTC) approach
    - Structure-activity relationships
    - Exposure scenarios based on intended use

Physical Safety Requirements

1. FCMs must ensure:
    - Absence of sharp edges, points, or burrs
    - Resistance to splintering under normal use conditions
    - Abrasion resistance appropriate to intended use
    - Resistance to accidental opening during transport and storage
    - Appropriate opening mechanisms for vulnerable populations (elderly, children, disabled persons)
    - Permeability/impermeability properties suitable for intended food (oxygen, moisture, light barriers)
    - Mechanical strength to maintain integrity during normal handling
2. Specific requirements for child-resistant packaging:
    - Compliance with ISO 8317 for reclosable packages
    - Compliance with EN 862 for non-reclosable packages

Environmental Requirements

1. FCMs must adhere to sustainability principles:
    - Prioritize reusable, recyclable, or compostable materials
    - Minimize single-use plastics unless no viable alternatives exist
    - Comply with restrictions on persistent organic pollutants
    - Reduce carbon footprint through material selection and design
2. Manufacturers must provide end-of-life information for FCMs including:
    - Recyclability classification
    - Biodegradability parameters
    - Proper disposal instructions
3. For reusable FCMs, manufacturers must provide:
    - Cleaning and sanitization protocols
    - Maximum number of reuse cycles
    - Criteria for determining end of service life

Packaging Gases

1. Authorized gases for modified atmosphere packaging (MAP) include:
    - Nitrogen (N_2)
    - Carbon dioxide (CO_2)
    - Oxygen (O_2)
    - Argon (Ar)
    - Helium (He)
2. All gases used must:
    - Meet food-grade purity standards (≥99.9% for CO_2, N_2, O_2)
    - Be stored separately from non-food-grade gases
    - Be traceable through batch documentation
    - Undergo regular quality testing
3. Prohibited gases include:
    - Carbon monoxide (except for specific applications with prior authorization)
    - Sulfur dioxide above established limits
    - Gases containing volatile organic compounds
4. The Authority may prohibit additional gases if:

- New scientific evidence indicates health risks
- Purity standards cannot be consistently met
- Risks of chemical migration or organoleptic changes are identified

Specific Requirements for Different Material Types

Plastic Materials

1. Plastic FCMs must:
    - Use only monomers and additives from the positive list
    - Comply with specific migration limits for each authorized substance
    - Meet overall migration limits of 60 mg/kg or 10 mg/dm²
    - Be tested using standardized food simulants and time-temperature conditions
2. Recycled plastics must additionally:
    - Originate from authorized recycling processes
    - Implement a documented quality assurance system
    - Use appropriate decontamination technologies
    - Undergo more frequent compliance testing

Paper and Board Materials

1. Paper and board FCMs must:
    - Not contain more than 0.5 mg/kg of pentachlorophenol
    - Comply with limits for heavy metals and fluorescent substances
    - Meet microbiological criteria for food-contact applications
    - Use only approved processing aids and functional additives
2. For recycled paper and board:
    - Only specified grades of recycled fiber may be used
    - Enhanced testing for contaminants is required
    - Functional barriers must be used for certain food types

Metal Materials

1. Metal FCMs must:

- Meet composition requirements for specific alloys
- Comply with release limits for metals into food
- Have appropriate corrosion resistance for intended use
- Use only approved surface treatments and coatings

2. For coated metal packaging:
    - Coatings must withstand processing conditions without degradation
    - Migration of coating components must be below established limits
    - Resistance to mechanical damage must be demonstrated

Glass and Ceramic Materials

1. Glass and ceramic FCMs must comply with migration limits for:
    - Lead (≤0.01 mg/kg)
    - Cadmium (≤0.002 mg/kg)
    - Other metals as specified by the Authority
2. Testing requirements include:
    - Surface area to volume ratio considerations
    - Repeated use protocols for reusable items
    - Edge and rim testing for drinking vessels

Documentation and Compliance Requirements

1. Manufacturers of FCM must maintain a Declaration of Compliance (DoC) containing:
    - Identity and address of the manufacturer
    - Identity of the materials/articles
    - Date of declaration
    - Confirmation of compliance with relevant legislation
    - Information on substances with restrictions
    - Specifications on use (food types, time, temperature)
2. Supporting documentation must include:
    - Test reports from migration testing
    - Risk assessments for non-regulated substances

- Manufacturing process controls
- Traceability information

3. The DoC must be:
    - Updated when composition or regulations change
    - Made available to authorities upon request
    - Provided to downstream users in the supply chain
    - Retained for a minimum of 5 years after last placing on market

Authority Powers and Enforcement

1. The Authority must:
    - Conduct regular market surveillance
    - Establish a risk-based inspection program
    - Develop standardized testing methodologies
    - Coordinate with international bodies on emerging risks
2. The Authority may:
    - Impose immediate bans on FCMs posing acute health risks
    - Set transitional periods for industry adaptation to new requirements
    - Grant temporary derogations in justified cases
    - Mandate recall of non-compliant Products
3. Enforcement measures must be:
    - Proportionate to the risk posed
    - Applied consistently across the market
    - Transparent in application
    - Subject to appeal procedures

Background for Regulators: References Table

Requirement	Primary Reference (Superior Quality)	Alternative International Reference
Migration Limits	EU Regulation (EU) 10/2011[10]	Codex CAC/GL 80-2023[34]

GMP Standards	EU Regulation (EC) 2023/2006913	Codex CAC/RCP 1-1969 (GMP)3
Recycled Materials	EU Regulation (EC) 2022/1616316	ISO 18604:2023 (Packaging Recyclability)
Risk Assessment	EFSA Guidelines613	WHO/IPCS Harmonization Approach4

Weights, Measures, and Quantity

Generic Rules

1. All food Products must be sold or supplied in accordance with internationally recognised standards for weights, measures, and quantity declarations, ensuring transparency, consumer protection, and fair trade.

2. The declared quantity of a food product must be accurate, not misleading, and based on the net content (excluding packaging), using units of the International System of Units (SI) as recommended by the United Nations Economic Commission for Europe (UNECE) and the International Organization of Legal Metrology (OIML)1.

3. The declaration of quantity must appear prominently on the principal display panel of the package, be easily readable, and indelible throughout the product's shelf life17.

Powers of the Authority

1. The Government or designated Authority is empowered to:

    - Adopt and update detailed rules for weighing, measuring, and quantity declarations for all food types, including but not limited to meat, fish, fruit, vegetables, and packaged goods.

    - Specify and periodically revise tolerances, sampling plans, and procedures in accordance with the Codex Alimentarius General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), the OIML R 87 (Quantity of Product in Prepackages), and relevant ISO standards.

    - Require the use of the Average Quantity System (AQS) or equivalent, as set out by Codex and OIML, for pre-packaged goods27.

    - Issue additional rules for specific food categories or sales formats (e.g., catch weight for meat and fish, count for eggs, volume for liquids)12.

    - Mandate the use and regular verification of certified weighing and measuring instruments, in accordance with OIML and national legal metrology regulations.

Average Quantity System and Tolerances

1. For prepackaged foods, the Average Quantity System must apply:
    - The average quantity of a batch may not be less than the stated (nominal) quantity marked on the packages[27].
    - A limited number of packages may contain less than the nominal quantity, provided the deficiency does not exceed the tolerable negative error (TNE) as defined by OIML R 87 or national regulations[247].
    - No individual package may be short by more than twice the TNE[247].
2. The Authority must define and publish TNE tables for various nominal quantities based on international best practice (e.g., OIML R 87, EU Directive 76/211/EEC).
3. Packers and importers must maintain records of checks and verifications to demonstrate compliance with the AQS and tolerances[7].

Specific Provisions for Small Manufacturers

1. Small manufacturers, such as artisan bakers and local producers, may be subject to simplified quantity control requirements, provided:
    - The average weight or measure of Products in each batch meets or exceeds the declared quantity[4].
    - The proportion of individual items below the nominal quantity does not exceed the tolerable negative error, with no item being short by more than twice the TNE.
    - For small batches (e.g., less than 100 units), sampling and checking requirements may be reduced, but must still ensure consumer protection.
2. Small manufacturers may be exempt from certain labelling or documentation requirements if they produce and supply only small quantities directly to consumers or local retailers, as defined by the Authority in line with Codex and relevant national or regional practice (e.g., less than 13,000 kg or 26,000 units per year, or within a 100 km radius)[5].
3. The Authority must provide clear guidance and support to small manufacturers, including sampling plans, checklists, and recommended practices for weighing, measuring, and record-keeping.

Equipment and Verification

1. All weighing and measuring equipment used for quantity control must be:

- Suitable for the intended purpose, regularly calibrated, and verified by an accredited[25] body in accordance with OIML and ISO standards.
- Maintained in good working order, with records of calibration and checks kept for inspection.

2. The Authority may, by virtue of … [26], specify minimum technical requirements for equipment divisions (e.g., no greater than 2 g for bread weighing).

Responsibilities and Record-Keeping

1. The food business operator responsible for the product must ensure compliance with all quantity requirements, whether as packer, importer, or marketer.

2. Records of quantity checks, batch sampling, and equipment verification must be kept for a period specified by the Authority and be available for inspection7.

Enforcement and Sanctions

1. The Authority must conduct regular and random inspections of packaged goods, using internationally recognised sampling plans (e.g., Codex, OIML, ISO)27.

2. Non-compliance with quantity requirements may result in corrective actions, withdrawal of Products, fines, or other sanctions as deemed appropriate by the Authority.

International and Cross-Reference Standards

1. Where possible, the Authority must reference and align with the following international instruments, unless stricter or more protective national or regional rules apply:
   - Codex Alimentarius General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)
   - OIML R 87: Quantity of Product in Prepackages
   - ISO 22000 and FSSC 22000 for food safety management
   - UNECE Recommendations on Units of Measurement
   - EU Directive 76/211/EEC and Regulation (EU) 1169/2011 for detailed tolerances and labelling if no equivalent international standard exists7

   2. In case of conflict between these international instruments, the Authority must refer to … (e.g. the most stringent set of rules).

[25] Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.
[26] Define the appropriate type of regulation.

Product Labelling

General Labeling Requirements

1. All food Products, whether prepacked or non-prepacked, must bear appropriate labelling information to ensure consumer safety, informed choice, and product traceability.

2. Every food product must bear the following mandatory information:
   a) The name of the food product, which must accurately reflect its true nature;
   b) The complete name and address of the manufacturer or importer;
   c) Contact information including telephone number and, where available, email address or website of the manufacturer or importer;
   d) Date of manufacture clearly indicated using the format "DD/MM/YYYY";
   e) A serial number, batch code, or lot identification to enable traceability;
   f) Net quantity expressed in metric units (grams, kilograms, milliliters, or liters);
   g) Complete list of ingredients in descending order of weight;
   h) Quantitative declaration of ingredients emphasized on the label or essential to characterize the food;
   i) Allergen information with clear emphasis (bold, underlined, or contrasting color) for any of the major allergens present.

3. The information required under paragraph 2 must be:
   a) Clearly legible and indelible;
   b) In the official language(s) of the territory where the product is marketed;
   c) Presented in a font size no smaller than 1.2mm (based on x-height).

Date Marking Requirements

1. All food Products must bear appropriate date marking as follows:
   a) "Use by" date for highly perishable foods that may constitute an immediate danger to human health after a short period;
   b) "Best before" date for foods where quality rather than safety is the primary concern.

2. The "use by" date must:
   a) Be preceded by the words "use by";
   b) Include the day, month, and, where appropriate, year in that order;
   c) Be followed by a description of the storage conditions that must be observed.

3. The "best before" date must:
   a) Be preceded by the words "best before" or "best before end";
   b) Include the day and month for Products with durability less than three months;
   c) Include the month and year for Products with durability between three and eighteen months;
   d) Include the year only for Products with durability exceeding eighteen months.

4. No person must sell, offer for sale, or otherwise distribute any food product that has passed its "use by" date.

5. Food Products that have passed their "best before" date may be sold, offered for sale, or otherwise distributed provided that:
   a) The food remains safe for consumption;
   b) The seller clearly indicates that the "best before" date has passed;
   c) The food is physically separated from foods that have not passed their "best before" date.

Nutritional Information Requirements

1. All prepacked food Products must bear a nutritional declaration containing the following information per 100g or 100ml:
   a) Energy value (in both kilojoules and kilocalories);
   b) Amounts of fat, saturates, carbohydrate, sugars, protein, and salt;
   c) Amount of any nutrient for which a nutrition or health claim is made;
   d) Amount of any other nutrient considered relevant for maintaining good nutritional status.

2. The nutritional declaration must be presented in a tabular format with the numbers aligned, or if space does not permit, in linear format.

3. For non-prepacked foods, nutritional information must be displayed on panels positioned directly above the food, with the panel size being at least half the size of the food recipient or display area.

Health-Related Color Code System

1. All food Products must be assessed against a uniform health-related color code system for key health parameters including, but not limited to:
   a) Salt/sodium content;
   b) Sugar content;
   c) Fat content;
   d) Saturated fat content;
   e) Calorie content.

2. The color code system must use the following designations:
   a) Green: Low levels (healthier choice);
   b) Amber: Medium levels (consume in moderation);
   c) Red: High levels (consume occasionally).

3. The Government or the Authority must determine, by virtue of … [27], and periodically review the thresholds for each color designation based on international nutritional guidelines and scientific evidence.

4. Food business operators must display the color codes on the front of the package, covering at least one-fifth (1/5) of the surface area.

5. For non-prepacked foods, the color codes must be displayed on panels positioned directly above the food, with the panel size being at least half the size of the food recipient or display area.

[27] Define the appropriate type of regulation.

Extended Traffic Light Nutrition Labelling System

Scope and Application

1. The traffic light labelling system must be applied to all prepackaged foods and beverages sold within the national territory.

2. Non-prepackaged foods (e.g., bakery items, ready-to-eat meals) must display equivalent information on panels above food recipients, covering ≥50% of the display area.

Key Health Parameters

The following parameters must be declared per 100g/100ml or per portion, with colour coding (red, amber, green) based on thresholds defined in Annex A:

- **Salt/sodium**: Total sodium (mg) or salt equivalent (g).
- **Calories**: Energy value (kcal/kJ) from carbohydrates, fats, proteins, and alcohol.
- **Saturated fat**: Fatty acids without double bonds (e.g., lauric, myristic acids) in grams.
- **Trans fat**: Industrially produced partially hydrogenated oils and ruminant-derived trans fats in grams.
- **Sugar**: Total monosaccharides and disaccharides (natural and added) in grams.
- **Added sugar**: Sugars/syrups added during processing, excluding naturally occurring sugars, in grams.
- **Alcohol**: Ethanol content (% ABV or mass).
- **Artificial sweeteners**: Non-nutritive/low-calorie substitutes (e.g., aspartame, sucralose) in mg or % ADI (Acceptable Daily Intake).
- **Microplastics**: Synthetic polymer particles ≤5mm (ppm/ppb).

Traffic Light Thresholds for Key Health Parameters

The following traffic light thresholds apply:

Parameter	Red (High)	Amber (Medium)	Green (Low)
Salt	>1.5g/100g (or >600mg Na)	0.3–1.5g/100g (120–600mg Na)	≤0.3g/100g (≤120mg Na)
Calories	>400kcal/100g	150–400kcal/100g	≤150kcal/100g

Saturated Fat	>5g/100g	1.5–5g/100g	≤1.5g/100g
Trans Fat	>2g/100g	0.3–2g/100g	≤0.3g/100g
Total Sugar	>22.5g/100g	5–22.5g/100g	≤5g/100g
Added Sugar	>10g/100g	2–10g/100g	≤2g/100g
Alcohol	>5% ABV	0.5–5% ABV	≤0.5% ABV (non-alcoholic)
Artificial Sweeteners	>50% ADI per serving	10–50% ADI per serving	≤10% ADI per serving
Microplastics	Detectable levels (≥0.01ppm)	Not applicable	Undetectable (<0.01ppm)

Threshold Revisions

The Authority must review thresholds every three years, aligning with:

- WHO dietary guidelines (e.g., <1% energy from trans fats).
- Codex Alimentarius standards (e.g., CXS 1-1985).
- EU Regulation (EU) 1169/2011 for nutrient profiling.

Exemptions

Small-scale producers (<10,000 units/year) may use simplified labels but must disclose all key health parameters in text format.

Warning Labels for Unhealthy Foods

1. Food Products falling within the amber or red color-coding ranges must display mandatory health warnings on the front of the package, covering at least one-fifth (1/5) of the surface area.

2. Food Products high in calories, sugar, sodium, or saturated fat must display front-of-package warning labels in the form of black stop-sign-shaped labels clearly indicating the unhealthy attribute (e.g., "HIGH IN SUGAR," "HIGH IN SODIUM").

3. Each black stop-sign warning label must:
   a) Be octagonal in shape;
   b) Have a black background with white text;
   c) Cover at least one-fifth (1/5) of the front surface of the package;
   d) Be positioned in the upper right corner of the package;

e) Be clearly visible and not obscured by other elements.

4. For non-prepacked foods high in calories, sugar, sodium, or saturated fat, warning labels must be displayed on panels positioned directly above the food, with the panel size being at least half the size of the food recipient or display area.

Label Design and Formatting

Misleading Claims

1. Labels may not contain misleading claims.
2. The claims "natural" or "wholesome" may not appear on Products with ≥1 red-coded parameters.
3. Medical claims may only be labelled when the conditions for medical claims set out in this Act are fulfilled.

Child-targeted design

Child-targeted design is banned for Products with ≥1 red-coded parameter, unless exempted for public health initiatives.

Front-of-Package Requirements

1. Colour-coded labels must occupy ≥ … (e.g. 20) % of the principal display panel.
2. Black stop-sign warnings must accompany red-coded parameters, stating: "HIGH IN [PARAMETER]".

Additional Declarations

The following additional declarations must be made where applicable:

- Microplastics: "Contains synthetic polymer particles" if ≥0.01ppm.
- Artificial sweeteners: "Contains non-nutritive sweeteners" if present.

