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# Laws

# Act Governing Food Safety and Sanitation

1. Full text including 32 articles promulgated on January 28, 1975.
2. Full text including 38 articles amended and promulgated on November 11, 1983.
3. Amendment to Articles 17 and 38 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-8600104850 dated May 7, 1997.
4. Full text including 40 articles amended and promulgated on February 9, 2000.
5. Amendment to Articles 14, 27, 29~33, 35 and 36, addition of Article 29-1 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-09100020680 dated January 30, 2002.
6. Amendment to Articles 2, 11, 12, 17, 19, 20, 24, 29, 31~33 and 36, addition of Articles 14-1 and 17-1 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-09700080101 dated June 11, 2008.
7. Amendment to Article 11 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-09900015801 dated January 27, 2010.
8. Amendment to Articles 31 and 34 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10000128141 dated June 22, 2011.
9. Amendment to Articles 11, 17-1 and 31 of the Act Governing Food Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10100177741 dated August 8, 2012.
10. Full text including 60 articles amended and promulgated on June 19, 2013.
11. Amendment to the title (original title: Act Governing Food Sanitation) and Articles 3, 4, 6-8, 16, 21, 22, 24, 25, 30, 32, 37, 38, 43-45, 47, 48, 49, 50, 52, 56 and 60, addition of Articles 48-1, 49-1, 55-1 and 56-1 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10300017801 dated February 5, 2014.
12. Amendment to Articles 5, 7, 9, 10, 22, 24, 32, 35, 43, 44, 47, 48, 49, 49-1, 56, 56-1 and 60, addition of Articles 2-1, 42-1 and 49-2 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10300184621 dated December 10, 2014.
13. Amendment to Articles 8, 25 and 48 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10400012551 dated February 4, 2015.
14. Amendment to Articles 41 and 48, addition of Article 15-1 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10400146741 dated December 16, 2015.
15. Amendment to Articles 9, 21, 47, 48, 49-1, and 56-1 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10600137341 dated November 15, 2017.
16. Amendment to Articles 28 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10700007751 dated January 24, 2018.
17. Amendment to Articles 4 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10800033101 dated April 3, 2019.
18. Amendment to Articles 3, 47 and 51, addition of Article 18-1 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10800037111 dated April 17, 2019.
19. Addition of Article 46-1 of the Act Governing Food Safety and Sanitation per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10800059261 dated June 12, 2019.

## Chapter I General Principles

**Article 1** This Act is enacted to govern the food sanitation, safety and quality, and protect the health of citizens.

**Article 2** For purposes of this Act, the term "competent authority" shall mean the competent health and welfare authority at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.

**Article 2-1** To enhance the coordination, monitoring, promotion, and inspection of national food safety affairs, the Executive Yuan shall establish the Food Safety Board. The Premier of the Executive Yuan shall serve as the convener with the participation of the heads of other relevant ministries and commissions, experts, scholars, and representatives of non-governmental organizations to take charge of inter-agency coordination for the food safety

risk assessment and management measures as well as establish the alert and auditing system of food safety and sanitation. The Food Safety Board shall meet once at least every three months. When necessary, a temporary meeting may be convened. The convener shall appoint a Minister without Portfolio or a head of ministries and commissions to act as the Chief Executive of the Food Safety Board and the central competent authority shall be in charge of staff affairs.

Each municipal/county/city government shall establish the Food Safety Board; the head of the municipality/county/city shall serve as the convener to take charge of inter-departmental coordination for the food safety management measures. A meeting shall be convened once at least every three months.

Decisions made by the Food Safety Board in Paragraph 1 shall be carried out and implemented in compliance by relevant ministries and commissions. Each quarter the Executive Yuan shall announce the supervision results included in its administrative policies report to the Legislative Yuan every year.

The regulations governing the formation, tasks, parliamentary procedures and other matters to be complied with for such Food Safety Board in Paragraph 1 shall be prescribed by the Executive Yuan.

Article 3 For purposes of this Act, the following terms shall have the meaning set forth below:

1. The term “foods” shall mean goods provided to people for eating, drinking, or chewing, and the raw materials of such goods.
2. The term “special dietary foods” shall mean infant and follow-up formula, formula for certain disease or other formula approved by the central competent authority to be consumed by people with special nutrient requirement.
3. The term "food additives" shall mean a single substance or combination of substances that are added to or brought into contact with foods for the purpose of coloring, seasoning, preserving, bleaching, emulsifying, flavoring, stabilizing quality, enhancing fermentation, increasing viscosity, enriching nutritional value, preventing oxidation or other necessary purpose. Contents of the food additive combinations shall be limited to food additives approved by the central competent authority. The single food additive shall be granted an approval number by the central competent authority.
4. The term "food utensils" shall mean instruments, tools, or containers that come into direct

- contact with foods or food additives.
5. The terms "food containers or packaging" shall mean containers and packaging materials that come into direct contact with foods and food additives.
  6. The term "food cleansers" shall mean substances used to disinfect or clean foods, food utensils, food containers and food packaging.
  7. The term "food businesses" shall mean those businesses that engage in the manufacture, processing, preparation, packaging, transportation, storage, sale, import or export of foods, or engage in the manufacture, processing, import, export or sale of food utensils, food containers or packaging, or food cleansers.
  8. The term "labels" shall mean wording, pictures, symbols or additional instruction sheet affixed to foods, food additives, food cleansers, food utensils, food containers or food packaging to indicate the product name or to give explanation.
  9. The term "nutrition label" shall mean the nutrients, contents or nutrient claims of the food affixed to food containers or packaging.
  10. The term "inspection" shall mean examination and testing.
  11. The term "genetic modification" shall mean the transferring of genetic materials or implant of live cells or organisms via genetic engineering, molecular biotechnology, or other related technologies to produce genetic recombination, exogenous genetic characteristics, or to suppress certain genes of the recipient. However, this does not include traditional breeding methods or techniques such as the merging, hybridization, mutation, in-vitro fertilization, somaclonal variation, and chromosome doubling of plants of the same species and protoplasts.
  12. The term "processing aid" shall mean any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product. Any residues of processing aids shall be removed before the food reaches its finished form and remaining in the food after processing should not perform a function in the final product.

## Chapter II Risk Management for Food Safety



Article 4 The actions taken by the competent authority in the governing of food safety and sanitation shall base on risk assessment and shall align with satisfying the citizens' right to have healthy and safe food and the right to know, as well as the principles of scientific evidence, precaution, and information transparency. The competent authority shall establish a risk assessment and advisory system.

For the risk assessment mentioned in the preceding paragraph, the central competent authority shall assemble experts and scholars specialized in food safety, toxicology, risk assessment, and etc., as well as non-governmental organizations, to form a food risk assessment advisory committee. Each gender shall not be less than one-third of the total number of the committee members.

The advisory system in Paragraph 1 shall refer to a council advisory committee comprising of experts and scholars specializing in food safety, nutrition, medicine, toxicology, risk management, agriculture, law, and humanities and social science to facilitate regulation of food sanitation and safety, nutrition, genetically modified foods, food advertising and labeling, and food testing methods. Each gender shall not be less than one-third of the total number of the committee members.

The members of the committee shall abide by the recusal regulation of Article 32 of the Administrative Procedure Act. The regulations governing the formation, proceedings, procedures, scope and other matters to be complied with for such council advisory committee shall be prescribed by the central competent authority.

Whenever necessary, the central competent authority may take the following actions on specified products and products from specified areas on the basis of the precautionary principle, the risk assessment or the epidemiological survey result when a significant or an unexpected food safety incident occurs:

1. to suspend import, manufacturing and processing of the specified products or products from specified areas, or to conduct control measures and requirements to restrict the import, manufacturing and processing of the specified products or products from specified areas.
2. to withdraw from the market, seal the products, recall within a prescribed time period, recondition within a prescribed time period, confiscate and destroy.

Article 5 The competent authority at all levels shall establish a food sanitation and safety monitoring

system based on scientific evidence. Upon discovery of incidents that may be harmful to food sanitation and safety during monitoring, an active inspection shall be conducted and an alert shall be issued or other necessary measures shall be implemented.

The issuance of the active inspection and alert or implementation of necessary measures referred to in the preceding paragraph which will be done by the competent authority shall include conducting sampling and testing, investigating the source of raw material and the flow of the product, publishing testing results, disclosing other relevant information and ordering food businesses to perform testing on their own.

Article 6 The competent authority at all levels shall establish a reporting system, distinguishing poisoning caused by either food or infections, to be under the jurisdiction of either the Food and Drug Administration, Ministry of Health and Welfare or Centers for Disease Control, Ministry of Health and Welfare, and to collect and handle the reporting of suspicious food poisoning incidents.

Upon diagnosing a patient suspected of food poisoning, a medical institution shall report to the local competent authority within 24 hours.

### Chapter III Sanitary Control of Food Businesses

Article 7 Food businesses shall implement self-management and enact food safety monitoring plan to ensure food sanitation and safety.

Food businesses shall test their raw materials, semi-products or end products on their own, or deliver them to other testing agency (institution), corporation, or organization for testing.

Food businesses that are Exchange-Listed, OTC-Listed or belonging to a category and scale designated by the central competent authority in a public announcement shall be equipped with laboratories to perform said self-testing.

The central competent authority shall prescribe in a public announcement on the category and scale of the food businesses that shall enact the food safety monitoring plan in Paragraph 1 and conduct testing in Paragraph 2, the minimum testing cycle, and other relevant matters in paragraph 2.

Upon discovery that food products may be harmful to sanitation and safety, the food businesses shall immediately cease manufacturing, processing, sale and recall such products

voluntarily and report to the municipal or county/city competent authority.

Article 8 The personnel, operation sites, sanitation management of facilities and quality assurance system of food businesses shall meet the regulations on good hygiene practice for foods.

Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall meet the regulations on food safety control system. Food businesses belonging to a category and scale designated by the central competent authority in a public announcement may commence its business operation only after applying for registration with the central competent authority, the municipal or county/city competent authority.

The regulations on good hygiene practice for foods referred to in Paragraph 1, the regulations on food safety control system referred to in Paragraph 2 and the regulations governing the condition, procedure, and the matters to be registered for the application for registration and application for amendment, revocation or termination of registration and other matters to be complied with mentioned in the preceding paragraph shall be prescribed by the central competent authority.

Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall obtain the certification of sanitation and safety management systems.

The certification in the preceding paragraph shall be performed by the institution accredited by the central competent authority. The regulations governing the condition or reason of the application, termination and revocation for accreditation; the charge, procedure, method for performing such certification; and other relevant matters shall be prescribed by the central competent authority.

Article 9 Food businesses shall retain the related source documents of the raw materials, semi-products and end products.

Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall establish their own traceability system for tracing the source and tracking the flow of the raw materials, semi-products and end products according to their respective industry modes.

To govern the food safety, sanitation and quality, and ensure the information accuracy of food traceability system, the central competent authority shall require the businesses in the preceding paragraph to use electronic uniform invoices in a phased public announcement, according to the necessity of tracing the source.

The central competent authority shall establish the traceability system in Paragraph 2. Food businesses shall use electronic methods to declare the information of the traceability system. The electronic declaration method and specification shall be prescribed by the central competent authority.

The types of documents to be retained and the period of retention mentioned in Paragraph 1 and the regulations governing the establishment, matters to be recorded, examination and other matters to be complied with for the traceability system mentioned in Paragraph 2 shall be prescribed by the central competent authority.

Article 10 Factory registration of food businesses shall be handled by the competent industrial authority in conjunction with the competent authority.

The construction and equipment of a food factory shall conform to the establishment standard, which shall be prescribed by the central competent authority in conjunction with the central competent industrial authority.

The food or food additive factory shall be independently established and shall not engage in non-food manufacturing, processing, or preparation at the same address and the same factory. However, this regulation shall not apply to those factories manufacturing both drug and food products, were examined and confirmed to conform to the Pharmaceutical Good Manufacturing Practice Regulations by the central competent authority.

For the factories mentioned in the preceding paragraph that were not independently established prior to the amendment of this Act on 18th November 2014, the central competent authority shall announce within six months after promulgation of this Act, and those factories shall complete independent establishment within one year after the announcement.

Article 11 Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall have sanitation control personnel.

The regulations governing the qualification, training, duty and other matters to be

complied with for the sanitation control personnel of the preceding paragraph shall be prescribed by the central competent authority.

Article 12 Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall have a certain percentage of professionals with vocational or technical certification in food, nutrition, catering etc. responsible for food sanitation and safety control.

The regulations governing the placement, duty, execution of business, and management of professionals with vocational or technical certification mentioned in the preceding paragraph shall be prescribed by the central competent authority.

Article 13 Food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall take out product liability insurance.

The insured amount and contents of the insurance contract of the preceding paragraph shall be prescribed by the central competent authority.

Article 14 The regulations governing the sanitation of public food and beverage sites shall be prescribed by the municipal or county/city competent authority based on the various sanitation standards or laws promulgated by the central competent authority.

#### Chapter IV Food Sanitation Control

Article 15 Foods or food additives with any one of the following circumstances shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed:

1. those that have deteriorated or rotten;
2. those that are unripe and thus harmful to human health;
3. those that are toxic or contain substances or foreign materials that are harmful to human health;
4. those that are contaminated by pathogenic organisms, or have been established by epidemiological survey to be cause of food poisoning;
5. those with pesticide or veterinary drugs residue exceeding the permissible tolerance;



6. those that have been contaminated by and contain nuclear fallout or radioactivity exceeding the permissible tolerance;
7. those that have been adulterated or counterfeited;
8. those that have passed their expiry date;
9. those that have never been provided for human consumption and proven to be harmless to human health;or
10. those that contain food additives that are not approved by the central competent authority.

The standards governing the permissible tolerance of pesticide or veterinary drugs residue, and the nuclear fallout or radioactivity mentioned in Subparagraphs 5 and 6 of the preceding paragraph shall be prescribed by the central competent authority through consultation with the relevant authorities.

Substance that is harmful to human health mentioned in Subparagraph 3 of Paragraph 1 includes skulls, brains, eyes, spinal marrow, ground beef, viscera and other related products from non-epidemic areas and countries still having Bovine Spongiform Encephalopathy or New Variant of Creutzfeldt-Jakob Disease cases in past ten years.

Beta-agonists shall not to be detected via tests in domestic and foreign meat products and other meat-related products, with the exception that the central competent authority may set a permissible tolerance of Beta-agonists after assessing risks in accordance to the citizens' diet habits.

In the event of food poisoning caused by consumption of meat products containing Beta-agonists of a permissible tolerance, the importation of meat products containing Beta-agonists shall be suspended immediately. If said domestic food poisoning case is confirmed, the government shall take responsibility to health care for such victims and assist them in seeking compensation from the attributable entities.

Article 15-1 The central competent authority may restrict the methods or conditions of manufacture, processing and preparation, edible parts, usage quantity, product form or other matters of the raw materials provided for food use.

The central competent authority shall prescribe in a public announcement on the items and restrictions for the raw materials that shall be restricted in the preceding paragraph.

Article 16 Food utensils, food containers or packaging, food cleansers under any of the following circumstances shall not be manufactured, sold, imported, exported or used:

1. those that are toxic;
2. those that tend to cause unfavorable chemical reactions;
3. those that are otherwise harmful to health; or
4. those that may be harmful to health through the risk assessment results.

Article 17 Foods, food cleansers, food utensils, food containers or packaging being sold shall conform to sanitation, safety and quality standards which are prescribed by the central competent authority.

Article 18 The product names, specification, use and limitation of food additives shall conform to the standards prescribed by the central competent authority.

The standards mentioned in the preceding paragraph shall be restricted to the minimum required for anticipated effect and shall be based on risk assessment of the citizen's diet habits while conforming to the provisions of specification standards.

Article 18-1 The processing aids which are used in the processing of food or its raw materials by food businesses shall conform to safety, sanitation and quality standards which are prescribed by the central competent authority.

The use of processing aids shall not include any circumstances that may be harmful to human health.

Article 19 Before the standards stipulated by Paragraph 2 of Article 15 and the preceding two Articles have been promulgated, the central competent authority may prescribe a provisional standard for responding to unexpected emergency and where sufficient experimental data cannot be obtained.

Article 20 Hygienic examination of the slaughtering and cutting of livestock and poultry at the slaughterhouses shall be conducted by the competent agricultural authority in accordance with relevant laws and regulations.

Hygienic examination of the carcasses, viscera and meat cuts in transport shall be made

by the competent health authority after delivery to the food businesses.

The sanitation of the manufacture, processing, preparation, packaging, transportation, storage, sale, import or export of carcasses, viscera and meat cuts which are in the possession of food businesses shall be subject to the governance of the competent authority at all levels in accordance with this Act.

The direction of the hygienic examination of Paragraph 2 shall be prescribed by the central competent authority in conjunction with the central competent agricultural authority.

Article 21 None of the foods, food additives, food cleansers, food utensils, food containers or packaging and food cleansers which are designated by the central competent authority in a public announcement shall be manufactured, processed, prepared, repacked, imported or exported without filing product registration with and procuring a permit document from the central competent authority. Any change in the registered matters shall be subject to the prior approval of the central competent authority.

None of the genetically modified food raw materials shall be used as the food raw materials without being reviewed by the central competent authority in the health risk assessment, filing product registration with and procuring a permit document.

Importers of genetically modified food raw materials, that have filed product registration with and procured a permit document from the central competent authority, shall establish a traceability system for tracing the source and tracking the flow of the genetically modified food raw materials in accordance to Paragraph 5 of Article 9.

The permits mentioned in the preceding paragraphs 1 and 2 shall be valid for a term of one year to five years subject to the decisions by the central competent authority. Application for extension shall be filed within three months prior to the expiration of the term with the central competent authority if continued manufacture, processing, preparation, repacking, importation or exportation is desired after the expiration. The term of each extension shall not exceed five years.

The regulations governing the revocation of the permits mentioned in Paragraphs 1 and 2, and issuance, replacement, re-issuance, extension, transfer, de-registration, and change in the registered matters of the permit document, etc. shall be prescribed by the central competent authority.

The product registration under Paragraphs 1 and 2 may be commissioned to another

institution in accordance with regulations which are prescribed by the central competent authority.

For the unregistered genetically modified food raw materials mentioned in Paragraph 2 prior to the amendment of this Act on 28th January 2014, shall complete review and registration within two years after promulgation of this Act.

## Chapter V Food Labeling and Advertisement

Article 22 The container or external packaging of food and food raw materials shall conspicuously indicate in Chinese and common symbols the following matters:

1. product name;
2. name of the ingredients; those that contain two or more ingredients shall indicate the respective ingredients in descending order of proportion;
3. net weight, volume or quantity;
4. name of food additives; in the case of a mixture of two or more food additives which are named according to its function shall indicate the name of each additive separately;
5. name, telephone number and address of the manufacturer or that of the responsible domestic company. The tracing sources of the domestic certified agricultural products; and the production systems prescribed by the central agricultural competent authority in a public announcement;
6. country of origin;
7. expiry date;
8. nutrition label;
9. genetically modified food raw materials;
10. other matters designated by the central competent authority in a public announcement.

Labeling of the ingredients mentioned in Subparagraph 2 of the preceding paragraph, shall indicate the percentage of the main ingredient. The labeling of food items, main ingredient, labeling content, labeling method, and the implementation date of each product shall be prescribed by the central competent authority.

The compliance matters of the labels mentioned in Subparagraphs 8 and 9 of paragraph 1 shall be prescribed by the central competent authority in a public announcement.

For the food only labels the name of the responsible domestic company prescribed in Subparagraph 5 of Paragraph 1, its name, telephone number, address of the manufacturers, and those businesses that are entrusted to manufacture or importers shall be reported to the local competent authority. The competent authority shall open those information to other competent authority for reviewing.

Article 23 In the event that labeling pursuant to the preceding paragraphs prove to be difficult due to the dimension, material or other special circumstances of the food container or external packaging, the central competent authority may exempt part of the labeling or allow labeling with other methods through public announcement.

Article 24 The container or external packaging of food additives and their raw materials shall conspicuously indicate in Chinese and common symbols the following matters:

1. product name;
2. printed words “Food Additive” or “Food Additive Raw Material”;
3. name of food additives or, in the case of a mixture of two or more ingredients, each of the ingredients shall be indicated separately. The labeling of the name of food additives shall be handled in accordance with the food additive items prescribed in Paragraph 1 of Article 18 or the names commonly known prescribed by the central competent agency in a public announcement;
4. net weight, volume or quantity;
5. name, telephone number and address of the manufacturer or that of the responsible domestic company;
6. expiry date;
7. scope of use, maximum allowance and limitation of use of food additives;
8. country of origin;
9. genetically modified food raw materials;
10. other matters designated by the central competent authority in a public announcement.

The labeling of food additive raw materials are not regulated to be handled in accordance with Subparagraph 3, 7, and 9 in the preceding paragraph. The compliance matters of labels on the flavoring agents of food additives mentioned in Subparagraph 3 and in



Subparagraph 9 of the preceding paragraph shall be prescribed by the central competent authority in a public announcement.

For the food only labels the name of the responsible domestic company prescribed in Subparagraph 5 of Paragraph 1, its name, telephone number, address of the manufacturers, and those businesses that are entrusted to manufacture or importers shall be reported to the local competent authority. The competent authority shall open those information to other competent authority for reviewing.

**Article 25** The central competent authority may require food labeling showing country of origin and other matters ought to be labeled in Chinese on specific food products supplied at food vending locations. For specific bulk food vendors, the central competent authority may prescribe restrictions on the vending location and methods, or may require food labeling showing product name, country of origin, genetically modified food raw materials, manufacturing date, expiry dates and other matters ought to be labeled in Chinese. The domestic certified agricultural products shall label the tracing sources, and the production systems if there are production systems prescribed by the central agricultural competent authority in a public announcement.

The central competent authority shall prescribe in a public announcement on the items, labeling, methods and scope for specific food products; also the items, restrictions and labeling for specific bulk foods in the preceding paragraph.

The provision concerning the labeling of tracing sources or production systems specified in Paragraph 1 amended on 20th January 2015 shall be implemented six months after promulgation of this Act.

**Article 26** Food utensils, food containers or packaging designated by the central competent authority in a public announcement shall conspicuously indicate in Chinese and common symbols the following matters:

1. product name ;
2. name of materials and thermal resistance temperature or, in the case of a mixture of two or more materials, each of the materials shall be indicated separately;
3. net weight, volume or quantity;
4. name, telephone number and address of the responsible domestic company;

5. country of origin;
6. manufacturing date, and the expiry date or the term of validity if the product has a limited duration of storage;
7. precautions for use or microwavable and other warnings;
8. other matters designated by the central competent authority in a public announcement.

Article 27 The container or external packaging of food cleansers shall conspicuously indicate in Chinese and common symbols the following matters:

1. product name;
2. chemical names of main ingredients or, in the case of a mixture of two or more ingredients, each of the ingredients shall be indicated separately;
3. net weight or volume;
4. name, telephone number and address of the responsible domestic company;
5. country of origin;
6. manufacturing date, and the expiry date or the term of validity if the product has a limited duration of storage;
7. applicable targets or purpose;
8. method of use, precautions for use or warnings;
9. other matters designated by the central competent authority in a public announcement.

Article 28 The labeling, promotion or advertisement of foods, food additives, food cleansers and food utensils, food containers or packaging designated by the central competent authority in a public announcement shall not be false, exaggerated or misleading.

Foods shall not be so labeled, promoted or advertised as having medical efficacy.

The central competent authority may prescribe restrictions on the sales, promotion or advertising for special dietary foods or foods which easily lead to chronic diseases or are unsuitable for long term consumption for children and persons with special needs. The regulations governing the food items, restrictions on the sales promotion or advertising, prohibition of publishing and broadcasting and other matters to be complied with shall be prescribed by the central competent authority.

The regulations governing the determining standards of the false, exaggerated or misleading labeling, promotion or advertisement referred to in Paragraph 1 and medical

efficacy referred to in Paragraph 2, contents, methods of the promotion or advertisement and other matters to be complied with shall be prescribed by the central competent authority.

Article 29 Media businesses being commissioned by a principal to publish or broadcast an advertisement shall maintain the particulars of its principal, such as its name or trade name, national ID Card number, establishment registration document number of company, business, corporation or organization, domicile or residence, representative office or business offices and telephone number, etc., for six months from the date of such advertisement, and shall not evade, impede or refuse any request by the competent authority for such particulars.

## Chapter VI Food Import Control

Article 30 Application for inspection with the central competent authority and declaration of the relevant information of the product are required and shall be in accordance with the customs commodity code and classification when importing foods, genetically modified food raw materials, food additives, food utensils, food containers or packaging and food cleansers designated by the central competent authority in a public announcement.

The central competent authority may impose preferential measures to the food businesses with excellent performances in the import inspections referred to in the preceding paragraph.

The importation of products under Paragraph 1 that are not intended for sale and whose value and quantity are consistent with the public announcement of the central competent authority, or are approved by the central competent authority, may be exempt from applying for inspection.

Article 31 The central competent authority may authorize or commission relevant agency (institution), corporation or organization to conduct inspection and declaration of imported products of the preceding paragraph.

Article 32 In order to investigate and prevent food sanitation and safety incidents, the competent

authority may require food businesses, non-food businesses or their representative to provide relevant records, documents and electronic files or databases of the imported products when necessary. In this case, the food businesses, the non-food businesses, or their representatives shall not evade, impede or refuse such requests.

The food businesses shall retain the related records, documents, electronic files, or database of imported products and genetically modified food raw materials mentioned in the preceding paragraph for five years.

The central competent authority shall prescribe in a public announcement on the information to be retained, method and scope of retention in the preceding paragraph.

**Article 33** Food businesses of imported products with special conditions due to their nature or inspection timeframe may apply for prior release of the imported goods and store them at a specific location. In the event where a deposit is deemed to be required after review by the inspection authority, the imported products may be granted prior release with provision of affidavit after payment of said deposit.

The storage location of the products granted prior release in accordance with the preceding paragraph may be designated by the food businesses or their representative. The products shall not be moved, used or sold before obtaining the import permit.

The regulations governing the inspection, declaration, commission of the inspection and declaration, preferential measures of import inspections and declarations for businesses with excellent performances, conditions of application to prior release, the criteria for which applications for prior release shall pay the deposit, standard of amount for deposit as referred to Articles 30, 31 and Paragraph 1 of this Article, and other matters to be complied with, shall be prescribed by the central competent authority.

**Article 34** In the event of significant food sanitation and safety incidents or in case of serious failure to comply upon inspection of imported products, the central competent authority may suspend the application for inspection of the relevant businesses, place of origin or product.

**Article 35** For the management and control of foods with a higher degree of safety risk, the central competent authority may perform systematic inspections before the importation thereof.

The regulations governing the scope of products, procedures and other relevant matters for the systematic inspections referred to in the preceding paragraph shall be prescribed by the central competent authority.

According to the needs for source control or due to a specific food sanitation and safety incident, the central competent authority may send personnel abroad to conduct on-site inspection of the sanitation and safety management of the imported foods.

When food businesses import food additive combinations, they shall attach product ingredients report issued by the manufacturer or responsible manufacturer of the origin country and official sanitary certificate issued by the export country for the examination of the competent authority at all levels. However, this regulation shall not apply to flavoring agents.

**Article 36** When carrying into the territories any offshore foods, food additives, food utensils, food containers or packaging and food cleansers that have been designated by the central competent authority in a public announcement and which may be harmful to the body or health of the people, the passenger shall declare the goods with the sanitation certificate issued by the health competent authority of the country of origin; if the item is seriously harmful to the body or health of the people, the central competent authority may prohibit the entry of such item in a public announcement.

Products violating the preceding paragraph, irrespective of who the owner is, shall be confiscated and destroyed.

## Chapter VII Food Testing

**Article 37** The testing for foods, food additives, food utensils, food containers or packaging and food cleansers shall be performed by the competent authority at all levels or the authorized and appointed relevant agency (institution), corporation or organization with approval.

The central competent authority may issue accreditation for the authorized and appointed relevant agency (institution), corporation or organization mentioned in the preceding paragraph. When necessary, the accreditation process may be commissioned to the authorized and appointed relevant agency (institution), corporation or organization.

The regulations governing the commission for testing, the accreditation conditions and



procedures of the agency (institution), corporation or organization, the commission process of the accreditation and other relevant matters mentioned in the two preceding paragraphs shall be prescribed by the central competent authority.

Article 38 The method of test for foods, food additives, food utensils, food containers or packaging and food cleansers to be used by the competent authority at all levels shall be consulted with and advised by the Council Advisory Committee of Food Testing Methods and then be prescribed by the central competent authority; In the absence of any prescribed method, an internationally recognized method may be used.

Article 39 Where food businesses object to the testing results, it may apply for a retesting from the original sampling agency (institution) within fifteen (15) days upon the receipt of the relevant notification. The agency (institution) receiving the application shall perform the retesting within three (3) days. However, specimen that is without appropriate methods of preservation may be rejected.

Article 40 When publishing testing information on food sanitation, the method of test, testing unit and the evidence used in interpreting the results shall be concurrently disclosed.

## Chapter VIII Food Examination and Control

Article 41 The municipal or county/city competent authority may take the following actions to ensure that foods, food additives, food utensils, food containers or packaging and food cleansers are in compliance with the provisions of this Act, and businesses shall cooperate with the competent authority and shall not evade, impede or refuse:

1. entering the place of manufacturing, processing, preparation, packaging, transportation, storage and sales, performing on-site examination and conducting sampling and testing;
2. when conducting the examination or sampling and testing referred to in the preceding paragraph, it may be required for the food businesses of the place referred to in the preceding paragraph to provide the source and amount of raw materials or products, processing, quality assurance, sales counterpart, sales amount, other

supporting information, evidence or records, and such may be reviewed, detained and copied;

3. foods, food additives, food utensils, food containers or packaging and food cleansers found to be not in compliance with the provisions of this Act according to the examination and testing results shall be sealed;
4. those with possible violations of Paragraph 1 of Article 8, Paragraphs 1 and 4 of Article 15, and Article 16, or standards prescribed by the central competent authority pursuant to Articles 17, 18 or 19, the food businesses may be ordered to suspend operations or cease such sales, and the products shall be sealed;
5. upon receipt of reports of food poisoning accidents, the relevant food businesses may be ordered to make correction within a prescribed time period or send the relevant food personnel to participate in at least four hours of food poisoning prevention seminar at agencies (institutions) certified by the competent authority at all levels. During the investigation, it may be ordered to suspend operations, cease sales or undertake disinfection and seal such products.

Where necessary, the central competent authority may also execute the measures described in the preceding paragraph.

Article 42 The regulations governing the examination, testing and control measures and other matters to be complied with referred to in the preceding article shall be prescribed by the central competent authority.

Article 42-1 In order to safeguard food safety and sanitation and effectively stem illicit behaviour of businesses, the police agency shall dispatch its personnel to assist the competent agency.

Article 43 The competent authority shall keep strictly confidential the particulars of, and may grant reward to, anyone informing against foods, food additives, food utensils, food containers or packaging, food cleansers, labels, promotional materials, advertisements or food businesses that are found to have violated the provisions of this Act. If civil services disclose the confidential information, they will be punished with criminal and administrative responsibilities.

The regulations governing the jurisdiction of the complaints received by the competent authority, processing time period, confidentiality, reward to informant and other matters to be complied with mentioned in the preceding paragraph shall be prescribed by the central competent authority.

Confidentiality of identity of informants in Paragraph 1 shall be subject to the same requirements by throughout litigation procedures.

## Chapter IX Penal Provisions

Article 44 Anyone committing any of the following shall be fined between NT\$60,000 and NT\$200,000,000. In severe circumstances, the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration within one (1) year shall be prohibited:

1. violating Paragraph 1 or 2 of Article 8, and failing to correct the violation within the time limit prescribed;
2. violating Paragraph 1 or 4 of Article 15 or Article 16;
3. incompliance with order by the competent authority to recover or destruct in accordance to Paragraph 2 of Article 52;
4. violating the public announcement by the central competent authority to ban the manufacture, sale, import or export in accordance to Paragraph 1 of Article 54.

The penalty standards of the fine mentioned in the preceding paragraph shall be prescribed by the central competent authority.

Article 45 Those with violations of Paragraph 1 of Article 28 or the regulations prescribed by the central competent authority pursuant to Paragraph 3 of Article 28 shall be fined between NT\$40,000 and NT\$4,000,000; violation of Paragraph 2 of such article shall be fined between NT\$600,000 and NT\$5,000,000. Where the offense is repeated the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is

revoked, re-application for new registration within one (1) year shall be prohibited.

Food businesses in violation of the preceding food advertisement provisions shall be consecutively fined by such authority for each violation until the publication or broadcast is ceased.

Severe violation of any of the advertisement provisions under Article 28 shall not only be punished by the preceding two provisions, the competent authority shall order to halt all sale, supply or display; and shall publish or broadcast a specific number of corrective advertising in the same size and time period as the original within thirty (30) days of receiving the sanction order, which shall express regret and convey the message for elimination of error.

Violation of the preceding provisions by continuing to sell, supply, display or failure to publish or broadcast corrective advertising shall be fined between NT\$120,000 to NT\$600,000.

Article 46 Media businesses in violation of Article 29 shall be fined between NT\$60,000 to NT\$300,000, and may be consecutively fined.

When the competent authority at the municipal level or county/city level impose fines in accordance with Paragraph 1 of the preceding article, the media businesses, and the relevant competent authority at the municipal or county/city level or industry competent authority shall be notified. The media businesses shall cease the broadcast or publication of the advertisement concerned from the day following its receipt of the above notification. Media businesses continuing to publish or broadcast following the notification referred to in the preceding paragraph, in violation of Paragraphs 1 and 2 of Article 28 or any limit on advertisements or relevant regulations relating to the permanent suspension of advertisements prescribed by the central competent authority pursuant to Paragraph 3 of Article 28, shall be fined between NT\$120,000 and NT\$600,000 and shall be consecutively fined by such authority for each violation until the publication or broadcast is ceased.

When media businesses fail to cease publication or broadcasting following receipt of notification referred to in Paragraph 2, in addition to imposing fines in accordance with the preceding paragraph, the competent authority at the municipal level or county/city level shall also notify the competent authority of the media businesses at the municipal

level or county/city level or its industry competent authority to address these issues.

Article 46-1 A person who disseminates a rumor or incorrect information concerning food safety and thus causes damage to the public or others shall be punished with imprisonment for not more than three years, detention, or a fine of not more than NT\$1,000,000.

Article 47 Anyone committing any of the following shall be fined between NT\$30,000 and NT\$3,000,000. In severe circumstances, the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration shall not be permitted within one year:

1. violating the public announcement prescribed by the central competent authority pursuant to Article 4;
2. violating Paragraph 5 of Article 7;
3. in the event that the registered, established or declared information pursuant to Paragraph 3 of Article 8 and Paragraph 2 or 4 of Article 9 is false, or the incorrect electronic uniform invoices issued pursuant to Paragraph 2 of Article 9 to affect the examination of food tracing or tracking;
4. violating Paragraph 1 of Article 11 or Paragraph 1 of Article 12;
5. violating the provisions concerning product liability insurance prescribed by the central competent authority pursuant to Article 13;
6. violating the regulations concerning the safety and sanitation of public food and beverage sites prescribed by the municipal or county/city competent authority pursuant to Article 14;
7. violating the standards prescribed by the central competent authority pursuant to Paragraph 1 of Article 18-1, and failing to correct the violation within the time limit prescribed;
8. violating Paragraphs 1 and 2 of Article 21, Paragraph 1 or public announcement made pursuant to Paragraphs 2 and 3 of Article 22, Paragraph 1 or public announcement made pursuant to Paragraph 2 of Article 24, Article 26 or Article 27;

9. other than the provisions specified in Paragraph 9 of Article 48, violating the provisions concerning the specification, use and limitation of food additives prescribed by the central competent authority pursuant to the standard prescribed in Article 18;
10. violating the public announcement prescribed by the central competent authority pursuant to Paragraph 2 of Article 25;
11. evading, impeding or refusing an examination, testing, seizure or seal stipulated in this Act;
12. refusing to provide or providing false information for the information which are required to be submitted in accordance with the provisions specified in this Act;
13. failing to observe a suspension on operation or cease of sales in accordance with the provisions specified in this Act;
14. violating Paragraph 1 of Article 30 which fails to declare the information of imported goods or the information declared is false; or
15. violating Article 53.