Organic Products

1. The term "organic" may only be used on food Products that:
   a) Contain at least 95% ingredients of agricultural origin that have been produced in accordance with organic production rules;
   b) Have been certified by a control body recognised by the Authority;
   c) Display the code number of the control body and, where appropriate, the official organic logo.

2. The criteria for organic production include:
   a) Prohibition of synthetic pesticides and fertilizers;
   b) Prohibition of genetically modified organisms;
   c) Maintenance of soil fertility through crop rotation and natural fertilizers;
   d) Animal welfare standards for livestock;

e) Restricted use of food additives, processing aids, and other substances.

3. Imported Products may be marketed as organic provided they:
   a) Have been produced in accordance with production rules equivalent to those set out in this Article;
   b) Have been subject to control arrangements equivalent to those referred to in this Article;
   c) Have been certified by a control body recognised by the Authority.

Non-Prepacked Foods

1. Non-prepacked foods must be accompanied by the following information:
   a) The name of the food;
   b) Allergen information;
   c) Country of origin where required;
   d) Any special storage conditions or conditions of use.

2. The information must be:
   a) Displayed on a label attached to the food;
   b) Displayed on a notice in close proximity to the food;
   c) Made available verbally by staff upon request, provided written information is readily available.

3. For non-prepacked foods subject to the health-related color code system or warning labels, the information must be displayed on panels positioned directly above the food, with the panel size being at least half the size of the food recipient or display area.

4. The Authority may establish simplified labelling requirements for small-scale producers of non-prepacked foods, provided that such requirements ensure an adequate level of consumer information regarding allergens and safety-critical information.

Powers of the Authority

1. The Government or designated Authority has the power to:
   a) Establish and update thresholds for the health-related color code system;
   b) Determine which food categories require specific warning labels;
   c) Establish product-specific labelling requirements to address particular risks;
   d) Grant exemptions for small producers or specific food categories where appropriate;
   e) Approve[28] alternative labelling formats that maintain the same level of consumer information;
   f) Establish transitional periods for implementation of new labelling requirements;
   g) Set out the conditions to be met by control bodies for organic Products, the working methods of these bodies and the procedural rules for their recognition.

2. The Authority must publish guidelines on the implementation of labelling requirements, including:
   a) Technical specifications for color codes and warning labels;
   b) Methodologies for assessing nutritional content;
   c) Procedures for verifying compliance.

3. The Authority must review and update labelling requirements at least once every five years to reflect advances in nutritional science and consumer information needs.

[28] Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.

Enforcement and Penalties

1. Food business operators are responsible for ensuring compliance with all labelling requirements applicable to their Products.

2. The Authority must conduct regular inspections to verify compliance with labelling requirements.

3. Non-compliance with the provisions of this Section may result in:
   a) Warning notices requiring corrective action within a specified timeframe;
   b) Prohibition on the sale of non-compliant Products;
   c) Recall of non-compliant Products;
   d) Administrative fines proportionate to the nature of the non-compliance and the size of the business;
   e) Criminal prosecution for serious or repeated non-compliance.

4. The Authority must publish guidance on enforcement priorities and penalties to ensure consistent application of these provisions.

Health and Nutrition Claims

Standardized Nutrient Profiling System

1. The Government must establish a nutrient profiling system to determine whether foods may bear health or nutrition claims. This system must set thresholds for:

- Total fat, saturated fat, trans fat, sugars, salt/sodium, and calories.
- Beneficial nutrients (e.g., dietary fiber, calcium, wholegrains).

   Thresholds must align with WHO dietary guidelines [and EU Regulation (EC) No 1924/2006, prioritizing stricter standards where international norms conflict].

2. The Authority has the power to define these thresholds. It may recognise nutrient profiling systems from jurisdictions with equivalent scientific rigor (e.g., EU, Singapore, Australia/New Zealand) if they meet or exceed local standards.

Scientific Substantiation of Claims

1. Health claims must be substantiated by:

- Human intervention studies demonstrating a causal relationship between the food/constituent and the claimed effect3.

- Systematic reviews of all available evidence, including studies with unfavorable outcomes3.

2. Claims based on proprietary data (e.g., trade-secret studies) must undergo independent verification by the Authority.

3. The Authority must evaluate claims based on:

- Biological plausibility, consistency of evidence, and dose-response relationships3.

- Statistical significance ($p \leq 0.05$) for observed effects.

Pre-Market Approval System[29]

1. Health claims must receive pre-market approval [via a centralised electronic submission system, modeled on the EU's E-Submission Food Chain (ESFC) platform] **OR** [in accordance with the procedure foreseen for approvals of …] **OR** [in accordance with the following procedure … (copy provisions from the Cross-sectoral Standard Provisions)].

2. Applications must include:
   - Detailed scientific dossiers in the national language or in English;
   - Proposed labeling text and target populations.

3. Claims authorized in jurisdictions with equivalent standards (e.g., EU, FDA, FSANZ) may be recognised or fast-tracked, provided they meet national nutrient profiles and labelling requirements.

Prohibited and Restricted Claims

1. Health claims directed at children (<16 years) are prohibited, unless the Authority grants exemptions for:
   - Essential nutrient fortification (e.g., vitamin D in milk).
   - Public health campaigns approved by the Authority1.

2. Claims implying prevention, treatment, or cure of diseases (e.g., "reduces cholesterol") are prohibited, unless:
   - The product is a licensed medicinal product; or
   - The Authority grants exemptions for disease risk reduction claims backed by EFSA-level evidence14.

"Healthier Choice" Designation

1. The term "healthier choice" may only be used if the product meets legally defined nutritional standards, including:
   - Lower thresholds for sodium, sugar, saturated fat, and trans fat compared to similar Products;
   - Higher thresholds for dietary fiber, calcium, or wholegrains7912.

2. Manufacturers must obtain certification from the Authority or a body entrusted by the Authority. Certification must be renewed biennially, with random post-market testing to ensure compliance78. The Government / Authority may, by virtue of … [30], set out the procedure and the conditions for certification and for the designation of a body as "entrusted body".

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[29] Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.

[30] Define the appropriate type of regulation.

Marketing and Advertising

Mandatory Indications in Publicity

1. All food and beverage advertising, whether in physical or digital media, must include the following indications:

   a) The true nature of the food product being advertised, using the same name as appears on the product label.

   b) Any health-related color codes that apply to the product, displayed with the same prominence as required on packaging.

   c) Any mandatory health warnings that apply to the product, displayed with the same prominence as required on packaging.

   d) For Products containing ingredients listed in … , the same warnings required on product labels must be included in the advertisement.

2. Digital advertising must comply with additional requirements:

   a) Mandatory indications must remain visible throughout the duration of the advertisement.

   b) For interactive advertisements, mandatory indications must appear before any interaction with the advertisement is possible.

   c) For advertisements on social media platforms, mandatory indications must be included in the initial view, before any scrolling or interaction.

3. Exemptions from paragraph 1 apply only to:

   a) Audio-only advertisements, which must include verbal statements of any applicable health warnings.

   b) Advertisements smaller than 10 square centimeters, which must include a clearly visible link or QR code directing to the full mandatory information.

Display of Color Coding and Health Warnings in Publicity

1. Color coding in physical and virtual publicity:

   a) Health-related color codes must occupy at least … (e.g. 15) % of the total advertisement area.

   b) Color codes must be positioned in the upper right corner of the advertisement.

   c) Color codes must maintain the same proportions and color scheme as required on product packaging.

d) For video advertisements, color codes must be displayed for the entire duration of the advertisement.

2. Health warnings in physical and virtual publicity:

a) Black stop-sign warnings for Products high in calories, sugar, sodium, or saturated fat must occupy at least … (e.g. 20) % of the total advertisement area.

b) Health warnings must be positioned adjacent to the product image or name.

c) Text of health warnings must be in a contrasting color to the background and in a font size no smaller than … (e.g. 20) % of the largest text in the advertisement.

d) For advertisements featuring multiple Products, warnings must be displayed for each applicable product.

3. For out-of-home advertising (billboards, transit advertisements):

a) Color codes and health warnings must be scaled proportionally to maintain visibility at the intended viewing distance.

b) For digital out-of-home advertising, color codes and health warnings must be displayed for at least … (e.g. 50) % of the total display time.

Placement and Promotion Restrictions

1. Restrictions on placement of Products high in fat, sugar, or salt (HFSS):

a) HFSS Products may not be placed in the following locations in retail stores with floor area exceeding … (e.g. 100) square meters:
i. Checkout areas or within 2 meters of any checkout facility
ii. Designated queuing areas or within 2 meters of a queue management system
iii. End-of-aisle displays
iv. Store entrances or within 3 meters of any entrance
v. Free-standing display units visible from the main circulation route

b) For online retail, HFSS Products may not be placed in the following digital locations:
i. Homepage or landing pages
ii. Shopping basket or checkout pages
iii. Pop-up windows
iv. Banner advertisements
v. "Recommended for you" sections unless specifically requested by the consumer

2. Restrictions on volume promotions:

a) Volume price promotions for HFSS Products are prohibited, including:
i. Multi-buy offers (e.g., "buy one get one free," "3 for 2")
ii. Extra-free promotions (e.g., "50% extra free," "bigger pack, same price")
iii. Combination offers linking HFSS Products with non-HFSS Products

b) Temporary price reductions that do not incentivize increased volume purchase are permitted.

c) Loyalty points or rewards that do not specifically incentivize increased volume purchase of HFSS Products are permitted.

3. Restrictions on free refills:

a) Free refill promotions for sugar-sweetened beverages are prohibited in all food service establishments.

b) A "free refill promotion" means any offer that provides the consumer with the same drink, or another sugar-sweetened beverage, for free after initial purchase.

c) This prohibition applies to self-service dispensers and server-provided refills.

d) Water, unsweetened tea, coffee without added sugar, and beverages containing no added sugars are exempt from this prohibition.

Child-Focused Marketing Restrictions

1. General prohibition:

a) Marketing of HFSS Products may not be directed at or appeal to persons under 18 years of age.

b) Marketing of HFSS Products is prohibited in media where at least … (e.g. 20) % of the audience is actually or reasonably expected to be under 18 years of age.

c) The prohibition applies to all forms of marketing, including but not limited to advertising, promotion, sponsorship, and product placement.

2. Restrictions on advertising during children's programming:

a) HFSS product advertising is prohibited during, immediately before, and immediately after television and radio programming primarily directed at persons under 18 years of age.

b) HFSS product advertising is prohibited between 06:00 and 22:00 on television channels, streaming services, and radio stations.

c) Online advertising of HFSS Products is prohibited on websites, platforms, and applications primarily directed at persons under 18 years of age.

3. Ban on child-directed marketing strategies:

a) The following marketing strategies may not be used for HFSS Products in any media:
i. Characters, celebrities, or influencers popular with persons under 18 years
ii. Cartoons, animations, or fictional characters appealing to persons under 18 years
iii. Games, competitions, or activities appealing to persons under 18 years
iv. Music, language, or colors primarily appealing to persons under 18 years
v. Free toys, gifts, or collectible items appealing to persons under 18 years

b) Product packaging for HFSS Products may not use any of the strategies listed in paragraph (a).

c) Brand characters historically associated with HFSS Products may only be used for marketing non-HFSS Products if there is clear differentiation to avoid confusion.

4. Ban on product placement:

a) HFSS Products may not be placed, arranged, or featured in:
i. Films, television programs, or video content primarily directed at persons under 18 years
ii. Games, apps, or interactive content primarily directed at persons under 18 years
iii. Educational materials or content for use in schools or educational settings
iv. Books, magazines, or publications primarily directed at persons under 18 years

b) Actors, presenters, or influencers in content primarily directed at persons under 18 years may not consume or interact with HFSS Products.

c) Virtual environments, including metaverse platforms and online games primarily directed at persons under 18 years, may not contain HFSS product placement.

Sponsorship and Brand Marketing Restrictions

1. Sponsorship restrictions:

a) HFSS product brands may not sponsor:
i. Sporting events, teams, or individuals primarily appealing to persons under 18 years
ii. Cultural events, performances, or exhibitions primarily appealing to persons under 18 years
iii. Educational institutions, programs, or materials
iv. Children's entertainment, including concerts, festivals, and theme parks

b) Corporate entities that produce HFSS Products may sponsor events or activities primarily appealing to persons under 18 years only if:
i. No HFSS Products are displayed, referenced, or promoted
ii. Corporate branding is clearly separated from HFSS product branding
iii. The sponsorship does not include sampling or distribution of HFSS Products

2. Brand marketing restrictions:

a) Brand equity characters, brand identifiers, and trade marks associated with HFSS Products may not be used in marketing directed at persons under 18 years.

b) Brand marketing that promotes a range of Products may not give greater prominence to HFSS Products than to non-HFSS Products.

c) Brand marketing in locations frequented by persons under 18 years may not include references to HFSS Products.

Digital Marketing Safeguards

1. Age verification requirements:

a) Digital platforms hosting HFSS product marketing must implement robust age verification mechanisms.

b) Social media platforms must ensure HFSS product marketing is not visible to users registered as under 18 years of age.

c) HFSS product websites must implement age gates requiring date of birth verification before access is granted.

2. Data protection safeguards:

a) Personal data of persons under 18 years may not be collected for the purpose of HFSS product marketing.

b) Behavioral advertising techniques may not be used to target HFSS product marketing based on browsing history or preferences of persons under 18 years.

c) Location-based advertising for HFSS Products may not be activated near schools, youth centers, or other locations primarily frequented by persons under 18 years.

3. Influencer marketing restrictions:

a) Social media influencers with an audience of which at least 20% is reasonably expected to be under 18 years may not promote HFSS Products.

b) All influencer marketing for food and beverage Products must clearly disclose the health-related color code and any applicable warnings.

c) Influencers may not portray excessive or inappropriate consumption of HFSS Products.

Enforcement and Monitoring

1. Monitoring system:

a) The Authority must, by virtue of … [31], establish a comprehensive monitoring system to assess compliance with marketing and advertising restrictions.

b) The monitoring system must include regular surveillance of:
i. Television and radio advertising
ii. Digital and social media platforms
iii. Outdoor and print advertising
iv. In-store promotions and displays
v. Sponsorship arrangements

c) The Authority must publish annual reports on compliance levels and enforcement actions.

2. Complaints mechanism:

a) The Authority must establish an accessible mechanism for the public to report potential violations of marketing and advertising restrictions.

[31] Define the appropriate type of regulation.

b) Reports of potential violations must be investigated within 30 days.

c) The Authority must publish anonymized summaries of complaints received and actions taken.

3. Penalties for non-compliance:

a) First violations may result in:
i. Written warnings
ii. Orders to modify or withdraw non-compliant marketing
iii. Publication of non-compliance notices

b) Repeated or serious violations may result in:
i. Administrative fines proportionate to the company's annual turnover
ii. Mandatory corrective advertising
iii. Temporary prohibition of all marketing for the relevant Products
iv. Criminal prosecution for intentional or reckless violations

c) The Authority must issue guidance on the application of penalties to ensure consistency and proportionality.

Evaluation and Review

1. The Authority must conduct a comprehensive evaluation of the effectiveness of marketing and advertising restrictions every three years.

2. The evaluation must assess:
a) Changes in exposure to HFSS product marketing, particularly among persons under 18 years
b) Impact on purchasing and consumption patterns
c) Industry compliance levels and enforcement challenges
d) Emerging marketing techniques not adequately addressed by existing restrictions

3. Based on evaluation findings, the Authority must recommend amendments to strengthen marketing and advertising restrictions as necessary.

4. The Authority must consult with public health experts, consumer organizations, and industry representatives when developing recommendations for amendments.

Food Environment and Access

School Food Environment

1. Ban on Sale and Marketing of Unhealthy Products in Schools:

a) The sale, provision, or marketing of foods and beverages high in calories, sugars, sodium, or saturated fats is prohibited in all educational institutions, including public and private schools, kindergartens, and childcare facilities.

b) This prohibition applies to all food service points within educational institutions, including cafeterias, kiosks, vending machines, and any other food retail or distribution points.

c) The prohibition extends to all school-related activities, including field trips, sporting events, and fundraising activities organized by the school or parent associations.

d) Foods and beverages displaying black warning labels or falling within the red category of the health-related color code system may not be sold, provided, or marketed in educational institutions.

2. Nutritional Standards for School Meals:

a) All meals and snacks provided in educational institutions must comply with nutritional standards established by the Authority, which must include:
i. Minimum portions of fruits and vegetables per meal
ii. Limits on sodium, added sugars, and saturated fats
iii. Requirements for whole grains
iv. Appropriate portion sizes by age group

b) Each school must employ or have access to a qualified nutritionist to ensure that meals are good for children in every sense, providing all nutrients that a particular age group needs.

c) School meals must include a variety of food groups, including:
i. Rice or grains (preferably whole grains)
ii. Protein sources (plant or animal-based)
iii. Vegetables (at least two varieties per meal)
iv. Fruit as dessert
v. Water as the primary beverage

3. Phase-out of Ultra-processed Foods:

a) Educational institutions must implement a gradual phase-out of ultra-processed foods from school menus according to the following timeline:
i. Identification of particularly detrimental ultra-processed items by the Authority within 12 months of this Act taking effect
ii. 50% reduction in identified items by …
iii. Complete elimination by …

b) The Authority must provide guidance, training, and resources to support schools in transitioning to healthier food options.

c) Schools must report annually to the Authority on their progress in reducing ultra-processed foods.

4. Regulation of Beverages:

a) The provision or sale of sugar-sweetened beverages is prohibited in all educational institutions.

b) Educational institutions must provide free, clean drinking water to all students throughout the school day.

c) Water fountains or dispensers must be installed in accessible locations throughout school facilities, with at least one fountain or dispenser for every 100 students.

d) Permitted beverages in schools are limited to:
i. Plain water
ii. Milk (unflavored, low-fat or non-fat)
iii. Plant-based milk alternatives (unsweetened)
iv. 100% fruit or vegetable juice (limited to specified portion sizes)

5. Enforcement and Compliance:

a) Educational institutions that violate these provisions will be subject to:
i. Written warning for first violations
ii. Fines for subsequent violations
iii. Mandatory corrective action plans

b) Schools must designate a compliance officer responsible for ensuring adherence to these provisions.

c) The Authority must conduct regular inspections of educational institutions to monitor compliance.

d) Parents and students must be informed of these requirements and provided with a mechanism to report violations.

Green Food Zones Around Schools

1. Establishment of Green Food Zones:

a) A "Green Food Zone" must be established within a 200-meter radius around all educational institutions where children under 18 years of age are educated or cared for.

b) Within Green Food Zones, the sale of foods and beverages high in calories, sugars, sodium, or saturated fats is prohibited.

c) Existing food businesses within designated Green Food Zones must:
i. Adapt their product offerings to comply with nutritional standards established by the Authority within 18 months
ii. Prominently display nutritional information for all Products
iii. Not display or advertise Products prohibited under paragraph (b)

d) Local authorities must establish clear signage indicating the boundaries of Green Food Zones.

2. Zoning Restrictions on Fast Food Outlets:

a) Local planning authorities may not grant planning permission for new fast food outlets within 400 meters of the boundary of an existing or proposed school or other educational institution for children under 18 years of age.

b) For the purposes of this provision, "fast food outlets" include establishments where hot food is provided for consumption on or off the premises, and where food is predominantly prepared for immediate consumption.

c) Local planning authorities must develop supplementary planning documents that:
i. Map existing fast food outlets in relation to schools
ii. Identify areas where restrictions apply
iii. Establish criteria for determining whether a food business qualifies as a fast food outlet

d) Existing fast food outlets within the restricted zone may continue to operate but may not expand their premises or extend their operating hours.

3. Advertising Restrictions in Green Food Zones:

a) Outdoor advertising for foods and beverages high in calories, sugars, sodium, or saturated fats is prohibited within Green Food Zones.

b) This prohibition includes:
i. Billboards and posters
ii. Digital displays
iii. Storefront signage
iv. Promotional materials visible from public spaces

c) Local authorities must remove or require the removal of non-compliant advertising within 6 months of this Act taking effect.

Community Access Initiatives

1. Incentives for Grocery Stores in Food Deserts:

a) Local authorities must identify "food deserts" within their jurisdiction, defined as areas with limited access to affordable and nutritious food, particularly in lower-income neighborhoods.

b) Business rates relief or equivalent tax incentives must be provided to grocery stores that:
i. Operate in identified food deserts
ii. Offer a minimum range of fresh fruits, vegetables, whole grains, and other nutritious foods as specified by the Authority
iii. Price nutritious foods affordably
iv. Accept food assistance program benefits

c) The rate of relief must be proportionate to the degree to which the store meets nutritional access criteria established by the Authority, with higher relief for stores providing greater access to nutritious foods.

d) Additional incentives may include:
i. Streamlined permitting processes
ii. Grants for equipment and infrastructure
iii. Technical assistance for business development
iv. Marketing support

2. Urban Planning Guidelines for Food Accessibility:

a) Local planning authorities must incorporate food accessibility considerations into planning decisions and development plans.

b) Development plans must include assessments of:
i. Existing food retail distribution
ii. Areas with limited access to nutritious food
iii. Transportation links to food retail outlets
iv. Opportunities for improving food accessibility

c) Planning authorities must require food access impact assessments for developments that could

affect food accessibility, particularly in underserved areas.

d) Planning authorities must support the development of:
i. Farmers' markets
ii. Community gardens
iii. Food cooperatives
iv. Mobile markets
v. Other innovative food distribution models

3. Water Fountain Requirements in Public Spaces:

a) Public spaces with a capacity of at least 300 people must install drinking water fountains according to the following requirements:
i. One fountain for each 300-person capacity
ii. Additional fountains for each additional 300-person capacity
iii. At least one fountain must be accessible to children and persons with disabilities

b) Applicable public spaces include:
i. Transportation hubs (railway stations, bus terminals, airports)
ii. Shopping centers and malls
iii. Sports facilities and stadiums
iv. Parks and recreational areas
v. Government buildings
vi. Cultural institutions (museums, theaters, libraries)

c) Water fountains must:
i. Provide clean, potable water free of charge
ii. Be maintained in good working order
iii. Be cleaned and sanitized regularly
iv. Include bottle-filling capabilities where feasible

4. Increasing Access Through Public Assistance Programs:

a) Food assistance programs must be designed to increase access to nutritious foods by:
i. Providing incentives for the purchase of fruits, vegetables, and other nutritious foods
ii. Implementing nutrition standards for foods eligible for purchase with program benefits
iii. Ensuring that benefits can be used at farmers' markets, community-supported agriculture programs, and other direct-to-consumer outlets

b) The value of benefits for purchasing fruits and vegetables must be increased through matching

programs or similar mechanisms.

c) Mobile markets and delivery services accepting food assistance benefits must be supported in areas with limited food retail options.

d) Education and outreach programs must be implemented to inform benefit recipients about nutritious food choices and how to prepare them.

Design Standards for Food Service Environments

1. Cafeteria Design Standards:

a) Cafeterias in public institutions, including schools, government buildings, hospitals, and other publicly funded facilities, must implement design features that promote healthier food choices, including:
i. Prominent placement of fruits, vegetables, and other nutritious options
ii. Positioning water and other healthy beverages at eye level and in easily accessible locations
iii. Using green salad bowls and attractive fruit displays
iv. Placing less healthy options in less accessible locations
v. Implementing traffic light or similar labeling systems to identify healthier choices

b) Cafeterias must provide clear, visible nutritional information for all food items.

c) Cafeterias must ensure that healthy options are priced competitively with or lower than less healthy alternatives.

d) The Authority must develop and disseminate guidelines for cafeteria design that incorporates evidence-based strategies for promoting healthy choices.

2. Vending Machines:

a) Vending machines in public buildings must:
i. Ensure that at least 75% of food options meet nutritional standards established by the Authority
ii. Ensure that at least 75% of beverage options are water, unsweetened tea or coffee, or other unsweetened beverages
iii. Display nutritional information for all Products
iv. Position healthier options at eye level

b) Operators of vending machines in public buildings must obtain permits from local authorities, which will be granted only if the machines comply with these requirements.

c) Public institutions must designate a responsible person to monitor compliance of vending machines with these requirements.

d) Non-compliant vending machines must be removed from public buildings within 30 days of notification of non-compliance.

3. Regulation of Portion Sizes:

a) Food service establishments must:
i. Offer smaller portion options for all menu items
ii. Price smaller portions proportionately to encourage their selection
iii. Not incentivize larger portions through pricing strategies

b) Single-serving packages of sugar-sweetened beverages may not exceed 330ml.

c) Food service establishments must clearly display calorie information for all portion sizes.

d) The Authority may establish maximum portion sizes for specific high-calorie, high-fat, high-sugar, or high-sodium foods and beverages.

Procurement, Subsidies, Standards and Incentives

1. Public Procurement and Subsidies:

a) Government food procurement programs must prioritize:
i. Fresh fruits and vegetables
ii. Whole grains
iii. Legumes and other plant-based proteins
iv. Minimally processed foods

b) At least 60% of public funds allocated to food procurement must be directed toward these healthier options.

c) Government subsidies for agricultural production must be restructured to increase support for:
i. Fruit and vegetable production
ii. Whole grain production
iii. Legume production
iv. Sustainable farming practices

d) The Authority must develop a transition plan to gradually shift subsidies from less healthy to healthier food options over a period of 5 years.

2. Standards for Healthier Products in Worksite and Community Settings:

a) Food service operations in workplaces with more than 50 employees must:
i. Ensure that at least 50% of food options meet nutritional standards established by the Authority
ii. Provide free, clean drinking water
iii. Display nutritional information for all food items
iv. Price healthier options competitively with or lower than less healthy alternatives

b) Community food programs, including those serving older adults, must comply with nutritional standards established by the Authority.

c) Food provided at government-sponsored events and meetings must comply with nutritional standards established by the Authority.

d) The Authority must develop guidance materials and provide technical assistance to help worksites and community settings implement these standards.

3. Incentives for Healthier Food Retail:

a) Food retailers that meet criteria for offering healthier food options may receive:
i. Tax incentives
ii. Streamlined permitting processes
iii. Technical assistance
iv. Marketing support

b) Criteria for incentives must include:
i. Percentage of shelf space dedicated to fruits, vegetables, whole grains, and other nutritious foods
ii. Pricing strategies that make healthier options affordable
iii. Prominent placement and promotion of healthier options
iv. Reduced promotion of less healthy options

c) Local authorities must develop programs to recognise and promote food retailers that meet these criteria.

d) The Authority must evaluate the effectiveness of these incentives and adjust them as needed to maximize their impact on food retail environments.

Implementation and Enforcement

1. Phased Implementation:

   a) The provisions of the previous Section must be implemented according to the following timeline:
   i. School food environment provisions: within 12 months
   ii. Green Food Zones: within 18 months
   iii. Water fountain requirements: within 24 months
   iv. Design standards for food service environments: within 24 months
   v. Procurement, subsidies, standards, and incentives: within 36 months

   b) The Authority must develop and publish detailed implementation guidelines for each provision within 6 months of this Act taking effect.

   c) The Authority must provide technical assistance, training, and resources to support implementation.

2. Monitoring and Evaluation:

   a) The Authority must establish a comprehensive monitoring and evaluation system to assess the implementation and impact of these provisions.

   b) The monitoring system must include:
   i. Regular inspections of educational institutions, food service establishments, and other relevant settings
   ii. Surveys of food availability, pricing, and marketing
   iii. Assessment of changes in food purchasing and consumption patterns
   iv. Evaluation of health outcomes

   c) The Authority must publish annual reports on the implementation and impact of these provisions.

   d) Based on monitoring and evaluation results, the Authority must recommend adjustments to these provisions as needed to maximize their effectiveness.

3. Enforcement Mechanisms:

   a) The Authority must designate enforcement officers responsible for monitoring compliance with these provisions.

   b) Enforcement officers have the power to:

i. Enter and inspect relevant premises

ii. Collect samples and evidence

iii. Issue warnings and notices of non-compliance

iv. Impose penalties for violations

c) Penalties for violations must be proportionate to the severity and frequency of the violation and may include:

i. Warnings

ii. Fines

iii. Suspension or revocation of licenses or permits

iv. Mandatory corrective action

d) The Authority must, by virtue of … [32], establish an appeals process for entities that dispute enforcement actions.

4. Public Awareness and Education:[33]

a) The Authority must develop and implement public awareness and education campaigns to inform the public about:

i. The provisions of the Sections …

ii. The importance of healthy food environments

iii. How to make healthier food choices

b) Educational materials must be culturally appropriate and accessible to diverse populations.

c) The Authority must engage with community organizations, healthcare providers, and other stakeholders to disseminate information and promote compliance.

d) The Authority must establish a mechanism for the public to report violations of these provisions.

Public Education and Information

1. Consumer Education for Healthy Diets:

a) The Authority must develop and implement comprehensive consumer education programs that:

i. Provide practical guidance on maintaining healthy diets

ii. Explain the relationship between diet and health outcomes

iii. Teach skills for interpreting food labels and health claims

[32] Define the appropriate type of regulation.

[33] Consider merging into the following.

iv. Offer strategies for healthy food preparation and meal planning

b) Consumer education programs must be:
i. Evidence-based and aligned with current nutritional science
ii. Culturally appropriate and accessible to diverse populations
iii. Available through multiple channels including digital platforms, community centers, and healthcare settings
iv. Regularly evaluated and updated based on effectiveness data

c) The Authority must collaborate with community organizations, healthcare providers, and educational institutions to maximize the reach and impact of consumer education efforts.

2. Public Health Campaigns:

a) The Authority must implement regular public education campaigns about the health impacts of food Products, which must:
i. Highlight both positive and negative health impacts of different food choices
ii. Be based on robust scientific evidence rather than one-directional information provision
iii. Include practical advice for implementing dietary changes
iv. Target specific population groups with tailored messaging

b) Campaigns must utilize multiple media channels including:
i. Television and radio
ii. Digital and social media platforms
iii. Out-of-home advertising
iv. Print materials in community settings

c) Campaign effectiveness must be evaluated through:
i. Pre and post-campaign surveys of knowledge, attitudes, and behaviors
ii. Monitoring of engagement metrics across different channels
iii. Assessment of changes in purchasing patterns where possible

d) Campaigns must be designed to complement other policy interventions rather than as standalone measures, recognizing that information provision alone has limited impact on behavior change.

3. Nutrition Education in Schools:

a) Nutrition education must be mandatory in all primary and secondary schools and must:
i. Be integrated across the curriculum, particularly in science, physical education, and food technology subjects
ii. Include both theoretical knowledge and practical skills
iii. Be age-appropriate and engaging
iv. Involve hands-on learning experiences with food

b) The curriculum must include:
i. Basic nutrition principles and the relationship between diet and health
ii. Food skills including preparation, cooking, and food safety
iii. Understanding food systems and sustainability
iv. Critical evaluation of food marketing and media messages

c) Schools must adopt a whole-school approach to nutrition education that:
i. Ensures consistency between classroom messages and the school food environment

ii. Involves parents and caregivers in nutrition education initiatives
iii. Includes sensory education approaches such as taste testing and cooking classes
iv. Utilizes school gardens where possible to connect children with food production

d) Nutrition education must be delivered by appropriately trained staff, with professional development opportunities provided for teachers.

e) The Authority must develop standardized resources and materials to support schools in delivering high-quality nutrition education.

4. Training Programs for Food Service Workers:

a) All food service workers involved in public food provision must complete training on healthy food preparation, which must cover:
i. Principles of healthy and balanced meals
ii. Techniques for reducing salt, sugar, and unhealthy fats while maintaining flavor
iii. Appropriate portion sizes for different age groups
iv. Menu planning to incorporate a variety of nutritious foods
v. Special dietary requirements and allergen management

b) Training programs must:
i. Be accessible in multiple languages and formats
ii. Include both theoretical knowledge and practical skills development
iii. Be updated regularly to reflect current nutritional guidelines
iv. Lead to recognised certification

c) Food service establishments must ensure that:
i. All staff receive initial training within three months of employment
ii. Refresher training is completed at least every three years
iii. At least one trained staff member is present during all operating hours
iv. Training completion records are maintained and available for inspection

5. Consumer Information Portals:

a) The Authority must establish and maintain a comprehensive online portal for nutrition information that:
i. Provides evidence-based information on healthy eating
ii. Explains current nutritional guidelines in accessible language
iii. Offers practical tools for meal planning and healthy food preparation
iv. Addresses common nutrition myths and misconceptions

b) The portal must include:
i. Interactive tools for assessing personal dietary patterns
ii. Customizable meal plans for different dietary preferences and requirements
iii. Recipes and cooking demonstrations for nutritious meals
iv. Information on interpreting food labels and health claims

c) The portal must be:
i. Regularly updated to reflect current scientific evidence

ii. User-friendly and accessible on multiple devices
iii. Available in multiple languages
iv. Free to access for all users

6. Digital Tools for Nutritional Tracking and Education:

a) The Authority must develop or approve digital tools that enable individuals to:
i. Track their food intake and compare it to nutritional guidelines
ii. Receive personalized feedback on their dietary patterns
iii. Set and monitor progress toward dietary goals
iv. Access educational content about nutrition and healthy eating

b) Digital tools must:
i. Be evidence-based and aligned with current nutritional guidelines
ii. Protect user privacy and data security
iii. Be accessible to users with different abilities
iv. Be available free of charge or at minimal cost

c) The Authority must establish standards for nutrition apps and digital tools to ensure they:
i. Provide accurate and evidence-based information
ii. Do not promote extreme or potentially harmful dietary patterns
iii. Are transparent about their data usage policies
iv. Disclose any conflicts of interest or commercial relationships

7. Evaluation and Quality Assurance:

a) All educational initiatives and information tools must be:
i. Regularly evaluated for effectiveness and impact
ii. Updated based on evaluation findings and emerging evidence
iii. Developed with input from nutrition experts, educators, and target users
iv. Free from commercial influence and conflicts of interest

b) The Authority must publish annual reports on:
i. The reach and engagement of educational initiatives
ii. Outcomes and impact measures where available
iii. Plans for improvement and future development
iv. Emerging needs and priorities for nutrition education

Governance, Compliance, Monitoring, Certification and Enforcement

N.B.:
- This Chapter can be supplemented by the provisions of Chapters J., K., L. and O. of the Cross-sectoral Standard Provisions and of the complementing List of Powers and Obligations.
- Consider merging the various provisions on powers in this collection of model provisions into this Chapter.

Establishment and Powers of the Food Safety and Nutrition Authority

1. There must be established a Food Safety and Nutrition Authority (hereinafter "the Authority") as the competent body for the implementation and enforcement of this Act.

2. The Authority must be composed of experts in the fields of:
   a) Nutrition science
   b) Food technology
   c) Public health
   d) Epidemiology
   e) Consumer protection
   f) Food law and regulation
   g) Veterinary medicine
   h) Environmental health

3. The Authority must operate independently of industry influence and must make decisions based solely on scientific evidence and public health considerations.