Article 48 Anyone committing any of the following and failing to correct the violation within the time limit prescribed shall be fined between NT\$30,000 and NT\$3,000,000. In severe circumstances, the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or the registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration shall not be permitted within one year:

1. violating Paragraph 1 of Article 7 for failing to enact food safety monitoring plan, or Paragraph 2 or Paragraph 3 for failing to be equipped with the laboratory;
2. violating Paragraph 3 of Article 8, failing to file registration; or violating Paragraph 5 of Article 8, failing to obtain certification;
3. violating Paragraph 1 of Article 9, failing to retain document or attain the required period of retention ;
4. violating Paragraph 2 of Article 9, failing to establish tracing or tracking system;
5. violating Paragraph 3 of Article 9, failing to issue electronic uniform invoices for the purpose of food tracing or tracking;
6. violating Paragraph 4 of Article 9, failing to declare in the electronic method or to

declare according to the method and specification prescribed by the central competent authority;

7. violating Paragraph 3 of Article 10;
8. violating any of the standards prescribed by the central competent authority in accordance with Article 17 or Article 19;
9. the products sold by the food businesses violating the specification, use and limitation of food additives prescribed by the central competent authority pursuant to the standard prescribed in Article 18;
10. violating Paragraph 4 of Article 22 or Paragraph 3 of Article 24, failing to report to the competent authority; or
11. violating Paragraph 4 of Article 35, failing to attach product ingredients report and official sanitation certificate issued by the export country.
12. violating the restrictions prescribed by the central competent authority in a public announcement pursuant to Paragraph 2 of Article 15-1.

Article 48-1 Anyone committing any of the following shall be fined between NT\$30,000 and NT\$3,000,000 by the central competent authority. In severe circumstances, the enterprise may be ordered to suspend, terminate or revoke its commission or accreditation. Enterprise which commission has been terminated or accreditation has been revoked, shall not be re-commissioned and shall not re-apply for accreditation within one year:

1. enterprise which is commissioned in accordance with this Act for conducting the certification of sanitation and safety control of food businesses, violates provisions made pursuant to Paragraph 6 of Article 8;
2. institution, corporation or organization which is accredited in accordance with this Act for testing, violates provisions concerning accreditation made pursuant to Paragraph 3 of Article 37; or
3. enterprise which is commissioned in accordance with this Act for conducting the accreditation of institution, corporation or organization for testing, violates provisions concerning accreditation commission made pursuant to Paragraph 3 of Article 37.

Article 49 In the event that the acts described in Subparagraphs 3, 7 and 10 of Paragraph 1 of Article 15 or Paragraph 1 of Article 16 are committed, imprisonment of not more than seven years,



and a fine of not more than NT\$80,000,000 may be imposed. If the offense is light, imprisonment of not more than five years, detention and/or a fine of not more than NT\$8,000,000 shall be imposed.

In the event that the acts described from Article 44 to the preceding article are severe and may be sufficient to harmful to human health, imprisonment of not more than seven years, and a fine of not more than NT\$80,000,000 may be imposed. For such acts are committed to the detriment of human health, imprisonment between one year to seven years and a fine of not more than NT\$100,000,000 may be imposed.

In the event that the acts described in the preceding paragraph results in death, a life imprisonment or imprisonment of not less than seven years, and a fine of not more than NT\$200,000,000 may be imposed. For such acts causing severe detriment of human body, imprisonment between three years and ten years, and a fine of not more than NT\$150,000,000 may be imposed.

Anyone committing any of the offenses described in Paragraphs 1 and 2 out of negligence shall be imprisoned for not more than two year, detained or fined NT\$6,000,000.

Where the representative of a legal entity or the agent, employees or other practitioners of a legal entity or natural person that commit the offenses from Paragraphs 1 to 3 during the performance of duties, not only shall the wrongdoer be punished but the legal entity or natural person shall also be fined not more than ten times of the fine stipulated in the respective preceding paragraphs.

When imposing a fine, the provision specified in Article 58 of the Criminal Code shall be considered.

Article 49-1 The scope and value of the proceeds of crime in violating this Act may be based on an estimation if the valuation is deemed difficult. The regulation governing such estimation shall be established by the Executive Yuan.

Article 49-2 Food businesses belonging to a category and scale designated by the central competent authority in a public announcement violate the provisions specified in Paragraph 1 or 4 of Article 15 or Article 16, or perform the actions described from Article 44 to Article 48-1 causing detriment of human health, their acquired assets or property interests shall be forfeited or retrieved.

If there are considerable and sufficient reasons for the competent authority to believe that the penalized person transfers his/her assets or property interests to the third party for avoiding being punished pursuant to the preceding paragraph, the competent authority may forfeit or retrieve the transferred assets or property interests of the third party. If the above assets or property interests cannot be forfeited in whole or in part, the equivalent value thereof shall be indemnified either by demanding a payment from the offender or be offset by the property of the offender.

To ensure the forfeit or retrieve of assets or property interests and a levy on payments or property compensation in the preceding two paragraphs, the competent authority may perform detainment pursuant to this Act or request the administrative court for provisional seizure or provisional disposition and is not required to provide guarantees.

The regulations governing the valuation of illegally obtained assets, property interests, a levy on payments or property compensation which forfeited or retrieved by the competent authority pursuant to this Article shall be prescribed by the Executive Yuan.

**Article 50** An employer may not discharge, transfer or otherwise take any adverse sanction against an employee who discloses an action which violates this Act to the competent authority or judicial authority, becomes witness of a litigation proceeding or refuses to participate in an action which violates this Act.

Any dismissal, demotion or reduction of wage imposed by the employer or supervisory employees who exercise the managerial authority on behalf of the employer for reasons as prescribed in the preceding paragraph shall be null and void.

For the person other than the employer who had participated in actions violating the provisions of this Act and under criminal responsibility but who discloses such action to the competent authority or judicial authority assisting the authority to uncover the violation of the employer, the penalty for such person shall be reduced or exempted.

**Article 51** The competent authority may impose sanctions in the event of the following:

1. at the occurrence of the circumstances described in Paragraph 14 of Article 47, the application for inspection in accordance with Paragraph 1 of Article 30 from the food businesses or their representatives may be suspended. For the products which are already released, the food businesses may recall, destroy or return such products

depending on the violation thereof.

2. in case of violation of Paragraph 3 of Article 30, for anyone who sells the products exempted from import inspection, application for inspection exemption may be suspended for one year.
3. in case of violation of Paragraph 2 of Article 33, for anyone who intentionally moves, uses or sells the products before receiving the import permit, or the confirmed storage location is inconsistent with the actual storage location. The competent authority may confiscate the deposit and temporarily suspend acceptance of an application for storage by the food businesses for one year. Anyone who sells the goods without authorization may be fined an amount that is between double and twenty times of the selling price of the goods.

Article 52 The municipal or county/city competent authority shall impose the following punishment based on examination or testing results for foods, food additives, food utensils, food containers or packaging and food cleansers that have been examined or tested in accordance with Article 41:

1. those under any one of the circumstances listed in Paragraph 1 or 4 of Article 15 or Article 16 shall be confiscated and destroyed;
2. those not conforming to the standards prescribed by the central competent authority pursuant to Article 17 and Article 18, or those violating Paragraphs 1 and 2 of Article 21, the products or products containing such materials shall be confiscated and destroyed. However, if those can be edible or used or not affecting human health after disinfecting or appropriate safety measures are implemented, a notice shall be given for such disinfecting, reconditioning or measures to proceed within a prescribed time period; in case the notice is not complied with within the time limit, those goods shall be confiscated and destroyed;
3. in case the labels violate Paragraph 1 or public announcement made pursuant to Paragraphs 2 and 3 of Article 22, Paragraph 1 or public announcement made pursuant to Paragraph 2 of Article 24, Article 26, Article 27 or Paragraph 1 of Article 28, a notice shall be given for the goods to be recalled and correction made within a prescribed time period; the goods in question shall not be sold before the violation is corrected. In case the notice is not complied with within the prescribed time limit or Paragraph 2

of Article 28 is violated, those goods shall be confiscated and destroyed; and

4. the punishment with respect to goods which are subject to a suspension of operation as well as cease of sales, and are sealed pursuant to Paragraph 1 of Article 41 shall, in the absence of any of the situations described in the preceding three subparagraphs, be cancelled, and such goods shall be unsealed.

The manufacturer, seller or importer of goods that are to be confiscated pursuant to Subparagraphs 1 to 3 of the preceding paragraph shall immediately announce the termination of use or consumption of such goods and recall and destroy those said goods. Where necessary, the municipal or county/city competent authority may act for such recall and destruction with necessary charges.

Goods that shall be recalled and destroyed pursuant to the preceding paragraph shall be recalled and destroyed in accordance with regulations prescribed by the central competent authority.

The municipal or county/city competent authority shall officially publish the company name, address, name of the responsible person, and product name of as well as the circumstances of the violations by, any food businesses manufacturing, processing, preparing, packaging, transporting, selling, importing or exporting goods under Subparagraph 1 or 2 of Paragraph 1.

The central competent authority shall restrict the importation of goods under Paragraph 1 which are found to have failed to comply with provisions upon inspection at ports of entry, and may also impose the punishment under any of the subparagraphs of Paragraph 1 and under Paragraph 2 and the preceding Paragraph, with respect to such goods.

Article 53 After the products have been recalled and destroyed within a prescribed time period or taken with other necessary measures by the municipal or county/city competent authority pursuant to Paragraph 1 of the preceding article, the food businesses shall report the information in relation to the procedure, result, as well as the status of the above to the municipal or county/city competent authority for their review before the deadline.

Article 54 In addition to being handled pursuant to Article 52, foods, food additives, food utensils, food containers or packaging and food cleansers which are found to be under any of the circumstances described in Subparagraph 1 or 2 of Paragraph 1 of Article 52 may be

subject to a ban by the central competent authority on manufacture, sale, import or export through a public announcement.

Where a product that is subject to prohibition according to the preceding paragraph was registered and licensed by the central competent authority, the relevant license may be revoked.

Article 55 Unless otherwise prescribed, the punishment prescribed in this Act shall be imposed by the municipal or county/city competent authority. The central competent authority may impose the punishment when necessary. However, upon the confirmation for the order of termination of business by the municipal or county/city competent authority, such order will be transferred to the industrial and business competent authority or other industry competent authority to revoke all or part of the items listed in the company registration, business registration or factory registration.

Article 55-1 The determining standards of the number of administrative penalty made in violation of this Act shall be prescribed by the central competent authority.

Article 56 Should food businesses violate Subparagraph 3, 7, or 10 of Paragraph 1 of Article 15 or Paragraph 1 of Article 16 and result in harms to consumers, they shall bear the responsibilities for compensation. But if food businesses prove the harms are not caused by their manufacturing, processing, preparation, packing, shipment, storage, sales, import and export or have paid attention to preventing from the harms, they shall be exempted from the responsibilities.

Consumers may claim a certain amount of monetary compensation, and may file for consumer litigation in accordance with the provisions specified from Article 47 to Article 55 of the Consumer Protection Law even without suffering property damage.

In the event of difficulty for consumers to provide or inability to provide evidence to support the actual amount of damage, he/she may request the Court to determine the compensation in the amount between NT\$500 and NT\$300,000 for each case of damage per person based on the circumstances of such damage.

The municipal or county (city) government shall assist consumers in accordance with Article 50 of Consumer Protection Law, when receiving complaints concerning the damage

from 20 or more consumers for a certain result of the same incident.

Attorneys who represent the consumer protection organizations to litigate according to Paragraph 1 of Article 49 of the Consumer Protection Act shall request the litigation remuneration and shall not be applicable to the latter part of Paragraph 2 of Article 49 of the Consumer Protection Act.

Article 56-1 The central competent authority may establish a food safety protection fund for protecting the consumer's right in the event of food safety and the fund may be commissioned to the authorized and appointed other agency (institution), corporation or organization.

The sources of funds mentioned in the preceding paragraph are as follows:

1. funds from the partial appropriation of administrative fines in violation of this Act;
2. criminal fines that are fined pursuant to this Act; and cash from confiscating or indemnifying or proceeds from the sale of the confiscated property due to the violation of this Act;
3. the partial appropriation of improper gains that are forfeited, retrieved, indemnified or offset pursuant to this Act or Administrative Penalty Act;
4. accrued interest income generated by the fund;
5. revenues from donations;
6. appropriations made by the government through budgetary process; or
7. other related revenues.

The sources of funds mentioned in the subparagraphs 1 and 3 of the preceding paragraph are applicable to the dispositions that become effective from the date after 21th June 2013.

The fund mentioned in Paragraph 1 is used for the following purposes:

1. to subsidize consumer protection groups the remuneration fees for the attorneys and the relevant fees for consumer litigation filed in accordance with the Consumer Protection Law and resulted from the food sanitation and safety incident;
2. to subsidize fees concerning human health risk assessment on specified food sanitation and safety incident which has been announced by a public notice;
3. to subsidize employee the remuneration of attorneys and relevant litigation fees for

restoring the original status, payment and damage compensation when an employee was fired, reassigned the jobs or otherwise took any adverse sanction by the employer due to disclosing the employers' behavior which violates this Act;

4. to subsidize rewards governed by the regulations in Paragraph 2 of Article 43; or
5. to subsidize other relevant fees concerning food safety promotion and consumer litigation.

The central competent authority shall establish a supervision panel for management and utilization of the fund which composed of experts and scholars, consumer protection organizations, and impartial citizens to supervise the subsidizing affairs.

The regulation governing the recipients of the subsidies, application qualifications, review procedures, subsidization standard, revocation of subsidies of the fund mentioned in Paragraph 4, the formation and operation of the supervision panel for management and utilization of the fund mentioned in the preceding paragraph and other matters to be complied with shall be prescribed by the central competent authority.

## Chapter X Supplementary Provisions

Article 57 The provisions of this Act regarding food utensils and food containers shall apply mutatis mutandis to toys that are often directly placed into the mouth of children.

Article 58 The central competent authority shall charge a review fee, testing fee, and license fee with respect to applications by food businesses for review, testing and issuance of permits. The respective amount of such fees shall be prescribed by the central competent authority.

Article 59 The enforcement rules of this Act shall be prescribed by the central competent authority.

Article 60 Other than the declaration procedure specified in Article 30 and the provision concerning the receipt of deposit specified in Article 33, and Subparagraph 5 of Paragraph 1 of Article 22, Article 26 and Article 27, which are to be implemented one year after promulgation, this Act shall be implemented as of its being promulgated.



Subparagraph 4 of Paragraph 1 of Article 22 shall be implemented on 19th June 2014.

Paragraph 3 of Article 21 amended on 28th January 2014 shall be implemented one year after promulgation of this Act.

The articles of this Act amended on 18th November 2014 shall be implemented as of its being promulgated. Other than the provision concerning the labeling of tracing sources or production systems specified in Subparagraph 5 of Paragraph 1 of Article 22 shall be implemented six months after promulgation of this Act; the provision concerning food businesses equipped with laboratories specified in Paragraph 3 of Article 7, Paragraph 4 of Article 22, the labeling of raw materials of food additives specified in Paragraph 1 of Article 24, Paragraph 3 of Article 24 and Paragraph 4 of Article 35 shall be implemented one year after promulgation of this Act.

## **Enforcement Rules of the Act Governing Food Safety and Sanitation**

1. Promulgated on November 20, 1981.
2. Amended and Promulgated on December 20, 1985.
3. Amended and Promulgated on September 7, 1994.
4. Amended and Promulgated on May 15, 2000.
5. Amended and Promulgated on May 3, 2001.
6. Amended and Promulgated on June 12, 2002.
7. Amended and Promulgated on April 1, 2009.
8. Amended and Promulgated on August 13, 2014.
9. Amended and Promulgated on July 13, 2017.

Article 1. These Enforcement Rules are prescribed in accordance with the provisions of Article 59 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).

Article 2. The term “infant and follow-up formula” prescribed in subparagraph 2 of Article 3 of this Act shall include infant formula, follow-up infant formula and infant formula for special medical purposes.

Article 3. The term “approval number granted by central competent authority” referred to in subparagraph 3 of Article 3 of this Act shall mean one of the following circumstances:

1. The registration number and product registration code obtained from the completion of registration under paragraph 3 of Article 8 of this Act.
2. The code prescribed in the Standards for Scope, Application and Limitation of Food Additives of the Appendix 1 of the Standards for Specification, Scope, Application and Limitation of Food Additives under Article 18 of this Act.
3. The registration approval number as stated in Paragraph 1 of Article 21 of this Act.

Article 4. The term “sanitation and safety management systems” referred to in Paragraph 5 of Article 8 of this Act shall mean the regulations on good hygiene practice for foods or the regulations on food safety control system as stated in Paragraph 1 or 2 of Article 8 of this Act.

Article 5. The term “toxic” referred to in subparagraph 3, paragraph 1 of Article 15 of this Act shall mean foods or food additives which contain natural toxins or chemicals and the ingredients

or contents of which are harmful to human health or may possibly harm the human health.

Article 6. The items that are contaminated by pathogenic organisms referred to in subparagraph 4, paragraph 1 of Article 15 of this Act shall mean foods or food additives contaminated by pathogenic organisms, or toxins derived from said pathogenic organisms, which are harmful to human health or may possibly harm human health.

Article 7. The labelling for the product names prescribed in subparagraph 1, paragraph 1 of Article 22 and paragraph 1 of Article 25 of this Act shall be handled in accordance with the following provisions:

1. The product names shall conform to the nature thereof.
2. The names of those that are stipulated by the central competent authority shall be set in accordance with the stipulated names provided; whereas names that are not stipulated by the central competent authority may either be set in accordance with National Standards of the Republic of China (CNS) or by their own.

Article 8. The net weight and capacity prescribed in subparagraph 3, paragraph 1 of Article 22 of this Act shall be labelled using the legal units of measurement or their symbols and shall be handled in accordance with the following provisions:

1. Those ingredients that are a mixture of liquid and solid materials shall indicate their respective contents; whereas those ingredients which are a homogeneous mixture that are hard to separate may merely indicate the net weight thereof.
2. Depending on the nature of the foods, the contents may be indicated as minimum quantity, maximum quantity, or both the minimum and maximum quantities.

Article 9. The name of food additives prescribed in subparagraph 4, paragraph 1 of Article 22 of this Act shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known by society, and shall be handled in accordance with the following provisions:

1. Sweeteners, preservatives and antioxidants shall indicate the names of their respective

functions.

2. Food additive combinations shall indicate the name of each material.

The labelling of the food additives is not required when the food additives contained in foods were made through legalized materials and the contents of which are apparently below the normal amount as added to the foods and do not provide functions thereof.

Article 10. The term “manufacturer” referred to in subparagraph 5, paragraph 1 of Article 22 and subparagraph 5, paragraph 1 of Article 24 of this Act shall mean one of the following circumstances:

1. Those businesses that manufacture, process or prepare the end products.
2. Those businesses that are entrusted to manufacture, process or prepare products.
3. For those products made through the repacking process such as sub packaging, cutting, assembling or combining, and that are enough to affect the sanitation and safety of the product, the repacking factory or businesses referred to in the two previous subparagraphs.

The labelling of the manufacturers referred to in the preceding paragraphs shall be handled in accordance with the following provisions:

1. Name and address of the manufacturer of imported foods or food additives shall be labelled in Chinese. For those names that are hard to recognize in Chinese, they may be labelled in commonly known characters or symbols.
2. Where the foods or food additives are manufactured by the factory belonging to the same company and registered under the same country, the labelling of the manufacturer can be either the head company or the manufacturing factory. The name, address and telephone number shall be labelled as of the head company or factory; when the registered place of the factory is different from that of the company's, the manufacturing factory that engaged in the actual manufacturing process shall be on the label.
3. The repacking factory referred to in the preceding subparagraph 3 shall be labelled as “repacking manufacturer.”

Article 11. The responsible domestic company referred to in subparagraph 5, paragraph 1 of Article 22,

subparagraph 5, paragraph 1 of Article 24, subparagraph 4 of Article 26 and subparagraph 4 of Article 27 of this Act shall mean food businesses that are responsible for the liability of the products.

Name, telephone number and address of the manufacturer or that of the responsible domestic company of the imported foods or food additives referred to in subparagraph 5, paragraph 1 of Article 22 and subparagraph 5, paragraph 1 of Article 24 shall mean the labelling of the names, telephone number and address of the responsible domestic company and the names, telephone number and address of the foreign manufacturer can also be labelled in addition. For those foods or food additives manufactured domestically, the labelling thereof shall be either the name, telephone number or address of the manufacturer or that of the responsible domestic company or both.

Article 12. The country of origin referred to in subparagraph 6, paragraph 1 of Article 22 of this Act shall mean the country or region where the end products are manufactured, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good.
2. Where the food product is not an assorted product of substantial transformation based on the Regulations Governing the Determination of Country of Origin of an Imported Good, the labelling of which shall be the respective country of origin based on the volume of contents it possesses.
3. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 13. The labelling of the expiry date prescribed in subparagraph 7, paragraph 1 of Article 22 of this Act shall be printed on the container or package and the year, month and day shall be marked in a way that is customarily decipherable. However, for products of which the shelf life is 3 months or longer, the expiry date may be marked with the year and month only and the last date of that month shall be the expiry date.

Article 14. Where the product names prescribed in subparagraph 1, paragraph 1 of Article 24 of this Act is for a single food additive, it shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known prescribed by the central competent authority in a public announcement; whereas when the product name is for food additive combinations, the names may be set by their own.

Product names set by their own in accordance with the preceding paragraph shall be sufficient to reflect the nature or function of the product.

Food additive that has been registered with the central competent authority and received a permit document prior to the amendment of this Enforcement Rules on 13th July 2017, the product name of which is unable to comply with the two preceding paragraphs shall apply for a change of the product name in accordance with paragraph 1 of Article 21 of this Act before 1st July 2018. The changed product name shall be labeled on the container or package from 1st January 2019.

Article 15. The food additive names prescribed in subparagraph 3, paragraph 1 of Article 24 shall be labelled in accordance with the food additive items prescribed in the Standards for Scope, Application and Limitation of Food additives of the Appendix 1 of the Standards for Specifications, Scope, Application and Limitation of Food Additives or the names commonly known prescribed by the central competent authority in a public announcement.

Article 16. The net weight and capacity prescribed in subparagraph 3, paragraph 1 of Article 24 of this Act shall be labelled using the legal units of measurement or their symbols.

Article 17. The labelling of the expiry date prescribed in subparagraph 6, paragraph 1 of Article 24 of this Act shall be printed on the container or package and the year, month and day shall be marked in a way that is customarily decipherable. However, for products of which the shelf life is 3 months or longer, the expiry date may be marked with the year and month only and the last date of that month shall be the expiry date.

Article 18. The country of origin referred to in subparagraph 8, paragraph 1 of Article 24 of this Act

shall mean the country or region where the end products are manufacture, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good; whereas the products cannot be determined as a substantial transformation because of classification, categorizations, sub-packaging, packaging, marking or relabeling in our country, the labelling shall still be set as the country or region where the end products are manufactured, processed or prepared.
2. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 19. The labelling of pre-packaged foods, food raw materials, food additives and their raw materials shall be handled in accordance with the following provisions:

1. The length and width of the characters marked on the labels shall not be less than two millimeters. However, where the area of the largest surface of a package is less than 80 square centimeters, the length and width of characters for all items other than the name of the product, the company name, and expiry date, may be less than two millimeters.
2. Where the products are domestically manufactured and their labels are in a foreign language, the labelling text in Chinese shall be primary and the labelling text in the foreign language is only supplementary.
3. Where the products are imported from overseas, the importer is allowed to import such products when a Chinese label is added in accordance with the provisions of Article 22 and 24 of this Act. However, where products need to be repackaged, sub-packaged or go through other processing procedure, such products shall label the product name, manufacturer name, and date, or have other labels or information for proof of the authenticity of the items at the time of importation, and the labelling in Chinese shall be completed prior to the sale of the products.

Article 20. The bulk foods referred to in paragraph 1 of Article 25 of this Act shall mean that the product



is without a package while vending or with a package but meets one of the following circumstances:

1. Does not have unpackaged identifiability.
2. Could not extend the shelf life.
3. Is not sealed.
4. The purpose of selling is no more than vending in a small area.

Article 21. The food utensils, food containers and packages prescribed in Article 26 of this Act shall be labelled in accordance with the following provisions:

1. The position of labels: labels shall be printed, stamped, pressed or marked on the package or object of the smallest unit of the vending products. The labeled content shall be clearly visible at the time of distribution and marketing. For those products prescribed by the central competent authority, the name of materials and thermal resistance temperature of its major part shall be printed, stamped or pressed on the object.
2. The method of labelling: if the labelling is made by way of printing or stamping, the ink shall sustain fading and shall not peel off.
3. Labelling of Date: the labelling of the date shall consist of the year, month and day and date shall be marked in a way that is customarily decipherable. Where the labelling of the date consists of only the year and month, the last day of that month shall be regarded as the last expiry date or date of the shelf life.
4. Font of Labelling: the length and width of the characters marked on the labels shall not be less than two millimetres.

Article 22. The labelling of food cleansers shall be handled in accordance with the following provisions:

1. The position of labels: labels shall be printed, stamped, pressed or marked on the package of the smallest unit of the vending products. The labeled content shall be clearly visible at the time of distribution and marketing.
2. The method of labelling: if the labelling is made by way of printing or stamping, the ink shall sustain fading and shall not peel off.
3. Labelling of Date: the labelling of the date shall consist of the year, month and day and date shall be marked in a way that is customarily decipherable. Where the labelling of

the date consists of only the year and month, the last day of that month shall be regarded as the last expiry date or date of the shelf life.

4. Font of Labelling: the length and width of the characters marked on the labels shall not be less than two millimetres.
5. Where the products are imported from overseas, the importer is allowed to import such products when a Chinese label is added in accordance with the provisions of Article 27 of this Act. However, where products need to be repackaged, sub-packaged or go through other processing procedure, such products shall label the product name, manufacturer name, and date, or have other labels or information for proof of the authenticity of the items at the time of importation, and the labelling in Chinese shall be completed prior to the sale of the products.

Article 23. The product name prescribed in subparagraph 1 of Article 26 and subparagraph 1 of Article 27 of this Act shall conform to the nature thereof.

Article 24. The net weight and capacity prescribed in subparagraph 3 of Article 26 and subparagraph 3 of Article 27 of this Act shall be labelled using the legal units of measurement or their symbols.

Article 25. The country of origin referred to in subparagraph 5 of Article 26 and subparagraph 5 of Article 27 of this Act shall mean the country or region where the end products are manufacture, processed or prepared.

The labelling of the country of origin referred to in the preceding paragraph shall be handled in accordance with the following provisions:

1. The Country of Origin of imported goods shall be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Imported Good; whereas the products cannot be determined as a substantial transformation because of classification, categorizations, sub-packaging, packaging, marking or relabeling in our country, the labelling shall still be set as the country or region where the end products are manufactured, processed or prepared.
2. Where the address of the manufacturer in Chinese can obviously represent the country of origin, the labelling may be exempted.

Article 26. The “main ingredients” or “ingredients” referred to in subparagraph 2 of Article 27 of this Act shall mean the ingredients that are contained in the food cleansers and the function of which is to disinfect or clean.

Article 27. Where the foods, food additives, food utensils, food containers, packages or food cleansers are exclusive for export, the labelling based on Article 22, 24, 26, and 27 of this Act may be exempted.

Article 28. The method of test, testing unit and the evidence used in interpreting the results prescribed in Article 40 of this Act, with the content as follows:

1. The method of test: including the basis of the method adopted, experiment procedure, instruments and equipment for the test and standard materials.
2. Testing Unit: including the name, address, contact information and responsible person of the laboratory.
3. Evidence used in interpreting the results: including the sampling method of the specimens, product names, source, package, batch number or manufacturing date or expiry date, data of finalized experiment, interpreting standard and its source or academic reference.

Article 29. Where foods, food additives, food utensils, food containers, food packages or food cleansers are confiscated, destroyed or are notified to be disinfected, reconditioned or remedied with safety measures within a set period in accordance with the provisions of subparagraphs 1 to 3, paragraph 1 of Article 52 of this Act, the scope of such confiscation, destruction, disinfection, reconditioning or remedies shall be extended to the finished products of the same expiry date, and shall be extended to all finished products on which no expiry date is marked or the expiry date is unintelligible. Products that are of unknown origin and cannot be notified to be disinfected, reconditioned or remedied with safety measures within a set time period shall be confiscated and destroyed.

Article 30. To meet the requirements of documentary proof, those engaging in the export of foods, food additives, food utensils or food containers may apply to the competent authority for an

inspection and examination. Those that comply with the regulations shall be approved with the issuance of an export proof document such as sanitary certificate, test report or certificate of free sales and manufacture.

Article 31. Other than Article 22 is implemented one year after promulgation, these Enforcement Rules shall be implemented as of its being promulgated.

# **The Relevant Regulations of Article 22 of the Act Governing Food Safety and Sanitation**

## Compilation of Product Name Labeling Requirements for Food Products

Promulgated on March 12, 2013

Amended on October 28, 2013

Amended on March 18, 2014

Amended on August 22, 2016

### 1. Legal basis

As per Article 22 of the Act Governing Food Safety and Sanitation, the container or external packaging of prepackaged food products shall conspicuously indicate the product name. Article 25 of the same Act stipulates that bulk food displayed for sale by food vendors that have completed company registration or business registration shall indicate product names, except for those that are on-site baked (roasted) or prepared for ready-to-eat. Furthermore, the Enforcement Rules of the same Act require that the product name shall conform to the nature of the food product .