4. The Authority has the following general powers:
   a) Develop and implement regulations related to food safety and nutrition
   b) Monitor compliance with the provisions of this Act
   c) Investigate potential violations
   d) Impose penalties for non-compliance
   e) Provide guidance to food business operators
   f) Conduct or commission research on food safety and nutrition
   g) Collaborate with international bodies on matters related to food safety and nutrition

5. The Authority must publish an annual report on the state of food safety and nutrition in the national territory, including:
   a) Progress in implementing the provisions of this Act
   b) Compliance rates with established standards
   c) Enforcement actions taken
   d) Recommendations for further action

Powers to Modify and Interpret Terms, Regulatory Requirements and other Provisions

1. The Authority has the power to:
   a) Designate additional key health parameters beyond those explicitly listed in this Act

b) Establish and revise thresholds for color-coding and warning labels

c) Set minimum and maximum values for nutrients in specific food categories

d) Mandate food fortification when necessary for public health

e) Impose additional health warnings for specific food categories

f) Establish specific requirements for novel foods and emerging technologies

g) Modify testing protocols and sampling procedures

h) Recognise equivalent standards from other jurisdictions

2. When exercising powers under paragraph 1, the Authority must:

a) Base decisions on robust scientific evidence

b) Consider international standards and best practices

c) Conduct public consultations for a minimum period of 60 days

d) Publish a detailed impact assessment

e) Provide reasonable implementation periods for industry compliance

f) Consider the special needs of small and medium enterprises

3. For designating additional key health parameters, the Authority must:

a) Evaluate scientific evidence demonstrating significant public health impact

b) Consider prevalence of the substance in the food supply

c) Assess feasibility of measurement and control

d) Publish a comprehensive scientific review

e) Establish appropriate thresholds based on risk assessment

f) Specify appropriate analytical methods

4. For establishing or revising color-code thresholds, the Authority must:

a) Consider consumption patterns in the national population

b) Evaluate nutritional needs of vulnerable groups

c) Align with WHO dietary guidelines where appropriate

d) Consider technological feasibility for reformulation

e) Establish category-specific thresholds where necessary

f) Review thresholds at least every five years

5. For mandating food fortification, the Authority must:

a) Identify population-wide nutrient deficiencies through surveillance data

b) Select appropriate food vehicles consumed by the target population

c) Establish safe and effective fortification levels

d) Specify permitted forms of micronutrients

e) Implement monitoring systems to prevent excessive intake

f) Evaluate cost-effectiveness and technical feasibility

6. The Authority may, by means of … , establish temporary emergency measures without prior consultation when necessary to protect public health, provided that:
   a) The measure addresses an immediate and serious risk
   b) Scientific uncertainty does not prevent protective action
   c) The measure is proportionate to the risk
   d) The measure is reviewed within 6 months
   e) A consultation is initiated as soon as practicable

7. The Authority may / must define the terms “high-risk product”. It may also decide which Products are to be regarded as high-risk Products.

8. The Authority may / must decide which Products are to be regarded as “specific high-risk product categories”.

9. The Authority may, by means of … , define other terms used in this Act.

10. The Authority may, by means of … , issue binding interpretations of obligations, requirements and other provisions set out in this Act.

Powers to Require Information and Documentation

1. The Authority may require food business operators to submit:
   a) Detailed product formulations and specifications
   b) Manufacturing processes and quality control procedures
   c) Self-monitoring records and test results
   d) Supply chain information and traceability documentation
   e) Marketing materials and promotional strategies
   f) Sales data for specific product categories
   g) Consumer research and product development information
   h) Any other information necessary to fulfill its regulatory functions

2. Information requests must be:
   a) Specific in scope and purpose
   b) Proportionate to regulatory need
   c) Accompanied by reasonable deadlines for submission
   d) Respectful of legitimate confidentiality concerns

3. The Authority must establish secure systems for:
   a) Electronic submission of required information
   b) Protection of commercially sensitive information
   c) Data management and analysis

d) Information sharing with other relevant authorities

4. The Authority may establish regular reporting requirements for:
   a) Nutritional composition of Products
   b) Progress on reformulation targets
   c) Implementation of allergen controls
   d) Food safety incidents and corrective actions
   e) Marketing practices for Products high in critical nutrients

5. Food business operators must retain all documentation related to compliance with this Act for a minimum of three years or the shelf life of the product plus six months, whichever is longer.

Powers to Conduct Inspections and Investigations

1. Authorised officers of the Authority has the power to:
   a) Enter any premises where food is produced, processed, stored, or sold during normal business hours without prior notice
   b) Inspect facilities, equipment, and vehicles used for food-related activities
   c) Examine any relevant documents and records
   d) Take photographs, videos, or other recordings
   e) Interview personnel
   f) Take samples for analysis
   g) Seize items that may be evidence of non-compliance

2. For premises used as private dwellings, authorised officers must:
   a) Obtain a warrant from a judicial authority, or
   b) Obtain consent from the occupier, or
   c) Have reasonable grounds to believe that an imminent risk to public health exists

3. When conducting inspections, authorised officers must:
   a) Present official identification
   b) Explain the purpose of the inspection
   c) Conduct inspections with minimal disruption to operations
   d) Provide a written report of findings to the food business operator
   e) Maintain confidentiality of proprietary information

4. The Authority must develop and implement a risk-based inspection program that considers:
   a) The nature and scale of food business operations
   b) Compliance history
   c) Inherent risks of specific food categories

d) Vulnerability of target consumer groups

e) Emerging food safety concerns

5. The frequency of routine inspections must be determined based on risk categorization:
   a) High-risk establishments: at least once every 6 months
   b) Medium-risk establishments: at least once every 12 months
   c) Low-risk establishments: at least once every 24 months

6. The Authority must conduct additional non-routine inspections in response to:
   a) Consumer complaints
   b) Food safety incidents
   c) New scientific information about emerging risks
   d) Information from other regulatory authorities
   e) Follow-up on previous non-compliance

Food Sampling and Testing

1. Authorised officers has the power to take samples of:
   a) Raw materials
   b) Ingredients
   c) Processing aids
   d) Finished Products
   e) Packaging materials
   f) Environmental samples from food production areas
   g) Water used in food production

2. When taking samples, authorised officers must:
   a) Follow standardized sampling protocols
   b) Take samples in the presence of the food business operator or their representative when possible
   c) Divide samples into three parts when appropriate:
   i. One for official analysis
   ii. One for the food business operator
   iii. One for reference in case of dispute
   d) Properly seal, label, and document all samples
   e) Maintain the cold chain or other necessary conditions during transport

3. The Authority must establish detailed sampling plans based on:
   a) Statistical principles to ensure representativeness
   b) Risk-based prioritization of food categories
   c) Known or suspected compliance issues

d) Emerging food safety concerns

e) International standards and recommendations

4. The Authority must establish a network of official laboratories that:
   a) Are accredited to ISO/IEC 17025 or equivalent standards[34]
   b) Use validated analytical methods
   c) Participate in proficiency testing programs
   d) Maintain appropriate quality assurance systems
   e) Have sufficient capacity for routine and emergency testing

5. Testing programs must include:
   a) Microbiological safety parameters
   b) Chemical contaminants
   c) Pesticide residues
   d) Veterinary drug residues
   e) Food additives
   f) Allergens
   g) Nutritional composition
   h) GMO content when relevant
   i) Authenticity testing to detect food fraud

6. The Authority must, by virtue of … [35], establish:
   a) Standard operating procedures for sample collection, transport, and analysis
   b) Criteria for interpretation of analytical results, including measurement uncertainty
   c) Protocols for confirmatory testing when necessary
   d) Systems for rapid reporting of results indicating serious health risks
   e) Procedures for challenging analytical results

7. The Authority must publish an annual sampling and testing program that includes:
   a) Priority food categories
   b) Parameters to be tested
   c) Sampling frequency and distribution
   d) Coordination with regional or international monitoring programs
   e) Special projects addressing emerging concerns

[34] Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.
[35] Define the appropriate type of regulation.

Import Controls and Border Inspection

1. All food Products imported into the national territory must:
   a) Comply with all requirements of this Act
   b) Be accompanied by required documentation
   c) Enter through designated points of entry
   d) Be subject to inspection and sampling

2. The Authority must establish a risk-based import control system that includes:
   a) Documentary checks for all consignments
   b) Identity checks at a frequency determined by risk assessment
   c) Physical checks and sampling at a frequency determined by risk assessment
   d) Intensified controls for high-risk Products or origins
   e) Reduced controls for Products with a history of compliance

3. Documentary checks must verify:
   a) Health certificates or other official attestations
   b) Test reports from accredited[36] laboratories
   c) Traceability information
   d) Compliance with labeling requirements
   e) Any other documentation required by the Authority

4. The Authority must, by virtue of … [37], maintain and regularly update a list of:
   a) High-risk food categories subject to enhanced import controls
   b) Countries or regions subject to special import conditions
   c) Establishments approved to export to the national territory
   d) Products subject to temporary import restrictions

5. The Authority may, by virtue of … [38], recognise the equivalence of import control systems of other countries when:
   a) The exporting country provides sufficient guarantees of compliance
   b) On-site audits confirm the effectiveness of the exporting country's control system
   c) Historical compliance data supports reduced border controls
   d) Reciprocal arrangements exist where appropriate

6. For imported Products found to be non-compliant, the Authority may, by virtue of … [39]:
   a) Refuse entry of the consignment

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[36] Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.
[37] Define the appropriate type of regulation.
[38] Define the appropriate type of regulation.
[39] Define the appropriate type of regulation.

b) Order destruction or re-export of the consignment

c) Permit special treatment to bring the product into compliance when safe and feasible

d) Implement intensified controls on subsequent consignments from the same origin

e) Suspend imports from specific establishments or countries

7. The Authority must establish an electronic information system for import controls that:

a) Facilitates pre-notification of incoming consignments

b) Enables risk-based targeting of inspections

c) Records inspection results and enforcement actions

d) Shares information with customs authorities

e) Interfaces with international rapid alert systems

Veterinary Controls

1. The Authority must establish a specialised veterinary control system for:

a) Live animals intended for food production

b) Products of animal origin

c) Animal feed and feed additives

d) Veterinary medicinal Products used in food-producing animals

2. Veterinary controls must include:

a) Ante-mortem and post-mortem inspection of slaughter animals

b) Hygiene controls in slaughterhouses and meat processing establishments

c) Residue monitoring for veterinary drugs and prohibited substances

d) Surveillance for zoonotic diseases

e) Controls on animal welfare as it relates to food safety

3. The Authority must, by virtue of … [40], establish specific requirements for:

a) Approval of establishments handling Products of animal origin

b) Hygiene practices in primary production of animal Products

c) Temperature controls throughout the production and distribution chain

d) Microbiological criteria for Products of animal origin

e) Identification and traceability of animals and animal Products

4. Veterinary inspectors appointed by the Authority must:

a) Hold appropriate veterinary qualifications

b) Receive specialized training in food safety

c) Follow standardized inspection protocols

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[40] Define the appropriate type of regulation.

d) Document all findings and enforcement actions

e) Participate in continuing professional development

5. The Authority must establish a national residue monitoring plan for:
   a) Veterinary drug residues
   b) Prohibited substances
   c) Environmental contaminants in animal Products
   d) Feed additives
   e) Pesticides in animal Products

6. The Authority must coordinate with animal health authorities to:
   a) Implement integrated surveillance for foodborne zoonoses
   b) Respond to animal disease outbreaks with food safety implications
   c) Control the use of veterinary medicines in food-producing animals
   d) Promote responsible antimicrobial use to minimize resistance

Monitoring and Surveillance

1. The Authority must establish comprehensive monitoring and surveillance systems for:
   a) Foodborne diseases and outbreaks
   b) Chemical and microbiological contaminants in food
   c) Nutrient composition of the food supply
   d) Food consumption patterns
   e) Emerging food safety risks
   f) Compliance with regulatory requirements

2. The monitoring system for foodborne diseases must:
   a) Collect data on incidence and prevalence
   b) Identify causative agents and food vehicles
   c) Detect and investigate outbreaks
   d) Track antimicrobial resistance in foodborne pathogens
   e) Share information with international surveillance networks

3. The monitoring system for food composition must:
   a) Track levels of key nutrients in priority food categories
   b) Monitor progress in reformulation efforts
   c) Assess compliance with compositional standards
   d) Identify emerging trends in food formulation
   e) Inform the development of nutrition policies

4. The Authority must conduct regular total diet studies to:
    a) Assess dietary exposure to contaminants
    b) Evaluate nutrient intake across population groups
    c) Identify priority areas for risk management
    d) Monitor trends over time
    e) Compare results with health-based guidance values

5. The Authority must establish an early warning system for:
    a) Detection of serious food safety incidents
    b) Rapid information exchange with other authorities
    c) Identification of emerging risks
    d) Coordination of response actions
    e) Communication with the public when necessary

6. The Authority must publish monitoring results annually, including:
    a) Compliance rates by food category
    b) Trends in key contaminants and nutrients
    c) Progress toward public health goals
    d) Emerging concerns requiring further action
    e) Recommendations for risk management priorities

N.B.: Complement this Section by provisions on risk management, see Chapter I. of the Cross-sectoral Standard Provisions.

Enforcement of Marketing Restrictions

1. The Authority must establish a specialised unit responsible for monitoring and enforcing compliance with marketing restrictions, with powers to:
    a) Monitor all forms of food marketing across all media channels
    b) Investigate potential violations
    c) Issue compliance notices
    d) Impose penalties for non-compliance
    e) Publish enforcement actions

2. The monitoring system for marketing practices must cover:
    a) Television and radio advertising
    b) Digital marketing, including social media and influencer marketing
    c) Print media
    d) Outdoor advertising
    e) Point-of-sale promotions
    f) Sponsorship activities

g) Product packaging and branding

3. The Authority must, by virtue of … [41], establish clear criteria for determining when marketing:
   a) Is directed at children
   b) Uses prohibited techniques
   c) Makes unauthorised health or nutrition claims
   d) Fails to display required warnings or information
   e) Otherwise violates the provisions of this Act

4. The Authority must develop technological tools to monitor digital marketing, including:
   a) Web crawlers to identify online food marketing
   b) Social media monitoring systems
   c) Artificial intelligence to analyse marketing content
   d) Age verification auditing tools
   e) Geolocation monitoring for proximity to schools

5. The Authority must establish a public reporting mechanism allowing consumers to:
   a) Report potential violations of marketing restrictions
   b) Submit evidence such as photographs or screenshots
   c) Track the status of their reports
   d) Receive notification of outcomes

6. For violations of marketing restrictions, the Authority may:
   a) Issue a warning for first minor violations
   b) Order immediate cessation of non-compliant marketing
   c) Require corrective advertising
   d) Impose monetary penalties proportionate to the scale of the violation and the size of the company
   e) Publish details of serious or repeated violations
   f) Seek court injunctions for persistent non-compliance

7. The Authority must publish annual reports on:
   a) Compliance rates with marketing restrictions
   b) Common types of violations
   c) Enforcement actions taken
   d) Emerging marketing techniques requiring regulatory attention
   e) Recommendations for strengthening marketing controls

[41] Define the appropriate type of regulation.

Enforcement Actions and Sanctions[42]

1. In case of non-compliance with the provisions of this Act, the Authority may take one or more of the following enforcement actions:
   a) Issue a written warning
   b) Issue an improvement notice specifying corrective actions and deadlines
   c) Impose administrative fines
   d) Order temporary suspension of operations
   e) Order product withdrawal or recall
   f) Revoke authorizations, registrations, or approvals
   g) Publish enforcement actions
   h) Refer cases for criminal prosecution

2. When determining appropriate enforcement actions, the Authority must consider:
   a) Nature and severity of the non-compliance
   b) Actual or potential harm to public health
   c) History of compliance
   d) Intentional or negligent nature of the violation
   e) Corrective actions already taken
   f) Size and economic capacity of the food business
   g) Other relevant factors

3. Administrative fines must be:
   a) Proportionate to the nature of the violation
   b) Sufficient to deter future non-compliance
   c) Higher for repeated violations
   d) Adjusted according to the size of the business
   e) Subject to appeal through administrative or judicial procedures

4. For serious violations that present an imminent risk to public health, the Authority may:
   a) Order immediate cessation of activities
   b) Seize and detain Products
   c) Close establishments temporarily or permanently
   d) Recall Products already on the market
   e) Issue public warnings

5. Criminal prosecution must be pursued for:
   a) Willful violations resulting in serious health risks

[42] Consider creating a separate Chapter on Sanctions with the help of the List of Sanctions and Collateral Measures.

b) Fraudulent practices

c) Obstruction of official controls

d) Repeated serious violations

e) Other circumstances specified in criminal law

6. The Authority must establish an enforcement policy that:
   a) Promotes consistent application of enforcement measures
   b) Emphasizes prevention and compliance assistance
   c) Establishes clear escalation procedures
   d) Ensures proportionality and fairness
   e) Provides transparency in enforcement decisions

7. Food business operators have the right to:
   a) Receive clear explanation of alleged non-compliance
   b) Respond to allegations before final enforcement decisions
   c) Appeal enforcement actions through established procedures
   d) Request review of disproportionate measures
   e) Access mediation or alternative dispute resolution when appropriate

Mandatory Testing and Self-Certification

1. Food business operators must implement a comprehensive self-testing program that:
   a) Verifies compliance with all applicable safety and quality requirements
   b) Follows internationally recognised testing methodologies
   c) Includes both routine monitoring and verification testing
   d) Is documented in a testing plan proportionate to the risk level of Products

2. The self-testing program must include:
   a) Microbiological testing for relevant pathogens and indicator organisms
   b) Chemical testing for contaminants, additives, and nutrients
   c) Physical testing for foreign materials and packaging integrity
   d) Sensory evaluation where appropriate for quality verification

3. Testing frequency must be determined based on:
   a) Risk categorization of the product
   b) Production volume
   c) Previous testing results and compliance history
   d) Changes in ingredients, processes, or suppliers

4. Food business operators must maintain testing records for a minimum of three years, including:
   a) Testing protocols and methods used
   b) Raw data and analytical results
   c) Corrective actions taken in response to non-compliant results
   d) Trend analysis of testing data

5. For high-risk Products, food business operators must:
   a) Submit annual self-certification declarations to the Authority
   b) Maintain a testing program exceeding minimum regulatory requirements
   c) Conduct challenge studies to validate control measures
   d) Implement environmental monitoring programs in production facilities

Mandatory Third-Party Certification of Operators

1. Food business operators producing high-risk categories of food must obtain certification from an accredited third-party certification body against a food safety standard recognised by the Authority.