### 2. The labeling requirements for various commercial food categories are thus compiled:

- (1) If the National Standards of the Republic of China (CNS) have established a product name for a commercial food product, the product shall be named according to that in CNS .
- (2) Commercial fresh agricultural, livestock, poultry, and aquatic products shall use the food category name or common name as product names.
- (3) The product name of those that are stipulated by the central competent authority are listed (only portions related to the requirement for product name labeling are excerpted and shown below; for the full text, please refer to the relevant regulations):

Regulation	Product name labeling requirements
1. Regulations Governing the Product Names and Labeling of Prepackaged Blended Oils (DOH No. 0991302553 on September 20, 2010 and the amendment of MOHW No. 1021350359 on September 10, 2013)	<ol style="list-style-type: none"> <li>1. The name of a retail prepackaged blended oil shall contain two (or less) kinds of oils.</li> <li>2. If only one kind of oil is specified in the name of the product, that oil shall account for more than 50% of the content of the product.</li> <li>3. If two kinds of oils are specified in the name of the product, each oil shall account for more than 30% of the content of the</li> </ol>

	<p>product. The order of the name shall be shown according to the content.</p> <p>4. A prepackaged blended oil that does not named after name of oils shall not show the name of oils on the packaging; for example, “○○○ flavor” or “○○○ recipe”.</p> <p>5. Peanut oil is a special blended oil in Taiwan, and it can still retain its unique flavor after blending with other vegetable oils. In order to comply with the dietary habit of the people, the naming method of peanut oil may not follow this regulation. However, “peanut flavored blended oil” shall still be included in the name of the product.</p>
2. Regulations Governing for the Labeling of Instant Noodles(DOH No. 0991301488 on May 28, 2010 and the amendment of MOHW No. 1021350360 on September 10, 2013)	<p>1. Those contain seasoning powder but do not contain food packet shall name themselves according to the seasoning powder, namely “○○ flavor noodles”, “○○ noodle soup”.</p> <p>2. Those contain seasoning powder and food packet shall name themselves according to the food packet, namely “○○ noodles”.</p>
2. Regulations on Labeling for Prepackaged Reduced Sodium Salt Products on the Market (DOH No. 1001303012 on November 7, 2011 and the amendment of MOHW No. 1021350352 on September 10, 2013)	<p>Prepackaged food grade salt products that have less than 65% of sodium chloride shall be named as “potassium salt” or “reduced sodium salt”.</p>
3. Regulation for the labeling of <i>Cordyceps sinensis</i> mycelium food products (DOH No. 1001303885 on February 9, 2012 and the amendment of MOHW No. 1021350319 on September 2, 2013)	<p>1. <i>Cordyceps sinensis</i> mycelium food products (hereinafter referred to as the “Food Product”) shall meet the following labeling requirements:</p> <p>(1) The warning “This product is not a Chinese medicine product made of <i>Cordyceps sinensis</i>” shall be indicated on the external packaging in an easily-noticed place. All character units may not be smaller than 4 mm in both</p>



	<p>length and width.</p> <p>(2) The name of the strain in Chinese and the scientific name in Latin shall be clearly indicated on the product's external packaging.</p> <p>(3) When the Food Product is labeled or advertised, the words "<i>Cordyceps sinensis</i> mycelium" shall be clearly labeled; and shall not only indicate "<i>Cordyceps sinensis</i>". All characters shall have the same character unit and size.</p> <p>2. If a Food Product is named "<i>Cordyceps sinensis</i> mycelium", the strain used shall be <i>Hirsutella sinensis</i> or a strain related to cordyceps isolated from <i>Cordyceps sinensis</i>.</p> <p>3. Effective date: February 9, 2014.</p>
<p>5. Regulations Governing the Labeling of Packaged Beverages Claimed to Contain Fruit and/or Vegetable Juice(DOH No. 1021350410 on October 2, 2013 and the amendment of MOHW No. 1031300643 on March 3, 2014)</p>	<p>1. These regulations apply to packaged beverages of which the packaging bears the names (product name included) and/or images (illustrations) of fruit and/or vegetable and sold for direct consumption. .</p> <p>2. Packaged beverages which contain at least 10% of fruit and/or vegetable juice and for mixed or assorted fruit and vegetable juice beverages whose product name is labeled fruit and vegetable juice shall meet the following requirements:</p> <p>(1) If the product name shows all the fruit and vegetable added in the product, their respective contents shall be indicated in descending order of weight.</p> <p>(2) If the product name does not show all the fruit or vegetable added in the product, the product name or the front of the package shall explicitly declare the word "assorted juice", "mixed juice" or other synonymous terms.</p> <p>3. Packaged beverages which contain less than 10% of fruit and/or vegetable juice, "fruit and vegetable juices" can only be labeled on the name of the ingredients and nowhere else</p>

	<p>4. Where the “name” of a product includes a fruit or vegetable name, the product name shall explicitly state “taste”, “flavored”, or other synonymous terms.</p> <p>5. Effective date: July 1, 2014.</p>
<p>6. Regulations Governing the Product Names and Labeling of Prepackaged Fresh Milk, Sterilized Milk, Flavored Milk, Milk Drink, and Milk Powder (MOHW No. 1031300193 on February 19, 2014)</p>	<p>1. Fresh milk: The name of product should be “Fresh milk” or “Milk”.</p> <p>2. Sterilized milk: The name of product should be “Sterilized milk”, “Milk”, or words of similar meaning. If the product name does not contain the words of “Sterilized milk”, the words of “Sterilized milk” in Chinese should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p> <p>3. Flavored milk: The name of product should be “Flavored milk”, “Milk”, or words of similar meaning. If the product does not contain the words of “Flavored milk”, the words of “Flavored milk” in Chinese should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p> <p>4. Sterilized flavored milk: The name of product should be “Sterilized flavored milk”, “Milk”, or words of similar meaning. If the product does not contain the words of “Sterilized flavored milk”, the words of “Sterilized flavored milk” in Chinese should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p> <p>5. Milk drink: The name of product should be “Milk drink”, “Milk”, or words of similar meaning. If the product does not contain the words of “Milk drink”, the words of “Milk drink” in Chinese should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p>

	<p>6. Sterilized milk drink: The name of product should be “Sterilized milk drink”, “Milk”, or words of similar meaning. If the product does not contain the words of “Sterilized milk drink”, the words of “Sterilized milk drink” should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p> <p>7. Milk powder: The name of product should be “Milk powder”</p> <p>8. Modified milk powder: The name of product should be “Modified milk powder”. If the product does not contain the words of “Modified milk powder”, the words of “Modified milk powder” in Chinese should be manifested on an easily visible section of the product’s outer package. Each font may not be smaller than 4 mm in both length and width.</p> <p>9. Effective date: July 1, 2014.</p>
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(4) Labeling principles for product name, as announced by the central competent authority:

Principles	Product name labeling principles
Regulations Governing the Claiming and Labeling of Whole Grain Products (DOH No. 1021301154 on April 30, 2013)	<p>1. If whole grain content accounts for more than 51%<sup>2</sup> of the total weight<sup>1</sup> of a solid product, it can claim to be a whole grain product. If a single kind of grain accounts for more than 51% of the total weight of the product, the product can be named after that grain. For example, “whole wheat ○ ○”, “whole buckwheat ○ ○”.</p> <p>2. If whole grain content does not account for more than 51% of the total weight of the product, it cannot claim to be a whole grain product. Only terms such as “Parts of the materials are made from whole grain powder. (For example, whole wheat)” or “The product contains some whole grain powder. (For example, whole-wheat flour)”</p> <p>3. If a product claims to be whole grain raw material powder<sup>3</sup>, it shall be 100 percent whole grain.</p> <p>Note1: Calculation of the percentage by weight of solid whole grain</p>

	<p>content in the formula is as follows. (Weight of whole grain content on a dry basis / Weight of the formula on a dry basis) x 100 % Dry basis is an expression of the weight calculation, in which the presence of water is ignored for the purposes of the calculation. For example, 100 g of milk contains 90 g of water. The weight on a dry basis is 100-90=10 (g).</p> <p>Note2: The calculation shall be correct to one decimal place and round to nearest integer according to CNS 2925 “Practices for Designating Significant Places in Specific Limiting Values”. Namely, if the whole grain content accounts for 50.4% of the total weight of the product, it is regarded as 50%. If the whole grain content accounts for 50.5% of the total weight of the product, it is regarded as 50%. If the whole grain content accounts for 50.6% of the total weight of the product, it is regarded as 51%.</p> <p>Note3: The whole grain raw material powder is made from whole grains and does not contain any material or additive. For example, whole-wheat flour, wholebarley flour, whole-buckwheat flour, whole-corn flour, brown rice flour, black rice flour, red glutinous rice flour, dehulled adlay flour, etc.</p>
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(5) Labeling principles for product name of general food:

Category	Description	Examples
1. Named after the ingredient as the product name	The food product is named after the ingredient that is accepted by the general public and which will not cause misunderstanding.	<p>(1) “Beef jerky(牛肉乾)” product contains the ingredient beef, and given the product name “beef jerky”.</p> <p>(2) “Abalone (鮑魚)” product contains the ingredient real abalone other than merely abalone sauce or extract (abalone DNA cannot be detected), and given the product name “abalone (鮑魚)” (DOH No.</p>

		<p>1001300123 issued on January 17, 2011).</p> <p>(3) “Sweet potato starch (地瓜粉)” product is made of ground sweet potato flour, and given the product name “sweet potato starch (地瓜粉)” (DOH No. 0991302303 issued by on July 26, 2010).</p> <p>(4) “Fig (無花果)” product is made of figs, and given the product name “fig (無花果)”. (DOH No. 0980006247 issued on March 11, 2009)</p>
2. Named after the breed of the ingredient as the food product name	The food product is named after the breed of the ingredient that is accepted by the general public and which will not cause misunderstanding.	“Wagyu”(和牛) differs from cattle raised in other countries because of its breed and farming methods, which resulted it unique taste and quality. Wagyu suppliers shall provide certificate of breed and place for reference.
3. Named after the common name of the edible part as the-product name	The food product is named after the common name of the edible part of the raw materials that is accepted by the general public and which will not cause misunderstanding.	“Matsusaka pork”(松阪豬) is the common name for pork neck. It is so called because its marbling is similar to “Matsusaka beef”(松阪牛).
4. Named after the place of origin as the-product name	The food product is named after the place of origin, due to the place’s unique raw materials or manufacturing process, and where the product name is accepted by the general public and will not cause	“Wanluan pork Knuckle”(萬巒豬腳) is so named because it refers to the unique manufacturing process of making pork knuckle that is practiced in Wanluan Township, Pingtung County.

	misunderstanding.	
5. The product name is a name by convention or a direct Chinese translation from a commonly used international name	The product name is conventional, and the public understands that the food product cannot possibly contain the raw materials mentioned in the product name; or is a direct Chinese translation from a commonly used international name that is accepted by the public and which will not cause confusion.	<p>(1) “Sun cake”(太陽餅) contains no “sun”; “sun cake” is named through convention because of its appearance.</p> <p>(2) “Ox-tongue cake” (牛舌餅) contains no “ox tongue”; “ox-tongue cake” is named through convention because of its appearance.</p> <p>(3) “Chocolate truffle” (松露巧克力) contains no “truffle”; “chocolate truffle” is named through convention because of its appearance.</p> <p>(4) “Hot spring egg”(溫泉蛋) contains no “hot spring”; “hot spring egg” is named through convention because of the solidified state of the yolks and egg whites.</p> <p>(5) Although “pineapple cake” (鳳梨酥) contains white gourd filling, it is named “pineapple cake” through convention.</p> <p>(6) The Chinese “(巧克力)” is a direct translation from the commonly used international name “chocolate”.</p> <p>(7) The Chinese “(熱狗)” is a direct transliteration from the commonly used international name, “hot dog”.</p>

(6) Labeling principles for product names of specific food:

Category	Explanation	Example
1. Named after the microorganism and its derivatives as the product name	<p>1. If the raw material is made of a microorganism or its derivatives, the microbial common name or group name may be used as the product name, such as “yeast” or “Lactic acid bacteria”.</p> <p>2. “Lactic acid bacteria” shall refer to bacteria that are able to produce lactic acid through carbohydrate fermentation, including <i>Bifidobacterium</i>, <i>Lactobacillus</i> and <i>Streptococcus</i>.</p>	<p>If the raw materials of a “yeast” food product contains yeast (<i>Saccharomyces cerevisiae</i>), emulsifier (glycerin fatty acid ester), and antioxidant (vitamin C), its product name may be labeled as “brewer’s yeast powder”, “yeast powder” or other synonymous words.</p>
2. Named after the edible mushroom raw material as product name	<p>1. If a food product contains edible mushroom fruiting body as its raw material, the common name or group name of the mushroom may be used as the product name, such as <i>Ganoderma</i> or <i>Antrodia cinnamomea</i>.</p> <p>2. “<i>Ganoderma</i>” widely refers to mushrooms of the <i>Ganoderma</i> genus, including <i>Ganoderma applanatum</i>, <i>Ganoderma formosanum</i>, <i>Ganoderma lucidum</i> (antler), <i>Ganoderma</i> (<i>Ganoderma lucidum</i>) and <i>Ganoderma tsugae</i>.</p> <p>3. If mushroom mycelium is added to the food product as raw material, the words “○○ mycelium” shall be properly labeled. The fonts shall be of the same size. It is prohibited to only label the common name or population name as the product name.</p>	<p>(1) If a “<i>Ganoderma</i>” food product contains raw material from the fruiting body of <i>Ganoderma lucidum</i> (antler), the product name may be labeled “<i>Ganoderma lucidum</i> (antler)”, “<i>Ganoderma</i>” or other synonymous words.</p> <p>(2) If a “<i>Ganoderma</i> mycelium” food product contains mycelium of <i>ganoderma</i> (<i>Ganoderma lucidum</i>), the product name may be labeled as “<i>Ganoderma</i> mycelium”, “<i>Ganoderma lucidum</i> mycelium” or other synonymous words.</p>



3. Named after Chinese herbal material fit for food as product name	<p>1. If Chinese herbal materials which can also be used for food is added into a product and after which the product is named, the naming shall conform to the requirements administered by the Chinese Medicine Committee of the Ministry of Health and Welfare.</p> <p>2. If the product name involves the name of a traditional Chinese medicine formula and the addition or subtraction thereto, the ingredients of the food product shall in fact contain the herbal materials of the traditional Chinese medicine formula and other food raw materials or food additives (such as nutritional additives). Moreover, if the traditional Chinese medicine formula and the additive or subtraction thereto is used as the food product name, the proportion of the formula shall not be the same as the traditional Chinese medicine formula. However, the product name cannot be directly claimed to be similar to the traditional Chinese medicine formula and the additive or subtraction thereto, and the overall presentation shall not mislead consumers that the product is Chinese medicine.</p>	<p>If a food product contains raw materials and food additives of <i>Rehmannia</i> root, Peony root, Chinese Angelica root, Chuanxiong Rhizoma, strawberry, and iron (as nutritional additive), and the proportions of said Chinese herbal materials differ from those of the formula of the traditional “Si Wu Soup”, the product name may be labeled as “strawberry si wu drink(草莓四物飲)”, “iron si wu drink(含鐵四物飲)” or “○○ si wu drink(○○四物飲)”.</p>
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(7) Labeling principles for product name of other food products:

Category	Description	Example
1. Named by co-listing both the Ingredient (raw	The name of a purified component of the a raw material may be used as the product name. However, the purified component shall conform to the requirements set out in the Standards for Specification, Scope,	(1) DHA is not a food raw material or food additive. It is an component of the raw material fish oil. So, DHA cannot be directly used as a product name. However, it can be used

material) and the component thereof as product name	Application and Limitation of Food Additives announced by the Department of Health of the Executive Yuan or shall be approved otherwise as a raw material for food product. If a purified component is not an ingredient directly added to the food product, or it fails to meet the standards of announced food additives, it shall be deemed as a component of a the raw material of the food product, therefore, this purified component shall not be directly claimed as the product name. The product name may only be named by co-listing both the raw material name and the purified component name.	together with other words, such as “fish oil DHA” or other synonymous words. (2) If “Lutein” that meets the requirements of Category Eight of nutritional additives in the Standards for Specification, Scope, Application and Limitation of Food Additives is added into a food product, the product name may claim “lutein”. However, if only marigold extract is added other than purified “lutein”, the product name may be labeled as “marigold extract (containing lutein)” or other synonymous words
Labeling of product name concerning its original English name	If the English product name of an imported food product does not mislead consumers nor imply medical efficacy, the English product name may still be used. In addition, the Chinese product name shall still meet the requirements of the Act Governing Food Safety and Sanitation.	(1) The product uses its original product name “Soy Bean Extract Tablets” for the Chinese translation “大豆萃取錠”, which is unlikely to cause misunderstanding or to imply medical efficacy, the English product name may still be used. (2) The original product name “Slim Tablets” implies a change in body figure, so the English product name cannot be used and the Chinese product name shall not be a direct translation from “Slim Tablets”.

## **Regulations Governing the Labeling of Flavoring Ingredients on Prepackaged Food Products**

Promulgated on December 27, 2013

Effective from December 27, 2013

Where a flavoring is added to or used in a food as an ingredient it may be declared as ‘flavoring’ or ‘flavor’; and natural flavor may be declared as ‘natural flavoring’ or ‘natural flavor’.

## **Regulation for “the Tracing Sources of the Domestic Certified Agricultural Products shall be Labeled”**

Promulgated on May 21, 2015

Effective from May 21, 2015

### **Article 1**

The labeling requirements that “the tracing sources of the domestic certified agricultural products shall be labeled” in accordance with Subparagraph 5 of Paragraph 1 of Article 22 and Paragraph 1 of Article 25 of the Act Governing Food Safety and Sanitation are formally explained herein and immediately take into effect.

### **Article 2**

The agricultural products with domestic production certification in the preceding paragraph shall refer to organic agricultural products, traceable agricultural products, and Certified Agricultural Standards (CAS) certified agricultural products that satisfy the product production and certification management regulations promulgated by the central agricultural competent authority. The tracing sources that are required to be labeled in the preceding paragraph shall refer to the producing farms, livestock or poultry farms, aquafarms, producer’s cooperative, agricultural production and marketing groups, producers.

Name, address and telephone number of the tracing sources shall be labeled.

## **Country of Origin Labeling Regulations of Packaged Products that Contain Beef and Other Edible Parts of Cattle**

Promulgated on October 2, 2013

Effective from October 2, 2013

1. Packaged products that contain beef and other edible parts of cattle shall clearly indicate their country (place) of origin in Chinese.
2. Beef and other edible parts of cattle do not include milk and beef fat.
3. The country (place) of origin of beef and other edible parts of cattle shall be the country (place) where the cattle are slaughtered.

## **Labeling Regulations on Country of Origin Packaged Products that Contain Pork and Other Edible Parts of Pig**

Promulgated on September 17, 2020

Effective from January 1, 2021

### **Article 1**

This regulation is established under the provision of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Packaged products that contain pork and other edible parts of pig shall clearly indicate their Country (place) of origin in Chinese.

### **Article 3**

The country (place) of origin of pork and other edible parts of pig shall be the country (place) where the pig are slaughtered.

**Shelf life and Storage Conditions of Fresh Milk, Skim Milk, Evaporated Milk, Sweetened Condensed Milk, Sweetened Skim Condensed Milk, Cream, Flavored Milk, Fermented Milk, Synthetic Milk and Other Liquid Dairy Products shall be Labeled**

Promulgated on August 4, 1986

Effective from August 4, 1986

1. This regulation is prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Shelf life and storage conditions of fresh milk, skim milk, evaporated milk, sweetened condensed milk, sweetened skim condensed milk, cream, flavored milk, fermented milk, synthetic milk and other liquid dairy products shall be labeled.



## **Regulations on Prepackaged Food Products Exempted from the Nutrition Labeling**

Promulgated on March 14, 2018

Effective from March 14, 2018

1. This regulation is established under the provisions of Article 23 of the Act Governing Food Safety and Sanitation.
2. Nutrition labeling is not required for the following categories of prepackaged products without nutrition claims:

- (1) Drinking water, mineral water, and ice.
- (2) Fresh, refrigerated, and frozen fruits, vegetables, meat, poultry, eggs, liquid eggs and seafood that do not contain other ingredients.
- (3) Tea leaves, coffee, dried beans, wheats, and other herbs and flower, fruits, and seeds, used for brewing that do not contain other ingredients or food additives.
- (4) Spices and stewed spice packages used for flavoring.
- (5) Salt and salt substitutes.
- (6) The calories and nutrient contents in nutrition labeling of other foods may be labeled as "0" if they meet the criteria of the "Regulations on Nutrition Labeling for Prepackaged Food Products".

If a nutrition labeling is voluntarily used in above categories of products, it shall be handled in accordance with the provisions of Article 22 of the Act Governing Food Safety and Sanitation.

3. Prepackaged foods and food raw materials are not for sell to consumers are exempt from nutrition labeling.

## Regulations on Nutrition Labeling for Prepackaged Food Products

Amended on April 27, 2021

Effective from April 27, 2021

### Chapter I. General Provisions

1. This regulation is established under the provisions of Item 3 of Article 22 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).
2. The terms used in this regulation are defined as follows:
  - 2.1 Trans fats (fatty acids): all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated carbon-carbon double bonds in the trans configuration.
  - 2.2 Carbohydrates: namely saccharides; the sum of carbohydrates.
  - 2.3 Sugars: the sum of all free mono and disaccharides.
  - 2.4 Dietary fibers: lignin and edible carbohydrate polymers with three or more monomeric units, which are not hydrolysed or absorbed by the endogenous enzymes in the small intestine of humans.
  - 2.5 Nutrition claims: any representation which states, suggests or implies that a food product has particular calorie or nutrition properties.
3. The nutrition labeling for a prepackaged food on the market shall provide the following information from top to bottom in tabular form orderly shown at a conspicuous place of the outer package or container of the product.
  - 3.1 Title of the “Nutrition Facts”.
  - 3.2 ◯ grams (or milliliters) per one serving (or per serving) and the number of servings contained in each package of the product.
  - 3.3 “Per serving (or per one serving)”, “per 100 grams (or milliliters)” or “per serving (or per one serving)”, “daily percentage reference value”.
  - 3.4 Contents of calories.
  - 3.5 Contents of protein.
  - 3.6 Contents of fats, saturated fats (or saturated fatty acids), and trans fats (or trans fatty acids).
  - 3.7 Contents of carbohydrates and sugar.
  - 3.8 Contents of sodium.

3.9 Conformed to the definition of nutrition claim of Article 2. Contents of other nutrients declared in the “Regulations on Nutrition Claim for Prepackaged Food Products”. Contents of other nutrients labeled voluntarily by the manufacturer.

Each or total dietary fiber, each sugar, sugar alcohol labeled voluntarily by the manufacturer can be labeled behind carbohydrates item, and after sugar item. Cholesterol, other fatty acids can be labeled behind fat item, and after trans fats (fatty acids) item. Amino acids can be labeled behind protein item.

If the vertical form can't be fully presented, it can be labeled in horizontal continuous form.

If multiple prepackaged food or tastes are commonly used in the same nutrient labeling, it can be combined.

Nutrition labeling on surface areas smaller than 100 cm<sup>2</sup> can be labeled those nutrition information sequentially in horizontal table form.

4. Caloric and nutritional content labeling for prepackaged foods on the market shall be labeled in Arabic numerals and processed under the following provisions:

4.1 Use “per one serving (or per serving)” and “per 100 grams (or milliliters)” for labeling, and the number of servings contained in each package of the product shall also be specified; or

4.2 Use “per one serving (or per serving)” and the provided “daily percentage of reference value” for labeling, and the number of servings contained in each package of the product shall also be specified. Labels shall also be specified the daily nutrient intake reference value if the daily nutrient intake reference value has been set (exempted from the prepackaged food surface areas smaller than 100 cm<sup>2</sup>). For products without a set daily nutrient intake reference value, the “\*” symbol shall precede the daily percentage reference value line and clearly note “\*Reference value not set.”

Regarding the formatting of Clauses 1 and 2 in the preceding item shall refer to Appendix 1. Infant foods and shall be labeled according to the format of Clause 1 in the preceding item. Products in the form of tablets and capsules (excluding candy foods) shall be labeled according to the format of Clause 2 in the preceding item.

5. The weight (quantity or volume) per serving of the various packaged food products shall consider every times consumption derived from domestic dietary habits and prepackaged food product type. Food products in the form of tablets and capsules (excluding candy foods)

shall be labeled as recommended amount (shall be an integer).

6. Measure units for prepackaged food nutrition labeling shall be labelled the following regulations:

- 6.1 Solid (semi-solid) shall be expressed in grams (g); liquid shall be expressed in milliliters (mL or ml).

- 6.2 Caloric value is expressed in kilocalories (Kcal or kcal).

- 6.3 Proteins, fats, saturated fats (fatty acids), and trans fats (fatty acids), total mono or polyunsaturated fats (fatty acids), carbohydrates, sugars, dietary fibers, and sugar alcohols are expressed in grams (g).

- 6.4 Sodium, cholesterol, and amino acids are expressed in milligrams (mg).

- 6.5 Vitamins and minerals units refer to Appendix 1.

- 6.6 Other nutritional values are expressed using the metric system or their common symbols.

If product with nutrition claims requires re-hydration, the nutrition labeling must comply with the content ("per serving, per one serving" or "per 100 milliliters") after re-hydration. If product without nutrition claims requires re-hydration, the nutrition labeling can be in according to the content before or after re-hydration. The re-hydration method shall be stated clearly shown at the outer package.

7. Daily caloric and other nutrient intake reference values shall be labeled according to Appendix 1.

8. The nutrient contents of energy, protein, fats, carbohydrate, sodium, saturated fats (fatty acids), trans fats (fatty acids) and sugars may be labeled as "0" if it meets the criteria in Appendix 2.

9. Data formatting of prepackaged food nutrition labeling units shall conform to the following regulations:

- 9.1 Each quantity, serving number, daily percentage reference value, caloric, protein, amino acid, fat, fatty acid, cholesterol, carbohydrate, sugar, sodium, dietary fiber, and other nutrients labeled voluntarily shall be labeled using whole integers or integers with one decimal point. The amount of caloric or nutrients per serving can be labeled using integers with two decimal points when the amount of caloric or nutrients per 100 grams (or milliliters) isn't meet the criteria of labeling as "0".

- 9.2 The serving size (weight or capacity) can be labeled using integers with two decimal points when it is too small to present the real value if labeled using integers with one

decimal points.

- 9.3 When an non-assembled prepackaged product with varied weight or its serving number is not divisible, the serving number can be labeled as “ This package contains (about) ○ serving(s)” after data formatting to whole integers.
- 9.4 Labels for vitamins and minerals shall not exceed three significant figures.
- 9.5 Data formatting shall refer to the Chinese National Standard CNS2925 “Practices for Designating Significant Places in Specific Limiting Values” or “Round half up” method.
10. The values on the nutritional labels of prepackaged foods must be derived from actual test analysis or calculations, and the range of allowable error shall meet the criteria in Appendix 3. If the characteristics of specific nutrient content of fermented food may change with time, the variation of the nutrients can be annotated.
11. The caloric calculation methods for nutritional labels of prepackaged foods shall conform to the following regulations:
- 11.1 Protein calories are calculated at 4 Kcal per gram.
- 11.2 Fats (fatty acids) calories are calculated at 9 Kcal per gram.
- 11.3 Carbohydrate calories are calculated at 4 Kcal per gram, except for carbohydrates in dietary fiber labeling, in which calories are calculated at 2 Kcal per gram.
- 11.4 Calories for erythritol labeling are calculated at 0 Kcal per gram. Calories for other sugar alcohol labeling are calculated at 2.4 Kcal per gram. Calories for organic acid labeling are calculated at 3 Kcal per gram. Calories for alcohol (ethanol) labeling are calculated at 7 Kcal per gram. The content of sugar alcohol shall be stated clearly in the nutrition labeling format. The content of organic acid and alcohol (ethanol) shall be stated clearly.
- 11.5 Calories for each serving can be calculated from the calories values per 100 grams (or milliliters), or calculated from the calories values of protein, fats, and carbohydrates per 100 grams (or milliliters) by (1) to (4) role.
12. This regulation shall not apply to prepackaged foods such as prepackaged vitamins or mineral category tablets/capsules.

## **Chapter II. Nutrition Labeling for Infant formula and Follow-up infant Formula**

13. The nutrition labeling for a infant formula and follow-up infant formula on the market shall provide the following information from top to bottom in tabular form orderly shown at a

conspicuous place of the outer package or container of the product.

### 13.1 Infant formula and infant formula for special medical purposes :

13.1.1 Title of the “Nutrition Facts”.

13.1.2 “Per 100 grams (or kilocalories)”, “per 100 milliliters”.

13.1.3 Contents of energy.

13.1.4 Contents of protein.

13.1.5 Contents of fats, saturated fats (or fatty acids), and trans fats (or fatty acids),  
linoleic acid, and -linolenic acid.

13.1.6 Contents of carbohydrate and sugars.

13.1.7 Contents of sodium.

13.1.8 Contents of water.

13.1.9 Contents of vitamins as listed in Appendix 4.

13.1.10 Contents of choline.

13.1.11 Contents of myo-inositol.

13.1.12 Contents of L-carnitine.

13.1.13 Contents of ash.

13.1.14 Contents of minerals as listed in Appendix 4 (excluding sodium).

13.1.15 Contents of other nutrients labeled voluntarily by the manufacturer.

Contents of vitamins or minerals labeled voluntarily by the manufacturer can be labeled behind  
contents of vitamins or minerals (excluding sodium) as listed in Appendix 4.

### 13.2 Follow-up infant formula :

13.2.1 Title of the “Nutrition Facts”.

13.2.2 “Per 100 grams (or kilocalories)”, “per 100 milliliters”.

13.2.3 Contents of energy.

13.2.4 Contents of protein.

13.2.5 Contents of fats, saturated fats (or fatty acids), trans fats (or fatty acids), and  
linoleic acid.

13.2.6 Contents of carbohydrate and sugars.

13.2.7 Contents of sodium.

13.2.8 Contents of water.

13.2.9 Contents of vitamins as listed in Appendix 4..

13.2.10 Contents of ash.

13.2.11 Contents of minerals as listed in Appendix 4. (excluding sodium, copper, manganese, and selenium).

13.2.12 Contents of other nutrients labeled voluntarily by the manufacturer.

Contents of vitamins or minerals labeled voluntarily by the manufacturer can be labeled behind contents of vitamins or minerals (excluding sodium, copper, manganese, and selenium) as listed in Appendix 4.

14. Measure units for nutrition labeling of infant formula and follow-up infant formula on the market shall conform to the following regulations:

14.1 Caloric value is expressed in kilocalories (Kcal or kcal).

14.2 Proteins, fats, saturated fats (fatty acids), and trans fats (fatty acids), carbohydrates, sugars, dietary fibers, water and ash are expressed in grams (g).

14.3 Total fatty acids are expressed in grams (g) or milligrams (mg).

14.4 Sodium, cholesterol, amino acids, choline, myo-inositol, and L-carnitine are expressed in milligrams (mg).

14.5 Vitamins and minerals units refer to Appendix 1. Contents of niacin shall be expressed in milligrams (mg), and vitamin B1, vitamin B2, and vitamin B6 may be expressed in micrograms (μg).

14.6 Other nutritional values are expressed using the metric system or their common symbols.

15. The values and the range of allowable error on the nutritional labels of infant formula and follow-up infant formula on the market shall meet the criteria in Appendix 4.

### **Chapter III. Nutrition Labeling for Formula for Certain Disease**

16. The nutrition labeling for a formula for certain disease on the market shall provide the following information from top to bottom in tabular form orderly shown at a conspicuous place of the outer package or container of the product.

16.1 Nutritionally complete food with balanced formula, nutritionally complete food with customized formula and nutrition adjusted supplementary formula food :

16.1.1 Title of the “Nutrition Facts,”.

16.1.2 ○ grams (or milliliters) per one serving (or per serving) and the number of servings contained in each package of the product.

16.1.3 “Per serving (or per one serving)”, “per 100 grams (or milliliters)” .



- 16.1.4 Contents of energy.
- 16.1.5 Contents of protein.
- 16.1.6 Contents of fats, saturated fats (or fatty acids), and trans fats (or fatty acids).
- 16.1.7 Contents of carbohydrate, sugars and total dietary fiber.
- 16.1.8 Contents of sodium.
- 16.1.9 Contents of other nutrients designated by the regulations governing the labeling of formula for certain disease is established under the provisions of Article 22 Paragraph 1 Subparagraph 10 of this Act. Lactose can be labeled behind carbohydrates item, and after sugar item.
- 16.1.10 Conformed to the definition of nutrition claim of Article 2. Contents of other nutrients declared in the “Regulations on Nutrition Claim for Prepackaged Food Products”. Contents of other nutrients labeled voluntarily by the manufacturer.

Contents of vitamins or minerals labeled voluntarily by the manufacturer can be labeled behind contents of vitamins or minerals (excluding sodium) that shall be labeled designated in the announcement.

## 16.2 Special modular formula food :

- 16.2.1 Title of the “Nutrition Facts”.
- 16.2.2 ◦ grams (or milliliters) per one serving (or per serving) and the number of servings contained in each package of the product.
- 16.2.3 “Per serving (or per one serving)”, “per 100 grams (or milliliters)” .
- 16.2.4 Contents of energy.
- 16.2.5 Contents of protein.
- 16.2.6 Contents of fats, saturated fats (or fatty acids), and trans fats (or fatty acids).
- 16.2.7 Contents of carbohydrate and sugars.
- 16.2.8 Contents of sodium.
- 16.2.9 Contents of specific nutrient.
- 16.2.10 Conformed to the definition of nutrition claim of Article 2.

Contents of other nutrients declared in the “Regulations on Nutrition Claim for Prepackaged Food Products”. Contents of other nutrients labeled voluntarily by the manufacturer.

## 17. Measure units for nutrition labeling of for certain disease on the market shall conform to

the following regulations:

- 17.1 Solid (semi-solid) shall be expressed in grams (g); liquid shall be expressed in milliliters (mL or ml). Contents of water and ash are expressed in grams (g).
  - 17.2 Caloric value is expressed in kilocalories (Kcal or kcal).
  - 17.3 Proteins, fats, saturated fats (fatty acids), and trans fats (fatty acids), carbohydrates, sugars and dietary fibers are expressed in grams (g).
  - 17.4 Amino acids, total fatty acids are expressed in grams (g) or milligrams (mg).
  - 17.5 Sodium, cholesterol are expressed in milligrams (mg).
  - 17.6 Vitamins and minerals units refer to Appendix 1.
  - 17.7 Other nutritional values are expressed using the metric system or their common symbols.
18. The values and the range of allowable error on the nutritional labels of formula for certain disease on the market shall meet the criteria in Appendix 5.

Appendix 1 Daily caloric and other nutritional intake reference values

Appropriate for Items	Over 4 years old	Between 1 and 3 years old	Pregnant or nursing mothers
Caloric Value	2000 Kcal	1200 Kcal	2200 Kcal
Protein	60 g	20 g	65 g
Fat	60 g	*	65 g
Carbohydrate	300 g	*	330 g
Sodium	2000 mg	1200 mg	2000 mg
Saturated fats	18 g	*	18 g
cholesterol	300 mg	*	300 mg
Dietary fiber	25 g	15 g	30 g
Vitamin A <sup>(1)</sup>	700 µg RE	400 µg RE	600 µg RE
Vitamin B1	1.4 mg	0.6 mg	1.1 mg
Vitamin B2	1.6 mg	0.7 mg	1.2 mg
Vitamin B6	1.6 mg	0.5 mg	1.9 mg
Vitamin B12	2.4 µg	0.9 µg	2.6 µg
Vitamin C	100 mg	40 mg	110 mg
Vitamin D	10 µg	5 µg	10 µg
Vitamin E <sup>(2)</sup>	13 mgα-TE	5 mgα-TE	14 mgα-TE
Vitamin K	120 µg	30 µg	90 µg
Niacin <sup>(3)</sup>	18 mg NE	9 mg NE	16 mg NE
Folic acid	400 µg	170 µg	600 µg
Pantothenic acid	5 mg	2 mg	6 mg
Biotin	30 µg	9 µg	30 µg
Choline	500 mg	180 mg	410 mg
Calcium	1200 mg	500 mg	1000 mg
Phosphorus	1000 mg	400 mg	800 mg
Iron	15 mg	10 mg	45 mg
Iodine	140 µg	65 µg	200 µg
Magnesium	390 mg	80 mg	355 mg
Zinc	15 mg	5 mg	15 mg

Fluorine	3 mg	0.7 mg	3 mg
Selenium	55 µg	20 µg	60 µg

\*Reference value not set.

Annotation 1: RE is Retinol Equivalent. 1 µg RE=1 µg Retinol=6 µg β-Carotene

Annotation 2: α-TE is α-Tocopherol Equivalent. 1 mgα-TE =1 mgα-Tocopherol

Annotation 3: NE is Niacin Equivalent. Niacin, including nicotinic acid and nicotinamide and tryptophan, is expressed in Niacin Equivalent. 1 mg NE= 60 mg tryptophan

Annotation 4: The Chinese unit can be expressed using the metric system or their common symbols. Gram can be expressed in “g”, milligram can be expressed in “mg”, and microgram can be expressed in “µg”.

#### Appendix 2 Conditions for “0” labeling of Caloric and Nutrients Value

Items	Conditions for “0” labeling
Caloric Value	Nutritional contents of every 100 grams of solid or 100 milliliters of liquid contained in this food product do not exceed 4 Kcal
Protein	Nutritional contents of every 100 grams of solid or 100 milliliters of liquid contained in this food product do not exceed 0.5 grams
Fat	
Carbohydrate	
Sodium	Nutritional contents of every 100 grams of solid or 100 milliliters of liquid contained in this food product do not exceed 5 milligrams
Saturated fats	Nutritional contents of every 100 grams of solid or 100 milliliters of liquid contained in this food product do not exceed 0.1 grams
Trans fats	Total fat content for 100 grams/milliliter of the food product does not exceed 1.0 grams; or Trans fat content per 100 grams/milliliter of the food product does not exceed 0.3 grams

Sugar	Nutritional contents of every 100 grams of solid or 100 milliliters of liquid contained in this food product do not exceed 0.5 grams
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#### Appendix 3 Range of allowable error for nutrition labeling values

Items	Range of allowable error
Proteins and Carbohydrates	80%-120% of the labeled value
Calories, Fats, Saturated fats, Trans fats, Cholesterols, Sodium, and Sugars	$\leq 120\%$ of the labeled value
Amino acids Vitamins (excluding Vitamins A and D) Minerals (excluding sodium) Dietary fiber Other nutrients labeled voluntarily	$\geq 80\%$ of the labeled value
Vitamins A and D	80%-180% of the labeled value

#### Appendix 4 Range of allowable error for nutrition labeling values of infant formula and follow-up infant formula

Items	Range of allowable error	Note
Protein, Carbohydrate, Energy, Fats, Water <sup>a</sup> , and Ash	80%-120% of the labeled value	<sup>a</sup> For powdered infant formula and follow-up infant formula on the market, the range of allowable error of water content shall be $\leq 120\%$ of the labeled value.
Saturated fats, Trans fats, Cholesterol, and Sugars	$\leq 120\%$ of the labeled value	
Vitamins	Vitamin A, Vitamin D, Vitamin E, and Vitamin K	
	Vitamin B1, Vitamin B2, Niacin, and Vitamin B6	
	Vitamin C, Vitamin B12, Folic acid, Pantothenic acid, and Biotin	

Minerals	Sodium, Potassium, Chlorine, Calcium, Phosphorus, and Magnesium	80%-150% of the labeled value	
	Iron, Zinc, Copper, Manganese, Selenium, and Iodine	80%-200% of the labeled value Items	
Amino acids, Poly/Mono unsaturated fat, Dietary fiber, Choline, Myo-Inositol, and L-Carnitine		80%-300% of the labeled value	
Other nutrients		$\geq 80\%$ of the labeled value	The upper level of the range of allowable error shall not exceed the maximum level in manufacturer's specifications.

Appendix 5 Range of allowable error for nutrition labeling values of formula for certain disease

Items	Range of allowable error
Protein, Carbohydrate, Energy, and Fats	80%-120% of the labeled value
Saturated fats, Trans fats, Cholesterol, Sodium, Sugars and Lactose	$\leq 120\%$ of the labeled value
Amino acids, Poly/Mono unsaturated fats, Vitamins (excluding Vitamins A and D), Minerals (excluding sodium), and Dietary fiber	$\geq 80\%$ of the labeled value
Vitamins A and D	80%-180% of the labeled value
Other nutrients	$\geq 80\%$ of the labeled value

## **Amendment on Partial Articles of Regulations on Nutrition Labeling for Prepackaged Food Products**

Amended on June 23, 2022

Effective from July 1, 2024

1. This regulation is established under the provisions of Item 3 of Article 22 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).
2. The terms used in this regulation are defined as follows:
  - 2.1 Trans fats (fatty acids): all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated carbon-carbon double bonds in the trans configuration.
  - 2.2 Carbohydrates: namely saccharides; the sum of carbohydrates.
  - 2.3 Sugars: the sum of all free mono and disaccharides.
  - 2.4 Dietary fibers: lignin and edible carbohydrate polymers with three or more monomeric units, which are not hydrolysed or absorbed by the endogenous enzymes in the small intestine of humans.
  - 2.5 Nutrition claims: any representation which states, suggests or implies that a food product has or does not have particular calorie or nutrition properties.
3. The nutrition labeling for a prepackaged food on the market shall provide the following information from top to bottom in tabular form orderly shown at a conspicuous place of the outer package or container of the product.
  - 3.1 Title of the “Nutrition Facts”.
  - 3.2 ○ grams (or milliliters) per one serving (or per serving) and the number of servings contained in each package of the product.
  - 3.3 “Per serving (or per one serving)”, “per 100 grams (or milliliters, tablets, capsules)” or “per serving (or per one serving)”, “daily percentage reference value”.
  - 3.4 Contents of calories.

3.5 Contents of protein.

3.6 Contents of fats, saturated fats (or saturated fatty acids), and trans fats(or trans fatty acids).

3.7 Contents of carbohydrates and sugar.

3.8 Contents of sodium.

3.9 Conformed to the definition of nutrition claim of Article 2. Contents of other nutrients declared in the “Regulations on Nutrition Claim for Prepackaged Food Products”. Contents of other nutrients labeled voluntarily by the manufacturer.

Each or total dietary fiber, each sugar, sugar alcohol labeled voluntarily by the manufacturer can be labeled behind carbohydrates item, and after sugar item. Cholesterol, other fatty acids can be labeled behind fat item, and after trans fats (fatty acids) item. Amino acids can be labeled behind protein item.

If the vertical form can't be fully presented, it can be labeled in horizontal continuous form.

If multiple prepackaged food or tastes are commonly used in the same nutrient labeling, it can be combined.

Nutrition labeling on surface areas smaller than 100 cm<sup>2</sup> can be labeled those nutrition information sequentially in horizontal table form.

6. Measure units for prepackaged food nutrition labeling shall be labelled in Chinese or using the metric system or their common symbols and conform to the following regulations:

6.1 The unit of “per serving” in the food nutrition labeling, solid (semi- solid) foods shall be expressed in grams; liquid foods shall be expressed in milliliters (mL or ml); tablets and capsules (excluding candy foods) shall be expressed in grams, tablets, or capsules.

6.2 Caloric value is expressed in kilocalories (Kcal or kcal).



6.3 Proteins, fats (fatty acids), saturated fats (fatty acids), and trans fats (fatty acids), unsaturated fats (fatty acids), carbohydrates, sugars, dietary fibers, and sugar alcohols are expressed in grams (g).

6.4 Sodium and cholesterols are expressed in milligrams (mg).

6.5 Amino acids are expressed in grams (g) or milligrams (mg)

6.6 Vitamins and minerals names and units shall refer to Appendix 1.

6.7 Other nutritional values are expressed using the metric system or their common symbols.

For products that using “per serving” and “100 grams (or milliliters)” for the one nutrition labeling in accordance with Subparagraph 1 of Paragraphs 1 of Article 4, the unit of “per serving” shall be consistent with the unit of “100 grams (or milliliters)”.

For products that require reconstitution with water for consumption products, may be labelled of units in accordance with the requirements for solids (semi-solid) before rehydration or liquids after rehydration mentioned in Subparagraph 1 of the preceding paragraph. However, if products with nutrition claims, the measurement standard unit adopted for the nutrition claim of the products shall be the basis for the application of this regulation. The re-hydration method shall be stated clearly shown at the outer package.

8. The nutrient contents of energy, protein, fats, carbohydrate, sodium, saturated fats (fatty acids), trans fats (fatty acids) and sugars may be labeled as “0” if it meets the criteria in Appendix 2. The contents of protein, fats or carbohydrate shall not be labeled as “0” if their subcategory nutrients are not labeled as “0”.
9. Data formatting of prepackaged food nutrition labeling units shall conform to the following regulations:

- 9.1 Each quantity, serving number, daily percentage reference value, shall be labeled using whole integers or integers with one decimal point. Per serving of food products in the form of tablets and capsules (excluding candy foods) expressed tablets or capsules units, shall be labeled using whole integers.
- 9.2 The serving size (weight or capacity) can be labeled using integers with two decimal points when it is too small to present the real value if labeled using integers with one decimal points.
- 9.3 When an non assembled prepackaged product with varied weight or its serving number is not divisible, the serving number can be labeled as “This package contains (about) ○ serving(s)” after data formatting to whole integers.
- 9.4 Caloric, protein, amino acid, fat, fatty acid, cholesterol, carbohydrate, sugar, sodium, dietary fiber, and other voluntary nutrients labeled using the principle of whole integers or integers with one decimal point.
- 9.5 Labels for vitamins and minerals shall not exceed three significant figures.
- 9.6 Data formatting shall refer to the Chinese National Standard CNS2925 “Practices for Designating Significant Places in Specific Limiting Values” or “Round half up” method.

## Appendix 2 Conditions for “0” labeling of Caloric and Nutrients Value

Items	Per serving and 100 g of solid (or 100 ml of liquid)
Caloric Value	Contained in this food product do not exceed 4 Kcal, and the content of carbohydrates, sugars, proteins, fats, trans fats, and saturated fats all meet its conditions for “0” labeling.
Protein	Contained in this food product do not exceed 0.5 g
Fat	
Carbohydrate	
Sodium	Contained in this food product do not exceed 5 mg
Saturated fats	Contained in this food product do not exceed 0.1 g
Trans fats	Total fat content in this food product does not exceed 1.0 g; or Trans fat content in this food product does not exceed 0.3 g
Sugar	Contained in this food product do not exceed 0.5 g

Annotation 1: When Infant formula and Follow-up infant formula using 100 grams (or kilocalories) and 100 milliliters for nutrition labeling, the calorie, the content of protein, fat, carbohydrate, sodium, saturated fat, trans fat, and sugars may be labeled as “0” if they meet the criteria in Appendix 2.

Annotation 2: Conditions for “0” labeling of caloric and nutrients value do not apply to the range of allowable error for nutrition labeling values of Article 10.

## **Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules**

Amended on November 7, 2019

Effective from November 7, 2019

1. The regulation is established under the provisions of Item 3 of Article 22 of the Act Governing Food Safety and Sanitation.
2. The prepackaged vitamin and mineral tablets and capsules mean which are adding nutritional additives as vitamins or minerals sources.
3. The nutrition labeling for prepackaged vitamin and mineral tablets and capsules on the market shall provide the following information from top to bottom in tabular form orderly shown at a conspicuous place of the outer package or container of the product.
  - (1) Title of “Nutrition labeling”
  - (2) Per one serving (or per serving) and the number of servings contained in each package of the product.
  - (3) “Per serving (or per one serving)”, “daily percentage reference value”.
  - (4) Vitamin contents
  - (5) Mineral contents
  - (6) Contents of other nutrients declared in the nutrition claim or labeled by manufacturer voluntarily on the container of food

If the vertical form can't be fully presented, it can be labeled in horizontal continuous form.

Nutrition labeling on surface areas smaller than 100 cm<sup>2</sup> can be labeled those nutrition information sequentially in horizontal table form.
4. Ways of labeling of contents of vitamins, minerals and other nutrients under the following provisions, and numbers shall be expressed in Arabic numerals: Use “per one serving (or per serving)” and the provided “daily percentage of reference value” for labeling, and the number of servings contained in each package of the product shall also be specified. Labels shall also be specified the daily nutrient intake reference value if the daily nutrient intake reference value has been set. For products without a set daily nutrient intake reference value, the “ \* ” symbol shall precede the daily

percentage reference value line and clearly note “\*Reference value not set.”

5. Daily nutrient intake reference values and measure units shall be labeled according to Appendix 1. Other nutrients not listed in Appendix 1 are expressed using the metric system or their common symbols.
6. The contents of vitamins, minerals and other nutrients shall be labeled in metric units. For Vitamins A, D and E, the contents shall be additionally labeled in IU.
7. Data formatting of prepackaged vitamin and mineral tablets and capsules nutrition labeling units shall conform to the following regulations:
  - (1) Each package shall label the serving number shall be expressed in whole integers.
  - (2) Daily percentage reference value shall be labeled using whole integers or integers with one decimal point.
  - (3) The contents of vitamins and minerals shall be expressed in not more than three significant figures.
  - (4) Other nutrients declared in the nutrition claim or other nutrients shall be labeled using whole integers or integers with one decimal point.
  - (5) Data formatting shall refer to the Chinese National Standard CNS2925 “Practices for Designating Significant Places in Specific Limiting Values” or “Round half up” method.
8. If the physiological functions of packaged vitamin and mineral tablets and capsules are to be described, the minimum daily intake must be 15% of the daily percentage reference value.
9. The values on the nutritional labels of prepackaged vitamin and mineral tablets and capsules must be derived from actual test analysis or calculations, and the range of allowable error shall meet the criteria in Appendix 2.
10. Prepackaged vitamin and mineral tablets and capsules shall be labeled the following warning at a conspicuous place of the outer package or container of the product: “No more than tablets (or capsules) each day.” and “Excessive intake does not benefit health.”.
11. “Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules” shall not apply to prepackaged tablets and capsules which are not adding nutritional additives as vitamins or minerals sources.

Appendix 1. Daily reference values of vitamins, minerals and other nutrients

Appropriate for Items	Over 4 years old	Between 1 and 3 years old	Pregnant or nursing mothers
Vitamin A <sup>(1)</sup>	700 µg RE	400 µg RE	600 µg RE
Vitamin B <sub>1</sub>	1.4 mg	0.6 mg	1.1 mg
Vitamin B <sub>2</sub>	1.6 mg	0.7 mg	1.2 mg
Vitamin B <sub>6</sub>	1.6 mg	0.5 mg	1.9 mg
Vitamin B <sub>12</sub>	2.4 µg	0.9 µg	2.6 µg
Vitamin C	100 mg	40 mg	110 mg
Vitamin D	10 µg	5 µg	10 µg
Vitamin E <sup>(2)</sup>	13 mg $\alpha$ -TE	5 mg $\alpha$ -TE	14 mg $\alpha$ -TE
Vitamin K	120 µg	30 µg	90 µg
Niacin <sup>(3)</sup>	18 mg NE	9 mg NE	16 mg NE
Folic acid	400 µg	170 µg	600 µg
Pantothenic acid	5 mg	2 mg	6 mg
Biotin	30 µg	9 µg	30 µg
Choline	500 mg	180 mg	410 mg
Calcium	1200 mg	500 mg	1000 mg
Phosphorus	1000 mg	400 mg	800 mg
Iron	15 mg	10 mg	45 mg
Iodine	140 µg	65 µg	200 µg
Magnesium	390 mg	80 mg	355 mg
Zinc	15 mg	5 mg	15 mg
Fluorine	3 mg	0.7 mg	3 mg
Selenium	55 µg	20 µg	60 µg
Sodium	2000 mg	1200 mg	2000 mg
Protein	60 g	20 g	65 g
Fat	60 g	*	65 g
Carbohydrate	300 g	*	330 g
Saturated fats	18 g	*	18 g
cholesterol	300 mg	*	300 mg

Dietary fiber	25 g	15 g	30 g
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\*Reference value not set.

Annotation 1: RE is Retinol Equivalent. 1  $\mu\text{g}$  RE=1  $\mu\text{g}$  Retinol=6  $\mu\text{g}$   $\beta$ -Carotene

Annotation 2:  $\alpha$ -TE is  $\alpha$ -Tocopherol Equivalent. 1 mg $\alpha$ -TE =1 mg $\alpha$ -Tocopherol

Annotation 3: NE is Niacin Equivalent. Niacin, including nicotinic acid and nicotinamide and tryptophan, is expressed in Niacin Equivalent. 1 mg NE= 60 mg tryptophan

Annotation 4: The Chinese unit can be expressed using the metric system or their common symbols. Gram can be expressed in “g”, milligram can be expressed in “mg”, and microgram can be expressed in “ $\mu\text{g}$ ”.

#### Appendix 2. Range of allowable error for nutrition labeling values

Items		Range of allowable error
Vitamin A and vitamin D		80%~180% of the labeled value
Vitamins (excluding vitamins A and D) and minerals (excluding Sodium)		$\geq 80\%$ of the labeled value
Nutrients labeled voluntarily	Protein, carbohydrates, Calories, lipids, saturated fats, trans fats, cholesterol, sodium, and sugars	$\leq 120\%$ of the labeled value
	Other nutrients	$\geq 80\%$ of the labeled value

## **Regulations on Nutrition Claim for Prepackaged Food Products**

Promulgated on March 3, 2015

Effective from January 1, 2016

1. This regulation is established under the provisions of Paragraph 3 of Article 22 of the Act Governing Food Safety and Sanitation.
2. The regulations are established to define the descriptive wording used to show the amount of nutrients in prepackaged food products. Nutrition claims are divided into two categories "moderate intake" and "supplementary intake" subject to the impact of the intake of the particular nutrient on national health.

(1) The nutrition claims for "moderate intake"

Excessive intake of calories, fat, saturated fatty acids, cholesterol, sodium, sugar, lactose, and trans fat are harmful to the health of the population, therefore such nutrients are listed in the declaration reading "moderate intake". The above nutrients shall be labeled in accordance with the following principles. No descriptive wording other than the following labeling principles is allowed in the declaration reading "moderate intake":

- A. Where the nutrient in the first column of Solid (Semi-solid) Food Labeling Table 1 is claimed "free," "without," or "zero" the amount of such nutrient per 100 g of food shall not be more than the amount specified in the second column of Table 1.
- B. Where the nutrient in the first column of Liquid Food Labeling Table 1 is claimed "free," "without," or "zero" the amount of such nutrient per 100 ml of food shall not be more than the amount specified in the third column of the Table 1.
- C. Where the nutrient in the first column of Solid (Semi-solid) Food Labeling Table 2 is claimed "low," "little," "weak," "light", or "slightly contained" the amount of such nutrient per 100 g of food shall not be more than the amount specified in the second column of Table 2.
- D. Where the nutrient in the first column of Liquid Food Labeling Table 2 is claimed "low," "little," "weak," "light", or "slightly contained" the amount of such nutrient



per 100 ml of food shall not be more than the amount specified in the third column of Table 2.

- E. Where the nutrient in the first column of Food Labeling Table 2 is claimed "reduced than..." or "less than..."(except for the less/reduced sodium salts) the difference between the amount of such nutrient in such solid (semi-solid) or liquid food and that in similar reference food must respectively reach or exceed the amount in the second or third column of the same table; the similar reference food being compared to shall be identified, and the amount or percentage reduced shall be specified.
- F. Food products are listed as "low Sodium", "little Sodium", "weak Sodium" or "slightly contained Sodium", the amount of Sodium shall respectively not be more than those described in the 2nd or 3rd column for per 100 g of solid (semi-solid) food or per 100 ml of liquid food of this table. Furthermore, the content of Potassium shall be stated clearly in the nutrition labeling format.

(2) The nutrition claims for “supplementary intake”

Inadequate intake of nutrients such as dietary fiber, Vitamin A, Vitamin B1, Vitamin B2, Vitamin C, Vitamin E, calcium and iron will affect national health, therefore such nutrients are claimed in the nutrition claims for "supplementary intake needed." The above nutrients shall be labeled in accordance with the following principles. No descriptive wording other than the following labeling principles is allowed in the nutrition claims for "supplementary intake needed":

- A. Where the nutrient in the first column of Solid (Semi-solid) Food Labeling Table 3 is claimed "high," "rich in," "strengthened" or "excellent source of," the amount of such nutrients per 100 g of food shall not be less than the amount specified in the second column of Table 3.

Notwithstanding, the foods listed in Table 5 shall be based on the amount of nutrient per 30 g (actual weight) of such food. The amount of the above nutrient contained in such foods shall not be less than the amount specified in the second

column of Table 3. The food listed in Table 6 shall be based on the amount of the nutrient per 1 g (dry food) of such foods. The amount of the above nutrients (except dietary fiber) contained in such foods must reach or exceed the amount specified in the second column of Table 3. In this way, the amount of nutrient in such foods can be claimed "high," "rich in," "strengthened" or "excellent source of" in the first column of Table 3.

- B. Where the nutrient in the first column of Liquid Food Labeling Table 3 is claimed as "high", "rich in", "strengthened" or "excellent source of" the amount of such nutrient per 100 ml of such foods shall not be less than the amount specified in the third column of Table 3, or per 100 kilocalories of such food shall not be less than the amount specified in the fourth column of Table 3.
- C. Where the nutrient in the first column of Solid (Semi-solid) Food Labeling Table 4 is claimed "source," "provide," or "contain" the amount of such nutrient per 100 g of such foods shall not be less than the amount specified in the second column of Table 4.

Notwithstanding, the foods listed in Table 5 shall be based on the amount of nutrient per 30 g (actual weight) of such food. The amount of the above nutrient contained in such foods shall not be less than the amount specified in the second column of Table 4. The foods listed in Table 6 shall be based on the amount of nutrient per 1 g (dry food) of such foods. The amount of the above nutrient contained in such foods shall not be less than the amount specified in the second column of Table 4. In this way, the nutrient in such foods can be claimed "source," "provide" or "contain" in the first column of Table 4.

- D. Where the nutrient in the first column of Liquid Food Labeling Table 4 is claimed "source," "provide" or "contain" the amount of such nutrient per 100 ml of food shall not be less than the amount specified in the third column of the same table, or per 100 kcal of food shall not be less than the amount specified in the fourth column of Table 4.
- E. Packaged salt products that are claimed "Iodized salt", "contains Iodized salt", "adds Iodized salt" or Synonyms shall not only be more than 12 parts per million,

but also be corresponded to the “Standards for Specification, Scope, Application and Limitation of Food Additives”. In addition, it shall label the following warning at a notable place: “This salt product contains iodine, a necessary nutrient, but it does not apply to patients who with high iodine hyperthyroidism and who are treated with iodine 131 radiotherapy.”.

- F. Where the nutrient in the first column of Food Labeling Table 4 is claimed "higher than..." or "increased than..." the difference between the amount of such nutrients in such solid (semi-solid) or liquid food and that in similar reference food must respectively reach or exceed the amount in the second, third or fourth column of Table 4; the similar reference food being compared to shall be identified, and the amount or percentage higher shall be specified.
- G. The foods listed in Table 7 shall not have nutrition claim such as "high, rich in, strengthened, excellent source of source, provide, contain, etc." in its declaration of nutrition facts and the descriptive wording of the physiological functions of nutrients.
3. When the minimum daily intake amount of products in capsule or tablet form labelled with a daily intake limit equals to or exceeds that listed in the second column of Table 3, the product can be claimed "high," "rich in," "strengthened" or "excellent source of". When minimum daily intake amount equals to or exceeds that listed in the first column of Table 4, the product can be claimed "source," "provide" or "contain".
4. For foods that require reconstitution with water for consumption or concentrated products (e.g., milk powder, juice powder, coffee and concentrated juice), it is acceptable to apply nutrition claims in "moderate intake" or "supplementary intake" category based on the amount of nutrient per 100 g solid food or per 100 ml liquid food as prepared in accordance to the recommendation on the product. For brewed food products, the nutrition claims shall base on the reconstituted liquid obtained using the recommended reconstitution method.
5. Where a product has two or more nutrients that meets the conditions for nutrition claims, such claims may be made for such product accordingly. For instance, "this product is a low-fat, high-fiber product" or "this product is a low-fat, high-fiber, zero cholesterol"

provided that the same product is measured on the same basis 【solid (semi-solid) or liquid】 .

6. Nutrients are not regulated as "moderate intake" or "supplementary intake" by the central management authorities that shall not be declared as "moderate intake" or "supplementary intake".
7. The descriptive wording of the physiological functions of nutrients are regulated as "supplementary intake" by the central management authorities that shall be subjected to provisions relevant to the amount of nutrients as specified in Subparagraphs 3 and 4 of Article 2-(2) “The nutrition claims for “supplementary intake” of these Regulations.
8. "Special Dietary Food" is not restricted to these regulations.

Table 1. Where the nutrients are listed as "free", "without" or "zero" in the 1<sup>st</sup> column, the amount of such nutrients shall respectively not be more than described in the 2<sup>nd</sup> or 3<sup>rd</sup> column for per 100 g of solid (semi-solid) food or per 100 ml of liquid food of this table.

The 1 <sup>st</sup> Column	The 2 <sup>nd</sup> Column	The 3 <sup>rd</sup> Column
Nutrient	Solid (Semi-solid) 100 g	Liquid 100 mL
Calories	4 Kcal	4 Kcal
Fats	0.5 g	0.5 g
Saturated fats	0.1 g	0.1 g
Trans Fats	0.3 g (The total saturated fats and trans fats shall not be more than 1.5 g, the amount of calories of saturated and trans fats shall not be more than 10% of total calories of the food.)	0.3 g (The total saturated fats and trans fats shall not be more than 0.75 g, the amount of calories of saturated and trans fats shall not be more than 10% of total calories of the food.)
Cholesterol	5 mg (The saturated fats shall not be more than 1.5 g, and the amount of calories of that shall not be more than 10% of total calories of the food.)	5 mg (The saturated fats shall not be more than 0.75 g, and the amount of calories of that shall not be more than 10% of total calories of the food.)
Sodium	5 mg	5 mg
Sugars	0.5 g	0.5 g
Lactose	0.5 g	0.5 g

Annotation 1: The Sugars is the total amount of monosaccharaides and disaccharides.

Annotation 2: For those products that are complied with the regulations in table 1, “zero” is suitable for the nutrient of the nutrition labeling.

Table 2. Where the nutrients are listed as "low", "little", "weak", "light" or "slightly contained" in the 1st column, the amount of such nutrients shall respectively not be more than those described in the 2<sup>nd</sup> or 3<sup>rd</sup> column for per 100 g of solid (semi-solid) food or per 100 ml of liquid food of this table.

The 1 <sup>st</sup> Column	The 2 <sup>nd</sup> Column	The 3 <sup>rd</sup> Column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL
Calories	40 kcal	20 kcal
Fats	3 g	1.5 g
Saturated fats	1.5 g (The amount of calories for saturated fats shall not be more than 10% of total calories of the food.)	0.75 g (The amount of calories for saturated fats shall not be more than 10% of total calories of the food.)
Cholesterol	20 mg (The saturated fats shall not be more than 1.5 g, and the amount of calories of that shall not be more than 10% of total calories of the food.)	10 mg (The saturated fats shall not be more than 1.5 g, and the amount of calories of that shall not be more than 10% of total calories of the food.)
Sodium	120 mg	120 mg
Sugars	5 g	2.5 g
Lactose (Dairy products only)	2 g	2 g

Annotation 1: The Sugars is the total amount of monosaccharaides and disaccharides.

Annotation 2: Dairy products are defined as “milk products and food produced from the milk of mammals”.

Annotation 3: Food products are listed as "low Sodium", "little Sodium", "weak Sodium" or "slightly contained Sodium", the amount of Sodium shall respectively

not be more than those described in the 2<sup>nd</sup> or 3<sup>rd</sup> column for per 100 g of solid (semi-solid) food or per 100 ml of liquid food of this table. Furthermore, the content of Potassium shall be stated clearly in the nutrition labeling format.

Annotation 4: Where the nutrient in the 1st column is listed as "reduced than..." or "less than..."(except for the less/reduced sodium salts) the difference between the amount of such nutrient in such solid (semi-solid) or liquid food and that in similar reference food shall respectively not be less than the amount in the 2nd or 3rd column of the same table; the similar reference food being compared to shall be identified, and the amount or percentage lower shall be specified.

Table 3. Where the nutrients are listed as "high", "rich in", "strengthened" or "excellent source of in the 1<sup>st</sup> column, the amount of such nutrients shall respectively not be less than those described in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> column for per 100 g of solid (semi-solid) food, per 100 ml or per 100 Kcal of liquid food of this table.

(1) Non-specific population

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL	Liquid 100 Kcal
Dietary fiber	6 g	3 g	3 g
Vitamin A	210 µg RE <sup>(1)</sup>	105 µg RE <sup>(1)</sup>	70 µg RE <sup>(1)</sup>
Vitamin B <sub>1</sub>	0.42 mg	0.21 mg	0.14 mg
Vitamin B <sub>2</sub>	0.48 mg	0.24 mg	0.16 mg
Vitamin C	30 mg	15 mg	10 mg
Vitamin E	3.9 mg α-TE <sup>(2)</sup>	1.95 mg α-TE <sup>(2)</sup>	1.3 mg α-TE <sup>(2)</sup>
Calcium	360 mg	180 mg	120 mg
Iron	4.5 mg	2.25 mg	1.5 mg

(2) Between 1 and 3 years old

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semisolid) 100 g	Liquid 100 mL	Liquid 100 Kcal
Dietary fiber	6 g	3 g	3 g
Vitamin A	120 µg RE <sup>(1)</sup>	60 µg RE <sup>(1)</sup>	40 µg RE <sup>(1)</sup>
Vitamin B <sub>1</sub>	0.18 mg	0.09 mg	0.06 mg
Vitamin B <sub>2</sub>	0.21 mg	0.11 mg	0.07 mg



Vitamin C	12 mg	6 mg	4 mg
Vitamin E	1.5 mg $\alpha$ -TE <sup>(2)</sup>	0.75 mg $\alpha$ -TE <sup>(2)</sup>	0.5 mg $\alpha$ -TE <sup>(2)</sup>
Calcium	150 mg	75 mg	50 mg
Iron	3 mg	1.5 mg	1 mg

(3) Pregnant or nursing mothers

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL	Liquid 100 Kcal
Dietary fiber	6 g	3 g	3 g
Vitamin A	180 $\mu$ g RE <sup>(1)</sup>	90 $\mu$ g RE <sup>(1)</sup>	60 $\mu$ g RE <sup>(1)</sup>
Vitamin B <sub>1</sub>	0.33 mg	0.17 mg	0.11 mg
Vitamin B <sub>2</sub>	0.36 mg	0.18 mg	0.12 mg
Vitamin C	33 mg	16.5 mg	11 mg
Vitamin E	4.2 mg $\alpha$ -TE <sup>(2)</sup>	2.1 mg $\alpha$ -TE <sup>(2)</sup>	1.4 mg $\alpha$ -TE <sup>(2)</sup>
Calcium	300 mg	150 mg	100 mg
Iron	13.5 mg	6.75 mg	4.5 mg

Annotation 1: RE is Retinol Equivalent.

$$1 \mu\text{g RE} = 1 \mu\text{g Retinol} = 6 \mu\text{g } \beta\text{-Carotene}$$

Annotation 2:  $\alpha$ -TE is  $\alpha$ -Tocopherol Equivalent.

$$1 \text{ mg } \alpha\text{-TE} = 1 \text{ mg } \alpha\text{-Tocopherol}$$

Table 4. Where the nutrients are listed as "source", "provide" or "contain" in the 1<sup>st</sup> column, the amount of such nutrients shall respectively not be less than those described in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> column for per 100 g of solid (semi-solid) food, per 100 ml or per 100 Kcal of liquid food of this table.

(1) Non-specific population

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL	Liquid 100 Kcal
Dietary fiber	3 g	1.5 g	1.5 g
Vitamin A	105 µg RE <sup>(1)</sup>	52.5 µg RE <sup>(1)</sup>	35 µg RE <sup>(1)</sup>
Vitamin B <sub>1</sub>	0.21 mg	0.11 mg	0.07 mg
Vitamin B <sub>2</sub>	0.24 mg	0.12 mg	0.08 mg
Vitamin C	15 mg	7.5 mg	5 mg
Vitamin E	1.95 mg α-TE <sup>(2)</sup>	0.98 mg α-TE <sup>(2)</sup>	0.65 mg α-TE <sup>(2)</sup>
Calcium	180 mg	90 mg	60 mg
Iron	2.25 mg	1.13 mg	0.75 mg
Iodine	12 ppm (And shall be corresponded to the “Standards for Specification, Scope, Application and Limitation of Food Additives”.)		

(2) Between 1 and 3 years old

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL	Liquid 100 kcal
Dietary fiber	3 g	1.5 g	1.5 g
Vitamin A	60 µg RE <sup>(1)</sup>	30 µg RE <sup>(1)</sup>	20 µg RE <sup>(1)</sup>

Vitamin B <sub>1</sub>	0.09 mg	0.05 mg	0.03 mg
Vitamin B <sub>2</sub>	0.11 mg	0.05 mg	0.04 mg
Vitamin C	6 mg	3 mg	2 mg
Vitamin E	0.75 mg $\alpha$ -TE <sup>(2)</sup>	0.38 mg $\alpha$ -TE <sup>(2)</sup>	0.25 mg $\alpha$ -TE <sup>(2)</sup>
Calcium	75 mg	37.5 mg	25 mg
Iron	1.5 mg	0.75 mg	0.5 mg

(3) Pregnant or nursing mothers

The 1 <sup>st</sup> column	The 2 <sup>nd</sup> column	The 3 <sup>rd</sup> column	The 4 <sup>th</sup> column
Nutrient	Solid (semi-solid) 100 g	Liquid 100 mL	Liquid 100 kcal
Dietary fiber	3 g	1.5 g	1.5 g
Vitamin A	90 $\mu$ g RE <sup>(1)</sup>	45 $\mu$ g RE <sup>(1)</sup>	30 $\mu$ g RE <sup>(1)</sup>
Vitamin B <sub>1</sub>	0.17 mg	0.08 mg	0.06 mg
Vitamin B <sub>2</sub>	0.18 mg	0.09 mg	0.06 mg
Vitamin C	16.5 mg	8.25 mg	5.5 mg
Vitamin E	2.1 mg $\alpha$ -TE <sup>(2)</sup>	1.05 mg $\alpha$ -TE <sup>(2)</sup>	0.7 mg $\alpha$ -TE <sup>(2)</sup>
Calcium	150 mg	75 mg	50 mg
Iron	6.75 mg	3.38 mg	2.25 mg

Annotation 1: RE is Retinol Equivalent.

$$1 \mu\text{g RE} = 1 \mu\text{g Retinol} = 6 \mu\text{g } \beta\text{-Carotene}$$

Annotation 2:  $\alpha$ -TE is  $\alpha$ -Tocopherol Equivalent.

$$1 \text{ mg } \alpha\text{-TE} = 1 \text{ mg } \alpha\text{-Tocopherol}$$

Annotation 3: Packaged salt products that are claimed “Iodized salt”, “contains Iodized salt”, “adds Iodized salt” or Synonyms shall not only be more than 12 parts per million, but also be corresponded to the “Standards for Specification, Scope, Application and Limitation of Food Additives”. In addition, it shall

label the following warning at a notable place: “This salt product contains iodine, a necessary nutrient, but it does not apply to patients who with high iodine hyperthyroidism and who are treated with iodine 131 radiotherapy.”.

Annotation 4: Where the nutrients in the 1st column are listed as "higher than..." or "increased than..." the difference between the amount of such nutrient in such solid (semi-solid) or liquid food and that in similar reference food shall respectively not be less than the amount in the 2nd, 3rd or 4th column of the same table; the similar reference food being compared to shall be identified, and the amount or percentage higher shall be specified.

Table 5. Where the nutrition claims for "Appropriate Intake Needed" shall be based on the amount of the nutrient per 30 gm (actual weight) of such food.

-cheese, cheese powder, cream, and cream powder
-Fried pork fiber, fried pork paste, ground meat sauce, pork fiber, fried, sliced dried meat, dried and cured meat
-Fried fish fiber, fish paste, pickled seafood and nori paste
-Bean curd cheese, vegetarian fried pork fiber, vegetarian fried pork paste and Chinese spaghetti sauce
-Fruit jam, peanut butter, sesame paste, peanut powder
-Western-style bakery products (including cookies, but excluding cakes, breads, and pizzas)
-Chinese pastries (including cookies)
-The other foods promulgated by the central authorities

Table 6. Where the nutrition claims for "Supplementary Intake" shall be based on the amount of the nutrients per 1 g (dry food ) of such food.

-Small dried shrimp skin, small dried shrimp, seaweed, dried mackerel fish, dried seaweed, Nori, dried laver, agar-agar, dried jelly fish
-The other food promulgated by the central authorities

Table 7. Where the food shall not have nutrition claims for "supplementary intake" such as "high", "rich in", "strengthened", "excellent source of", "source", "provide" and "contain".

-The snack foods which added food nutritional additives

Rice crackers, swelling and pressing products

Preserve and dried vegetables, fruits

Seed products

Drupaceous fruit products

Bean products

Seafood snacks

-Soda water and cola which the amount of calories of sugars shall not be more than 10% of total calories of the drink

- The candies which added food nutritional additives (excluding chewing gum, bubble gum that be subjected to provisions relevant to the amount of sugar as specified in Table 1 of these Regulations)

Hard candy

Soft sweets products

Preserved wax-gourd, preserved papaya candy, preserved sweet potato

Chocolate

Fresh cavity candy

The other candies

-Seasoning products

Dried powder products

Miso and black bean

Dressing oil products

Dressing products (used in large quantities)

Dipping sauces (used in small quantities)

Agaric sauce and black pepper sauce

Spaghetti sauce

Sugar products

    Solid products

    Liquid products

MSG, flavor enhancers

Fried garlic and fried shallot

Star anise and powdered spices

Osmanthus sauce

The other seasonings

-Salted and preserved vegetables

-The other foods appointed by the central management authorities

## **Labelling Requirements for Prepackaged Food Containing Ingredients of Genetically Modified Organisms (GMOs)**

Amended on May 29, 2015

Effective from December 31, 2015

1. The regulation is established under the provisions of Paragraph 3 of Article 22 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act).
2. The GMOs referred in this regulation comply with the GMOs authorized by Paragraph 2 of Article 21 of the Act.

Prepackaged food that contains GMOs shall display the words “genetically-modified” or “with genetic modification”.

Prepackaged food that uses GMOs directly during the manufacturing process yet the final product does not contain transgenic DNA fragment or transgenic proteins shall display following one of words,

- (1) “genetically-modified”, “with genetic modification” or “use genetically modified \_\_\_\_\_(organisms)”
  - (2) “this product is made of genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins ” or “this product’s raw materials contain genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins”.
  - (3) “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_(organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_(organisms)”.
3. The labelling requirements shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 3 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.
  4. Prepackaged food contains non-GMOs which exist international approvals to cultivation or food of GMOs may display the words “un-genetically-modified” or



“with un-genetic modification” and could displays the words“the proportion of material which contains, consists of or is produced from GMOs considered individually is approved for use in a regulation of \_\_\_\_\_(country)or other synonymous terms” or the proportion of material which contains, consists of or is produced from GMOs considered individually.