2. Recognised standards include:
   a) Standards benchmarked by the Global Food Safety Initiative (GFSI)
   b) ISO 22000 Food Safety Management Systems
   c) Other standards determined by the Authority to be equivalent

3. Certification bodies must:
   a) Be accredited to ISO/IEC 17065 by a recognised accreditation body
   b) Employ auditors with appropriate qualifications and experience
   c) Implement robust conflict of interest policies
   d) Share audit findings with the Authority when requested

4. The certification process must include:
   a) A comprehensive on-site audit of facilities, processes, and documentation
   b) Review of HACCP plans and food safety management systems
   c) Verification of compliance with applicable regulatory requirements
   d) Assessment of food safety culture within the organization

5. Certification status must be:
   a) Renewed at intervals determined by the Authority based on risk assessment
   b) Immediately reviewed following significant food safety incidents
   c) Subject to surveillance audits between recertification periods
   d) Withdrawn if critical non-conformities are identified

6. The Authority must, by virtue of … [43], establish a recognition system for food business operators with robust certification records, which may include:
   a) Reduced frequency of official inspections
   b) Expedited processing of applications and approvals
   c) Recognition on the Authority's public registry
   d) Eligibility for export certification facilitation

Mandatory Third-Party Product Certification

1. For specific high-risk product categories designated by the Authority, product certification is required in addition to system certification.

2. Product certification must:
   a) Verify that individual product types meet all applicable safety and quality requirements

[43] Define the appropriate type of regulation.

b) Include batch testing according to statistically valid sampling plans
c) Consider both production processes and final product characteristics
d) Be renewed annually or when significant product or process changes occur

3. Product certification bodies must:
   a) Be accredited[44] to ISO/IEC 17065 for the relevant product scope
   b) Employ technical experts with specific knowledge of the product category
   c) Maintain independence from the manufacturer
   d) Implement robust product testing protocols

4. Certified Products must bear a certification mark that:
   a) Is clearly visible on the product packaging
   b) Identifies the certification body
   c) Includes a unique identifier for traceability
   d) Cannot be transferred to non-certified Products

5. The Authority must maintain a publicly accessible database of certified Products that includes:
   a) Product name and description
   b) Manufacturer details
   c) Scope of certification
   d) Validity period
   e) Certification body

Government / Authority Powers regarding Mandatory Certification

1. The Government / Authority may/must, by virtue of … [45], lay down detailed rules on
   a) the qualification requirements;
   b) the designation and supervision of certification bodies;
   c) the procedures for the withdrawal of such designations; and
   d) the procedural and other obligations of certification bodies.[46]
2. The Government / Authority may, by virtue of … [47], require that certification bodies be subject to prior accreditation by specifically designated nationally or internationally recognised accreditation bodies.[48]

Recognised Voluntary Third-Party Certification Systems

1. The Authority may, by virtue of … [49], recognise voluntary third-party certification systems that:
   a) Are based on standards that meet or exceed regulatory requirements

[44] Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.
[45] Define the appropriate type of regulation.
[46] The procedures commonly used for licensing can also be used in this context. Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.
[47] Define the appropriate type of regulation.
[48] Even where accreditation is mandatory, this power is useful because some accreditation bodies are more trustworthy than others. Regarding accreditation, see Chapter E of these Cross-sectoral Standard Provisions for Regulation.
[49] Define the appropriate type of regulation.

b) Use competent and impartial auditors

c) Employ robust audit methodologies

d) Maintain appropriate oversight and integrity controls

e) Share relevant information with the Authority

2. Recognition of third-party certification systems must require:

a) Detailed assessment of the certification standard

b) Evaluation of the certification body's competence and independence

c) Review of audit protocols and auditor qualifications

d) Ongoing monitoring of system performance

e) Periodic reassessment

3. Food businesses with recognised third-party certification may benefit from:

a) Reduced frequency of official inspections

b) Streamlined administrative procedures

c) Expedited processing of certain applications

d) Recognition in the Authority's public reporting system

e) Other incentives as determined by the Authority

4. The Authority must maintain oversight of recognised third-party certification systems through:

a) Periodic witness audits

b) Review of certification decisions

c) Investigation of complaints

d) Analysis of compliance data

e) Regular communication with certification bodies

5. The Authority may, by virtue of … [50], suspend or withdraw recognition of a third-party certification system if:

a) The system fails to maintain standards equivalent to regulatory requirements

b) There is evidence of systematic failures in identifying non-compliance

c) The certification body loses its accreditation or competence

d) The system fails to share required information with the Authority

e) Other circumstances arise that undermine confidence in the system

Community-Based Monitoring Mechanisms

1. The Authority must establish a community-based nutrition and food safety monitoring system that:

a) Generates regular, integrated information on the nutritional and safety conditions within communities

[50] Define the appropriate type of regulation.

b) Provides timely data to local decision-makers
c) Enhances the visibility of nutrition-related activities within communities
d) Serves as a vehicle for community-wide food safety planning

2. Community monitoring must include:
   a) Participatory data collection by trained community representatives
   b) Regular community forums to discuss findings and develop solutions
   c) Integration with official monitoring systems
   d) Feedback mechanisms to food businesses operating within the community

3. The Authority must support community monitoring through:
   a) Development of simplified monitoring tools and protocols
   b) Training programs for community monitors
   c) Technical assistance for data analysis and interpretation
   d) Grants to support sustainable monitoring activities

4. Community monitoring results must be:
   a) Validated through appropriate quality control measures
   b) Documented in standardized formats
   c) Shared with relevant authorities and stakeholders
   d) Used to inform local food safety and nutrition interventions

5. The Authority must establish mechanisms to respond to community monitoring findings, including:
   a) Rapid investigation of reported food safety concerns
   b) Technical support to address identified issues
   c) Recognition of communities demonstrating improved outcomes
   d) Integration of findings into official risk assessment processes

Alert Portal[51] and Whistleblower Protection[52]

1. Any person who discloses information about suspected wrongdoing of actors governed by this Act to the Authority must be protected from detrimental treatment or victimization if:
   a) The disclosure is made in good faith
   b) The person reasonably believes the information is substantially true
   c) The disclosure is made in the public interest
   d) The information concerns matters within the Authority's jurisdiction

2. Protected disclosures include information about:
   a) Criminal offenses related to food safety or fraud
   b) Failure to comply with legal obligations
   c) Endangerment of health and safety
   d) Damage to the environment related to food production
   e) Deliberate concealment of information about any of the above

3. Whistleblowers and witnesses must be protected from:
   a) Dismissal or redundancy
   b) Denial of promotion
   c) Disciplinary action

[51] See Section 68 of the Cross-sectoral Standard Provisions.
[52] Regarding whistleblower protection, see also Chapter E. of these Cross-sectoral Standard Provisions for Regulation.

d) Harassment or intimidation
e) Discrimination in any form

4. The Authority must take active measures to protect whistleblowers and witnesses from retaliation or harm.[53] This includes providing legal protections, support services, and relocation assistance if necessary. Regular follow-ups must be conducted to ensure the safety and well-being of whistleblowers and witnesses throughout the investigation process.

5. The Authority must establish secure channels for receiving disclosures and alerts, including:
a) Dedicated hotlines with 24/7 availability
b) Secure online reporting platforms
c) Designated contact persons within the Authority
d) Options for anonymous reporting

6. The Authority must:
a) Acknowledge receipt of disclosures within 7 days
b) Assess and investigate disclosures in a timely manner
c) Inform whistleblowers and witnesses of the outcome where appropriate
d) Maintain confidentiality of the whistleblower's identity
e) Publish anonymized statistics on disclosures received and actions taken

7. Food business operators must:
a) Establish internal whistleblowing procedures
b) Inform employees about whistleblower and witness protections
c) Train managers on handling disclosures appropriately
d) Prohibit retaliation against whistleblowers and witnesses

Competitor Lawsuits[54]

1. Food business operators may initiate legal proceedings against competitors who violate the provisions of this Act when such violations create unfair competitive advantages or harm market integrity.

2. To have standing for a competitor lawsuit, the following requirements must be met:
a) The plaintiff must be a registered food business operator in direct competition with the alleged violator;
b) The plaintiff must demonstrate actual or potential economic injury resulting from the alleged violation;
c) The alleged violation must constitute a substantive breach of this Act, not merely a technical or minor infringement.

3. The following procedural safeguards apply to prevent vexatious litigation:
a) The Authority must conduct a preliminary review of competitor lawsuits within 30 days to filter frivolous claims;
b) Plaintiffs must provide prima facie evidence of violation before proceedings may continue;
c) Courts may require plaintiffs to post security bonds for potential legal costs if claims appear questionable;
d) Plaintiffs found to have initiated vexatious litigation must be liable for the defendant's legal costs

[53] It is recommended to complement these provisions by those of Sections 69 and 70 of the Cross-sectoral Standard Provisions.

[54] See also the more detailed provisions of Section 67 of the Cross-sectoral Standard Provisions.

plus additional penalties.

4. In successful competitor lawsuits, the following remedies must be available:
   a) Injunctive relief to halt ongoing violations;
   b) Compensation for demonstrable economic losses directly attributable to the violation;
   c) Corrective advertising to remedy consumer misinformation caused by the violation;
   d) Recovery of reasonable legal costs for successful claims;
   e) Publication of judgment in industry publications at the defendant's expense.

5. The following limitations must apply to competitor lawsuits:
   a) Claims must be filed within 12 months of discovering the alleged violation;
   b) Damages must be limited to actual economic harm suffered, excluding punitive damages;
   c) Competitor lawsuits may not proceed simultaneously with Authority enforcement actions for the same violation unless specifically authorized.

Technology-Enabled Monitoring Systems

1. The Authority must develop and implement technology-enabled monitoring systems to enhance food safety surveillance, including:
   a) Cloud-based platforms for real-time data collection and analysis
   b) Remote monitoring of critical control points
   c) Automated compliance verification tools
   d) Risk prediction models based on data analytics

2. Food business operators must, where specified by the Authority based on risk assessment:
   a) Implement compatible digital monitoring systems
   b) Ensure automated recording of critical parameters
   c) Establish electronic traceability systems
   d) Participate in data sharing initiatives

3. Technology-enabled monitoring must include:
   a) Continuous temperature monitoring in cold storage facilities
   b) Automated allergen control verification
   c) Digital record-keeping with tamper-evident features
   d) Real-time alerts for deviations from critical limits

4. The Authority must establish data standards for technology-enabled monitoring that:
   a) Ensure interoperability between systems
   b) Protect commercially sensitive information
   c) Enable efficient data exchange
   d) Support automated compliance verification

5. The Authority must provide incentives for adoption of approved technology solutions, including:
   a) Technical assistance for implementation
   b) Recognition in the public reporting system
   c) Reduced frequency of on-site inspections
   d) Grants or tax incentives for small businesses

Risk Communication Frameworks

1. The Authority must establish a comprehensive risk communication framework that:
   a) Ensures timely, accurate, and clear communication about food safety risks
   b) Facilitates two-way communication between the Authority and stakeholders
   c) Promotes understanding of risk assessment and management decisions
   d) Builds public trust in the food safety system

2. Risk communication must be:
   a) Based on scientific evidence
   b) Transparent about uncertainties
   c) Tailored to different audiences
   d) Coordinated across relevant agencies
   e) Consistent with international best practices

3. The risk communication framework must include protocols for:
   a) Routine communication about ongoing food safety matters
   b) Crisis communication during food safety emergencies
   c) Communication about emerging risks
   d) Communication about long-term food safety and nutrition issues

4. Food business operators must:
   a) Designate responsible persons for risk communication
   b) Develop internal protocols aligned with the Authority's framework
   c) Participate in training on effective risk communication
   d) Cooperate with the Authority during food safety incidents

5. The Authority must regularly evaluate the effectiveness of risk communication activities by:
   a) Assessing public understanding of key messages
   b) Monitoring behavioral responses to communications
   c) Gathering feedback from stakeholders
   d) Reviewing the timeliness and accuracy of communications
   e) Identifying areas for improvement

6. The Authority must maintain multiple communication channels, including:
   a) Official website with dedicated risk communication section
   b) Social media platforms for rapid dissemination of information
   c) Direct notification systems for food businesses and consumers
   d) Media partnerships for broader reach
   e) Community engagement forums for two-way dialogue

Public Reporting of Inspection Results

1. The Authority must establish a transparent system for public disclosure of food safety inspection results that:
   a) Provides consumers with accessible information about compliance status
   b) Motivates food business operators to maintain high standards
   c) Recognises businesses with excellent compliance records
   d) Identifies businesses requiring improvement

2. The public reporting system must include:
   a) A standardised rating scheme that is easily understood by consumers
   b) Online access to inspection reports and compliance history
   c) Mobile applications for accessing information at point of purchase
   d) Mechanisms for businesses to respond to published results

3. Food business operators must:
   a) Display their most recent inspection result at the entrance to their premises
   b) Include a link to their inspection history on their websites
   c) Make inspection reports available to consumers upon request
   d) Not misrepresent their compliance status

4. The public reporting system must include:
   a) Date and type of inspection
   b) Specific findings and violations identified
   c) Corrective actions required and timeframes
   d) Follow-up inspection results
   e) Historical compliance trends

5. The Authority must evaluate the effectiveness of the public reporting system on an annual basis, assessing:
   a) Impact on compliance rates
   b) Consumer awareness and use of the information
   c) Business response to increased transparency
   d) Technological improvements to enhance accessibility

Transparency and Public Reporting

1. The Authority must establish a public-facing information system that provides access to:
   a) Results of food safety inspections
   b) Compliance status of food businesses
   c) Enforcement actions taken
   d) Food recalls and alerts
   e) Monitoring data on food safety and nutrition

2. The inspection reporting system must include:
   a) A standardized rating system that is easily understood by consumers
   b) Detailed inspection findings
   c) Corrective actions required
   d) Follow-up inspection results
   e) Historical compliance information

3. Food businesses must be required to:
   a) Display their most recent inspection result at the entrance to their premises
   b) Include a link to their inspection history on their websites
   c) Make inspection reports available to consumers upon request

d) Not misrepresent their compliance status

4. The Authority must publish timely alerts regarding:
   a) Food recalls
   b) Foodborne disease outbreaks
   c) Emerging food safety risks
   d) Fraudulent food Products
   e) Other significant food safety concerns

5. The Authority must maintain a publicly accessible database of:
   a) Approved food additives and their conditions of use
   b) Authorised health and nutrition claims
   c) Maximum levels for contaminants
   d) Microbiological criteria
   e) Other regulatory standards

6. The Authority must publish an annual food safety and nutrition report that includes:
   a) Overview of the national food control system
   b) Summary of inspection and sampling activities
   c) Compliance trends
   d) Major food safety incidents and responses
   e) Progress on nutrition improvement initiatives
   f) Strategic priorities for the coming year

Impact Assessment for New Products and Technologies

1. Before placing on the market any of the following, food business operators must submit a comprehensive impact assessment to the Authority:
   a) Novel foods as defined in this Act
   b) Foods produced using new processing technologies
   c) New types of food additives or ingredients
   d) Foods derived from new varieties of genetically modified organisms
   e) New types of food contact materials
   f) Any other product or technology designated by the Authority

2. The impact assessment must include:
   a) Detailed description of the product or technology
   b) Scientific evidence demonstrating safety
   c) Nutritional impact assessment
   d) Environmental impact assessment where relevant

e) Socioeconomic impact analysis

f) Post-market monitoring plan

3. The safety assessment component must address:
   a) Toxicological profile
   b) Allergenicity potential
   c) Nutritional implications
   d) Microbiological safety
   e) Potential for long-term effects
   f) Vulnerable population considerations

4. The Authority must establish expert committees to review impact assessments, comprising specialists in:
   a) Toxicology
   b) Nutrition
   c) Food technology
   d) Microbiology
   e) Environmental science
   f) Public health
   g) Other relevant disciplines

5. The Authority must make decisions on impact assessments within 180 days of submission, unless:
   a) Additional information is requested from the applicant
   b) The complexity of the assessment requires additional time
   c) External scientific advice is needed

6. The Authority may:
   a) Approve[55] the product or technology without conditions
   b) Approve with specific conditions or restrictions
   c) Require additional studies or data
   d) Reject the application if safety cannot be adequately demonstrated
   e) Implement a phased introduction with close monitoring

7. The Authority must publish summaries of impact assessments and decisions, excluding confidential business information.

[55] Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.