5. Based on this regulation, the labelling method shall be displayed after the name of the product and the ingredients in principle, or other obvious locations of the container or packaging. The length and the width of the font shall as following,
  - (1) Labelling“genetically-modified”, “with genetic modification”or “use genetically modified \_\_\_\_\_(organisms)” shall make a distinction with other words, and the length and the width of the font shall not be less than 2 mm.
  - (2) Labelling“this product is made of genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins ”, “this product’s raw materials contain genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins”, “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_(organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_(organisms)”, the length and the width of shall not be less than 2 mm.
  - (3) Labelling “un-genetically-modified” or “with un-genetic modification”, the length and the width of the font do not be stipulated.

**Food Products that Contain Aspartame (Including Sugar Substitute in Tablet and Powder forms) shall be Clearly Labelled with “Not Suitable for Phenylketonurics” or Synonymous Words.**

Promulgated on June 2, 1988

Effective from June 2, 1988

Food products containing aspartame (including sugar substitute tablet and powder forms) shall be clearly labelled with “Not suitable for Phenylketonurics” or synonymous words.

**Capsules or Ingots Sold in Containers or Prepackages shall be Marked with the Term "Food" on Their Outer Packaging and Label. The Font of the Term “Food” shall not be Smaller than the Font of the Trademark or Product Name**

Promulgated on July 1, 1989

Effective from July 1, 1989

1. The regulation is prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Capsules or ingots sold in containers or prepackages shall be marked with the term "food" on their outer packaging and label. The font of the term “food” shall not be smaller than the font of the trademark or product name.

**Acidity (The Percentage of Acetic Acid, %) and Usage of the Artificial Vinegar shall be Specified. This Regulation shall Come into Force 3 Months after the Announcement**

Promulgated on April 18, 1997

Effective from July 18, 1997

1. The regulation is prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Acidity (the percentage of acetic acid, %) and usage of the artificial vinegar shall be indicated. This regulation shall come into force 3 months after the announcement.

**Domestic Producer of Packaged Water and Bottled Water which Filled in Containers and Sold on Site shall Clearly Label the “Category of Source Water” and the “Location of Water Source” on their Products**

Promulgated on September 10, 2013

Effective from September 10, 2013

**Legal Basis**

Article 28 of the Drink Water Management Act and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

**Article 1**

Businesses selling packaged (sealed package and in unit packages) or bottled (on site filled in containers) drinking water shall clearly label the category of sources water and the locations of water source.

**Article 2**

The source water can be classified into four categories, namely the surface water body, groundwater body, tap water or others (with specific explanations). The location of the water source shall be in principle the actual address of the water source. If there is no address, the cadastral data shall be used instead. If tap water is used as the source water, the address shall be the location where the water is taken.

**Article 3**

Businesses of drinking water shall label according to the aforementioned regulations which shall be effective immediately. Any who fails to comply six months after this announcement is publicized shall be deemed to have violated Subparagraph 10 of paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation and shall be subject to the punishment set out in Article 47 of the same Act.

## Regulation Governing the Labeling of Irradiated Foods

Promulgated on September 10, 2013

Effective from September 10, 2013

1. The Regulation is prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Foods that are treated with radiation shall bear the symbol for radiation on their outer packaging obviously.



**Regulation Governing the Term “Edible” or-Synonymous Terms shall be Labeled on Containers or Packages as the Weight of Edible Milk Powder, Buttermilk Powder or Whey Powder is 10 kg or more**

Promulgated on June 29, 2005

Effective from June 29, 2005

Regulation governing the term “Edible” or synonymous terms shall be labelled on containers or packages as the weight of edible milk powder, buttermilk powder or whey powder is weights 10 kg or more

## **Commercial Jelly Products Containing Konjac shall Bear Warning Statement**

Promulgated on September 30, 2005

A warning statement shall be labeled on commercial jelly products containing Konjac:

1. Commercial jelly products containing konjac with the following characteristics shall be labeled with a warning statement or its synonym according to this announcement on the external packaging of each individual products. The scope of the specifications is as follows:

- (1) Size of product: the product is globular or close to globular with the diameter of the cross-section smaller than 4.5 cm (inclusive), or the product is not globular with the diameter of the cross-section smaller than 3.1 cm (inclusive).
- (2) Shape of product: the product is of ball shape, oval shape, ellipse shape or with circular section (round edge, cylinder shape, cone shape etc.)
- (3) Structure of product: the product has smooth and slippery surface after entering the mouth (this type of jelly is slippery and easily moving from tongue to the end of oral cavity, so that consumers cannot easily control the direction and place of its movement which is likely to cause swallowing without first chewing).
- (4) Ingredients: containing Konjac.
- (5) Fonts of labeling: The characters shall be no smaller than 2mm in both length and width.
- (6) Position of labeling: The opening or close to the opening of the seal of the jelly product

2. The product shall be labeled with one of the following warning statement:

- (1) Please do not sip with force and swallow the entire jelly at once;
- (2) Do not give the product to children under five years old;
- (3) When the elderly or children are to eat the product, an adult shall be accompanied and use spoon to cut the jelly into smaller pieces;
- (4) Please chew the product slowly to prevent choking;
- (5) Please do not eat the product while playing;
- (6) Please chew and do not swallow the entire jelly.

### **Article 2**



This public announcement shall take effect on January 1, 2006 (based on the date of manufacturing).

## **Regulations Governing the Labeling of Caffeine of Prepackaged Caffeinated Beverages**

Amended on September 10, 2013

Effective from September 10, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. The product names and labeling of prepackaged caffeinated beverages shall meet the following requirements.
  - (1) For a product that contains more than 20mg/100mL caffeine, the caffeine content shall be measured and labelled in milligrams of caffeine in 100 mL of coffee. The tolerance allowed shall be ruled by the the factory standard.
  - (2) For a product that contains less than 20mg/100mL caffeine, its caffeine content shall be indicated as “Less than 20mg/100mL of caffeine”.
  - (3) Coffee, tea and chocolate beverages that contain less than 2mg/100mL caffeine can use the term “low caffeine” instead of “Less than 20mg/100mL of caffeine”.
3. Instant coffee powder sold in small prepackage shall indicate its caffeine content by the amount of caffeine contained in serving per bag. The tolerance allowed shall be ruled by the factory standard.
4. This regulation does not apply to other kinds of beverage sold in the form of powder.
5. The caffeine content labeling mentioned in preceding paragraphs shall not be included in the Nutrition Facts label, so as not to make consumers mistake caffeine for nutrient.
6. This announcement shall come into force since January 1, 2008. (Subject to the date of manufacture)
7. If the manufacturer fails to use up the inventory of packaging materials before the implementation date of the announcement, it shall report to the local health bureau through the association on the amount of inventory and the estimated usage period before December 1, 2007.

## Regulations Governing the Labeling of Packaged Vegetarian Foods

Amended on September 10, 2013

Effective from September 10, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. If a packaged food is claimed to be vegetarian, it should be labeled as “vegan (*Su* vegetarian)”, “ovo vegetarian”, “lacto vegetarian”, “ovo-lacto vegetarian” or “vegan”.
3. Definitions of related terms in the notice:
  - (1) Vegan (*Su* vegetarian, 全素) : Vegans do not consume any animal products or by-products and vegetables in the allium family (namely, onion, garlic, scallions, leeks, chives, or shallots.)
  - (2) Ovo Vegetarian: Ovo-vegetarians do not consume meat or dairy products. However, ovo-vegetarians do consume egg products.
  - (3) Lacto Vegetarian: Lacto-vegetarians do not consume meat or eggs. However, lacto-vegetarians do consume dairy products such as cheese, milk and yogurt.
  - (4) Ovo-lacto vegetarian (or lacto-ovo vegetarian): Ovo-lacto vegetarian products include animal products such as eggs, milk, and honey.
  - (5) Vegan (植物五辛素): Vegans consume only vegetal products. (Milk or eggs shall be specified.)
4. Since the implementation date, the word "vegetarian food" shall not be used anymore.

## Regulations Governing the Labeling of Instant Noodles

Amended on September 10, 2013

Effective from September 10, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Principles of instant noodles labeling:
  - (1) Those contain seasoning powder but do not contain food packet shall name themselves according to the seasoning powder, namely “○○ flavor noodles”, “○○ noodle soup”.
  - (2) Those contain seasoning powder and food packet shall name themselves according to the food packet, namely “○○ noodles”.
3. Labeling of notice regarding instant noodles:
  - (1) Only one of the terms “reference for cooking” and “recommendation for cooking” is needed to be shown on the packaging.
  - (2) Font size: Font size shall not be smaller than 6 mm.
  - (3) Labeling position: Visible on the picture of the minimum unit packaging.
  - (4) Remark: The color of the notice shall be contrast sufficiently with the background so as to be easy to read.

## **Regulations Governing the Labeling of Vacuum-packed Foods on the Market**

Amended on August 5, 2013

Effective from August 5, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Content of labeling: Whether the product needs to be refrigerated or frozen shall be specified; otherwise, the term “Not ready-to-eat. Should be fully heated before consumption.” shall be clearly shown on the packages (except fresh fruit and vegetables, livestock and aquatic products).
3. Label position: The label shall be obvious and on the front of the packaging of the smallest unit for sale.
4. Font size: The term “Needed to be refrigerated” or “Needed to be frozen” shall not be smaller than 1 cm in length and width; the term “Not ready-to-eat. Should be fully heat before eating.” should not be smaller than 0.5 cm in length and width.
5. Notice: The color of term “Needed to be refrigerated”, “Needed to be frozen” or “Not ready-to-eat. Should be fully heat before eating.” shall be clearly distinguishable from the background color

## **Regulations on Labeling for Prepackaged Reduced Sodium Salt Products on the Market**

Amended on September 10, 2013

Effective from September 10, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Scope of application: Prepackaged food grade salt products that contain less than 65% of sodium chloride on the market.
3. The labeling required the following matters:
  - (1) Prepackaged food grade salt products that have less than 65% of sodium chloride shall be named as “potassium salt” or “reduced sodium salt”.
  - (2) The information shall be labeled on the prepackaged reduced sodium salt products: “Sodium-reduced” and the potassium content, and shall conspicuously labeled the warning statement in Chinese: “Nephropathy patient shall consult your physician or dietitian before use this product.”.
  - (3) The font of the warning shall not be less than 4 millimeter in length and width and its color shall be clearly distinguishable from the background color of the product packaging.

## **Regulations Governing the Product Names and Labeling of Prepackaged Blended Oils**

Amended on September 10, 2013

Effective from September 10, 2013

1. The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. The product names and labeling of prepackaged blended oils shall meet the following rules:

(1) Names and labeling principles of prepackaged blended oils:

- 1) The name of a retail prepackaged blended oil shall contain two (or less) kinds of oils.
- 2) If only one kind of oil is specified in the name of the product, that oil shall account for more than 50% of the content of the product.
- 3) If two kinds of oils are specified in the name of the product, each oil shall account for more than 30% of the content of the product. The order of the name shall be shown according to the content.
- 4) A prepackaged blended oil that does not named after name of oils shall not show the name of oils on the packaging; for example, “○○○ flavor” or “○○○ recipe”.
- 5) Peanut oil is a special blended oil in Taiwan, and it can still retain its unique flavor after blending with other vegetable oils. In order to comply with the dietary habit of the people, the naming method of peanut oil may not follow this regulation. However, “peanut flavored blended oil” shall still be included in the name of the product.

(2) Font of “blended oils”:

- 1) The term “blended oil” shall be shown clearly on the outer packaging of the product.
- 2) The font of the term “blended oils” shall be no smaller than 6 mm in length and width.

- 3) The color of the term “blended oils” shall be contrast sufficiently with the background so as to be easy to read.



## **Regulations Governing the Labeling of Restructured and Artificially Marbled Meat Products**

Promulgated on March 17, 2022

Effective from July 1, 2022

### **Article 1**

The regulation is established under the provisions of subparagraph 10 of paragraph 1 of Article 22 and paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

This regulation of restructured meat products is applicable to meat or fishery products made of one or more of the processing technology by reformed, combined or pressure-shaped, and the appearance of the product for the steak (slice), could lead to consumers' misleading as whole pieces of meat products.

### **Article 3**

This regulation of artificially marbled meat products is applicable to the meat products injected, prepared with fat or fat mixed with raw materials, food additives.

### **Article 4**

Prepackaged foods of Restructured or Artificially Marbled meat shall be labeled in Chinese with the word "Restructured", "Artificially Marbled", or the words with equivalent meaning shall be marked in the product name. The note "only for well cooked" or the words with equivalent meaning shall also be labeled.

### **Article 5**

Food vendors with business registration selling Restructured, Artificially Marbled bulk foods shall label the product name in Chinese with the word "Restructured", "Artificially Marbled", or the words with equivalent meaning shall be marked in the product name. The note "only for well cooked" or the words with equivalent

meaning shall also be labeled.

Methods of labeling: Card, mark (label), notice board are permitted options for selecting either posting, hanging, erecting (inserting), sticking or other ways that can be clearly identified. The length and width of the character unit for the place of origin of mark (label) shall not be less than 2 millimeters, and not less than 2 centimeters if labeled by other methods.

#### **Article 6**

Food catering business shall label in Chinese with the word "Restructured", "Artificially Marbled", or the words with equivalent meaning shall be marked in the product name if the meals are prepared from Restructured, Artificially Marbled foods. The note "well cooked" or the words with equivalent meaning shall also be labeled.

Methods of labeling: Card, mark (label), menu or notice board are permitted options for selecting either posting, hanging, erecting (inserting), sticking or other ways that can be clearly identified. The length and width of the character unit for the place of origin of mark (label) shall not be less than 2 millimeters, and not less than 2 centimeters if labeled by other methods.

## **Regulations Governing the Labeling of Frozen Foods on the Market**

Promulgated on November 20, 2013

Effective from November 20, 2013

- (1) The regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).
- (2) This regulation applies to the frozen foods on the market, including frozen ready-to-eat food that can be served without heating and cooking, and frozen food that can only be served after heating and cooking.
- (3) Besides being labeled in accordance with the Act Governing Food Safety and Sanitation Article 22 Paragraph 1 Subparagraph 1 to Subparagraph 10, frozen foods on the market shall specify storage methods and conditions on the packaging
- (4) Frozen foods on the market that need to be heated before serving shall specify the heating conditions in addition to items mentioned in the preceding paragraphs.

## **Regulation Governing the Warning Label of Prepackaged Foods Co-Mingled with Toys**

Promulgated on February 4, 2016

Effective from January 1, 2017

If prepackaged foods co-mingled with toys, the warning statement shall be labeled on products as follows: “This product contain toys, do not swallow or inhale, adult supervision recommended” or other synonymous terms.

## **The Regulations on Fluorine Labeling for Prepackaged Food Grade Salt Products**

Promulgated on June 15, 2016

Effective from July 1, 2016

### **Article 1**

These Regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The name, reminder and nutrition labeling of prepackaged food grade salt products that add Potassium Fluoride or Sodium Fluoride shall be handled in accordance with the following provisions:

1. Products name shall be as follows: “Fluoridated salt”, “contains Fluoridated salt”, or “adds Fluoridated salt”.
2. A reminder shall be labeled on the prepackaged food grade salt with Potassium Fluoride or Sodium Fluoride added as follows: “If fluoride tablet is taken while consuming fluoridated salt, please consult your dentist before use.”, and “The fluoridated salt shall be restricted to use at home.”
3. The nutrition labeling shall be handled in accordance with “Regulations on Nutrition Labeling for Prepackaged Food Products”, and the content of Fluorine shall be stated clearly in the nutrition labeling format.

### **Article 3**

The following information may be labeled on the prepackaged food grade salt products: “May help to improve dental health.”.

### **Article 4**

The characters of the reminder shall not be less than 4 millimeter in length and width. The color of the font shall be clearly distinguishable from the background color of the product packaging.

## Regulations Governing the Product Name and Labeling of Chocolate

Amended on March 2, 2021

Effective from January 1, 2022

### Article 1

These regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 and Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### Article 2

The “chocolate” referred to herein is a food preparation of cocoa butter, cocoa powder or cocoa mass mixed with the addition of sugar, milk or food additives. The name of product shall be labeled in accordance with the following provisions:

1. The product name labeled as “dark chocolate” shall contain total cocoa solids at least 35%, cocoa butter at least 18% and fat-free cocoa solids at least 14%.
2. The product name labeled as “white chocolate” shall contain cocoa butter at least 20% and milk solids at least 14%.
3. The product name labeled as “milk chocolate” shall contain total cocoa solids at least 25%, fat-free cocoa solids at least 2.5% and milk solids at least 12%.
4. The product name labeled as “chocolate” shall be made from the raw materials with contents met with three previous requirements.

### Article 3

For chocolate that contain vegetable fats but content does not exceed the 5% of the total weight of the product, the text of “adding with vegetable fats” or texts with the same meaning shall be labeled near the product name.

### Article 4

“Filled Chocolate” is a product with one or more of the chocolates defined in the regulations with other composition. The chocolate must make up at least 25% of the total weight of the product, and the product name shall be labeled “filled chocolate” or “processed chocolate” or other synonymous terms.

## **Article 5**

The product name labeled as "chocolate spread" or "chocolate syrup" or other synonymous shall use cocoa butter, cocoa powder or cocoa mass as raw material, and add other food ingredients to semi-solid or fluid forms. The total cocoa solids is at least 5% or cocoa butter is at least 2%.

## **Article 6**

The labeling prescribed in the regulations of chocolate shall be in accordance with the following provisions:

1. Prepackaged chocolates shall be in accordance with the requirements stipulated in Article 2, Article 3, Article 4 or Article 5 of the Regulations. The font shall be larger than 2 millimeter in length and width.
2. Food vendors with Governing Taxation Registration selling bulk chocolate foods shall properly label the products at the business venue in accordance with Article 2, Article 3, Article 4 or Article 5 of the Regulations. The label may be in the form of cards, mark (label) or notice boards which in turn are either posted, hung, erected (inserted), stuck or utilized in other ways which are clearly visible. The vendors who choose to label the products with mark (label) shall make sure the font of the reminder is larger than 2 millimeter in length and width. Those who choose to label the products with other means of communication shall make sure the font of the reminder is larger than 2 centimeter in length and width.

## **Article 7**

If the labeling of the product does not comply with this regulation, it is false, exaggerated or misleading, it shall be handled in accordance with the relevant regulations of this law.

## **The Regulations on Iodine Labeling for Prepackaged Food Grade Salt Products**

Promulgated on November 1, 2016

Effective from July 1, 2017

### **Article 1**

These Regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The name, reminder and nutrition labeling of prepackaged food grade salt products that add Potassium Iodide or Potassium Iodate shall be handled in accordance with the following provisions:

1. Products name shall be as follows: “Iodized salt”, “contains Iodized salt”, or “adds Iodized salt”.
2. A reminder shall be labeled on the prepackaged food grade salt with Potassium Iodide or Potassium Iodate added as follows: “Iodine is a necessary nutrient. This salt product adds Iodine. Please consult your doctor before use if you are a thyroid patient.”
3. The nutrition labeling shall be handled in accordance with “Regulations on Nutrition Labeling for Prepackaged Food Products”, and the content of Iodine shall be stated clearly in the nutrition labeling format.

### **Article 3**

Prepackaged food grade salt products that do not add Potassium Iodide or Potassium Iodate shall have on its packaging a reminder that states “Iodine is a necessary nutrient. This salt product does not add Iodine”.

### **Article 4**

If prepackaged food grade salt products that also add Potassium Fluoride or Sodium Fluoride, products name can be as follows: “○○ salt”, “contains ○○ salt”, or “adds ○○ salt”. The “○○” means “Iodized and Fluoridated” or “Fluoridated and Iodized”.



**Article 5**

The characters of the reminder shall not be less than 4 millimeter in length and width.

The color of the font shall be clearly distinguishable from the background color of the product packaging

## **Regulations Governing the Product Names and Labeling of Prepackaged Coffee Creamer (奶精 Nai-jing) Products**

Promulgated on November 10, 2016

Effective from July 1, 2017

Prepackaged Coffee Creamer products that are labeled or claimed “奶精(Nai-jing)” in Chinese characters shall be labeled with reminder information, if the products do not contain milk or contain less than 50% of milk. The reminder label “不含乳(奶)(Non-dairy)” or “非乳(奶)為主(Not dairy based)” in Chinese shall be manifested after the product name on the product's outer package. The font size of the reminder label shall be the same as the product name.

## **Regulations Governing the Product Names and Labeling of Prepackaged Butter, Cream, Margarine and Fat Spreads**

Promulgated on February 6, 2017

Effective from July 1, 2017

### **Article 1**

The Regulations are prescribed in accordance with the provision of Subparagraphs 10 of Paragraph 1 of the Act Governing Food Safety and Sanitation Article 22.

### **Article 2**

The product names and labeling of prepackaged butter and cream shall meet the following definition.

1. Butter : A product in the form of an emulsion of the type water-in-oil containing edible butter made from fat-containing products of dairy derivatives through pasteurization, agitation, and refinement with at least 80% of milkfat.
2. Cream : A product containing fat physically separated from the milk and processed into a product in the form of an emulsion of the type oil-in-water, staying in fluidity or non-fluidity liquid state if kept above the freezing temperature, and having milkfat content at least 10%, but less than 80%.

### **Article 3**

Margarine and fat spreads are those fat-containing products in a plastic and liquid state, made from a blend of edible fats, oils, water and legal food additives, modified by the process of emulsification, chilling and kneading, or with the absence of chilling and kneading. The product names and labeling of prepackaged margarine and fat spreads shall meet the following definition.

1. If fat content of product is at least 80%, the name of it shall be “margarine”.
2. If fat content of product is at least 10% but less than 80%, the name of it shall be “fat spreads”.
3. The words that are recognized as vegetable butter shall not appear on the packages.

## **Regulations Governing the Labeling of Prepackaged Vinegar**

Promulgated on June 6, 2017

Effective from July 1, 2018

1. The Regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. For the purpose of the Regulations, vinegar refers to blended vinegar and artificial vinegar.
3. Blended vinegar produced from brewed vinegar with addition of other materials except artificial vinegar or other acidulant shall clearly indicate “blended” on the package.
4. Artificial vinegar produced by using diluted acetic acid solution or glacial acetic acid solution, adding sugar, acidulant, seasoning agent and salt, or by mixing thereof with brewed vinegar, shall clearly indicate “artificial” on the package.

## **Regulations Governing the Label Processing Method of Prepackaged Soy Sauce Products**

Promulgated on March 8, 2018  
Effective from January 1, 2019

### **Article 1**

The regulations are established under the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The “Soy sauce” referred to herein is a food preparation of materials containing plant protein such as soybean, defatted soybean, black bean and / or cereal processed by the methods described in this regulations and may add salt, sugars, alcohol, seasonings, food additives, etc.

### **Article 3**

For those products using plant protein hydrolyzed by acid or enzymes to obtain amino acids solution and with soy sauce mash or soy sauce added to perform fermentation and maturation, shall label processing method "rapid fermentation" on the packaging.

### **Article 4**

For those products using plant protein hydrolyzed by acid or enzymes to obtain amino acids solution and without the process of fermentation, which is "hydrolysis soy sauce", and shall label processing method "hydrolysis" on the packaging.

### **Article 5**

For those products that mixing with two or more soy sauce, which is "mixed or blending soy sauce", and shall label processing method "mixed" or "blending" on the packaging.

### **Article 6**

For those Products label processing method as "fermentation", which be use the materials containing plant protein made by cultivating koji mold and fermentation, the total amount of nitrogen not less than 0.8 grams/100 ml (the total amount of nitrogen of black bean soy sauce products are not less than 0.5 grams/100ml).

## Regulation of Food Allergen Labeling

Promulgated on August 21, 2018

Effective from July 1, 2020

### Article 1

This regulation is established under the provision of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### Article 2

Prepackaged food products containing following substances which cause an allergic reaction in susceptible individuals shall be labeled with the warning information on the package:

- (1) Crustacea and products thereof.
- (2) Mango and products thereof.
- (3) Peanut and products thereof.
- (4) Milk, goat milk and products thereof, except lactitol derived from milk and goat milk.
- (5) Egg and products thereof.
- (6) Nuts and products thereof.
- (7) Sesame and products thereof.
- (8) Cereals containing gluten and products thereof, except glucose syrup, maltodextrin and alcohol produced from cereals.
- (9) Soybean and products thereof, except highly refined or purified soybean oil (fat), tocopherols and their deviation, phytosterols and phytosterol esters.
- (10) Fish and products thereof, except fish gelatine used as carrier for vitamin or carotenoid preparations; fish gelatine used as fining agent in alcohol.
- (11) The use of sulphites etc., at concentrations of 10 mg/kg or more in term of total SO<sub>2</sub> which are to be calculated for final products.

### Article 3

The warning information prescribed in Article 2 shall be labeled as either way:

- (1) Labeling on the package with the term of “This product contains \_\_\_\_\_”, “This

product contains \_\_\_\_\_, unsuitable for susceptible individuals”, or other synonymous terms.

- (2) The product name claims \_\_\_\_\_, label in this way, all the allergic substances of product should be included in the product name.

## **Regulations Governing Food Allergen Labeling on the Recommended Labeling Allergens**

Amended on August 21, 2018

Effective from July 1, 2020

### **Article 1**

For prepackaged foods, food allergen labeling is required for the products that contain any of the following 11 allergens as an ingredient or food additive, regulated under Point 2 of the Regulation of Food Allergen Labeling: Crustacean shellfish, mango, peanuts, sesame seeds, milk and goat milk, eggs, tree nuts, gluten-containing cereals, soybeans, fish, and sulphite as the residue sulphur dioxide for 10 or more milligrams per kilogram of food. Besides the mandatory labeling allergens, food allergen labeling is also recommended for the products that contain any of the following allergens as an ingredient or food additive:

- (1) Cephalopods and cephalopod products: cuttlefish (calamari), neritic squid (small squid and squid), octopus, squid, etc. and relevant products such as takoyaki and dried shredded squid.
- (2) Spiral shells and Spiral shell products thereof: escargot, mussel, clam, oyster, scallop, mytilus, meretrix lusoria, abalone, etc. and relevant products such as scallop sauce, scallop candy and spiral shell sauce.
- (3) Seeds and seed products: Sunflower seed, melon seed, etc. However, sunflower seed oil, which is highly refined or purified from sunflower seeds, is not included.
- (4) Kiwis and kiwi products thereof: Kiwi jam, dried kiwi, etc.

### **Article 2**

Control measures shall be set in place to prevent food from cross contamination in the production process. If there is a risk of a food product being affected by allergen cross-contamination, such as using the same plant, equipment or production line for food containing allergenic ingredients or additives, the following statement of precautionary allergen labeling is suggested: “ The plant, equipment or production line used to produce the product is also used to process○○” or the synonymous terms.



## **Regulations Governing the Labeling of Liquid Egg Products**

Promulgated on November 7, 2019

Effective from January 1, 2020

### **Article 1**

The regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 and Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The container or external packaging of prepackaged liquid egg products shall be labelled with the storage conditions, and the word “pasteurized” or “unpasteurized” in the product name additionally. Besides, unpasteurized liquid egg products shall also be labelled with the words as follows: “The product must be used in the production of foods that will be sufficiently heated or other processing methods sufficient for effective pasteurization “or other synonymous terms.

### **Article 3**

The length and width of the font marked on the labels that indicated in the Article 2 of the Regulations shall not be less than 2 millimeters. The font size of the words "pasteurized" or "unpasteurized" shall be the same as the other font size of the product name.

### **Article 4**

Bulk liquid egg products shall label the products in accordance with Article 2 of the Regulations. The expiry date and country of origin shall also be labelled. The label may be in the form of mark (label), cards or notice boards which in turn are either stuck, posted, hung, erected (inserted) or utilized in other ways which are clearly visible.

The font that marked on the mark (label) in the preceding paragraph shall not be less

than 2 millimeters in length and width, and not less than 2 centimeters if labelled by other means. The font size of the words "pasteurized" or "unpasteurized" shall be the same as the other font size of the product name.

## Regulations Governing the Labeling of Small Prepackaged Food

Promulgated on September 1, 2021

Effective from September 1, 2021

### Article 1

The Regulations are prescribed in accordance with Article 23 of the Act Governing Food Safety and Sanitation.

### Article 2

Prepackaged food where the largest surface area is less than 20 cm<sup>2</sup> and being sold in the market may choose one of the following labeling methods:

1. Only the following items shall be labeled on the outer packaging of the product :
  - (1) product name;
  - (2) expiry date;
  - (3) name and telephone number of the responsible domestic company;
  - (4) country of origin and the country of origin of raw materials designated by the central competent authority in a public announcement;
  - (5) reminder information such as allergens.
2. In addition to the product name and expiry date shall be labeled on the outer packaging of the product, the labeling items according to Article 22 Paragraph 1 Subparagraphs 2 to 6 and 8 to 10 of the Act Governing Food Safety and Sanitation, shall be disclosed electronically on the outer packaging of the product by using "QR Code" or other electronic means. The reminder information shall also be accompanied on the top or bottom of the electronic labeling as follows: "Scan here to get product information" or equivalent words.

# **Regulations Governing the Labeling of Prepackaged Honey and its Syrup Products**

Promulgated on May 11, 2022

Effective from July 1, 2023

## **Article 1**

The Regulations are prescribed in accordance with the provision of Subparagraphs 10 of Paragraph 1 of the Act Governing Food Safety and Sanitation Article 22.

## **Article 2**

For prepackaged honey and its syrup products with a honey content at or higher than 60%, the font size of the product name shall be consistent, and shall also meet the following requirements:

1. For products with added sugar (syrup), the name of the product shall be labeled with "Sugar Added Honey" or equivalent words.
2. For products with added materials other than sugar (syrup), and without added sugar (syrup), the name of the product shall be labeled with "With ○○ (name of non-honey material) Honey" or "Blended Honey" or equivalent words.

## **Article 3**

Prepackaged honey and its syrup products with less than 60% honey content, and whose names contain the word "Honey", shall be labeled with "Honey Flavor" or equivalent words in the product name, and the font size of the product name shall be consistent.

## **Article 4**

Country of origin of the honey material shall be labeled on the outer packaging of prepackaged honey and its syrup products, and shall be labeled in descending order according to the honey content of the product.

## **Article 5**

The prepackaged honey product is labeled as "Honey", "100% Honey", "Pure Honey"

or equivalent words, which shall be product with only honey component.

For syrup products without honey, the name of the product shall not be labeled with the word "Honey" or equivalent words.

#### **Article 6**

If the labeling of the product does not comply with this regulation, and appears to be false, exaggerated or misleading, it shall be fined in accordance with the relevant regulations of this law.

## **Labeling of the Ingredients shall Indicate the Percentage of the Main Ingredient**

## Regulations Governing the Labeling of Packaged Rice Vermicelli

Promulgated on November 29, 2013

Effective from July 1, 2014

1. The Regulations are prescribed in accordance with Subparagraph 10 of Paragraph 1 and Paragraph 2 of Article 22 of the Act Governing Food Safety and Sanitation.
2. This regulation is applicable to products made more than 50% of rice (rice flour) through processes of gelatinization, extrusion, cooking and drying. These products include:
  - (1) (Pure) rice vermicelli (純米粉(絲)、米粉(絲)): Products made 100% of rice.
  - (2) Blended rice vermicelli (調合米粉(絲)): Products made of at least 50% percent of rice while containing other kinds of grain powder as ingredients.
3. Pure rice vermicelli, rice vermicelli and blended rice vermicelli products for sale shall indicate the percentage of rice or other terms of same meaning on the package. The color of the indication shall be contrast sufficiently with the background. The font shall not be smaller than 4 mm in length and width.
4. The percentage of rice content mentioned in the preceding paragraph refers to the percentage of rice weight to total weight of pure rice vermicelli, rice vermicelli and blended rice vermicelli minus the weight of food packet, oil packet and seasoning powder.
5. Every character of the name of pure rice vermicelli, rice vermicelli and blended rice vermicelli products shall be fully indicated and shown in same font on the package.

## **Regulations Governing the Product Names and Labeling of Prepackaged Fresh Milk, Sterilized Milk, Flavored Milk, Milk Drink, and Milk Powder**

Promulgated on February 19, 2014

Effective from July 1, 2014

1. The Regulations is enacted pursuant to Article 22 Paragraph 1 Subparagraphs 2 and 10 of the Act Governing Food Safety and Sanitation.
2. Definition of terms referred:
  - (1) Fresh milk: It refers to the milk product made from raw milk subjected to pasteurization and refrigeration after packaging, and thereafter sold for consumption. Included milk fat adjustment fresh milk (high-fat, whole, low-fat, skimmed), fortified fresh milk, low-lactose fresh milk.  
Fortified fresh milk can add nutrients contained in raw milk
  - (2) Sterilized milk: It refers to the milk product made from raw milk or fresh milk subjected to high-pressure or high-temperature sterilization process, packed in aseptic package, and thereafter sold for consumption; or it refers to the bottled (canned) milk product made from fresh milk subjected to high-pressure or high-temperature sterilization process and sold for consumption, can be stored at room temperature.
  - (3) Flavored milk: It refers to the processed milk product containing at least 50% of raw milk, fresh milk, or sterilized milk for major ingredients mixed with flavor additive.
  - (4) Sterilized flavored milk: It refers to the milk product made from flavored milk subjected to high-pressure or high-temperature sterilization process, packed in aseptic package and sold for consumption; or it refers to the bottled (canned) flavored milk product subjected to high-pressure or high-temperature sterilization process and sold for consumption.
  - (5) Milk drink: It refers to the processed milk product reconstituted by combining



dry milk powder or concentrated milk with water following the same proportion constituting the original milk, and the milk ingredients therein contained constitute at least 50% of the product; or it refers to the processed milk product combining powder with raw milk, fresh milk, or sterilized milk, wherein milk ingredients constitute at least 50% of the product; the non-milk based raw materials and food additives may be used.

- (6) Sterilized milk drink: It refers to the milk drink subjected to high-pressure or high-temperature sterilization process, packed in aseptic package and sold for consumption; or it refers to the bottled (canned) milk drink subjected to high-pressure or high-temperature sterilization process and sold for consumption.
  - (7) Milk powder: It refers to the milk product in powder form obtained after raw milk has been dehydrated. Included milk fat adjustment milk powder (high-fat, whole, low-fat, skimmed), fortified milk powder, low-lactose milk powder. Fortified milk powder can add nutrients contained in raw milk.
  - (8) Modified milk powder: It refers to the milk product in powder form which used raw milk, fresh milk, or milk powder for major materials, and mixed with edible whey powder or added with other nutrients, flavor ingredients, or a variety of essential food additives, then processed into a powder mixture.
3. Prepackaged milk products in compliance with the foregoing provisions and being sold in the market shall be properly labeled pursuant to Article 22 Paragraph 1 Subparagraphs 1 to 8 of the Act Governing Food Sanitation. The product name appearing on the label should comply to the following regulations:
- (1) Fresh milk: The name of product should be “Fresh milk” or “Milk”.
  - (2) Sterilized milk: The name of product should be “Sterilized milk”, “Milk”, or words of similar meaning. If the product name does not contain the words of “Sterilized milk”, the words of “Sterilized milk” in Chinese should be manifested on an easily visible section of the product’s outer package.
  - (3) Flavored milk: The name of product should be “Flavored milk”, “Milk”, or

words of similar meaning. If the product does not contain the words of “Flavored milk”, the words of “Flavored milk” in Chinese should be manifested on an easily visible section of the product’s outer package.