Emergency Response and Crisis Management

1. The Authority must establish a food safety emergency response system to:
   a) Detect and evaluate food safety incidents
   b) Coordinate rapid response actions
   c) Communicate effectively with stakeholders
   d) Minimise public health impacts
   e) Restore normal operations as quickly as possible

2. The Authority must maintain a crisis management plan that includes:
   a) Clear definition of roles and responsibilities
   b) Decision-making procedures
   c) Communication protocols
   d) Resource mobilization mechanisms
   e) Coordination with other agencies

3. When a serious food safety incident occurs, the Authority must:
   a) Establish a crisis management team
   b) Assess the nature and extent of the risk
   c) Implement appropriate control measures
   d) Communicate transparently with the public
   e) Document actions taken and outcomes

4. The Authority has emergency powers to:
   a) Order immediate product recalls
   b) Temporarily prohibit the sale of specific foods
   c) Close establishments posing immediate health risks
   d) Require mandatory testing of suspected Products
   e) Implement other measures necessary to protect public health

5. After resolution of a food safety emergency, the Authority must:
   a) Conduct a thorough investigation of causes
   b) Evaluate the effectiveness of the response
   c) Identify lessons learned
   d) Implement system improvements
   e) Publish a report on the incident and response

6. The Authority must conduct regular exercises to test and improve emergency response capabilities.

Funding and Resources

1. The Authority must be provided with adequate resources to effectively carry out its functions, including:
   a) Qualified personnel
   b) Laboratory facilities and equipment
   c) Information technology systems
   d) Training programs
   e) Operational funding

2. Funding for the Authority must come from:
   a) Government budget allocations
   b) Registration and authorization fees
   c) Inspection fees for certain activities
   d) Penalties collected for violations
   e) Other sources as permitted by law

3. The Authority must establish a fee structure that:
   a) Reflects the cost of providing services
   b) Does not create undue burden on small businesses
   c) Is transparent and predictable
   d) Is reviewed periodically
   e) Complies with applicable international trade agreements

4. The Authority must develop and implement a human resource strategy that ensures:
   a) Recruitment of qualified personnel
   b) Ongoing professional development
   c) Retention of expertise
   d) Ethical conduct and independence
   e) Adequate staffing levels based on workload assessment

5. The Authority must establish performance indicators to measure:
   a) Efficiency in use of resources
   b) Effectiveness in achieving objectives
   c) Quality of services provided
   d) Timeliness of regulatory processes
   e) Stakeholder satisfaction

6. The Authority must undergo periodic external audits to ensure financial integrity and operational effectiveness.

Surveillance Obligations of Private Actors and their Staff[56]

Obligations of All Economic Actors

1. All economic actors involved in the food supply chain must:

   a) Implement a food safety surveillance system proportionate to the nature, size, and complexity of their operations

   b) Designate a qualified person responsible for food safety compliance and surveillance activities

   c) Maintain records of all surveillance activities for a minimum of three years or the shelf life of the product plus one year, whichever is longer

   d) Cooperate with other economic actors in the food chain to ensure effective surveillance throughout the supply chain

   e) Immediately report to the Authority any reasonable suspicion that a food product presents a risk to human health

2. The surveillance system must include:

   a) Regular monitoring of compliance with food safety requirements

   b) Procedures for identifying and evaluating food safety risks

   c) Mechanisms for receiving, documenting, and responding to food safety complaints

   d) Procedures for tracing Products in case of safety concerns

   e) Regular testing and verification activities appropriate to the nature of the operation

3. Economic actors must ensure that all staff involved in food safety surveillance:

   a) Receive appropriate training for their responsibilities

   b) Have access to necessary resources and equipment

   c) Are authorised to take immediate action when safety risks are identified

   d) Are protected from retaliation when reporting food safety concerns

Mandatory Traceability Obligations for Food Business Operators

1. Food business operators must implement traceability systems that enable:
   a) Identification of the immediate supplier of ingredients, food-producing animals, and any substance intended to be incorporated into food
   b) Identification of businesses to which their Products have been supplied
   c) Rapid location and withdrawal of unsafe Products from the market

[56] See also Chapter G. of the Cross-sectoral Standard Provisions.

d) Provision of accurate information to consumers and the Authority

2. Traceability systems must record:
   a) Name and address of suppliers and customers (except final consumers)
   b) Nature and quantity of Products
   c) Date of transaction and delivery
   d) Batch or lot identification
   e) Any other information specified by the Authority

3. Traceability information must be:
   a) Maintained for a minimum of three years or the shelf life of the product plus six months, whichever is longer
   b) Stored in a readily accessible format
   c) Made available to the Authority upon request
   d) Capable of being transmitted electronically

4. Food business operators must:
   a) Test their traceability systems at least annually
   b) Document the results of traceability tests
   c) Implement improvements based on test results
   d) Ensure staff are trained in traceability procedures

5. For high-risk food categories, enhanced traceability requirements include:
   a) Implementation of electronic traceability systems
   b) Recording of additional data points throughout the supply chain
   c) Ability to complete full traceability exercises within four hours
   d) Integration with blockchain or other secure verification technologies where specified by the Authority

Obligations of Manufacturers

N.B.: Complement this Section by provisions on risk management, see Chapter I. of the Cross-sectoral Standard Provisions.

1. Registration of Products:

   a) Manufacturers must register all food Products in the product database provided by the Authority before placing them on the market

   b) Registration must include:
   i. Detailed product specifications and formulations
   ii. Manufacturing processes and quality control procedures
   iii. Risk assessment for key health parameters
   iv. Compliance documentation for applicable standards
   v. Traceability information for ingredients and packaging

   c) Manufacturers must update their registration information within 30 days of any significant change to product formulation, manufacturing processes, or safety information

   d) The Authority may establish simplified registration procedures for small-scale manufacturers producing limited quantities or selling within restricted geographical areas

2. Surveillance of Supply Chain:

a) Manufacturers must implement a supplier verification program that includes:
i. Initial and ongoing assessment of suppliers' food safety systems
ii. Audits of high-risk suppliers at a frequency determined by risk assessment
iii. Testing of incoming materials based on risk assessment
iv. Documentation of all verification activities

b) Manufacturers must alert the Authority within 24 hours upon discovering:
i. Serious infringements by suppliers or service providers involved in manufacturing
ii. Infringements by importers or distributors that may affect product safety
iii. Any other food safety issue in the supply chain that may pose a risk to consumers

3. Information and Communication:

a) Manufacturers must provide importers and distributors with:
i. Clear information on their respective obligations under this Act
ii. Product-specific handling, storage, and transportation requirements
iii. Training materials on proper product handling when necessary
iv. Regular updates on any changes to product specifications or safety information

b) Information must be provided in a clear, accessible format and in the official language(s) of the territory where the product is marketed

4. Response to Safety Issues:

a) Manufacturers must establish and maintain a system for:
i. Receiving and documenting all reports of potential safety issues
ii. Investigating reported safety issues within timeframes proportionate to the potential risk
iii. Implementing corrective actions to address identified safety issues
iv. Verifying the effectiveness of corrective actions

b) For reports indicating serious risk to human health, manufacturers must:
i. Begin investigation within 24 hours
ii. Provide an initial response to the reporter within 48 hours
iii. Document all investigation steps and findings
iv. Notify the Authority of the investigation outcome

5. Alerting and Recall Procedures:

a) When a manufacturer identifies a safety issue that may pose a risk to human health, they must:
i. Alert the Authority within 24 hours, providing all relevant information
ii. Inform all affected importers and distributors within 24 hours
iii. Implement recall procedures appropriate to the level of risk
iv. Provide the Authority with regular updates on the progress of the recall

b) For safety issues requiring immediate response to avoid health risks, manufacturers must:
i. Alert the general public via all available media, including internet media
ii. Provide clear information on the nature of the risk and actions consumers should take
iii. Establish dedicated communication channels for consumer inquiries
iv. Coordinate public communication with the Authority

6. Transparency of Inspection Results:

a) Manufacturers must report public inspection results:
i. In a clearly visible way to all their clients
ii. On their website in an easily accessible location
iii. In commercial documentation provided to business customers

b) Reports must include:
i. Date and scope of the inspection
ii. Summary of findings

iii. Any corrective actions required and their implementation status
iv. Link to the full inspection report if available from the Authority

7. Post-Market Surveillance:

a) Manufacturers must implement a post-market surveillance system that includes:
i. Regular sampling and testing of Products on the market
ii. Monitoring of consumer complaints and adverse events
iii. Trend analysis to identify emerging safety issues
iv. Periodic review of the effectiveness of the surveillance system

b) The frequency and intensity of surveillance activities must be based on:
i. The inherent risk profile of the product
ii. The vulnerability of the target consumer population
iii. The compliance history of the product
iv. New scientific information about potential hazards

Obligations of Suppliers and Service Providers in Manufacturing

1. Suppliers of raw materials, ingredients, and food contact materials must:

a) Implement a surveillance system to monitor the safety and compliance of their Products

b) Provide manufacturers with complete and accurate information about:
i. The composition and properties of supplied materials
ii. Any known hazards or safety concerns
iii. Appropriate handling and storage conditions
iv. Country of origin and traceability information

c) Maintain records of all batches supplied to manufacturers, including:
i. Production date and batch identification
ii. Quality control test results
iii. Distribution details
iv. Any safety-related incidents

d) Alert manufacturers within 24 hours of discovering any safety issue that may affect Products already supplied

e) Cooperate with manufacturers in investigating safety issues related to supplied materials

2. Service providers involved in manufacturing (e.g., co-packers, contract manufacturers) must:

a) Comply with all manufacturing obligations under this Act as if they were the manufacturer

b) Implement surveillance systems equivalent to those required of manufacturers

c) Provide the contracting manufacturer with:
i. Regular reports on surveillance activities
ii. Immediate notification of any safety issues identified
iii. Documentation of compliance with agreed specifications
iv. Access to facilities for audit purposes

d) Maintain clear documentation of responsibilities allocated between the service provider and the contracting manufacturer

e) Ensure traceability of all Products manufactured on behalf of others

3. Testing laboratories and analytical service providers must:

   a) Maintain accreditation to ISO/IEC 17025 or equivalent standards

   b) Implement quality assurance systems to ensure the reliability of test results

   c) Alert clients immediately of any test results indicating a serious safety risk

   d) Maintain records of all testing performed for food safety purposes

   e) Cooperate with the Authority in verification of test results when requested

4. Equipment and technology providers must:

   a) Provide accurate information about the capabilities and limitations of their equipment

   b) Alert manufacturers of any identified defects or malfunctions that could affect food safety

   c) Provide clear instructions for maintenance procedures critical to food safety

   d) Maintain records of equipment installation, maintenance, and calibration services provided

   e) Report to the Authority any systematic issues identified that may affect multiple manufacturers

Obligations of Importers

1. Pre-Import Verification:

   a) Importers must verify before importing food Products that:
   i. The manufacturer has registered the product in the Authority's database
   ii. The product complies with all applicable requirements under this Act
   iii. The manufacturer has implemented appropriate food safety management systems
   iv. The product is properly labeled according to requirements in this Act

   b) Verification must include:
   i. Review of manufacturer documentation
   ii. Risk-based sampling and testing of Products
   iii. Audit of manufacturer facilities when appropriate based on risk assessment
   iv. Confirmation of product traceability systems

2. Registration and Documentation:

   a) Importers must register with the Authority before engaging in import activities

   b) Importers must maintain records of:
   i. All imported Products with full traceability information
   ii. Verification activities conducted
   iii. Any safety issues identified and actions taken
   iv. Distribution of imported Products

   c) Records must be maintained for a minimum of three years or the shelf life of the product plus one year, whichever is longer

3. Surveillance during Import:

   a) Importers must ensure that during import, food Products:

i. Are transported and stored under appropriate conditions
ii. Maintain integrity of packaging and labeling
iii. Are protected from contamination
iv. Are subject to visual inspection for obvious defects or damage

b) Any Products showing signs of damage, tampering, or inappropriate storage conditions must be segregated and evaluated for safety before distribution

4. Post-Import Surveillance:

a) Importers must implement a surveillance system for imported Products that includes:
i. Regular sampling and testing based on risk assessment
ii. Monitoring of consumer complaints
iii. Verification that Products continue to meet specifications
iv. Coordination with manufacturers on emerging safety issues

b) Importers must alert the Authority within 24 hours upon discovering:
i. Safety issues with imported Products
ii. Non-compliance with requirements under this Act
iii. Information indicating potential risks not previously identified

5. Communication and Coordination:

a) Importers must:
i. Inform manufacturers of any safety issues identified with their Products
ii. Alert distributors of safety requirements and any identified issues
iii. Cooperate with manufacturers in product recalls
iv. Provide translation of safety information when necessary

b) Importers must serve as the primary point of contact for the Authority regarding imported Products when the manufacturer is located outside the national territory

6. Response to Safety Issues:

a) When notified of safety issues by manufacturers or the Authority, importers must:
i. Immediately cease distribution of affected Products
ii. Assist in tracing and recovering Products already distributed
iii. Communicate safety information to distributors and retailers
iv. Implement corrective actions as directed by the manufacturer or Authority

b) For safety issues identified by the importer, they must:
i. Alert the manufacturer and the Authority within 24 hours
ii. Quarantine affected Products still under their control
iii. Initiate recall procedures if Products have been distributed
iv. Document all actions taken

Obligations of All Distributors

1. Verification Before Distribution:

a) Before distributing a food product, distributors must verify that:
i. The product is properly registered in the Authority's database
ii. The product bears all required labeling and safety information
iii. The packaging is intact and shows no signs of tampering or damage
iv. Storage and transportation conditions have been maintained as required

b) Distributors may not distribute Products that:
i. Have exceeded their "use by" date

ii. Show signs of spoilage or contamination
iii. Have packaging damage that may compromise safety
iv. Are subject to recall or withdrawal notices

2. Surveillance During Distribution:

a) Distributors must implement a surveillance system that includes:
i. Regular inspection of Products during storage and handling
ii. Monitoring of temperature and other critical conditions
iii. Verification of product traceability information
iv. Procedures for handling consumer complaints

b) Distributors must maintain records of:
i. Products received and distributed, with batch identification
ii. Surveillance activities conducted
iii. Any safety issues identified and actions taken
iv. Staff training on food safety

3. Response to Safety Issues:

a) Upon discovering any safety issue, distributors must:
i. Immediately segregate affected Products
ii. Alert the manufacturer and/or importer within 24 hours
iii. Alert the Authority if the issue presents a serious risk to human health
iv. Cooperate in recall activities as directed

b) When notified of safety issues by manufacturers, importers, or the Authority, distributors must:
i. Immediately locate and segregate affected Products
ii. Follow instructions for return or disposal of affected Products
iii. Maintain records of all actions taken
iv. Assist in notifying customers as appropriate

4. Communication and Coordination:

a) Distributors must:
i. Inform downstream distributors and retailers of any safety issues
ii. Provide accurate information on proper handling and storage requirements
iii. Forward relevant safety information received from manufacturers or importers
iv. Maintain open communication channels with suppliers and customers

Obligations of Wholesalers in Addition to Those Applicable to all Distributors

1. Enhanced Traceability:

a) Wholesalers must implement enhanced traceability systems that:
i. Record both immediate suppliers and immediate customers (one step back, one step forward)
ii. Include batch or lot identification for all Products
iii. Enable rapid location of specific batches in case of safety issues
iv. Allow for efficient communication with affected customers

b) For high-risk food categories, wholesalers must maintain distribution records that allow for complete traceability within four hours of request

2. Storage and Transportation Surveillance:

a) Wholesalers must implement surveillance systems for storage facilities that include:
i. Continuous monitoring of temperature in refrigerated and frozen storage areas

ii. Regular inspection for pest activity and structural integrity
iii. Separation of different food categories to prevent cross-contamination
iv. Rotation of stock to ensure first-expired, first-out (FEFO) principles

b) For transportation, wholesalers must:
i. Verify that vehicles are appropriate for the food being transported
ii. Monitor temperature during transportation of temperature-sensitive foods
iii. Inspect vehicles for cleanliness and maintenance
iv. Ensure proper segregation of different food types during transport

3. Bulk Product Handling:

a) Wholesalers handling bulk, unpackaged foods must:
i. Implement additional surveillance measures to prevent contamination
ii. Regularly test food-contact surfaces and environmental conditions
iii. Maintain detailed records of bulk lot identification and subdivision
iv. Ensure that all containers used for bulk foods are food-grade and properly maintained

4. Information Dissemination:

a) Wholesalers must:
i. Promptly distribute safety alerts and recall notices to all affected customers
ii. Provide training materials to smaller retailers when appropriate
iii. Share market surveillance information with manufacturers and importers
iv. Maintain systems for rapid communication with customers in emergencies

Obligations of Retailers in Addition to Those Applicable to all Distributors

1. Point-of-Sale Surveillance:

a) Retailers must implement surveillance systems at the point of sale, including:
i. Daily inspection of displayed Products for quality and safety
ii. Regular temperature checks of refrigerated and hot-holding display units
iii. Rotation of Products to ensure FEFO principles
iv. Removal of Products that have passed their "use by" date

b) For self-service areas, retailers must:
i. Implement additional monitoring to prevent contamination
ii. Regularly clean and sanitize serving utensils and containers
iii. Monitor customer handling practices and intervene when necessary
iv. Maintain appropriate temperature controls

2. Consumer Information:

a) Retailers must:
i. Display required health warnings and nutritional information for non-prepacked foods
ii. Provide allergen information for all foods, including those prepared on-site
iii. Make product recall information prominently visible to consumers
iv. Train staff to answer basic consumer questions about food safety

b) For Products sold in loose or bulk form, retailers must:
i. Display origin, ingredient, and allergen information
ii. Provide instructions for safe handling and storage
iii. Maintain traceability information linking displayed food to its source

3. On-Site Food Preparation Surveillance:

a) Retailers preparing food on-site must:
i. Implement surveillance systems equivalent to those required for manufacturers
ii. Conduct regular microbiological testing of high-risk prepared foods
iii. Maintain detailed records of ingredients used in prepared foods
iv. Implement enhanced allergen management protocols

b) Staff involved in food preparation must:
i. Receive specific training on food safety hazards relevant to their activities
ii. Be subject to regular supervision and performance evaluation
iii. Follow documented procedures for safe food handling
iv. Report any safety concerns immediately to management

4. Consumer Complaint Handling:

a) Retailers must:
i. Establish clear procedures for receiving and documenting consumer complaints
ii. Investigate all safety-related complaints promptly
iii. Alert manufacturers and the Authority of patterns of complaints
iv. Maintain records of complaints and actions taken for a minimum of three years

Obligations of Internet Service Providers

1. Online Marketplaces:

a) Operators of online marketplaces that facilitate the sale of food Products must:
i. Verify that food business operators selling through their platform are registered with the Authority
ii. Require sellers to provide complete product information, including registration numbers
iii. Implement systems to prevent the listing of prohibited food Products
iv. Provide mechanisms for consumers to report safety concerns

b) When notified of non-compliant or unsafe food Products, online marketplace operators must:
i. Remove the listings within 24 hours
ii. Notify affected consumers who have purchased the Products
iii. Preserve records related to the sale of affected Products
iv. Cooperate with the Authority in any investigation

2. Food Delivery Platforms:

a) Operators of food delivery platforms must:
i. Verify that food businesses using their platform are registered with the Authority
ii. Implement systems to monitor temperature control during delivery
iii. Ensure delivery personnel receive basic training in food safety
iv. Maintain records of all deliveries for traceability purposes

b) Food delivery platforms must establish procedures for:
i. Handling consumer complaints related to food safety
ii. Reporting repeated safety issues with specific food businesses to the Authority
iii. Suspending food businesses with serious safety violations from the platform
iv. Communicating food safety alerts to consumers

3. Content Hosting Services:

a) Providers hosting content related to food Products (e.g., reviews, blogs, forums) must:
i. Remove content promoting unsafe food practices when notified by the Authority
ii. Cooperate with the Authority in disseminating urgent food safety information
iii. Implement systems to identify and flag potentially dangerous food-related content
iv. Maintain records of removed content for a period specified by the Authority

4. Digital Advertising Services:

   a) Providers of digital advertising services must:
   i. Verify that food Products advertised on their platforms comply with registration requirements
   ii. Ensure that advertisements include required health warnings and color codes
   iii. Remove non-compliant food advertisements within 24 hours of notification
   iv. Maintain records of food advertisements for a period specified by the Authority