- (4) Sterilized flavored milk: The name of product should be “Sterilized flavored milk”, “Milk”, or words of similar meaning. If the product does not contain the words of “Sterilized flavored milk”, the words of “Sterilized flavored milk” in Chinese should be manifested on an easily visible section of the product’s outer package.
  - (5) Milk drink: The name of product should be “Milk drink”, “Milk”, or words of similar meaning. If the product does not contain the words of “Milk drink”, the words of “Milk drink” in Chinese should be manifested on an easily visible section of the product’s outer package.
  - (6) Sterilized milk drink: The name of product should be “Sterilized milk drink”, “Milk”, or words of similar meaning. If the product does not contain the words of “Sterilized milk drink”, the words of “Sterilized milk drink” should be manifested on an easily visible section of the product’s outer package.
  - (7) Milk powder: The name of product should be “Milk powder”.
  - (8) Modified milk powder: The name of product should be “Modified milk powder”. If the product does not contain the words of “Modified milk powder”, the words of “Modified milk powder” in Chinese should be manifested on an easily visible section of the product’s outer package.
4. Prepackaged sterilized milk, sterilized flavored milk, and sterilized milk drink products sold in the market should clearly declare the sterilization process of the product in Chinese on an easily visible section of the package.
  5. Prepackaged modified milk powder products sold in the market should bear a label indicating the percentage of milk powder content in Chinese on an easily visible section of the package.

The term “Percentage of the Milk Powder Content” refers to the weight percentage of milk powder contained in the solid milk powder product vis-à-vis the total weight of the formula; computation formula is as shown below:

$$\text{Milk powder content (\%)} = \frac{\text{Weight of Milk Powder}}{\text{Total Weight of the Formula}} \times 100\%$$

6. The font size of the following label scripts should exceed 4 mm and the color tone of the text should be in apparent contrast to the background color of the package:
  - (1) On the matter of products under Paragraph 3, if the product name does not contain the words of “Sterilized milk”, “Flavored milk”, “Sterilized flavored milk”, “Milk drink”, “Sterilized milk drink”, or “Modified milk powder”, the product outer package should manifest the words of “Sterilized milk,” “Flavored milk”, “Sterilized flavored milk”, “Milk drink”, “Sterilized milk drink”, or “Modified milk powder”.
  - (2) The percentage of the milk powder content of modified milk powder products.
7. Infant formula, follow-up infant formula, and infant formula for special medical purposes are not regulated within the scope of this provision.

## **Regulations Governing the Labeling of Packaged Beverages Claimed to Contain Fruit and/or Vegetable Juice**

Promulgated on March 3, 2014

Effective from July 1, 2014

1. These regulations are established pursuant to Article 22, Paragraph 1, Subparagraph 10 and Paragraph 2 of the Act Governing Food Safety and Sanitation.
2. Scope of Application: Packaged beverages of which the packaging bears the names (product name included) and/or images (illustrations) of fruit and/or vegetable and sold for direct consumption.
3. Packaged beverages which contain at least 10% of fruit and/or vegetable juice shall be labeled in accordance with the following requirements:
  - 3.1 Explicitly declare the juice content percentage of fruit/vegetable on the front of the package.
  - 3.2 For mixed or assorted fruit and vegetable juice beverages whose product name is labeled fruit and vegetable juice shall meet the following requirements:
    - 3.2.1 If the product name shows all the fruit and vegetable added in the product, their respective contents shall be indicated in descending order of weight.
    - 3.2.2 If the product name does not show all the fruit or vegetable added in the product, the product name or the front of the package shall explicitly declare the word “assorted juice”, “mixed juice” or other synonymous terms.
4. Packaged beverages which contain less than 10% of fruit and/or vegetable juice, “fruit and vegetable juices” can only be labeled on the name of the ingredients and nowhere else. It shall be declared on the front of the package with the word “fruit (vegetable) juice content less than 10%”, or explicitly indicate the fruit/vegetable juice content percentage as an alternative.
5. Packaged beverages containing no fruit or vegetable juice shall be labelled in accordance with the following requirements:

5.1 It is required that the front of the package shall explicitly declare “no real fruit or vegetable juice contained” or other synonymous terms.

5.2 Where the “name” of a product includes a fruit or vegetable name, the product name shall explicitly state “taste”, “flavored”, or other synonymous terms.

6. The foregoing which shall explicitly declare on the front of the package as “assorted juice”, “mixed juice”, the juice content percentage of fruit/vegetable”, “no fruit or vegetable juice contained”, “fruit and vegetable juice content less than 10%”, or other synonymous terms shall be printed in a color different from the background color for clarity. The font size should comply with the form below

Product Volume(mL)	Font Size(cm) (Length & Width)
150 or less	Each 0.3 or more
151-300	Each 0.5 or more
301-600	Each 0.8 or more
601 or more	Each 1.2 or more

# **Other Principles and Guidelines**

## **Guidelines for Evaluation of Expiry Dates of Prepackaged Food Products**

Promulgated on April 24, 2013

Amended on December 20, 2022

### **1. Objective:**

Prepackaged food products shall label expiry dates according to Subparagraph 7, Paragraph 1, Article 22.

This Guideline provides guidance for food product manufacturers to evaluate expiry dates of their products. Food businesses can refer to this Guideline to design appropriate evaluation plan to determine the expiry date of each food product by self-management, so as to ensure the food product will not deteriorate or rot, nor will any circumstance contrary to the Act Governing Food Safety and Sanitation occur, before the expiry date.

This Guideline also serves as guidance and reference for the health competent authorities to implement expiry dates inspection of food products produced by manufacturers.

### **2. Responsibilities for determining expiry date:**

The “expiry date” of a food product is affected by various factors, such as the raw material used, manufacturing process, transportation, storage, and physical display environment. As a result, food shelf-life test shall be designed according to the aforementioned individual factors so as to determine the expiry date. Food manufacturers have the responsibility to self-evaluate, or entrust food experts to design the expiry date evaluation plan.

### **3. Applicable scope of food businesses:**

Food product manufacturers.

### **4. Definition of terms:**

- (1) Prepackaged food: Shall refer to a food product that is packed in a sealed package, with tamper-evident characteristic, and thus enabling its longer-time keeping, and wider-area selling.
- (2) Shelf life: Shall refer to the time range within which a prepackaged food product will maintain its product value under specific storage conditions, such as “Shelf life: Two years”.
- (3) Expiry date: Shall refer to the last date that a prepackaged food product will maintain its product value under specific storage conditions, such as “Expiry date: YYYY/MM/DD”.
- (4) Water activity ( $a_w$ ): Shall refer to the free water inside a food product, that is, the ratio between the vapor pressure of the food product and the saturated vapor pressure of pure water at the same temperature inside a fully-sealed container.
- (5) Sensory evaluation: Shall refer to the scientific method used to measure and analyze the appearance, flavor, and texture of a food product by using the five human senses, that is sight, smell, taste, touch, and hearing.
- (6) Product value: Shall include the sanitation, safety, nutritional quality, and sensory quality of a food product.
- (7) Accelerated shelf-life studies: Generally conducted by deliberately accelerate product deterioration by increasing the temperature, to estimate the shelf life of a food product under normal storage conditions.

5. Determination of the expiry date of a food product and factors to be considered:

When the expiry date of a food product is determined, it must consider the composition and manufacturing process of the food product as well as other environmental affecting factors such as changes in temperature, humidity, light, and time. As a result, these factors should be analyzed to produce a food product deterioration curve, according to which the expiry date is predicted, so as to ensure the effectiveness and safety when the food product is consumed. In other words, the food product must be safe for consumption, and its appearance, taste, texture, and flavor well preserved, as well as its nutrition labeling conformed, before the expiry date.

Different countries have different requirements on date labeling of prepackaged food products, which may result in different labeling meanings. For example, “use by” and “expiration date” are similar in definition to Taiwan’s “expiry date”. In addition, “best before” and “best if eaten by this date” mean that the food product



can maintain the best quality before this date and does not mean that the food product is unsafe or deteriorated after this date. As a result, when the food businesses label the expiry date on imported food product, said expiry date labeled on the imported food product can differ from the “best before” or “best if eaten by this date” labeled on the original package only if the manufacturer can provide relevant information to prove that it is equivalent to the definition of Taiwan’s “expiry date”. If the aforementioned supporting evidence is not provided, then “best before” and “best if eaten by this date” shall be deemed to be the “expiry date”.

- (1) The characteristics of each individual food product should be fully considered. The expiry date shall be determined by using objective indicators, and by accurately evaluating the food product’s safety and quality.
  - (2) Objective indicators should refer to quantitative indicators, such as “physical test”, “chemical test”, and “microbiological test”. The “color” and “flavor” in the “sensory evaluation” of general subjective indicators can be regarded as objective indicators under appropriate control conditions and the data obtained by qualified evaluator with correct methods. It is different from the subjective accumulated “experience value”.
  - (3) The characteristics of each individual test and indicator must be fully understood and implemented to ensure the reliability, appropriateness, and objectivity of the results. The expiry date is thus determined through a comprehensive judgement.
  - (4) The deterioration data can be established according to the internal and external factors of the food product, as well as by referring to the regulatory standards. This is followed by the evaluation method listed in 6(1) or 6(2) so as to determine the expiry date.
6. Evaluation method for the expiry date:

(1) Direct method: Must contain the following six steps.

① Step 1: Analyze factors that contribute to the deterioration of the food product.

- I. The intrinsic deterioration factors of the product itself: Raw materials, composition and formulation of the product, water activity ( $a_w$ ), pH

value, redox potential (Eh), oxygen permeability.

- II. Deterioration factors during processing and storage: Processing procedure, sterilization method, manufacturing environment and equipment, packaging materials and storage environment, temperature, and humidity.
- III. Deterioration factors in the product circulation and sales process: Storage, transportation and exhibition sales environment, temperature, and humidity and other conditions.

② Step 2: Select a method to evaluate product quality or safety.

According to Step 1, find out the factors that may affect the food deterioration, then select the appropriate analysis method.

The health regulations clearly set out sanitation standards for different categories of food products. As a result, microbiological analysis is the primary evaluation indicator for the expiry date. Components or nutritional labeling must comply with the Regulations on Nutrition Labeling for Prepackaged Food Products; they are thus the second evaluation indicator. Physical and chemical analyses, as well as sensory evaluation, can be used to evaluate and analyze the quality of the food product before the expiry date; they have no correlation to deterioration caused by microorganisms. Therefore, they are listed as the third indicator.

- I. Microbiological analysis: Use microbiology method to evaluate the quality deterioration of food from the date of manufacturing, and select microorganism indicators that can achieve effective evaluation (such as total plate count, coliform count, *E. coli* count, low temperature bacteria psychrophile count, spore-former count) in accordance with the food category, manufacturing method, temperature, time, and packaging materials and other storage conditions. These indicators provide objective, useful, reasonable and scientific data. It is recommended that

the microbiological test be conducted according to the test method prescribed by the Ministry of Health and Welfare. However, microbiological rapid testing may be adopted if it produces the same test results as the prescribed method without sacrificing food safety.

II. Sensory evaluation: Evaluate the characteristics of the food product by way of a person's sight, smell, and taste senses by following different individual techniques under specific conditions. Compared with tests done by instrument, sensory tests may have higher variation rates. The reproducibility of the results is affected by factors such as the evaluator's physical conditions and time of evaluation. However, sensory evaluation remains an effective method in the event that an appropriate instrument has not yet been developed, or instrument sensitivity is not as high as that of human. In order to enhance the reliability and validity of data, sensory evaluation must be conducted by trained evaluators using the correct methods under adequately controlled conditions. The data must be statistically analyzed using statistics.

III. Physical and chemical analyses: According to the characteristics of food, select indicators that are capable of reflecting the traits of the food product, and use physical and chemical analyses to evaluate the deterioration from the manufacturing date in order to determine the expiry date. The analyzing indicators may include viscosity, turbidity, specific gravity, peroxide value, acid value, pH value, brix, acidity, headspace gas analysis, free fatty acid, and volatile gas. These indicators can provide objective, useful, reasonable, and scientific data. The test values of these indicators on the manufacturing date are compared with values obtained at different time points after the manufacturing date to determine the deterioration in quality.

IV. Component analysis: Deterioration of nutrients or specific components from the date of food manufacturing, such as vitamins, polyphenols, or fatty acids.

These indicators can express the content of nutrients or specific components with objective data. It is used to judge whether it meets the label value of the component.

③ Step 3: Design the evaluation plan for the expiry date.

- I. Select the testing experiment.
- II. Determine the length of the shelf-life test, and frequency of sampling.  
It is recommended that the time points of sampling include at least the starting point on the manufacturing date, the projected expiry date as the final time point, and the time in between as the third time point. Sampling may be conducted beyond the projected final time point to confirm the appropriateness of the selected final time point.
- III. The number of samples for each sampling test shall be three repetitions, or it shall be determined in the evaluation plan according to the product characteristics.
- IV. When to begin the shelf-life test: This can be conducted at the final stage of product development or at the time when the products are manufactured to sell on the market. Moreover, the test must be conducted in the season (usually during the summer) when stability is most likely to be affected. Product variation must also be considered. It is recommended that more than one experiment be arranged.

④ Step 4: Implement the evaluation plan for the expiry date.

When the evaluation is implemented, it is preferable that the food products are in the same transportation and storage conditions as those in the normal process from manufacture through to consumption, or that the food product is stored under specific temperature and humidity. All conditions should be accurately controlled and recorded in detail.

⑤ Step 5: Determine the expiry date.

Refer to the regulatory standards to set the expiry date: If the microbiological method is adopted to evaluate the deterioration of the food product, the microbiological standards of different food product must be considered. Conform to the microbiological standards of different foods categories prescribed by the Ministry of Health and Welfare.

⑥ Step 6: Monitor the expiry date.

If there is any change in the manufacturing process or environment that may affect the expiry date of the product, the expiry date shall be re-evaluated. Sampling tests must be run from the transportation and retail system when the product is launched on the market. If the test results show that the expiry date is not appropriate, it must be revised.

(2) Indirect method:

- ① For products with longer expiry dates, accelerated shelf-life studies may be adopted to estimate the expiry date. Common practice is to increase the storage temperature in order to accelerate the deterioration of the food product and thus estimate the expiry date under specific storage conditions.
- ② If the manufacturer's own (or other) factory has a product having similar formula or process that has been on the market for more than one year, and there has no product abnormality or customer complaint within the expiry date, then this can be used as the reference for evaluating the expiry date.

7. Expiry date evaluation case studies:

(1) Frozen pre-fried chicken nuggets

① Product description

Name of ingredients	Batter-dipped restructured chicken nuggets
Processing method	Inspection and acceptance of raw materials → Storage → Pretreatment → Processing (including pre-frying) → Freezing → Packaging

Packaging method and explanation	Laminated bag
Storage and transportation	Stored at -18°C
Consumption method	Reheat/cook before consumption

② Refer to Step 1 in Fig. 1: Since the processing of the frozen chicken nuggets requires pre-frying, also normal microorganisms will not grow during frozen storage, determination of the expiry date is more related to the acceptance of sensory evaluation.

③ Refer to Step 2 in Fig. 1: Select evaluation of rancid odor and texture changes.

④ Refer to Steps 3 and 4 in Fig. 1: Design and implement evaluation method. Given that rancid odor and texture changes arise slowly and, in addition, similar product sold on market has a shelf life of 12 months, storage tests of 0, 6, 9, 12 and 15 months can be planned and implemented.

⑤ Refer to Step 5 in Fig. 1: Determine the shelf life during which that the product still maintains its original good flavor and texture, according to sensory evaluation acceptance. This is used to estimate the expiry date.

⑥ Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor any possible change in product safety and quality which is caused by storage, transportation and retailing. The expiry date is then revised accordingly.

## (2) Chilled vegetable salad

### ① Product description

Name of ingredients	Fresh vegetable
Processing method	Inspection and acceptance of raw materials → Storage → Washing → Cutting → Packaging → Refrigeration
Packaging method and	Laminated bag

explanation	
Storage and transportation	Stored at 0–7°C
Consumption method	Ready to eat

- ② Refer to Step 1 in Fig. 1: Because the initial bacterial count of the product is high and the product has not been sterilized, the growth of microorganisms is easy to cause spoilage of the product. In addition, given that the product is freshly cut vegetables, its color and scent may change rapidly.
- ③ Refer to Step 2 in Fig. 1: Select evaluation of microorganisms and sensory quality of scent and color.
- ④ Refer to Steps 3 and 4 in Fig. 1: Design and implement evaluation method. The changes can occur rapidly, and similar product on the market has a shelf life of 5 days. Thus, the storage tests of 0, 1, 3, 5, 7 days can be planned and implemented to analyze microorganisms as well as sensory qualities of scent and color.
- ⑤ Refer to Step 5 in Fig. 1: The expiry date is determined in accordance with the occurrence of the earliest change to an unacceptable indicator. According to the regulatory standards, the maximum level of microorganisms in fresh vegetable salad shall conform to the Sanitation Standards for Foods microorganisms. Note that the product quality (color and flavor) may become unacceptable although the product is safe for human consumption and microorganisms are under limit. The best way to determine the most appropriate shelf life is to consider both changes in microorganisms and quality during the storage period. The expiry date is then estimated accordingly.
- ⑥ Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor any possible changes in product safety and quality caused by storage, transportation, or and retailing. The expiry date is then revised accordingly.
- (3) Green tea beverage registered as health food
- ① Product description

Name of ingredients	Water, soluble fiber, green tea, sodium L-ascorbate,
Processing method	Inspection and acceptance of raw materials → Storage → Pretreatment → Processing → Sterilization → Packaging
Packaging method and explanation	Aseptic filling to PET bottles
Storage and transportation	Room temperature
Consumption method	Ready to drink

- ② Refer to Step 1 in Fig. 1: The product has been sterilized at high temperature and aseptically filled, there is less chance for hygiene and safety problems to occur. Therefore, the consideration is changes in flavor or color. At the same time, since the product is registered as a health food, it must conform to the labeled content of its index component, i.e., soluble fiber.
- ③ Refer to Step 2 in Fig. 1: Select evaluation ingredient indicator and changes in flavor or color.
- ④ Refer to Steps 3 and 4 in Fig.1: Design and implement evaluation method. Since the index component and flavor/color change slowly, and, in addition, a similar product on market has a shelf life of 9 months, storage tests of 0, 6, 9, 12 months can be planned and implemented to analyze the soluble fiber content and changes in flavor or color.
- ⑤ Refer to Step 5 in Fig. 1: Determine the shelf life in accordance with the content of the pre-determined index component and the results of sensory evaluation of the product. The expiry date is then estimated accordingly.
- ⑥ Refer to Step 6 in Fig. 1: After the product is launched on the market, continue to monitor for any possible changes in product safety or quality that are caused by storage, transportation, or exhibition and retailing. The expiry date is then revised accordingly.



8. Note:

- (1) Food additive businesses may refer to this Guidelines when determining and implementing the expiry date for their products.
- (2) Refer to the website of the Food and Drug Administration of the Ministry of Health and Welfare (<http://www.fda.gov.tw>).

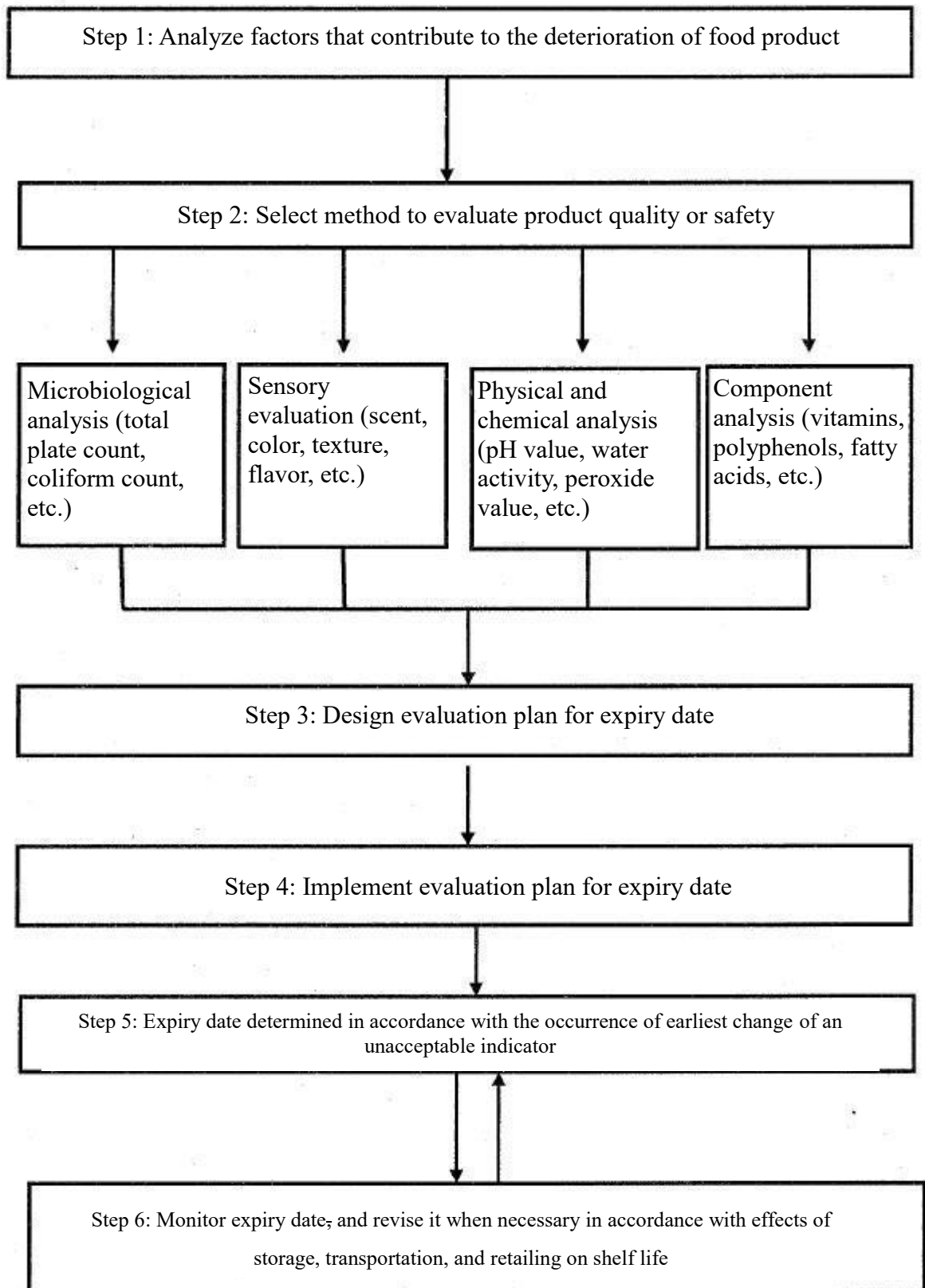


Fig. 1: Expiry date evaluation procedure for prepackaged food products

9. Checklist (for use by food businesses )

<b>Evaluation of expiry date for packaged food product</b> <b>Self-check form</b>			
<b>Factory (company) name:</b>		<b>Inspection date: YYYY /MM /DD</b>	
<b><u>Product information</u></b>			
Product name:			
Ingredients:			
Processing method:			
Shelf life:			
Intended consumption method:			
Product description: Check (✓) all that apply			
<input type="checkbox"/> New product <input type="checkbox"/> Product already on market for more than one year <input type="checkbox"/> Frozen storage <input type="checkbox"/> Cold storage <input type="checkbox"/> Room temperature storage <input type="checkbox"/> $a_w \geq 0.85$ <input type="checkbox"/> $a_w < 0.85$ <input type="checkbox"/> $pH \geq 4.6$ <input type="checkbox"/> $pH < 4.6$ <input type="checkbox"/> Vacuum packaging <input type="checkbox"/> Nitrogen gas packaging <input type="checkbox"/> Ordinary packaging			
<b><u>Check items</u></b>			
Item No.	Contents	Result (✓)	Note
1	Reference made to supporting evidence of similar product by own (other) factory	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2	Design detailed processing procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Fully aware of related product deterioration factors	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Use appropriate method to evaluate product's quality and safety	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5	Determination of the expiry date is supported by lab data	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6	Clearly list reference standards from regulations	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Adopt sound method to monitor expiry date	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8	Put into place correction measures if there is any abnormality of the product prior to the expiry date	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Opinion for handling:			
Signature of inspector:			
Signature of supervisor:			

10. Checklist (For use by health authority)

Evaluation of expiry date for packaged food product Checklist		
<div style="display: flex; justify-content: space-between;"> <span>_____ Health Bureau</span> <span>Inspection date: YYYY /MM /DD</span> </div>		
<b><u>Basic information</u></b>		
Factory (company) name:		
Factory (company) address:		
Factory (company) telephone number:		
<b><u>Check items</u></b>		
Product category/  Product name	Contents (Results of inspection(✓))	
	Factory has retained basis for determining expiry date of packaged food product	Factory has maintained relevant self-check forms and completed signature records
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Opinion for handling:		
Signature of factory:		
Signature of inspector:		
Signature of competent authority supervisor:		

## **Guidelines for Labeling of Ready-to-Eat Bulk Food Products**

Amended on March 17, 2021

### **I. Introduction:**

Consumer behavior has seen gradual changes in recent years given that they have started to buy ready-to-eat food in convenience stores and supermarkets. Encouraging food businesses to disclose more product information on the packaging of ready-to-eat bulk food products, in addition to the already-required labeling of product name and country of origin as per Article 25 of the Act Governing Food Safety and Sanitation, will benefit consumers in that they will have more information when choosing food products. Therefore, this guidance is formulated for food businesses to follow.

### **II. Scope:**

This guidance applies to ready-to-eat bulk food, excluding freshly baked (grilled) foods, freshly cooked ready-to-eat foods, and fresh fruit, vegetable, livestock, poultry, and marine products that have not been processed.

### **III. Definition:**

Definitions of terms in this guidance are as follows:

- (1) Ready-to-eat food product: Fresh or prepared food that is stored at temperatures from 0 to 18°C, and which can be directly eaten or needs to be heated (reheated) before being ready to eat (the heating method is not intended to sterilize the food through high temperatures).
- (2) Ready-to-eat bulk food product: Bulk food that conforms to Article 20 of the Enforcement Rules of the Act Governing Food Safety and Sanitation, as well as subparagraph 1 of Paragraph 1 of this Definition of terms.

### **IV. Labeled categories:**

- (1) Name of ingredient: those that contain two or more ingredients shall indicate

the respective ingredients.

- (2) Net weight, volume, or quantity.
- (3) Names of food additives: The names shall conform to the names formulated by the central competent authority. If the food product contains a mixture of two or more food additives, shall indicate the name of each additive separately.
- (4) Name, telephone number, and address of the manufacturer or that of the responsible domestic company.
- (5) Expiry date.
- (6) Other voluntary labeling: Storage methods and conditions; if the food product needs to be prepared before eating, the preparation method, nutrition labeling, and allergen labeling.

The value and the range of allowable error in the aforementioned nutrition labeling shall meet the criteria Table 1. The nutrition labeling may be labeled according to the Guidelines for Front of Package Nutrition Labeling for Food Products or be disclosed electronically in the form of a QR Code.

The QR Code in the preceding paragraph shall be in the form of a fixed or printed label that is not prone to wear and tear. The words “Scan here to view nutrition information” or words of the same meaning shall be indicated above or below the QR Code. Moreover, the QR Code shall be readable by QR Code scanner apps installed in commercially-available mobile devices (such as smartphones) or QR Code scanner equipment supplied in the place of sales, so consumers can directly read the nutrition information.

V. Characters size: The size of characters shall conform to Article 19 of the Enforcement Rules of the Act Governing Food Safety and Sanitation.

Table 1: Range of allowable error for nutrition labeling values.

Item	Range of allowable error
Protein, Carbohydrates	80%~120% of the labeled value
Calories; Fat, Saturated fat, Trans fat, Cholesterol, Sodium, Sugar	$\leq 120\%$ of labeled value
Other labeled nutrients	$\geq 80\%$ of labeled value
Vitamin A, Vitamin D	80%~180% of the labeled value

## Regulations Governing the Claiming and Labeling of Whole Grain Products

Amended on May 1, 2013

1. Principles of the claiming and labeling of whole grain products:
  - (1) If whole grain content accounts for more than 51%<sup>2</sup> of the total weight<sup>1</sup> of a solid product, it can claim to be a whole grain product. If a single kind of grain accounts for more than 51% of the total weight of the product, the product can be named after that grain. For example, “whole wheat ○ ○”, “whole buckwheat ○ ○”.
  - (2) If whole grain content does not account for more than 51% of the total weight of the product, it cannot claim to be a whole grain product. Only terms such as “Parts of the materials are made from whole grain powder. (For example, whole wheat)” or “The product contains some whole grain powder. (For example, whole-wheat flour)”
  - (3) If a product claims to be whole grain raw material powder<sup>3</sup>, it shall be 100 percent whole grain.

Note1: Calculation of the percentage by weight of solid whole grain content in the formula is as follows. (Weight of whole grain content on a dry basis / Weight of the formula on a dry basis) x 100 % Dry basis is an expression of the weight calculation, in which the presence of water is ignored for the purposes of the calculation. For example, 100 g of milk contains 90 g of water. The weight on a dry basis is 100-90=10 (g).

Note2: The calculation shall be correct to one decimal place and round to nearest integer according to CNS 2925 “Practices for Designating Significant Places in Specific Limiting Values”. Namely, if the whole grain content accounts for 50.4% of the total weight of the product, it is regarded as 50%. If the whole grain content accounts for 50.5% of the total weight of the product, it is regarded as 50%. If the whole grain content accounts for 50.6% of the total weight of the product, it



is regarded as 51%.

Note3: The whole grain raw material powder is made from whole grains and does not contain any material or additive. For example, whole-wheat flour, whole barley flour, whole-buckwheat flour, whole-corn flour, brown rice flour, black rice flour, red glutinous rice flour, dehulled adlay flour, etc.

2. Definitions of grain and whole grain are as follows.

Name	Definition	Description
Grain (Grain and grain powder)	<ol style="list-style-type: none"> <li>1. True grains and pseudograins for human consumption.</li> <li>2. Grains included in this definition:  <b>True grains:</b> Include rice, wheat, corn, oats, barley, rye, sorghum, millet, adlay, Job's tears, wild rice, teff, triticale, fonio, canary seed, etc.  <b>Pseudograins:</b> Include amaranth, buckwheat, quinoa, etc </li> </ol>	<ol style="list-style-type: none"> <li>1. In order to comply with international standards, the international definition of grains is referred.</li> <li>2. Beans, oilseeds, and root crops are not considered as grains.</li> </ol>
Whole grain (Whole grain and grain powder)	Grains with an attached fruit layer (bran), germ and endosperm.	A whole grain is still regarded as a whole grain even if it is broken, crushed, grounded into powder, or flake, but retains the same proportion of endosperm, germ, and bran as the original grain.

## **Principles for Managing the Labeling of Foods (including Raw Materials) with Intact Package for Business Use**

Promulgated on January 20, 2014

### **Article 1**

The labeling of prepackaged foods (including raw materials) for business use, whether manufactured locally or imported, shall be completely labeled in accordance with Article 22 of the Act Governing Food Safety and Sanitation. Interpretation letters DOH No. 0910065723, DOH No. 0910053196 and DOH No. 0910037302, issued by the former Department of Health of the Executive Yuan on October 15, 2002, September 3, 2002, and December 6, 2013, respectively, are no longer applicable.

### **Article 2**

Imported foods (including raw materials) that need to be repackaged, sub-packaged or further processed, the complete labeling in Chinese on the external packaging ~~is~~ may not be required if there is identifiable original label or information for managing the products. For all other situations, Chinese labeling shall be completed prior to the sale (object including food factories, catering industry, or consumers) of the products.

(Interpretation letter TFDA No. 1029009423 issued on December 6, 2013; Interpretation letter TFDA No. 1021351991 issued on January 20, 2014)

## Regulations Governing the Labeling of Fungi Product

Promulgated on March 2, 2015

Effective from July 1, 2015

1. Scope of application: Foods made from fungi.
2. The outer packaging of foods that contain fungi shall clearly state the Chinese name and Latin name of the fungi used in production, with the parts used (fruit body, mycelium, or both) and the cultivation methods specified.
3. A product that contains fruit body can use the generic or family name of the fungus in its name. For example, Ganoderma (靈芝), Antrodia cinnamomea (樟芝).
4. A product that contains mycelium but does not contain fruit body shall specify “○○ mycelium” in its name and other kinds of labeling. The font of the term “○○ mycelium” shall be the same as other words in the name of the product. Pictures of the fruit body of the fungus shall not appear on the outer packaging of the product.
5. A product that contains mixture of fruit body and mycelium and is named after the generic or family name of the fungus shall clearly show the statement “This product contain mixture of ○○ mycelium and fruit body” or other term that have the same meaning on the outer packaging of it. The font of the statement shall not be smaller than 5 mm in length and width.

## **Regulation for the Labeling of Commercial “Starch Powder(太白粉)” Products**

Promulgated on May 16, 2016

Effective from January 1, 2017

### **Article1**

According to Subparagraph 2 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation, food product containing two or more ingredients shall indicate the respective ingredients in descending order of proportion.

### **Article2**

“Starch powder” products shall label the name of the raw material (such as “tapioca starch” or “potato starch”) actually used. If starch powder is used as one of the raw materials, “tapioca starch”, “potato starch”, etc. shall be labeled in the ingredients as it actually used.

### **Article3**

All related food products manufactured from January 1, 2017 onwards shall be labeled according to this announcement, failure to comply shall be deemed to have violated Article 28 of the Act Governing Food Safety and Sanitation and shall be subject to the punishments provided in Articles 45 and 52 of the Act.

## Regulation for the Labeling of Commercial “Barley(大麥)” Products

Promulgated on May 16, 2016

Effective from January 1, 2017

### Article1

According to Article 7 of the Enforcement Rules of the Act Governing Food Safety and Sanitation, the product name of food products shall use the name established in the National Standards of the Republic of China (CNS). If no such name is provided for in CNS, food businesses may set the name by themselves. In the event that the product name is set by a food business, the product name shall conform to the nature thereof , in order to avoid causing confusion.

### Article2

In order to convey correct and transparent information of “barley” products and at the same time take into consideration that product names which are widely known by consumers for years, the external packaging may not only label “small barley(小薏仁)” or “pearl barley(珍珠薏仁 or 洋薏仁)”. The raw materials shall also be indicated, such as “barley (small barley 小薏仁)” or “barley (pearl barley 珍珠薏仁 or 洋薏仁)”, and moreover “barley(大麥)” shall be labeled in the ingredients as it actually used. If barley is one of the raw materials, “barley(大麥)” shall be labeled in the ingredients as it actually used.

### Article3

All related food products manufactured from January 1, 2017 onwards shall be labeled according to this announcement, failure to comply shall be deemed to have violated Article 28 of the Act Governing Food Safety and Sanitation and shall be subject to the punishments provided in Articles 45 and 52 of the Act.

## Labeling Requirements on Food Products that Use Specific Fish Species as Product Names

Promulgated on July 14, 2016

Effective from January 1, 2017

### Article1

According to Article 28 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the “Act”), the labeling, promotion, and advertisement of foods may not be false, exaggerated or misleading. In addition, Article 7 of the Enforcement Rules of the Act Governing Food Safety and Sanitation stipulates that the product names shall conform to the nature thereof.

### Article2

Based on the data from the Fish Database of Taiwan, Fisheries Research Institute of the Council of Agriculture, and Biodiversity Research Center of the Academia Sinica, the fish species of the “Gadiformes (鱈形目)” can only be labeled as “cod”, including *Gadus morhua*(大西洋鱈), *Gadus macrocephalus*(大頭鱈, 太平洋鱈), *Gadus ogac*(格陵蘭鱈), *Gadus chalcogrammus*(黃線狹鱈, 阿拉斯加鱈), *Melanogrammus aeglefinus*(黑線鱈), *Pollachius pollachius*(青鱈), *Pollachius virens*(綠青鱈), *Merluccius productus*(北太平洋無鬚鱈), *Macruronus novaezelandiae*(藍尖尾無鬚鱈), *Urophycis tenuis*(長鰭鱈) that are now circulated in Taiwan’s market.

### Article3

The commercial name “Patagonian toothfish (圓鱈)” is actually either “*Dissostichus eleginoides*”(小鱗犬牙南極魚) and “*Dissostichus mawsoni*”(鱗頭犬牙南極魚) (commonly known as “Chilean seabass(智利海鱸)”) that are of the “Perciformes”(鱸形目); “Greenland Halibut(扁鱈)” is in fact “*Reinhardtius hippoglossoides*”(馬舌鰈), *Hippoglossus hippoglossus* (庸鰈) and *Hippoglossus stenolepis*(狹鱗庸鰈) (commonly known as “halibut”(大比目魚) that are of the “Pleuronectiformes (鰈形目)”.

### Article4

The local health bureaus are requested to actively provide guidance for the relevant businesses in their local jurisdictions. The fish species of the “Gadiformes”(鱈形目) can only be labeled as “cod”. Fish species not belonging to the “Gadiformes” but labeled as “cod” shall be deemed to constitute mislabeling. However, considering that “Patagonian toothfish (圓鱈) and Greenland Halibut(扁鱈)” are the product names that are commonly used by the public, at this stage, businesses should be advised to either label “Patagonian toothfish (圓鱈) and Greenland Halibut(扁鱈)” with their common names or label “Patagonian toothfish (圓鱈) and Greenland Halibut(扁鱈)” together with the name of the fish species. Regardless, such fish cannot be labeled as “cod”. From January 1, 2017 onwards, “Patagonian toothfish (圓鱈) and Greenland Halibut(扁鱈)” product have not been clearly labeled in accordance with the above requirements in such a way as to mislead consumers to believe it is “cod”, the food business will be deemed to have violated Article 28 of the Act and will be punished with a fine between NT\$40,000 and NT\$4,000,000; and the products shall be recalled and corrected before the deadline stipulated in Article 52 of the Act.

#### **Article 5**

In addition, if a specific fish species is used as the product name of a product, the ingredients of the product shall indeed contain said fish species that is claimed in the product name. If the ingredients do not contain the claimed fish species and instead species or seasonings are used to create the flavor of the claimed fish species, the words “flavor”/“taste” shall be indicated in the product name or an obvious place close to the product name. In the event that the labeling fails to meet the aforementioned requirements, it shall be deemed to have violated Article 28 of the Act Governing Food Safety and Sanitation and shall result in the punishments provided in Articles 45 and 52 of the Act.

# Guidelines for Front of Package Nutrition Labeling of Food Products

Promulgated on November 15, 2017

## I. Introduction

In recent years, many countries have encouraged business to voluntarily label simple and succinct nutrition information diagrams, in addition to the nutrition labeling, on the packaging of food products. This is intended to provide consumers with quickly and easy-to-understand nutrition information symbols, so that consumers are able to select the products that meet their needs most.

In order to encourage food businesses to implement Front of Package Nutrition Labeling (FoP), this guidance is thus formulated for food businesses to follow.

## II. Scope

This Guideline applies to all packaged food products, except for special dietary foods. For those that are exempted from nutrition labeling, if food businesses of such food products voluntarily have FoP, they are not required to comply with the Regulations on Nutrition Labeling for Prepackaged Food Products. However, the correctness of labeled values shall be assured.

## III. Definitions

1. The terms used in this guideline are defined as follows :

- (1) “Front of Package Nutrition Labeling (FoP)”: the labeling of calories, nutrients content, and percentage of daily reference value in the form of a diagram on the front package of food products.
- (2) “Per serving”: the weight (or volume) of per serving of the various prepackaged food products, which is identical to Article 5<sup>1</sup> of Regulations on Nutritional Labeling for Prepackaged Food Products.
- (3) “Percentage of daily reference value”: the daily calories and other nutrient

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<sup>1</sup> The weight (quantity or volume) per serving of the various packaged food products shall consider every time consumption derived from domestic dietary habits and prepackaged food product type. Food products in the form of tablets and capsules (excluding candy foods) per serving shall be labeled as recommended amount (shall be an integer).



intake reference values of prepackaged food products, which is identical to Article 7<sup>2</sup> of Regulations on Nutrition Labeling for Prepackaged Food Products.

#### **IV. Principles for FoP nutrition labeling of prepackaged food products**

1. Location of the label: Any place on the front of package (main display side) of the product.
2. Items of labeling, to include any of the following:
  - (1) Calories;
  - (2) Calories, Saturated Fat, Sugar, Sodium; or
  - (3) Calories, Saturated Fat, Sugar, Sodium, and maximum of two voluntarily claimed nutrients<sup>3</sup>.
3. Format of labeling:
  - (1) Refer to Regulations on Nutrition Labeling for Prepackaged Food Products; use “per serving” as the labeling unit.
  - (2) Provide “content for every nutrient per serving” and its “percentage of daily reference value”.
4. The order of the labeling content should be listed from top to bottom in accordingly as:
  - (1) Unit (per serving);
  - (2) Calories or nutrient names ;
  - (3) Content;
  - (4) Percentage of daily reference value (%Daily value, %DV). For nutrients without a set daily reference value, the percentage of daily reference value will be exempted.
5. Figure of labeling:
  - (1) The figure design of the FoP is not restricted. Nevertheless, the size of each figure shall be identical.

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<sup>2</sup> Daily caloric and other nutrient intake reference values shall be labeled according to Attachment 2 of Regulations on Nutrition Labeling for Prepackaged Food Products.

<sup>3</sup> The two of other nutrients labeled voluntarily shall be declared in nutrition labeling according Regulations on Nutrition Labeling for Prepackaged Food Products.

(2) The figure shall be presented in two colors, that is, white color with another color, such as black and white, blue and white, or red and white. And, the colors of FoP shall be distinguishable from the package color of the food product.

(3) The samples of FoP are provided in attachment.

6. Characters size: The size of characters shall conform to Article 19 of the Enforcement Rules of the Act Governing Food Safety and Sanitation<sup>4</sup>.

#### Attachment

##### 1. Sample of FoP 1: Calorie label only

(1) The FoP meaning: Per serving is 120g of the product, there are 500 calories, which is 25% of the daily diet.

(2) Sample of FoP:

Per serving (120 g)



?: the percentage of daily reference value

Per serving (120g)



?: the percentage of daily reference value

##### 2. Sample of FoP 2: Calories, saturated fat, sugar and sodium are labeled.

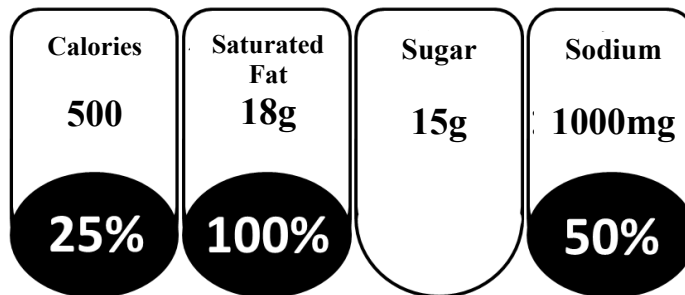
(1) The FoP meaning: Per serving is 120g of the product, there are 500 calories, which is 25% of the daily diet; there are 18g of saturated fat, which is 100%

<sup>4</sup> The length and width of the characters marked on the labels shall not be less than two millimeters. However, where the area of the largest surface of a package is less than 80 square centimeters, the length and width of characters for all items other than the name of the product, the company name, and expiry date, may be less than two millimeters.

of the daily diet; there are 15g of sugar (there is without set nutrient intake daily reference value, so there is no percentage of daily reference value); there are 1000mg of sodium, which is 50% of the daily diet.

(2) Sample of FoP:

**Per serving (120g)**



?: the percentage of daily reference value

**Per serving (120g)**



?: the percentage of daily reference value

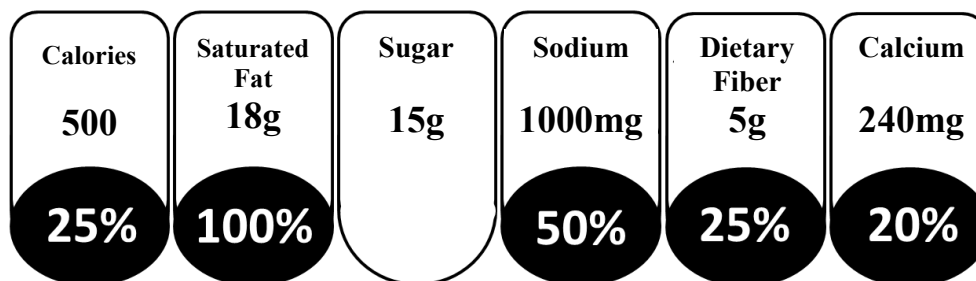
3. Sample of FoP 3: Calories, saturated fat, sugar, sodium, and two of other nutrients labeled voluntarily (such as dietary fiber and calcium) are labeled.

(1) The FoP meaning: Per serving is 120g of the product, there are 500 calories, which is 25% of the daily diet; there are 18g of saturated fat, which is 100% of the daily diet; there are 15g of sugar (there is without set nutrient intake of daily reference value, so there is no percentage reference value); there are 1000mg of sodium, which is 50% of the daily diet; there are 5g of dietary fiber, which is 25% of the daily diet; and there are 240mg of calcium,

which is 20% of the daily diet.

(2) Sample of FoP :

**Per serving (120g)**



?: the percentage of daily reference value

**Per serving (120g)**



?: the percentage of daily reference value

## **Regulation for the Labeling of “Slightly Sweet”, “Not Sweet” or other Sweetness Claim on Prepackaged Food**

Promulgated on September 20, 2019

Effective from July 1, 2021

### **Article 1**

According to Article 28 of the Act Governing Food Safety and Sanitation, the labeling, promotion or advertisement of foods shall not be false, exaggerated or misleading.

### **Article 2**

Consumers usually assume the sweetness claim on prepackaged food as a reference of the level of sugar content when choosing foods. When the term such as “Slightly Sweet”, “Not Sweet” which are not in compliance with the “Light Sugar”, “Free Sugar” and other claims that specified in the “Regulations on Nutrition Claim for Prepackaged Food Products” were put on the label of prepackaged food, it may lead to misleading due to the method of verifying “Slightly Sweet” or “Not Sweet” etc. is still unavailable based on science knowledge nowadays.

### **Article 3**

All professional associations are advised to notice their members to comply the above mentioned regulation, and local health authorities are encouraged to provide guidance to businesses under their jurisdiction.

### **Article 4**

Effective from July 1, 2021, prepackaged products (based on the date of manufacturing) shall be labeled in accordance with the aforementioned regulations. Failure to comply shall be deemed to have violated Article 28 of the Act Governing Food Safety and Sanitation and shall be subject to the punishments provided in Articles 45 and 52 of the same Act.

# **The Relevant Regulations of Article 24 of the Act Governing Food Safety and Sanitation**

## **Regulations Governing the Labeling of Flavoring Ingredients in Food Additive Products**

Promulgated on May 20, 2014

Effective from May 20, 2014

Where flavoring ingredients is added to or used in a food additive product including flavorings sold as such, it may be declared as ‘flavoring’ or ‘flavor’; and natural flavor may be declared as ‘natural flavoring’ or ‘natural flavor’. But the name of other ingredients present shall be given.

## **Regulation of the Individual Food Additive Shall be Clearly Label the Product Registration Code**

Promulgated on September 9, 2014

Effective from September 9, 2014

The container or external packaging of individual food additive shall clearly label with approval number from registration.



## Labelling Requirements for Food Additives Containing Ingredients of Genetically Modified Organisms (GMOs)

Amended on May 29, 2015

Effective from December 31, 2015

1. The regulation is established under the provisions of Paragraph 2 of Article 24 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act).
2. The GMOs referred in this regulation comply with the GMOs authorized by Paragraph 2 of Article 21 of the Act. Food additives that contains food additives produced from GMOs or GMOs shall display the words “genetically-modified” or “with genetic modification.” Food additives that uses GMOs directly during the manufacturing process yet the final product does not contain transgenic DNA fragment or transgenic proteins shall display following one of words,
  - (1) “genetically-modified”, “with genetic modification” or “use genetically modified \_\_\_\_\_( organisms)”
  - (2) “this product is made of genetically modified \_\_\_\_\_( organisms), but do not contain any transgenic DNA fragment or transgenic proteins ” or “this product’s raw materials contain genetically modified \_\_\_\_\_( organisms), but do not contain any transgenic DNA fragment or transgenic proteins”.
  - (3) “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_( organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_( organisms)”.
3. The labelling requirements shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 3 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.
4. Food additives contains GMOs which exist international approvals to cultivation or food of GMOs may display the words “un-genetically-modified” or “with un-

genetic modification” and could displays the words “the proportion of material which contains, consists of or is produced from GMOs considered individually is approved for use in a regulation of \_\_\_\_\_(country)or other synonymous terms” or the proportion of material which contains, consists of or is produced from GMOs considered individually.

5. Based on this regulation, the labelling method shall be displayed after the name of the product and the ingredients in principle, or other obvious locations of the container or packaging. The length and the width of the font shall as following,
  - (1) Labelling “genetically-modified”, “with genetic modification” or “use genetically modified \_\_\_\_\_(organisms)” shall make a distinction with other words, and the length and the width of the font shall not be less than 2 mm.
  - (2) Labelling “this product is made of genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins ”, “this product’s raw materials contain genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins”, “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_(organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_(organisms)”, the length and the width of shall not be less than 2 mm.
  - (3) Labelling “un-genetically-modified” or “with un-genetic modification”, the length and the width of the font do not be stipulated.

## Common Names of Food Additives

Promulgated on March 4, 2016

Effective from March 4, 2016

Chinese product name listed in the Standards for Specification, Scope, Application and Limitation of Food Additives	Common name
Monosodium L-Glutamate L-麩酸鈉	MSG 味精
Benzoic acid 苯甲酸	BA 安息香酸
Sodium benzoate 苯甲酸鈉	Sodium benzoate 安息香酸鈉
Potassium benzoate 苯甲酸鉀	Potassium benzoate 安息香酸鉀
Sodium bicarbonate 碳酸氫鈉	Baking soda 小蘇打
Glycine 胺基乙酸	Gly 甘胺酸
Alanine 胺基丙酸	Ala 丙胺酸
L-Lysine 二胺基己酸	Lysine 離胺酸
Sorbic acid 己二烯酸	Sorbic acid 山梨酸
Potassium sorbate 己二烯酸鉀	Potassium sorbate 山梨酸鉀
Sodium sorbate 己二烯酸鈉	Sodium sorbate 山梨酸鈉
Calcium sorbate 己二烯酸鈣	Calcium sorbate 山梨酸鈣
Dehydroacetic acid 去水醋酸	DHA 脫氫乙酸
Calcium hydroxide 氫氧化鈣	Hydrated lime 熟石灰
Calcium oxide 氧化鈣	Quicklime 生石灰或石灰
Casein 乾酪素	Casein 酪蛋白
Sodium caseinate 乾酪素鈉	Sodium caseinate 酪蛋白鈉
Calcium caseinate 乾酪素鈣	Calcium caseinate 酪蛋白鈣
Steviol glycoside 甜菊糖苷	Steviol glycoside 甜菊糖
Calcium pantothenate 本多酸鈣	Calcium pantothenate 泛酸鈣
Sodium pantothenate 本多酸鈉	Sodium pantothenate 泛酸鈉
DL- Methionine DL-蛋胺酸	DL- Methionine DL-甲硫胺酸
L-Methionine L-蛋胺酸	L-Methionine L-甲硫胺酸

Xanthan gum 玉米糖膠	Xanthan gum 三仙膠
D-Sorbitol D-山梨醇	Sorbitol 山梨糖醇
Vitamin ○ 維生素○	Vitamin ○ 維他命○

## **Regulation of the Food Additives Shall be Conspicuously Label the Registration Number**

Promulgated on March 8, 2016

Effective from January 1, 2017

The container or external packaging of food additives shall label the words “registration number” and the number.

# **The Relevant Regulations of Article 25 of the Act Governing Food Safety and Sanitation**

## **Regulations on Bulk Food Labeling**

Amended on September 17, 2020

Effective from January 1, 2021

### **Article 1**

These regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

This regulation is applicable to the Bulk Food of defined in Article 20 of the Enforcement Rules of the Act Governing Food Safety and Sanitation.

### **Article 3**

Food business operators with company registration or business registration, which sell the Bulk Food shall label the product name and the country of origin. Except for foods for baking (roasting) and dealing with ready-to-eat foods on-site.

### **Article 4**

Food business operators without company registration or business registration, which sell the following Bulk Food shall label the country of origin of the product: Fresh, chilled, frozen, dehydrated, dried, crushed, ground, simple cutting Peanuts, Red beans, Mung beans, Black beans, Soybeans, Buckwheat, Barley, Quinoa, Sesame, Foxtail millet, Garlic, Shiitake, Tea, Red dates, Wolfberry, Hang Chrysanthemum, Chicken, Pork, Mutton ( lamb and goat meat) and Beef.

### **Article 5**

Food business operators sell the Bulk Food products that contain beef, pork and other edible parts of cattle and pig shall label the beef, pork and edible parts of cattle and pig of raw material of the country. The country of origin of beef, pork and other edible partsof cattle and pig shall be the country where the cattles and pigs are slaughtered.

The beef and edible parts of cattle mentioned in the above paragraph do not include milk, fat of cattle.

## **Article 6**

The Bulk Food labeling as provisioned by these Regulations shall be labelled in Chinese and in the form of cards, mark (label) or notice boards which in turn are either posted, hung, erected (inserted), stuck or utilized in other ways which are clearly visible. The vendors who choose to label the products with the mark (label) shall make sure the front of the remainder is larger than 2 millimeter in length and width. Those who choose to label the products with other means of communication shall make sure the front of the remainder is larger than 2 centimeters in length and width.



## **Regulations Governing the Labeling of Country of Origin of Beef and Other Edible Parts of Cattle at Food Vending Locations**

Promulgated on September 6, 2012  
Effective from September 12, 2012

### **Article 1**

These regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

These regulations are applicable to food containing beef and other edible parts of cattle at food vending locations.

### **Article 3**

Labeling requirements:

- 1 Food that contains beef and other edible parts of cattle shall be clearly labeled with country of origin or other synonymous terms.
- 2 These Regulations regulate beef and other edible parts of cattle, not including milk and fat products.
- 3 Country (place) of origin of beef and other edible parts of cattle shall be the country (place) where the cattle are slaughtered.
- 4 The food labeling shall be in Chinese and in the form of cards, notes on the menu, mark (label) or notice boards which in turn are either posted, hung, erected (inserted), stuck or utilized in other ways which are clearly visible.
- 5 The vendors who choose to label the beef and other edible parts of cattle with notes on the menu shall make sure that the font is not smaller than 4 millimeters in length and width. Those who choose to label the products with other forms shall make sure that the font size is not smaller than 2 centimeters in length and width.

## Labelling Requirements for Unpackaged Food Containing Ingredients of Genetically Modified Organisms (GMOs)

Amended on May 29, 2015

Effective from December 31, 2015

1. The regulation is established under the provisions of Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act).
2. The GMOs referred in this regulation comply with the GMOs authorized by Paragraph 2 of Article 21 of the Act.

Prepackaged food that contains GMOs shall display the words “genetically-modified” or “with genetic modification”.

Unpackaged food that uses GMOs directly during the manufacturing process yet the final product does not contain transgenic DNA fragment or transgenic proteins shall display following one of words,

- (1) “genetically-modified”, “with genetic modification” or “use genetically modified \_\_\_\_\_(organisms)”
  - (2) “this product is made of genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins ” or “this product’s raw materials contain genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins”.
  - (3) “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_(organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_(organisms)”.
3. The labelling requirements shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 3 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

4. Unpackaged food contains GMOs which exist international approvals to cultivation or food of GMOs may display the words “un-genetically-modified” or “with un-genetic modification” and could displays the words “the proportion of material which contains, consists of or is produced from GMOs considered individually is approved for use in a regulation of \_\_\_\_\_(country)or other synonymous terms” or the proportion of material which contains, consists of or is produced from GMOs considered individually.
5. Based on this regulation, the labelling method shall comply with the following matters:
  - (1) The labelling method: In sales locations, cards, mark (label) or notice board are permitted options for selecting either hanging, erecting(inserting), sticking or other ways that can be clearly identified.
  - (2) The length and width of mark (label) shall as following,
    - i. Labelling “genetically-modified”, “with genetic modification ”or “use genetically modified \_\_\_\_\_(organisms)” shall make a distinction with other words, and the length and the width of the font shall not be less than 2 mm.
    - ii. Labelling “this product is made of genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins ”, “this product’s raw materials contain genetically modified \_\_\_\_\_(organisms), but do not contain any transgenic DNA fragment or transgenic proteins” , “this product do not contain any transgenic DNA fragment or transgenic proteins, but is made of genetically modified \_\_\_\_\_(organisms)”, or “this product do not contain any transgenic DNA fragment or transgenic protein, but with genetically modified \_\_\_\_\_(organisms)”, the length and the width of shall not be less than 2 mm.
    - iii. Labelling “un-genetically-modified” or “with un-genetic modification”, the length and the width of the font do not be stipulated.
  - (3) The length and width of other means shall not be less than 2 cm.

## **Regulation on Bulk Food Labeling of Domestic Certified Agricultural Products**

Promulgated on July 10, 2015

Effective from August 4, 2015

### **Article 1**

The Regulations are prescribed in accordance with Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Implementating Objects and Items

- 1 Objects: Food vendors with company registration or business registration.
- 2 Items: Certified bulk food, including organic agricultural products, traceable agricultural products and Certified Agricultural Standards (CAS) products in accordance with Agricultural Production and Certification Act promulgated by Central Competent Authority of Agriculture.

### **Article 3**

Labeling requirements : Name, address and phone number of the producing farms, livestock or poultry farms, aquafarms, producer's cooperative, agricultural production and marketing groups, producers.

### **Article 4**

The labeling shall be in Chinese and in the form of cards, mark (label) or notice boards which in turn are either posted, hung, erected (inserted), stuck or utilized in other ways which are clearly visible.

The font size of the mark (label) should not be smaller than 2 millimeters in length and width. The font size with other forms should not be smaller than 2 centimeters in length and width.

## **Regulation for the Labeling of Soup Bases of Hot Pot Served at Food Vending Locations**

Promulgated on June 30, 2015

Effective from July 31, 2015

### **Article 1**

The Regulations are prescribed in accordance with Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Food vending locations with business registration for hot pot in food vending locations shall conspicuously indicate in Chinese the information of the hot pot served on site in accordance with the following provisions :

- 1 Method for preparing soup bases : including main ingredients, seasoning powders and one of the following labeling based on facts: 「 Soup bases of hot pot (product name) made of○○(ingredients) 」 , 「 Soup bases of hot pot (product name) made of ○○seasoning powders 」 , 「 Soup bases of hot pot (product name) made of both ○○(ingredients)and○○seasoning powders 」 .
- 2 Ingredients of the seasoning powders ⊕ (including food additives): those that contain two or more ingredients shall indicate the respective ingredients in descending order of proportion. Whereas those that contain two or more seasoning powders shall be respectively labeled.

### **Article 3**

Methods of labeling shall clearly indicate the soup bases of hot pot. Card,-menu note, mark (label) or notice board are permitted options for selecting either posting, hanging, erecting (inserting), sticking or other ways that can be clearly identified. The length and width of the character unit for menu note or mark (label) shall not be less than 2 millimeters, and not less than 2 centimeters if labeled by other means.

## **Regulation for the Labeling of Freshly Made Beverages in Chain Drink Stores, Convenience Stores, and Fast Food Restaurants**

Promulgated on June 7, 2022

Effective from January 1, 2023

### **Article 1**

The Regulations are prescribed in accordance with Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Chain beverage stores, convenience stores and fast food restaurants (hereinafter referred to as chain stores) that have a taxation registration certificate and sell freshly made beverages shall follow this regulation.

### **Article 3**

The chain operators mentioned in the preceding Section refer to those who use the same name in the company or business registration, or use the same name through franchise, authorization, etc.

### **Article 4**

For beverages prepared on site, the amounts of total sugar and total calorie in the drink shall be labeled. The acceptable error range of the labeled total sugar and total calorie shall comply with the provisions of "Regulations on Nutrition Labeling for Prepackaged Food Products". The amounts of total sugar and total calorie can be expressed by the highest value of the content, in which case the term "the highest value" shall be labeled.

The amount of total sugar in the preceding Section can be expressed in the number of sugar cubes (with each sugar cube calculated as 5 grams).

For on-site prepared beverages containing caffeine, the highest value of the total caffeine content in the beverage shall be labeled as "the highest value"; or the total caffeine content shall be indicated with red, yellow, and green marks or symbols.

- (1) Red represents the total caffeine content above 201 mg per cup.

- (2) Yellow represents the total caffeine content between 101 mg and 200 mg per cup.
- (3) Green represents the total caffeine content below 100 mg per cup.

## Article 5

Beverages containing tea or coffee, or named with fruits or vegetables shall be labeled according to the following regulations:

(1) Beverages with tea or tea spices:

- 1. For beverages prepared with tea leaves, tea powder, tea soup, concentrated tea soup, or raw materials obtained from natural tea leaves, the (country of) origin of the raw tea materials shall be indicated. For raw tea materials from more than one origins (country), the origins shall be labeled in the descending order of the amount of content.
- 2. For beverages containing no tea leaves, tea powder, tea soup, concentrated tea soup, or raw materials obtained from natural tea leaves, but prepared with tea spices, the phrase of "○○ flavor" shall be used in the product names.

(2) Beverages with coffee:

For beverages prepared with coffee, the (country of) origin of the coffee shall be indicated. For raw coffee materials from more than one origins (country), the origins shall be labeled in the descending order of the amount of content.

(3) For beverages named with fruits or vegetables:

- 1. Beverages containing more than 10% of fruit or vegetable content can use "○○ juice" as the product name.
- 2. Beverages containing less than 10% of fruit or vegetable content shall use "○○ drink" in the product name, or synonymous terms.
- 3. Beverages containing no fruit and vegetable content shall use "○○ flavor" or "○○ taste" in the product name.

## **Article 6**

The food labeling shall be in Chinese in the forms of cards, notes on the menu, marks (labels), notice plaques (boards), QR Codes or other electronic forms, and shall be displayed by either posting, hanging, erecting (inserting), sticking or utilizing in other ways which are clearly visible.

Those who choose to label the products with notes on the menu shall make sure that the font size is no less than 2 millimeters in height and width. Those who choose to label the products with other forms shall make sure that the font size is no less than 1 centimeter in height and width.

## **Article 7**

Labelling in the forms of QR Codes or other electronic forms in the preceding paragraph shall include the phrase "Scan to obtain the labeling information" or synonymous terms above or below the labeling, and mobile devices for decoding the code shall be provided on site.



## **Labeling Requirements at Food Vending Locations for Food Containing Ingredients of Genetically Modified Organisms (GMOs)**

Promulgated on August 11, 2015

Effective from December 31, 2015

1. The regulation is established under the provisions of Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act).
2. The GMOs referred in this regulation comply with the GMOs authorized by Paragraph 2 of Article 21 of the Act.

Food that contains GMOs at food vending locations with business registration shall display the words “genetically-modified” or “with genetic modification”.

3. The labeling requirements shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 3 percent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.
4. Food at food vending locations with business registration contains non-GMOs which exist international approvals to food of GMOs may display the words “un-genetically-modified” or “with un-genetic modification” and could displays the words“ the proportion of material which contains, consists of or is produced from GMOs considered individually is approved for use in a regulation of \_\_\_\_\_(country)or other synonymous terms” or the proportion of material which contains, consists of or is produced from GMOs considered individually.
5. Based on this regulation, the labeling method shall comply with the following matters:

- (1) The labeling method: cards, menu annotation, mark (label) or notice board are permitted options for selecting either hanging,

erecting(inserting), sticking or other ways that can be clearly identified.

- (2) In mark (label), the length and width of the font shall not be less than 2 mm. In other ways, the length and width of the font shall not be less than 2 cm.
- (3) Labeling “un-genetically-modified” or “with un-genetic modification”, the length and the width of the font do not be stipulated.

## **Regulations Governing the Labelling of Food Products Sold by Vending Machines**

Promulgated on June 2, 2017

Effective from July 1, 2017

### **Article 1**

The Regulations are prescribed in accordance with Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

This Regulation applies to food products sold by vending machines. The term "vending machines businesses" refers to those businesses that sell food by means of vending machines (hereinafter referred to as "machines").

### **Article 3**

The vending machines businesses shall be clearly displayed on the exterior of the machine the company name or personal name, address and the telephone number.

### **Article 4**

The vending machine businesses shall mark the following items on food sold by the machine:

- (1) Prepackaged food: the labels on such prepackaged products shall follow Article 22 of the Act Governing Food Safety and Sanitation and its relevant Regulations.
- (2) Bulk food
  - i. product name ;
  - ii. name of the ingredients and food additives ;
  - iii. name, telephone number, address and registration number of the manufacturer or that of the responsible company of the food products ;
  - iv. country of origin ;
  - v. expiry date ;
  - vi. allergen ;

- vii. genetically modified food raw materials ;
- viii. restructured meat products ;
- (3) Food meals for vending machines:
  - i. product name ;
  - ii. name of the ingredients and food additives ;
  - iii. name, telephone number, address and registration number of the manufacturer or that of the responsible company of the food products ;
  - iv. country of origin ;
  - v. allergen ;
  - vi. genetically modified food raw materials ;
  - vii. restructured meat products ;

## **Article 5**

The allergen, genetically modified food raw materials and restructured meat products prescribed in Article 4 with paragraph 2 and paragraph 3 shall follow the following requirements, except their type and manner:

- (1) Allergen: the “Regulations Governing Food Allergen Labelling”.
- (2) Genetically modified food raw materials:
  - i. Bulk food : the “Labelling requirements for unpackaged food containing ingredients of genetically modified organisms (GMOs)”, labelling “genetically-modified”, “with genetic modification” or “use genetically modified \_\_\_\_\_ (organisms)” shall make a distinction with other words.
  - ii. Food meals for vending machines: the “Labelling requirements at food vending locations for food containing ingredients of genetically modified organisms and the application of food items”.
- (3) Restructured meat products :
  - i. Bulk food : the “Regulations Governing the Labeling of Restructured Meat Products ” of the Article 2 and Article 4.
  - ii. Food meals for vending machines: the “Regulations Governing the Labeling of Restructured Meat Products” of the Article 2 and Article 5.

## **Article6**

The expiry date of bulk food products prescribed in Paragraph 2 and Paragraph 3 of Article 4 shall be labelled on the exterior of the packaging or container of the product, other required food label information shall be displayed by mark (label), or notice board are permitted options for selecting either posting, hanging, sticking or other ways that can be clearly identified and shall be fixed, the length and width of the character unit that marked on the mark (label) shall not be less than 2 millimeters, and not less than 2 centimeters if labelled by other means.

## **Regulations of the Labeling of Country of Origin of Pork and Other Edible Parts of Pig for Directly Supply Food Served in Catering Place**

Promulgated on September 17, 2020

Effective from January 1, 2021

### **Article 1**

These regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 25 of the Act Governing Food Safety and Sanitation.

### **Article 2**

All food meals that contain pork and other edible parts of pig for directly supply food served in catering place shall clearly indicate their country (place) of origin.

### **Article 3**

The country (place) of origin of pork and other edible parts of pig shall be the country (place) where the are pig slaughtered.

### **Article 4**

The food labeling as provisioned by these Regulations shall be labelled in Chinese and in the form of menu, cards, mark (label) or notice boards which in turn are either posted, hung, erected (inserted), stuck or utilized in other ways which are clearly visible.

Those who choose to label the products with the menu or mark (label) shall make sure the front of the remainder is larger than 4 millimeter in length and width. Those who choose to label the products with other means of communication shall make sure the front of the remainder is larger than 2 centimeters in length and width.

## **The Relevant Regulations of Article 28 of the Act Governing Food Safety and Sanitation**

## **Regulations Governing of Criteria for the Label, Promotion and Advertisement of Foods and Food Products Identified as False, Exaggerated, Misleading or Having Medical Efficacy**

Amended on May 24, 2021

### **Article 1**

The Regulations are prescribed in accordance with the provisions of Paragraph 4, Article 28 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “the Act”).

### **Article 2**

The “foods” and “food products” referred in the Regulations are defined as foods, food additives, food cleansers and food utensils, food containers or packaging designated by the central competent authority in the public announcement.

### **Article 3**

The determining standards of the false, exaggerated or misleading labeling, promotion or advertisement referred to in Paragraph 1, Article 28 and medical efficacy referred to in Paragraph 2 in the Act shall be comprehensively judged by the overall presentation of the name, description, image, symbol, visual, audio or other messages conveyed to consumers of the product.

### **Article 4**

The labeling, promotion or advertisement of foods and food products referred to in Paragraph 1, Article 28 of the Act is identified as false, exaggerated or misleading if involving any of the following condition:

- (i) The description does not conform to facts.
- (ii) The description has no evidence or insufficient evidence to support it.
- (iii) The description involves maintaining or altering the physiology, appearance or function of human organs and tissue.
- (iv) The content description refers to any number of official letters or any word or sentence with similar meanings; however, the use of approved official letter



number complied with the laws and regulations are not subject to the limit.

If the word "health" as part of the food product name, it is identified as misleading. However, this regulation shall not apply to food product issued with a health food permit.

The phrases in Appendix 1 and the physiological functional description of the nutrients and specified components as in the Appendix 2 can be used for the labeling, promotion or advertisement of food products. The above descriptions are considered not false, exaggerated, or misleading.

#### **Article 5**

The labeling, promotion or advertisement of the foods referred to in Paragraph 2, Article 28 in the Act shall be identified as having medical efficacy if involving any of the following statement:

- (i) The description is related to prevention, improvement, mitigation, diagnosis or treatment of any diseases, syndromes or symptoms.
- (ii) The description is related to alleviation or reduction of any substances in human body caused by diseases.
- (iii) The description is related to the efficacy of raw materials in traditional Chinese medicine.

#### **Article 6**

The Regulations shall be implemented upon promulgation.

Articles 4 of these Regulations, amended and promulgated on 4 August 2020, shall take force from 1 July 2022.