Obligations of Other Service Providers

1. Transportation and Logistics Providers:

   a) Providers of transportation and logistics services for food Products must:
   i. Implement surveillance systems for vehicles and storage facilities
   ii. Monitor and record temperature conditions for temperature-sensitive foods
   iii. Train personnel in appropriate food handling practices
   iv. Report any incidents that may affect food safety to their clients

   b) Transportation and logistics providers must maintain:
   i. Records of all food shipments handled
   ii. Documentation of temperature monitoring
   iii. Cleaning and maintenance records for vehicles and equipment
   iv. Training records for personnel

2. Cold Storage Providers:

   a) Operators of cold storage facilities must:
   i. Implement continuous temperature monitoring systems with alarms
   ii. Conduct regular calibration of temperature monitoring devices
   iii. Maintain separate areas for different food categories when necessary
   iv. Implement pest control and sanitation programs

   b) Cold storage operators must:
   i. Alert food business operators immediately of any temperature excursions
   ii. Maintain detailed inventory records for traceability purposes
   iii. Implement backup systems to maintain temperature in case of equipment failure
   iv. Conduct regular testing for environmental contaminants

3. Food Testing Laboratories:

   a) Food testing laboratories must:
   i. Maintain accreditation to ISO/IEC 17025 or equivalent standards
   ii. Implement quality assurance programs for all testing methods
   iii. Alert clients immediately of test results indicating serious safety risks
   iv. Maintain records of all food safety testing performed

   b) Laboratories must report to the Authority:
   i. Any patterns of non-compliance identified across multiple clients
   ii. Detection of serious contaminants or adulterants
   iii. Evidence of emerging food safety risks
   iv. Any attempts to influence or falsify test results

4. Waste Management Service Providers:

   a) Providers handling food waste must:
   i. Implement procedures to prevent contamination of food Products
   ii. Ensure secure disposal of recalled or withdrawn food Products
   iii. Maintain records of food waste disposal, particularly for high-risk categories

iv. Report any irregularities in food waste disposal to the Authority

5. Cleaning and Sanitation Service Providers:

a) Providers of cleaning and sanitation services for food establishments must:
i. Use only approved chemicals and methods for food contact surfaces
ii. Implement verification procedures for cleaning effectiveness
iii. Train personnel in food safety requirements
iv. Report persistent sanitation issues to their clients and, if necessary, to the Authority

Obligations of Natural Persons Working for Economic Actors

1. General Obligations:

a) All persons working for food business operators must:
i. Follow food safety procedures established by their employer
ii. Maintain appropriate personal hygiene
iii. Report any illness that may affect food safety to their supervisor
iv. Report any observed food safety issues to their supervisor

b) Persons may not:
i. Conceal information about potential food safety risks
ii. Falsify records related to food safety
iii. Obstruct surveillance or inspection activities
iv. Retaliate against others who report food safety concerns

2. Specific Obligations by Role:

a) Persons responsible for receiving food Products must:
i. Verify that Products meet safety and quality specifications
ii. Check temperature of temperature-sensitive Products
iii. Inspect packaging for integrity
iv. Document any deviations and take appropriate action

b) Persons handling food Products must:
i. Follow established procedures to prevent contamination
ii. Use appropriate personal protective equipment
iii. Maintain separation between raw and ready-to-eat foods
iv. Follow proper handwashing and sanitation procedures

c) Persons responsible for monitoring critical control points must:
i. Conduct monitoring at required frequencies
ii. Accurately record monitoring results
iii. Take immediate corrective action when deviations occur
iv. Report persistent or serious deviations to management

d) Persons involved in cleaning and sanitation must:
i. Follow established cleaning procedures and schedules
ii. Use chemicals according to manufacturer instructions
iii. Verify effectiveness of cleaning activities
iv. Report any issues that may affect cleaning effectiveness

3. Training and Competence:

a) Persons working for food business operators must:
i. Complete all required food safety training
ii. Demonstrate competence in their food safety responsibilities
iii. Participate in refresher training as required

iv. Seek clarification when uncertain about food safety requirements

b) Supervisory personnel must:
i. Verify that staff under their supervision are properly trained
ii. Monitor staff compliance with food safety procedures
iii. Take corrective action when non-compliance is observed
iv. Promote a positive food safety culture

4. Reporting Obligations:

a) All persons must report to their supervisor:
i. Any observed violations of food safety procedures
ii. Equipment malfunctions that may affect food safety
iii. Signs of pest activity or contamination
iv. Consumer complaints related to food safety

b) If internal reporting does not result in appropriate action, persons must:
i. Escalate concerns to higher management
ii. If serious risks remain unaddressed, report to the Authority
iii. Cooperate with any investigation by the Authority
iv. Maintain documentation of their reporting efforts

5. Protection for Whistleblowers:

a) Persons reporting food safety concerns in good faith must be protected from:
i. Termination of employment
ii. Demotion or other adverse employment actions
iii. Harassment or intimidation
iv. Any form of retaliation

b) The Authority must establish secure channels for confidential reporting of food safety concerns by employees of food business operators

International Cooperation and Overseas Controls

International Cooperation for Enforcement

1. The Authority may/must establish mechanisms for cooperation with food safety authorities in other countries to enhance enforcement of food safety and nutrition standards, including:

a) Information exchange on food safety incidents that may have cross-border implications

b) Coordination of enforcement actions for Products distributed in multiple jurisdictions

c) Mutual assistance in investigations of food fraud and other serious violations

d) Joint inspections of food business operators with operations in multiple countries

e) Sharing of laboratory resources for specialized testing

2. For enforcement cooperation with foreign authorities, the Authority may/must:

    a) Establish direct communication channels with competent authorities in other jurisdictions

    b) Designate liaison officers responsible for facilitating cross-border enforcement

    c) Develop protocols for urgent enforcement matters requiring immediate action

    d) Share enforcement best practices and lessons learned

    e) Provide technical assistance to authorities in developing countries when appropriate

3. The Authority has the power to:

    a) Permit officers from foreign food safety authorities to participate in domestic inspections and investigations, subject to appropriate supervision

    b) Authorise domestic officers to participate in inspections and investigations conducted by foreign food safety authorities

    c) Investigate cases on behalf of foreign authorities when the matter concerns Products that may affect the domestic market

    d) Request foreign authorities to investigate cases on its behalf when the matter concerns Products originating in their jurisdiction

    e) Recognise foreign certificates or approvals based on reciprocity, without requiring formal agreements

4. The Authority may exercise extraterritorial jurisdiction over food safety matters when:

    a) The conduct affects the health and safety of domestic consumers

    b) The conduct involves food Products intended for the domestic market

    c) The conduct involves a domestic food business operator's foreign operations

    d) The conduct involves serious food fraud or adulteration with potential cross-border implications

5. When exercising extraterritorial jurisdiction, the Authority must:

    a) Consider the principle of comity and respect for the sovereignty of other states

    b) Seek cooperation with relevant foreign authorities whenever possible

    c) Apply enforcement measures proportionate to the seriousness of the violation and the degree of connection to the domestic jurisdiction

    d) Consider whether effective enforcement action is being taken by foreign authorities

6. The Authority must establish a reciprocity framework that allows for:

a) Recognition of foreign enforcement actions without formal agreements when the foreign jurisdiction provides equivalent recognition of domestic enforcement actions

b) Mutual recognition of inspection results and laboratory testing when the foreign jurisdiction maintains equivalent standards

c) Coordinated enforcement responses to cross-border food safety incidents based on reciprocal cooperation

d) Exchange of confidential enforcement information with foreign authorities that provide equivalent confidentiality protections

e) Simplified procedures for joint enforcement operations with jurisdictions demonstrating a history of effective cooperation

7. For confidential information received from foreign authorities, the Authority must:

a) Protect such information from unauthorized disclosure

b) Use the information only for the purposes for which it was provided, unless the providing authority consents to other uses

c) Obtain prior consent before sharing with third parties

d) Implement secure systems for transmission and storage

e) Limit access to authorized personnel with a need to know

8. The Authority has the power to enforce foreign food safety judgments and decisions when:

a) The foreign authority has exercised jurisdiction in accordance with internationally accepted principles, including the principle of rule of law and the protection of human rights

b) The foreign proceedings provided due process protections substantially equivalent to domestic standards

c) Enforcement would not be contrary to domestic public policy, principles and human rights

d) The foreign jurisdiction provides reciprocal enforcement of domestic judgments and decisions

9. The Authority must maintain a public register of foreign jurisdictions that:

a) Maintain food safety standards substantially equivalent to domestic standards

b) Provide reciprocal enforcement cooperation

c) Protect confidential information in a manner substantially equivalent to domestic protections

d) Demonstrate a history of effective food safety enforcement

10. The Authority may/must develop detailed guidelines for:

a) Determining when to exercise extraterritorial jurisdiction

b) Evaluating the equivalence of foreign food safety systems

c) Coordinating cross-border enforcement actions

d) Protecting confidential information in international enforcement cooperation

e) Resolving conflicts of jurisdiction with foreign authorities

Extraterritorial Application and Enforcement

1. This Act applies to conduct occurring outside the national territory when:

   a) The conduct is committed by a domestic food business operator

   b) The conduct involves food Products intended for the domestic market

   c) The conduct has substantial effects on domestic consumers

   d) The conduct is part of a scheme that includes domestic violations

2. When exercising jurisdiction over extraterritorial conduct, the Authority must consider:

   a) The extent of the connection between the conduct and the national territory

   b) The impact of the conduct on domestic consumers

   c) The principle of comity and the need to respect the sovereignty of other states

   d) The likelihood of effective enforcement

3. The Authority has the power to:

   a) Issue and serve administrative subpoenas to foreign food business operators doing business in the national territory

   b) Require foreign food business operators to designate a domestic agent for service of process

   c) Impose administrative penalties on foreign food business operators for violations affecting the domestic market

   d) Order the detention of imported Products from non-compliant foreign food business operators

   e) Publish information about non-compliant foreign food business operators

4. For serious violations committed by foreign food business operators, the Authority may:

   a) Prohibit the importation of all Products from the non-compliant operator

   b) Require pre-shipment inspection and certification of Products from the non-compliant operator

c) Impose enhanced surveillance requirements for Products from the non-compliant operator

d) Require the non-compliant operator to implement specific corrective actions as a condition for market access

e) Refer the matter to appropriate authorities for criminal prosecution when warranted

5. The Authority may/must, by virtue of … [57], establish procedures for:

a) Notifying foreign food business operators of alleged violations

b) Providing foreign food business operators with an opportunity to respond to allegations

c) Considering evidence and arguments presented by foreign food business operators

d) Issuing reasoned decisions regarding violations and sanctions

e) Providing for administrative and judicial review of enforcement actions

6. The Authority may/must develop guidelines for the exercise of extraterritorial jurisdiction, including:

a) Factors to consider when determining whether to pursue enforcement action

b) Procedures for coordinating with foreign authorities

c) Approaches to resolving conflicts of jurisdiction

d) Methods for obtaining evidence located in foreign jurisdictions

e) Strategies for ensuring compliance with remedial measures

Reciprocity in Recognition and Enforcement[58]

1. The Authority may/must recognise and enforce foreign food safety decisions and judgments when:

a) The foreign authority exercised jurisdiction in accordance with internationally accepted principles

b) The foreign proceedings provided due process protections substantially equivalent to domestic standards

c) Recognition and enforcement would not be contrary to domestic public policy

d) The foreign jurisdiction provides reciprocal recognition and enforcement of domestic decisions and judgments

2. For purposes of this Article, "foreign food safety decisions and judgments" include:

a) Administrative orders requiring the recall or withdrawal of unsafe food Products

[57] Define the appropriate type of regulation.
[58] See also Chapter F. of the Cross-sectoral Standard Provisions.

b) Administrative penalties imposed for food safety violations

c) Judicial judgments in civil or criminal proceedings related to food safety

d) Injunctions or similar orders prohibiting specific practices related to food safety

e) Settlements or consent agreements resolving food safety enforcement actions

3. The Authority must maintain a public register of foreign jurisdictions that provide reciprocal recognition and enforcement of domestic food safety decisions and judgments.

4. For foreign jurisdictions not listed in the register, the Authority may recognise and enforce foreign food safety decisions and judgments on a case-by-case basis when:

a) The specific foreign authority has demonstrated a commitment to food safety

b) The specific decision or judgment is based on scientific evidence and risk assessment

c) Recognition and enforcement would protect domestic consumers

d) The foreign authority has indicated a willingness to provide reciprocal recognition and enforcement

5. The Authority may/must, by virtue of … [59], establish procedures for:

a) Receiving and evaluating requests for recognition and enforcement of foreign food safety decisions and judgments

b) Providing notice to affected parties

c) Considering objections to recognition and enforcement

d) Issuing orders implementing foreign decisions and judgments

e) Coordinating enforcement activities with foreign authorities

6. When enforcing foreign food safety decisions and judgments, the Authority may:

a) Order the recall or withdrawal of food Products from the domestic market

b) Prohibit the importation of non-compliant food Products

c) Require specific corrective actions by domestic food business operators

d) Publish information about the foreign decision or judgment

e) Take other appropriate measures to protect domestic consumers

7. The Authority has the power to modify the enforcement of foreign food safety decisions and judgments when:

[59] Define the appropriate type of regulation.

a) Full enforcement would be impracticable in the domestic context

b) Domestic law provides for different but equally effective remedies

c) Partial enforcement would adequately protect domestic consumers

d) Changed circumstances warrant modification

8. The Authority may/must develop guidelines for the recognition and enforcement of foreign food safety decisions and judgments, including:

a) Criteria for evaluating the equivalence of foreign due process protections

b) Methods for authenticating foreign decisions and judgments

c) Approaches to translating and interpreting foreign decisions and judgments

d) Strategies for coordinating enforcement with foreign authorities

e) Procedures for resolving conflicts between foreign decisions and judgments and domestic law

Other International Cooperation

1. The Authority may/must actively participate in international standard-setting bodies, including:

a) The Codex Alimentarius Commission and its committees

b) The International Organization for Standardization (ISO) technical committees related to food

c) Regional standardisation bodies

d) International scientific advisory bodies on food safety and nutrition

e) International forums on emerging food safety and nutrition issues

2. The Authority may/must contribute to international standard-setting by:

a) Providing scientific data and expertise to support standard development

b) Participating in working groups and expert committees

c) Hosting international meetings and workshops

d) Commenting on draft standards during public consultation periods

e) Promoting the adoption of science-based international standards

3. The Authority may/must establish mechanisms for regulatory cooperation with foreign authorities, including:

a) Information sharing on:
i. Planned regulatory initiatives
ii. Risk assessments
iii. Scientific research
iv. Emerging hazards
v. New technologies and their safety implications

b) Joint research projects on food safety and nutrition topics of mutual interest

c) Staff exchanges and secondments to build capacity and share expertise

d) Peer reviews of regulatory systems and practices

e) Collaborative approaches to addressing global food safety and nutrition challenges

4. The Authority has the power to:

a) Enter into non-binding arrangements with foreign authorities to facilitate regulatory cooperation

b) Establish joint expert committees with foreign authorities to address specific food safety issues

c) Develop common risk assessment methodologies with foreign authorities

d) Coordinate regulatory responses to emerging food safety issues

e) Share non-confidential regulatory information with foreign authorities without requiring formal agreements

5. The Authority must, by virtue of … [60], establish a framework for recognizing the equivalence of foreign food safety measures when:

a) Scientific evidence demonstrates that different measures achieve the same level of protection

b) The exporting country provides sufficient guarantees regarding implementation and verification

c) Appropriate monitoring confirms continued effectiveness

d) The measures address the same food safety objectives

e) Recognition facilitates trade without compromising public health protection

6. The Authority has the power to:

a) Conduct on-site assessments in foreign jurisdictions to evaluate food safety controls, with the consent of the foreign jurisdiction

b) Approve foreign establishments for export to the domestic market based on direct inspection or recognition of foreign certification

c) Implement special import conditions for Products from specific foreign jurisdictions based on risk assessment

[60] Define the appropriate type of regulation.

d) Adjust the frequency and intensity of import controls based on the compliance history of foreign jurisdictions

e) Prohibit imports from foreign jurisdictions that fail to maintain adequate food safety controls

7. The Authority must establish mechanisms for international coordination during food safety emergencies, including:

a) Rapid notification of incidents with potential international implications

b) Sharing of analytical methods and laboratory results

c) Coordination of risk communication messages

d) Joint investigation of the source of contamination

e) Collaborative approaches to managing affected Products

8. The Authority has the power to:

a) Implement emergency measures to address serious food safety risks originating from foreign jurisdictions

b) Share confidential information with foreign authorities during emergencies when necessary to protect public health

c) Coordinate recall actions with foreign authorities for Products distributed internationally

d) Deploy experts to assist foreign authorities in investigating food safety emergencies that may affect the domestic market

e) Request assistance from foreign authorities in addressing domestic food safety emergencies

9. The Authority must develop a framework for providing technical assistance to developing countries, focusing on:

a) Strengthening food safety regulatory frameworks

b) Building laboratory capacity for food testing

c) Training food safety inspectors and other regulatory personnel

d) Developing risk-based inspection systems

e) Implementing effective food safety management systems

10. The Authority must report annually on international cooperation activities, including:

a) Participation in international standard-setting activities

b) Implementation of technical assistance programs

c) Recognition of foreign food safety systems and measures

d) International research collaborations

e) Cooperation during food safety emergencies

Sanctions and Collateral Measures

N.B.:

- This Chapter can be supplemented by provisions the Module 1 of these Cross-sectoral Standard Provisions for Regulation and the elements of the List of Sanctions and Accompanying Measures.
- Consider merging the various provisions on sanctions and similar measures in this collection of model provisions into this Chapter.

The Government / Authority may, by virtue of … [61], establish a framework for progressive sanctions to ensure that enforcement actions are proportionate and escalate appropriately in response to repeated or severe violations. This includes defining the criteria and procedures for progressive sanctions, ensuring fairness, and promoting accountability and transparency.[62]

The Government / Authority must/may, by virtue of … [63], establish administrative sanctions to penalise non-compliance with regulations and standards. These sanctions must be proportionate to the severity of the violation and may include fines, suspension or revocation of licenses, and other disciplinary actions.

The Government / Authority must/may, by virtue of … [64], establish criminal offenses to address serious breaches of regulations and standards that pose significant risks to public health, safety, or welfare. This includes defining the elements of criminal offenses, setting penalties, and ensuring that criminal proceedings are fair and impartial.

The Government / Authority may, by virtue of … [65], establish criminal penalties to deter and punish severe violations of regulations and standards. These penalties must be proportionate to the severity of the offense and may include imprisonment, fines, community service, and other sanctions.

The Government / Authority must/may, by virtue of … [66], establish provisions for aggravated offenses to address violations that involve intentional misconduct, repeat offenses, or significant harm to vulnerable populations. This includes enhancing penalties for aggravated offenses and ensuring that aggravating factors are considered in sentencing.

The Authority has the power to impose administrative sanctions, including fines, penalties, and disciplinary actions, for violations of regulations and standards. This includes the authority to determine the severity of sanctions based on the nature and extent of the violation.

The Authority has the power to refer cases of suspected criminal activity to tribunals, courts or other law enforcement institutions for further investigation and prosecution. This includes the authority to collaborate with these institutions, share evidence, and support criminal proceedings.

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61 Define the appropriate type of regulation.

62 In quite some jurisdictions an authority cannot be empowered to set out sanctions in which case the sanctions regime needs to be set out by the Law. See Section 65 and Module 1 of the Cross-sectoral Standard Provisions, the complementing List of Sanctions and Accompanying Measures and the Sanctions of the Regulatory Institute's Model Law on Corruption as inspiration for a sanctions regime.

63 Define the appropriate type of regulation.

64 Define the appropriate type of regulation.

65 Define the appropriate type of regulation.

66 Define the appropriate type of regulation.

Liability of Actors

See Chapter H. of these Cross-sectoral Standard Provisions for Regulation.

Dispute Resolution

See Chapter M. of these Cross-sectoral Standard Provisions for Regulation.

Data and Information

See Chapter N. of these Cross-sectoral Standard Provisions for Regulation.

Financial Implementation

See Chapter P. of these Cross-sectoral Standard Provisions for Regulation.

Fiscal and Economic Measures

Sugar-Sweetened Beverage Taxation

1. An excise tax shall be imposed on all sugar-sweetened beverages as follows:

   a) A specific excise tax of … (e.g. 2) monetary units per liter shall apply to all beverages containing added caloric sweeteners

   b) For the purposes of this Article, "sugar-sweetened beverages" include:
   i. Carbonated soft drinks containing added sugar
   ii. Fruit drinks containing less than 100% fruit juice with added sugar
   iii. Sports and energy drinks containing added sugar
   iv. Sweetened waters and flavored beverages
   v. Ready-to-drink teas and coffees with added sugar
   vi. Syrups, concentrates, and powders used to prepare sugar-sweetened beverages

   c) The following beverages shall be exempt from this tax:
   i. 100% fruit or vegetable juices with no added sugar
   ii. Milk and milk substitutes without added sugar
   iii. Infant formula and therapeutic dietary beverages
   iv. Beverages for medical purposes

2. In addition to the specific excise tax, a tiered sugar-content tax shall be applied as follows:

a) Beverages containing 5-8 grams of sugar per 100ml: additional 0.5 monetary units per liter

b) Beverages containing more than 8 grams of sugar per 100ml: additional 1.0 monetary units per liter

c) The sugar content shall be determined based on laboratory analysis using methods approved by the Authority

3. The tax rates specified in paragraphs 1 and 2 must be adjusted annually for inflation based on the consumer price index.

4. Manufacturers and importers of sugar-sweetened beverages must:

a) Register with the tax authority within … (e.g. 30) days of commencing operations

b) Submit monthly reports detailing:
i. Volume of beverages produced or imported
ii. Sugar content of each product
iii. Tax calculation for each product
iv. Total tax payable

c) Pay the calculated tax within … (e.g. 15) days after the end of each calendar month

5. Revenue generated from the sugar-sweetened beverage tax must be allocated as follows:

a) … (e.g. 50) % to the national health promotion fund

b) … (e.g. 30) % to school meal programs

c) … (e.g. 20)% to subsidize production and distribution of healthy foods

High-Calorie Food Taxation

1. An excise tax of 8% shall be imposed on non-essential food Products with high caloric density, defined as foods containing 275 kilocalories or more per 100 grams.

2. Foods subject to this tax include but are not limited to:

a) Snack foods including chips, crackers, and similar Products

b) Confectionery Products including candies and chocolates

c) Bakery Products with high sugar or fat content

d) Ice cream and similar frozen desserts

e) Peanut and other nut butters with added sugar or fat

f) Breakfast cereals with high sugar content

3. The following foods shall be exempt from this tax:

a) Basic staple foods regardless of caloric density

b) Unprocessed nuts, seeds, and dried fruits when used as ingredients

c) Foods specifically formulated for medical purposes

d) Foods produced by small-scale manufacturers with annual production below thresholds established by the Authority

4. Manufacturers and importers of taxable high-calorie foods must:

a) Determine the caloric density of their Products through laboratory analysis using methods approved by the Authority

b) Submit quarterly reports detailing:
i. Volume of taxable Products produced or imported
ii. Caloric density of each product
iii. Tax calculation for each product
iv. Total tax payable

c) Pay the calculated tax within 30 days after the end of each quarter

5. The Authority must publish and regularly update a comprehensive list of food categories subject to this tax.

Progressive Taxation Based on Nutritional Content

1. A progressive taxation system shall be established for processed food Products based on their content of critical nutrients of concern:

   a) Sugar content

   b) Sodium content

   c) Saturated fat content

   d) Trans fat content

2. The tax rates shall be determined according to the following schedule:

   a) For sugar content:
   i. Foods containing 5-10g of sugar per 100g: … (e.g. 10) % tax
   ii. Foods containing 10-15g of sugar per 100g: … (e.g. 20) % tax
   iii. Foods containing more than 15g of sugar per 100g: … (e.g. 30) % tax

   b) For sodium content:
   i. Foods containing 300-500mg of sodium per 100g: … (e.g. 2) % tax
   ii. Foods containing 500-900mg of sodium per 100g: … (e.g. 4) % tax
   iii. Foods containing more than 900mg of sodium per 100g: … (e.g. 6) % tax

   c) For saturated fat content:
   i. Foods containing 2-5g of saturated fat per 100g: … (e.g. 5) % tax
   ii. Foods containing 5-10g of saturated fat per 100g: … (e.g. 10) % tax
   iii. Foods containing more than 10g of saturated fat per 100g: … (e.g. 15) % tax

   d) For trans fat content:
   i. Foods containing any [artificially produced] trans fat: … (e.g. 30) % tax

3. When a food product exceeds thresholds for multiple nutrients of concern, the applicable tax rates must be cumulative.

4. The Authority must review and adjust the thresholds and tax rates every three years based on:

   a) Changes in consumption patterns

b) Nutritional science developments

c) Public health outcomes

d) Industry reformulation progress

5. Manufacturers and importers must:

a) Determine the content of critical nutrients through laboratory analysis using methods approved by the Authority

b) Submit nutritional content information for all Products to the Authority

c) Update this information whenever product formulations change

d) Pay the calculated tax quarterly based on sales volume

Broad-Based Taxation on Processed Foods

1. A broad-based tax shall be applied to:

a) All packaged processed foods that exceed thresholds for critical nutrients as defined in Section [X]

b) Foods served in chain restaurants with ten or more locations nationally

2. The tax rate shall be:

a) … (e.g. 10) % for foods exceeding thresholds for one critical nutrient

b) … (e.g. 20) % for foods exceeding thresholds for two critical nutrients

c) … (e.g. 30) % for foods exceeding thresholds for three or more critical nutrients

3. Chain restaurants must:

a) Determine the nutritional content of all menu items through laboratory analysis

b) Submit this information to the Authority

c) Update this information whenever menu items or recipes change

d) Calculate and pay the applicable tax quarterly based on sales

4. Small independent restaurants with fewer than ten locations must be exempt from this tax.

5. The Authority must, by virtue of … [67], develop simplified compliance procedures for medium-sized restaurant chains with 10-25 locations.

Government Powers to Set Health Taxes

1. The Government has the power to:

a) Establish new health taxes on food Products based on emerging scientific evidence

b) Adjust tax rates and thresholds to reflect changing public health priorities

c) Expand the scope of taxation to additional food categories

d) Modify the allocation of tax revenue to maximize public health impact

2. When exercising these powers, the Government must:

a) Base decisions on scientific evidence and public health considerations

b) Conduct impact assessments, including effects on vulnerable populations

c) Consult with relevant stakeholders, including health experts, industry, and consumer representatives

d) Provide reasonable implementation periods for new or modified taxes

3. The Government must establish a technical advisory committee comprising experts in:

a) Nutrition science

b) Public health

[67] Define the appropriate type of regulation.

c) Economics

d) Food technology

e) Consumer behavior

4. The technical advisory committee must:

a) Review scientific evidence on the health impacts of food components

b) Recommend appropriate tax structures and rates

c) Evaluate the effectiveness of existing health taxes

d) Identify emerging nutritional concerns that may warrant taxation

5. The Government must publish an annual report on:

a) Revenue generated from health taxes

b) Allocation and use of this revenue

c) Changes in consumption patterns

d) Public health outcomes

e) Industry reformulation efforts

Subsidies for Local Production of Nutritious Foods

1. A subsidy program may/must be established to support local production of nutritious foods, with priority given to:

a) Fruits and vegetables

b) Whole grains

c) Legumes

d) Nuts and seeds

e) Low-fat dairy or plant-based alternatives

2. Eligible producers must receive:

a) Direct financial subsidies based on production volume of eligible foods

b) Tax credits for investments in facilities and equipment for producing nutritious foods

c) Reduced-interest loans for expanding production capacity

d) Technical assistance for improving productivity and quality

3. To qualify for subsidies, producers must:

a) Register with the Authority

b) Comply with food safety standards

c) Demonstrate that their Products meet nutritional criteria established by the Authority

d) Commit to making their Products accessible to local markets

4. Small-scale producers may/must receive enhanced subsidies, including:

a) Higher subsidy rates per unit of production

b) Simplified application procedures

c) Dedicated technical assistance

d) Priority access to financing

5. The Authority may/must establish mechanisms to:

a) Verify production volumes and compliance with program requirements

b) Process subsidy payments efficiently

c) Monitor the impact of subsidies on local food availability and prices

d) Adjust subsidy rates and eligibility criteria based on program outcomes

Subsidies for Healthy Foods in Food Assistance Programs

1. Food assistance programs must allocate at least … (e.g. 50) % of their budget to subsidize:

    a) Fresh fruits and vegetables

    b) Whole grain Products

    c) Legumes and other plant-based proteins

    d) Nuts and seeds

    e) Low-fat dairy or plant-based alternatives

2. Participants in food assistance programs must receive:

    a) Increased purchasing power for healthy foods through matching funds or discounts

    b) Additional benefits when purchasing directly from local producers

    c) Nutrition education to support healthy food choices

    d) Cooking demonstrations and recipes for preparing healthy meals

3. Retailers participating in food assistance programs must:

    a) Stock a minimum variety and quantity of healthy foods

    b) Display healthy foods prominently

    c) Price healthy foods competitively

    d) Accept food assistance benefits for online orders and delivery where available

4. The Authority must develop and implement:

    a) Electronic benefit systems that can apply different subsidy rates to different food categories

b) Mobile applications to help participants identify eligible healthy foods

c) Data collection systems to monitor purchasing patterns

d) Evaluation mechanisms to assess program impact on dietary quality

5. At least … (e.g. 20) % of revenue from health taxes must be allocated to expanding healthy food subsidies in food assistance programs.

Tax Incentives for Manufacturers of Healthier Products

1. Manufacturers shall be eligible for tax incentives when they:

   a) Reformulate existing Products to reduce critical nutrients of concern

   b) Develop new Products that meet enhanced nutritional standards

   c) Invest in research and development for healthier food technologies

   d) Implement marketing strategies that promote healthier options

2. Tax incentives must include:

   a) Corporate income tax reductions of up to 30% for qualifying activities

   b) Accelerated depreciation for investments in equipment used to produce healthier foods

   c) Tax credits for research and development expenses related to healthier product formulations

   d) Reduced import duties on ingredients and equipment used exclusively for healthier food production

3. To qualify for tax incentives, manufacturers must:

   a) Register with the Authority

   b) Submit detailed information on product formulations

   c) Demonstrate significant nutritional improvements compared to industry averages

d) Commit to maintaining these improvements for a minimum of three years

4. Small and medium enterprises must receive enhanced incentives, including:

   a) Higher tax reduction rates

   b) Simplified application procedures

   c) Technical assistance for product reformulation

   d) Priority processing of applications

5. The Authority must:

   a) Establish clear criteria for qualifying Products and activities

   b) Develop transparent application and approval procedures[68]

   c) Monitor compliance with program requirements

   d) Evaluate the impact of tax incentives on product offerings and consumer choices

School Meal Funding from Health Tax Revenue

1. At least … (e.g. 30) % of revenue from health taxes must be allocated to improving school meal programs, with the following priorities:

   a) Increasing the nutritional quality of meals

   b) Expanding access to free or reduced-price meals

   c) Upgrading kitchen facilities and equipment

   d) Training food service staff in healthy food preparation

   e) Implementing farm-to-school programs

[68] Regarding licensing, see Chapter D of these Cross-sectoral Standard Provisions for Regulation.

2. Schools receiving funding must:

    a) Comply with nutritional standards established by the Authority

    b) Eliminate foods high in critical nutrients of concern from menus

    c) Increase the proportion of meals prepared from scratch using whole ingredients

    d) Incorporate locally produced foods when available

    e) Implement nutrition education integrated with meal programs

3. The Authority may/must develop:

    a) Standardised nutritional guidelines for school meals

    b) Menu planning resources for food service staff

    c) Procurement guidelines that prioritize healthy and local foods

    d) Monitoring systems to ensure compliance with program requirements

    e) Evaluation mechanisms to assess program impact on student nutrition

4. Schools serving disadvantaged communities may/must receive priority funding and enhanced support, including:

    a) Higher per-student funding allocations

    b) Additional technical assistance

    c) Grants for kitchen equipment and infrastructure

    d) Support for implementing innovative programs

5. The Authority must report annually on:

    a) Allocation and use of school meal funding

    b) Improvements in meal nutritional quality

c) Changes in student participation rates

d) Impact on student dietary patterns and health outcomes

Research and Innovation Programs

1. A dedicated program may/must be established to support research and innovation in healthier food formulations, with the following priorities:

   a) Reducing critical nutrients of concern while maintaining consumer acceptability

   b) Developing cost-effective alternative ingredients

   c) Improving food processing technologies to preserve nutritional quality

   d) Creating innovative packaging and portion control solutions

   e) Advancing understanding of consumer preferences and behavior

2. The program may/must provide:

   a) Research grants to academic institutions and research organizations

   b) Public-private partnership opportunities

   c) Innovation challenges with financial prizes

   d) Support for commercialisation of promising technologies

   e) Knowledge sharing platforms and networks

3. At least 10% of revenue from health taxes must be allocated to this program.

4. Research priorities must be determined by an independent scientific committee comprising experts in:

   a) Food science and technology

   b) Nutrition

c) Consumer behavior

d) Public health

e) Food manufacturing

5. All research findings supported by this program must be:

a) Made publicly available through open-access publications

b) Presented at annual innovation conferences

c) Translated into practical guidance for food manufacturers

d) Incorporated into technical assistance programs

Technical Assistance for Small Producers

1. A comprehensive technical assistance program may/must be established for small food producers, with the following components:

a) Product formulation support to develop healthier options

b) Food safety training and certification

c) Business development and marketing assistance

d) Access to testing facilities and equipment

e) Networking opportunities with retailers and distributors

2. The program must provide:

a) On-site consultations with food technology experts

b) Group workshops and training sessions

c) Online resources and tools

d) Mentoring relationships with established manufacturers

e) Laboratory services for product testing and analysis

3. To qualify for the program, producers must:

a) Have annual revenue below thresholds established by the Authority

b) Demonstrate commitment to developing healthier Products

c) Participate in all required training components

d) Share non-proprietary learnings with other program participants

4. The Authority must:

a) Develop standardized technical assistance protocols

b) Train and certify technical assistance providers

c) Monitor program implementation and quality

d) Evaluate program impact on product offerings and business success

e) Adjust program components based on participant feedback and outcomes

5. At least 5% of revenue from health taxes must be allocated to this program.

Integration with National Health Insurance Incentives

1. The Authority may/must collaborate with the national health insurance system to develop integrated incentives for healthy eating, including:

a) Premium discounts for participants who purchase healthier foods

b) Expanded coverage for nutrition counseling and education

c) Prescription programs for fruits and vegetables

d) Rewards programs for maintaining healthy dietary patterns

e) Integration of dietary data with preventive healthcare services

2. The integrated incentive system must:

a) Use digital technologies to track food purchases and dietary patterns

b) Protect participant privacy and data security

c) Provide meaningful financial benefits to encourage healthy choices

d) Target enhanced benefits to high-risk populations

e) Include evaluation mechanisms to assess impact on dietary quality and health outcomes

3. Food retailers participating in the integrated incentive system must:

a) Implement compatible point-of-sale systems

b) Train staff on program operations

c) Promote the program to customers

d) Provide data on program utilization

e) Maintain confidentiality of participant information

4. Healthcare providers must receive training on:

a) Program benefits and enrollment procedures

b) Integrating nutrition incentives into treatment plans

c) Monitoring and supporting patient participation

d) Accessing and interpreting dietary data

e) Coordinating with dietitians and nutrition professionals

5. The Authority must establish an oversight committee comprising representatives from:

    a) The national health insurance system

    b) Healthcare provider organizations

    c) Food retailer associations

    d) Consumer advocacy groups

    e) Public health experts

Final Provisions / Miscellaneous

See Chapter Q. of these Cross-sectoral Standard Provisions for Regulation.