## Appendix 1

Rules
<p>Phrases of that of similar meaning considered acceptable:</p> <ol style="list-style-type: none"> <li>1. Help normal development of teeth and bones.</li> <li>2. Improve digestion.</li> <li>3. Maintain digestive health.</li> <li>4. Improve bacteria colonization.</li> <li>5. Relieve constipation.</li> <li>6. Improve constitution.</li> <li>7. Moderate physiological functions.</li> <li>8. Nourish and strengthen body.</li> <li>9. Enhance energy.</li> <li>10. Increase vitality.</li> <li>11. Care for beauty.</li> <li>12. Help sleeping.</li> <li>13. Supplement nutrition.</li> <li>14. Maintain health.</li> <li>15. Preserve youth and beauty.</li> <li>16. Care for pre- and post-childbirth and illness recovery.</li> <li>17. Improve metabolism.</li> <li>18. Quench thirst.</li> <li>19. Help produce saliva and control thirst.</li> <li>20. Improve appetite.</li> <li>21. Stimulate appetite.</li> <li>22. Cool down internal heat.</li> <li>23. Reduce internal heat.</li> <li>24. Help fragrant breath.</li> <li>25. Faciliate salivation.</li> <li>26. Soothe throat.</li> <li>27. Help produce saliva and control thirst.</li> </ol>

## Appendix 2

Rules	
Nutrients or specified components	Acceptable physiological functional description or description with similar meanings
Vitamin A or $\beta$ -carotene	<ol style="list-style-type: none"> <li>1. Help to maintain vision in darkness.</li> <li>2. Improve health of skin and mucous membrane.</li> <li>3. Help development of teeth and bones.</li> </ol>
Vitamin D	<ol style="list-style-type: none"> <li>1. Increase calcium absorption.</li> <li>2. Help development of bones and teeth</li> <li>3. Help releasing the bone calcium for blood calcium concentration balance.</li> <li>4. Help maintain physiology of nerves and muscles.</li> </ol>
Vitamin E	<ol style="list-style-type: none"> <li>1. Reduce oxidation of unsaturated fat acid.</li> <li>2. Help maintain the integrity of cells membrane.</li> <li>3. Facilitate antioxidation.</li> <li>4. improve health of skin and blood cells.</li> <li>5. Help reduce free radicals</li> </ol>
Vitamin K	<ol style="list-style-type: none"> <li>1. Help blood coagulation.</li> <li>2. Improve bone calcification.</li> <li>3. Activate coagulated protein in liver and blood.</li> </ol>
Vitamin C	<ol style="list-style-type: none"> <li>1. Stimulate formation of collagen to help healing wounds.</li> <li>2. Help to maintain the tightness of cell arrangement.</li> <li>3. Help development of body connective tissue, bones and teeth.</li> <li>4. Improve iron absorption.</li> </ol>

	<p>5. Facilitate antioxidation.</p> <p>6. Help maintain normal function of Gums and skin.</p>
Vitamin B1	<p>1. Help maintain proper energy metabolism.</p> <p>2. Help maintain normal function of skin, heart and the nervous system.</p> <p>3. Help maintain proper appetite.</p>
Vitamin B2	<p>1. Help maintain proper energy metabolism.</p> <p>2. Help maintain skin health.</p>
Niacin	<p>1. Help maintain proper energy metabolism.</p> <p>2. Improve the health of skin, the nervous system, mucosa membrane and digestive system.</p>
Vitamin B6	<p>1. Help maintain the proper metabolism of amino acids.</p> <p>2. Help formation the porphyrin of the red blood cells.</p> <p>3. Help the conversion of tryptophan into niacin.</p> <p>4. Keep red blood cell in proper regular state.</p> <p>5. Improve nervous system.</p>
Folic acid	<p>1. Help formation of red blood cells.</p> <p>2. Help formation of nucleic acids and nucleoprotein.</p> <p>3. Facilitate fetus growth.</p>
Vitamin B12	<p>1. Help formation of red blood cells.</p> <p>2. Improve health of the nervous system.</p>
Biotin	<p>1. Maintain proper metabolism of energy and amino acids.</p> <p>2. Help synthesis of fat and glycogen.</p> <p>3. Help the synthesis of purine.</p>

	4. Improve the health of skin and mucous membrane.
Pantothenic acid	<ol style="list-style-type: none"> <li>1. Help maintain proper energy metabolism.</li> <li>2. Improve the health of skin and mucous membrane.</li> <li>3. Help synthesis of body fat and cholesterol and the metabolism of amino acids.</li> </ol>
Calcium	<ol style="list-style-type: none"> <li>1. Maintain growth and development of bones and teeth.</li> <li>2. Help the blood coagulation function.</li> <li>3. Improve the normal contraction function of muscles, heart, and the sensitivity of nerves.</li> <li>4. Activate prothrombin to be converted into thrombin to help blood coagulation.</li> <li>5. Regulate cell permeability.</li> </ol>
Iron	<ol style="list-style-type: none"> <li>1. Help formation of red blood cells.</li> <li>2. An important component of the haem and myoglobin.</li> <li>3. Help the transfer and utilization of oxygen.</li> </ol>
Iodine	<ol style="list-style-type: none"> <li>1. An important component to synthesize thyroid hormone.</li> <li>2. Maintain proper growth and development of neuromuscular.</li> <li>3. Regulate cell oxidation.</li> <li>4. Maintain the secretion of thyroid hormone.</li> <li>5. Help to maintain the normal metabolism.</li> </ol>
Magnesium	<ol style="list-style-type: none"> <li>1. Maintain the growth and development of bones and teeth.</li> <li>2. Maintain metabolism of carbohydrates.</li> <li>3. Maintain normal function of the heart, muscle and the nervous system.</li> </ol>

	4. Help normal metabolism.
Zinc	<ol style="list-style-type: none"> <li>1. An important component of for insulin and a variety of enzymes.</li> <li>2. Maintain the metabolism of energy, carbohydrates, protein and nucleic acids.</li> <li>3. Improve the skin health.</li> <li>4. Maintain normal sense of taste and appetite.</li> <li>5. Help growth and the reproductive function.</li> <li>6. Help synthesis of skin tissue and proteins.</li> </ol>
Chromium	Maintain normal metabolism of carbohydrates.
Protein	<ol style="list-style-type: none"> <li>1. An important substance of human cells, tissues and organs.</li> <li>2. Help growth and development.</li> <li>3. Help tissue repairment.</li> <li>4. An important substance for muscle synthesis.</li> <li>5. Help the muscle growth.</li> </ol>
Dietary fiber	<ol style="list-style-type: none"> <li>1. Improve intestinal motility.</li> <li>2. Increase feeling of fullness.</li> <li>3. Soften stool and ease constipation.</li> <li>4. The amount of dietary fiber helps increase excretion.</li> </ol>
<p>Notes</p> <ol style="list-style-type: none"> <li>1. The nutrient content shall comply with Regulations on Nutrition Labeling for Prepackaged Food Products and Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules in order to include descriptions of physiological functions in labeling, promotion and advertisement of the products.</li> <li>2. The minimum daily intake of chromium should be at least 6µg in a product for it to claim the physiological functional description in the labeling, promotion and advertisement.</li> <li>3. When using physiological functional description of nutrients and specified</li> </ol>	

components in the labeling, promotion and advertisement of the products, the nutrients and specified components for each physiological functional description shall be specified respectively.

# **The Relevant Regulations for Labeling of Food Ingredients**



## **The Use Restrictions and Labeling Requirements of *Antrodia cinnamomea* Food Products**

Promulgated on July 10, 2015

### **Article 1**

If a food product contains *Antrodia cinnamomea* as raw material, the food businesses shall submit the relevant supporting documents of detailed processing or manufacturing process, specifications, and repeated dose 90-day oral toxicity study in rodents to the Ministry of Health and Welfare for future reference before the said food product is introduced to the market.

### **Article 2**

The *Antrodia cinnamomea* food products shall be labeled in accordance with the following regulations:

- (1) The following warning statement shall appear on the outer packaging of the product in Chinese: “Infants, toddlers, pregnant and breastfeeding women should consult their doctors or medical professionals before taking this product.”
- (2) The type of raw materials, fruiting bodies or mycelia, used in the product and the cultivation methods shall be clearly described on the outer packaging.

### **Article 3**

Implementation date: The above regulatory requirements of the first and second points shall take effect one year from the day after the announcement and one year and six months from the day after the announcement respectively.

## The Use Restrictions and Labeling Requirements of *Cordyceps militaris* as a Food Ingredient

Promulgated on July 26, 2017

Effective from July 26, 2017

### Article 1

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

For use as food ingredients, *Cordyceps militaris* shall comply with the following requirements:

#### 1. *Cordyceps militaris* sporocarp:

- (1) The *Cordyceps militaris* sporocarp is obtained by artificially inoculating *Cordyceps militaris* strains on a culture medium, so there are no insect bodies; the sporocarp is consumed directly after harvest or provided for food processing after drying and grinding.
- (2) The daily intake of *Cordyceps militaris* sporocarp shall not exceed 600 mg on dry basis. The daily intake of the extracts calculated by cordycepin and adenosine are 3.6 mg and 0.5 mg, respectively.

#### 2. *Cordyceps militaris* mycelium:

- (1) *Cordyceps militaris* mycelium is obtained by inactivating the strains at high temperature after the strains are cultured in liquid state.
- (2) The daily intake of *Cordyceps militaris* mycelium shall not exceed 2 g on dry basis. The daily intake of the extracts calculated by cordycepin and adenosine are 3.6 mg and 0.5 mg, respectively.

### Article 2

The labeling of food products containing *Cordyceps militaris* shall bear the following warning statements in Chinese:

1. Not recommended for consumption by infants, children, pregnant women and those with fungal allergies.
2. Products in the form of capsules or tablets should be labelled in accordance with daily intake with " Do not exceed ○ servings (or granules, pills or tablets) per day.

## **The Use Restrictions and Labeling Requirements of Senna as a Food Ingredient**

Promulgated on January 9, 2018

Effective from July 1, 2018

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

1. Food products using senna as an ingredient shall comply with the following requirements:

- (1) Only fresh or directly dried leaves and pods, which are not subjected to extraction or any other processing are permitted for use.
- (2) This ingredient can only be used in tea bags for brewing beverage.
- (3) The daily intake of sennosides contained in the food product shall be less than 12 mg.
- (4) The labelling of food product's outer package shall bear the following statements:
  - i. The amount of sennosides.
  - ii. The warning statements or their equivalents sentences "This product may cause diarrhea", Have it once a day at night and no more than three times a week. Consult a doctor before consumption for more than a week", and "Not suitable for patients with chronic diarrhea, intestinal obstruction, intestinal stricture, fatigue, inflammatory bowel diseases (such as Crohn's disease, ulcerative colitis), appendicitis, non-specific abdominal pain accompanied with water-electrolyte imbalance, severe dehydration or chronic constipation, as well as pregnant women, lactating women and

children less than 10 years of age."

2. Implementation date: The regulations will be implemented on July 1, 2018, governing all products with the date of production on and after that date.

## **The Use Restrictions and Labeling Requirements of Chitosan Obtained from Shrimps, Crab Shell or *Aspergillus niger* Mycelium as a Food Ingredient**

Promulgated on March 19, 2019

Effective from July 1, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

For use as a food ingredient, the ochratoxin A content of chitosan produced from *Aspergillus niger* mycelium shall be less than 1 ppb.

### **Article 3**

The labeling of food products containing chitosan produced from shrimps, crab shell or *Aspergillus niger* mycelium shall bear the following warning statements: “People taking chronic disease medicines shall consult the doctors before consumption” and “Not recommended for consumption by pregnant or lactating women, infants and young children”.

## **The Use Restrictions and Labeling Requirements of olive (*Olea europea*) Pomace Extracts (Containing Hydroxytyrosol) as a Food Ingredient**

Promulgated on March 27, 2019

Effective from March 27, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

For use as food ingredients, the olive (*Olea europea*) pomace extracts (containing hydroxytyrosol) shall comply with the following requirements:

1. The olive (*Olea europea*) pomace extracts (containing hydroxytyrosol) referred to herein are produced by the pomace of *Olea europaea* fruits after oil extraction and then processed via a sequential steps including hot water extraction, centrifugation, concentration, sterilization and dehydration.
2. The content of hydroxytyrosol shall be 15% to 40%.
3. The daily intake of hydroxytyrosol shall not exceed 20 mg.

### **Article 3**

Food products using the olive (*Olea europea*) pomace extract (containing hydroxytyrosol) as a ingredient shall label the following warning statements on its container or external packaging in Chinese: "Not suitable for pregnant women, infants and young children".

## **The Use Restrictions and Labeling Requirements of Green Coffee bean Extracts as a Food Ingredient**

Promulgated on July 25, 2019

Effective from July 25, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

For use as a food ingredient, the green coffee bean extracts shall comply with the following requirements:

1. The green coffee bean extracts referred to herein are obtained by extracting the unroasted dry seeds of *Coffea arabica* and *Coffea canephora*.
2. The daily intake shall not exceed 400 mg. If the caffeine content of green coffee bean extracts is less than 0.05%, the daily intake shall not exceed 1,500 mg.

### **Article 3**

The labeling of food products containing green coffee bean extracts shall bear the following warning statements: Not suitable for children under the age of 12, pregnant women and patients with dyspepsia and serious diseases".



## Regulation of Labeling Requirement for Food Containing *Cordyceps sinensis* Mycelium

Amended on October 18, 2019

Effective from October 18, 2019

### Article 1

The regulations are prescribed in accordance with Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### Article 2

Food products containing *Cordyceps sinensis* mycelium (hereinafter referred to as the “Food Products”) shall meet the following labeling requirements:

- (1) Warning statement of “This product is not made with Chinese herbal medicine *Cordyceps sinensis*” shall be labeled at a conspicuous place on the outer packaging that is easily visible. Each character shall be no smaller than 4 mm in both length and width.
- (2) The name of the strain in Chinese and the scientific name thereof in Latin shall be clearly labeled on the package of the product.
- (3) The words of “*Cordyceps sinensis* mycelium” in their complete seven Chinese characters shall be clearly labeled in the same font and size, and may not indicate “*Cordyceps sinensis*” in only four Chinese characters.

### Article 3

The strain used shall be *Hirsutella sinensis* or the strains isolated from *Cordyceps sinensis*.

### Article 4

If *Hirsutella sinensis* is used as the raw materials, the suppliers of the Food Product should have a certificate of identification of the strain.

## Article 5

If strains other than *Hirsutella sinensis* are used as raw material, the supplier of food product shall have the relevant supporting documents regarding the source of *Cordyceps sinensis* from which the strains were isolated, the detailed processing or manufacturing process, specifications, and food safety documents and submitted to the Ministry of Health and Welfare for future reference.

## **The Use Restrictions and Labeling Requirements of the Vine of *Cissus quadrangularis* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the vine of *Cissus quadrangularis* as a food ingredient shall not exceed 300 mg.

### **Article 3**

The labelling of food products containing the vine of *Cissus quadrangularis* shall bear the following warning statement "Not suitable for pregnant women, children, and adolescents."

## **The Use Restrictions and Labeling Requirements of the Extract Powder from the Underground Tuber of *Stachys floridana* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the extract powder from the underground tuber of *Stachys floridana* as a food ingredient shall not exceed 25 mg.

### **Article 3**

The labelling of food products containing the extract powder from the underground tuber of *Stachys floridana* shall bear the following warning statement: "Excessive consumption may cause abdominal bloating and pain."

## **The Use Restrictions and Labeling Requirements of the Bark Extract of *Terminalia arjuna* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the bark extract of *Terminalia arjuna* as a food ingredient shall not exceed 300 mg.

### **Article 3**

The labelling of food products containing the bark extract of *Terminalia arjuna* shall bear the following warning statements: "Not suitable for pregnant women , infants and young children" and " People taking medicines for cardiovascular or hyperlipidemia disease should consult a doctor before consumption"

## **The Use Restrictions and Labeling Requirements of *Echinacea purpurea* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation

### **Article 2**

The daily intake of *Echinacea purpurea* used as a food ingredient shall not exceed 900 mg.

### **Article 3**

The labeling of food products containing *Echinacea purpurea* shall bear the following warning statements: Children under the age of two, patients with diabetics, immune-related diseases or those taking immune-related medicines should consult with medical personnel before use.

## **The Use Restrictions and Labeling Requirements of the Root of *Harpagophytum Procumbens* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the root of *Harpagophytum procumbens* as a food ingredient shall not exceed 4.5 mg based on dry roots, or 100 mg based on harpagoside.

### **Article 3**

The labelling of food products containing the root of *Harpagophytum procumbens* shall bear the following warning statements: "Patients with gastric ulcer, duodenal ulcer, heart palpitations, hyperacidity, and gallstone, and pregnant women shall avoid consuming. The product should not be taken with antibiotics, anti-inflammatory drugs, and anticoagulant medicines".

## **The Use Restrictions and Labeling Requirements of Eggshell Membrane as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the eggshell membrane as a food ingredient shall not exceed 500 mg.

### **Article 3**

The labelling of food products containing the eggshell membrane shall bear the following warning statements: "Pregnant women, lactating women and people with allergy to eggs shall avoid consumption."



## **The Use Restrictions and Labeling Requirements of the Bark Extracts of *Uncaria Tomentosa* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of the bark extract of *Uncaria tomentosa* as a food ingredient shall not exceed 700 mg.

### **Article 3**

The labelling of food products containing the bark extract of *Uncaria tomentosa* shall bear the following warning statements: "Not suitable for pregnant women, lactating women, infants and children under 3 years old" and "People taking anticoagulant medicines should consult a doctor before consumption."

## **The Use Restrictions and Labeling Requirements of Tissue Cultures of *Saussurea involucrata* as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of tissue cultures of *Saussurea involucrata* as a food ingredient shall not exceed 60g based on fresh weight or 3g based on dry weight .

### **Article 3**

The labelling of food products containing tissue cultures of *Saussurea involucrata* shall bear the following information:

1. A full display of the name "tissue cultures of *Saussurea involucrata*", and the font size of all the characters should be the same.
2. The warning statement "Infants, young children, and pregnant women should avoid consumption."
3. The statement "This is a product of tissue cultures of *Saussurea involucrata*, not naturally grown *Saussurea involucrata*".

## **The Use Restrictions and Labeling Requirements of Sucromalt as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Sucromalt used as a food ingredient shall comply with the following requirement:

- 1.This ingredient is derived from sucrose and maltose which are subjected to enzymatic treatment by alternansucrase from strains of *Leuconostoc citreum* or *Bacillus licheniformis*
- 2.This ingredient is composed of fructose (35% to 45%), leucrose (7% to 15%), other monosaccharides and disaccharides (not more than 5%), and oligosaccharides (not less than 40%, with the degree of polymerization less than 12).
- 3.The daily intake shall not exceed 12 g.

### **Article 3**

The labelling of food products containing Sucromalt shall bear the following warning statements: "People having fructose intolerance shall avoid consumption."

## **The Use Restrictions and Labeling Requirements of the Fruits of *Citrus Aurantium* and theirs extracts as Food Ingredients**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The fruits of *Citrus aurantium* and theirs extracts used as food ingredients shall meet the following requirements:

1. The amount of synephrine shall be less than 6%.
2. The daily intake of synephrine shall not exceed 20 mg.
3. This ingredient shall not be used with any other ingredients containing caffeine in the same food products.

### **Article 3**

The labelling of food products containing the fruit of *Citrus aurantium* or theirs extracts shall bear the following warning statements:

1. Not suitable for children, pregnant women, lactating women, the elderly, and people with cardiovascular diseases.
2. The product should not be taken with foods and drinks which containing caffeine.
3. People taking any medications should consult a doctor before consumption.

## **The Labeling Requirements of Creatine or Creatine Monohydrate as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The labeling of Food products containing creatine or creatine monohydrate shall be bear the following warning statements: "Creatine is not suitable for general consumption. Those intending to use shall consult physicians and nutritionists for professional advice. Inappropriate use may cause side effects, including muscle laceration, fluid retention, increased heart load, renal failure in those with poor kidney functions, cramps or vomiting due to dilution of electrolytes with increased water intake, and gastrointestinal discomfort (diarrhea)."

## **The Labeling Requirements of the kiwi (*Actinidia chinensis*) seed extracts and the strawberry( *Fragaria x ananassa*) seed extracts as Food Ingredients**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The labeling of food products containing the kiwi (*Actinidia chinensis*) seed extracts and strawberry (*Fragaria x ananassa*) seed extracts shall bear the following warning statements: “This product may cause allergy in children” and "People taking medications and cannot drink grapefruit juice should pay particular attention."

## **The Labeling Requirements of *Echinacea angustifolia* Roots as Food Ingredients**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The labeling of food products containing *Echinacea angustifolia* roots shall bear the following warning statements: Children under the age of 2, patients with diabetics, immune-related diseases or those taking immune-related medicines should consult with medical personnel before use.

## **The Labeling Requirements of *Salvia hispanica* seeds as Food Ingredients**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The labeling of food products containing *Salvia hispanica* seeds shall bear the following warning statements: People allergic to peanuts and other nuts should consume with caution.



## **The Use Restrictions and Labeling Requirements of the Aerial Part Extracts of *Caralluma fimbriata* and *Phellinus linteus* Mycelium as Food Ingredients**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

For use as a food ingredient, The aerial part extracts of *Caralluma fimbriata* shall comply with the following requirements:

1. The daily intake shall not exceed 50 mg.
2. The labeling of food products containing aerial part extracts of *Caralluma fimbriata* shall bear the following warning statements: "Not suitable for pregnant women and infants."

### **Article 3**

For use as a food ingredient, *Phellinus linteus* mycellium shall comply with the following requirements:

1. The daily intake shall not exceed 3 g.
2. The labeling of food products containing *Phellinus linteus* mycellium shall bear the following information:
  - (1) The display of the full name of "*Phellinus linteus* mycelium" while the font size of all the characters should be the same.
  - (2) The warning statement "Not suitable for infants, young children, pregnant and lactating women."

## **The Use Restrictions and Labelling Requirements of Coenzyme Q10 as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of Coenzyme Q10 used as a food ingredient shall not exceed 30 mg.

### **Article 3**

The labeling of food products containing coenzyme Q10 shall bear the following warning statements: Not suitable for children under the age of 15, pregnant or lactating women, and patients taking anticoagulant drug of warfarin.

## **The Use Restrictions and Labelling Requirements of Glutathione, produced, from Torula Yeast Fermentation as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The daily intake of glutathione produced from torula yeast fermentation as a food ingredient shall not exceed 250 mg.

### **Article 3**

The labeling of food products containing glutathione produced from torula yeast fermentation shall bear the following warning statements: "People allergic to glutathione, pregnant or lactating women, infants and young children shall avoid consumption".

## **The Use Restrictions and Labeling Requirements of Methylsulfonyl Methane (MSM) as a Food Ingredient**

Promulgated on October 18, 2019

Effective from October 18, 2019

### **Article 1**

The regulations are prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

For use as a food ingredient, methylsulfonyl methane (MSM) shall comply with the following requirements:

1. The daily intake shall not exceed 6 g, and a single dose shall not exceed 2 g.
2. If MSM is synthesized by dimethyl sulfoxide (DMSO) and hydrogen peroxide, the residue of DMSO in the final product shall be less than 0.05%.

### **Article 3**

The labeling of food products containing MSM shall bear the following warning statements: "Avoid taking before going to bed. Pregnant and lactating women shall consult the doctor before consumption."

## **Regulation for The Use Restriction and Labeling Requirement of Cocoa (*Theobroma cacao*) Bean Hull as a Food Ingredient**

Promulgated on November 24, 2020

Effective from November 24, 2020

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The cocoa (*Theobroma cacao*) bean hull shall be dried and can only be used for brewing beverage.

### **Article 3**

The labelling of food products containing cocoa bean hull shall bear the following warning statement: Children, pregnant women and lactating women should avoid consuming.

## **Regulation for The Use Restriction and Labeling Requirement of 2'-fucosyllactose Produced by Genetically Modified *Escherichia coli* strain BL21 (DE3) #1540 as a Food Ingredient**

Promulgated on December 16, 2020

Effective from December 16, 2020

Amended on February 7, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The 2'-fucosyllactose (2'-FL) referred to herein is produced by fermentation process using genetically modified *Escherichia coli* strain BL21 (DE3) #1540 (hereinafter referred to as “*E. coli* BL21 (DE3) #1540”). The 2'-FL liquid concentrate can be purified from the fermentation medium via a sequence of purification steps including cation and anion exchange chromatography, concentration, activated carbon treatment, filtration, electrodialysis etc. The 2'-FL powder is derived from the 2'-FL liquid concentrate by spray drying. The final 2'-FL liquid concentrate and powder shall not contain any genetically modified microorganism and its transgenes.

### **Article 3**

For use as a food ingredient, the 2'-FL produced by *E. coli* BL21 (DE3) #1540 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for infant and follow-up formula, and milk powder or similar products for children under 7 years old.
3. The maximum level of 2'-FL is 1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer.
4. The container or external packaging of 2'-FL produced by *E. coli* BL21 (DE3) #1540 shall be displayed one of the following information: “The 2'-fucosyllactose is produced by genetically modified microorganism” or “The 2'-fucosyllactose is produced by genetically modified microorganism, but ultimately does not contain

any genetically modified microorganism and its transgenes”. Final products containing 2'-FL as one of its ingredients are exempted from this labeling requirement.

## Appendix

### Specifications of the 2'-fucosyllactose produced by genetically modified *Escherichia coli* strain BL21 (DE3) #1540

Chemical name	: $\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranose
Chemical formula:	: C <sub>18</sub> H <sub>32</sub> O <sub>15</sub>
Molecular weight	: 488.44 g/mol
CAS No	: 41263-94-9
Physical parameter	: 2'-fucosyllactose is a white to off white powder and the liquid concentrate aqueous solution is a colourless to slight yellow clear aqueous solution

Purity	
2'-fucosyllactose	: $\geq$ 90%
Lactose	: $\leq$ 5.0%
3-fucosyllactose	: $\leq$ 5.0%
Difucosyllactose	: $\leq$ 5.0%
Fucosylgalactose	: $\leq$ 3.0%
Glucose	: $\leq$ 3.0%
Galactose	: $\leq$ 3.0%
Fucose	: $\leq$ 3.0%
Genetically modified microorganisms detection	: Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
Water	: $\leq$ 9.0% (powder)
Solids content	: 45% w/v ( $\pm$ 5% w/v) (liquid)
Sulphated ash	: $\leq$ 0.5%
Residual proteins	: $\leq$ 0.01%

Heavy Metals	
Lead	: $\leq$ 0.02 mg/kg
Arsenic	: $\leq$ 0.2 mg/kg
Cadmium	: $\leq$ 0.1 mg/kg
Mercury	: $\leq$ 0.5 mg/kg

\* Specifications listed in this appendix apply to concentrated liquid and powder except for those specifically indicated applicable type



## **Regulation for The Use Restriction and Labeling Requirement of Coffee Leaves (*Coffea arabica*, *Coffea canephora*) as Food Ingredients**

Promulgated on January 5, 2021

Effective from January 5, 2021

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The coffee leaves (*Coffea arabica*, *Coffea canephora*) shall be dried and can only be used for brewing beverage.

### **Article 3**

The labelling of food products containing coffee leaves shall bear the following warning statement: Children, pregnant women and lactating women shall avoid consuming.

## **Regulation for The Use Restriction and Labeling Requirement of Guayusa Leaves (*Ilex guayusa*) as Food Ingredients**

Promulgated on February 4, 2021

Effective from February 4, 2021

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The guayusa leaves (*Ilex guayusa*) shall be dried and can only be used for brewing beverage.

### **Article 3**

The labelling of food products containing guayusa leaves shall bear the following warning statement: Children, pregnant women and lactating women shall avoid consuming.

## **Regulation for The Use Restrictions and Labeling Requirements of Astaxanthin Produced by Genetically Modified *Escherichia coli* strain Ast12 as a Food Ingredient**

Promulgated on March 11, 2021

Effective from March 11, 2021

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The astaxanthin referred to herein is produced by genetically modified *Escherichia coli* strain Ast12 (hereinafter referred to as “The astaxanthin produced by *E. coli* Ast12”). The manufacturing process includes the following steps: fermentation to obtain astaxanthin-rich microbial biomass, sterilization of the fermentation broth, centrifugation, drying, extraction of astaxanthin from microbial biomass by ethyl acetate, filtration to separate and remove microbial biomass, crystallization of astaxanthin by ethanol. The final pure crystallized astaxanthin shall not contain any genetically modified microorganism (*E. coli* Ast12) and its transgenes.

### **Article 3**

For use as a food ingredient, the astaxanthin produced by *E. coli* Ast12 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. The daily intake of the astaxanthin shall not exceed 2 mg.
3. The container or external packaging of the astaxanthin produced by *E. coli* Ast12 shall be displayed one of the following information: “The astaxanthin is produced by genetically modified microorganism” or “The astaxanthin is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”.

#### **Article 4**

The labelling of food products containing the astaxanthin produced by *E. coli* Ast12 shall bear the following warning statement: Children under twelve years old, pregnant women, lactating women and people taking drugs for hepatic or metabolic diseases shall avoid consuming.

## Appendix

### Specifications of the astaxanthin produced by genetically modified

#### *Escherichia coli* strain Ast12

Chemical name	: 3,3'-dihydroxy- $\beta,\beta$ -carotene-4,4'-dione
Chemical formula	: $C_{40}H_{52}O_4$
Molecular weight	: 596.84 g/mol
CAS No.	: 472-61-7
Appearance	: Violet brown powder
Total carotenoids	: $\geq 95\%$
Astaxanthin	: $\geq 80\%$
Genetically modified microorganisms detection	: Negative (detected by Real-Time Quantitative Polymerase Chain Reaction, qPCR)
Loss on drying	: $\leq 0.1\%$
Lead	: $\leq 2$ mg/kg
Arsenic	: $\leq 3$ mg/kg
Heavy metal ( as Pb)	: $\leq 10$ mg/kg

## **Regulation for The Use Restriction and Labeling Requirement of 2'-fucosyllactose Produced by Genetically Modified *Escherichia coli* strain K-12 DH1 MDO MAP1001d as a Food Ingredient**

Promulgated on June 16, 2021

Effective from June 16, 2021

Amended on February 7, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The 2'-fucosyllactose (2'-FL) referred to herein is produced by fermentation process using genetically modified *Escherichia coli* strain K-12 DH1 MDO MAP1001d (hereinafter referred to as "*E. coli* K-12 MAP1001d"). The 2'-FL powder can be purified from the fermentation broth via a sequence of purification steps including ion removal, activated charcoal treatment, filtration, concentration, crystallization with acetic acid, solid-liquid separation, washing and drying etc. The final 2'-FL powder shall not contain any genetically modified microorganism and its transgenes.

### **Article 3**

For use as a food ingredient, the 2'-FL produced by *E. coli* K-12 MAP1001d shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for infant and follow-up formula, and milk powder or similar products for children under 7 years old.
3. The maximum level of 2'-FL is 1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer.
4. The container or external packaging of 2'-FL produced by *E. coli* K-12 MAP1001d shall be displayed one of the following information: "The 2'-fucosyllactose is produced by genetically modified microorganism" or "The 2'-

fucosyllactose is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”. Final products containing 2'-FL as one of its ingredients are exempted from this labeling requirement.

## Appendix

### Specifications of the 2'-fucosyllactose produced by genetically modified *Escherichia coli* strain K-12 DH1 MDO MAP1001d

Chemical name	: $\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranose
Chemical formula	: C <sub>18</sub> H <sub>32</sub> O <sub>15</sub>
Molecular weight	: 488.44 g/mol
CAS No.	: 41263-94-9
Physical parameter	: 2'-fucosyllactose is a white to off white powder

#### Purity

2'-fucosyllactose	: $\geq$ 94%
D-Lactose	: $\leq$ 3.0%
L-Fucose	: $\leq$ 1.0%
Difucosyllactose	: $\leq$ 1.0%
2'-Fucosyl-D-lactulose	: $\leq$ 1.0%
Sum of 2'-fucosyllactose, D-lactose, L-fucose and Difucosyllactose	: $\geq$ 96%
Genetically modified microorganisms detection	: Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
pH (20°C , 5% solution)	: 3.2-5.0
Water	: $\leq$ 5.0%
Acetic acid	: $\leq$ 1.0%
Sulphated ash	: $\leq$ 1.5%
Residual proteins	: $\leq$ 0.01%
Heavy Metals	
Lead	: $\leq$ 0.1 mg/kg



## **Regulation for The Use Restriction and Labeling Requirement of the *Ganoderma microsporum* Globulin-like Protein Concentrate Produced by Genetically Modified *Pichia pastoris* Ey72 as a Food Ingredient**

Promulgated on February 16, 2022

Effective from February 16, 2022

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The *Ganoderma microsporum* globulin-like protein concentrate referred to herein is produced by fermentation process using genetically modified *Pichia pastoris* Ey72. The fermentation broth is concentrated via sequential steps including membrane filtration, concentration, membrane separation, mixing with water, sodium chloride and legal food additives, sterile filtration etc. The final *Ganoderma microsporum* globulin-like protein concentrate shall not contain any genetically modified microorganism and its transgenes.

### **Article 3**

For use as a food ingredient, the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall comply with the following requirements:

1. The detection result of genetically modified microorganism and its transgenes by real-time quantitative polymerase chain reaction (qPCR) shall be negative.
2. The content of the *Ganoderma microsporum* globulin-like protein shall be  $5.5 \pm 1.5$  mg/mL.
3. The daily intake of the *Ganoderma microsporum* globulin-like protein shall not exceed 6 mg.
4. The container or external packaging of the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall be displayed one

of the following information: “The *Ganoderma microsporum* globulin-like protein concentrate is produced by genetically modified microorganism” or “The *Ganoderma microsporum* globulin-like protein concentrate is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”. Final products containing the protein concentrate as one of its ingredients are exempted from this labeling requirement.

#### **Article 4**

The labelling of food products containing the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall bear the following warning statement: Children under twelve years old, pregnant women, lactating women and people with allergies shall avoid consuming.

## **Regulation for The Use Restrictions and Labeling Requirement of Aloe as a Food Ingredient**

Promulgated on March 17, 2022

Effective from January 1, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

Only the completely peeled leaves of *Aloe vera* and *Aloe ferox* can be used as food ingredients.

### **Article 3**

Food products containing the aloe leaves referred to in Article 2 shall comply with the following requirements:

1. The aloin content shall not exceed 10 ppm.
2. The labelling of food products shall bear the following warning statement:  
Pregnant women shall avoid consuming. Food products with analytical reports issued by analytical institutes indicating aloin levels below 1 ppm are exempted from the warning statement requirement.

### **Article 4**

The regulation will be implemented on 1 January 2023. However, food products containing aloe leaves can be placed on the market until their expiry date if the production date of domestic products or the imported date of imported products are before the implementation date.

## **Use Restrictions and Labeling Requirements of 2'-Fucosyllactose Produced by Genetically Modified *Escherichia coli* Strain K-12 MG1655 INB000846 as a Food Ingredient**

Promulgated on June 1, 2023

Effective from June 1, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The 2'-fucosyllactose (2'-FL) referred to herein is produced by fermentation process using genetically modified *Escherichia coli* strain K-12 MG1655 INB000846. The 2'-FL powder can be purified from the fermentation broth via a sequence of purification steps including filtration, removing the antifoaming agents, electrodialysis, ion exchange chromatography, activated charcoal treatment, evaporation, crystallization, and spray drying etc. The final 2'-FL powder shall not contain any genetically modified microorganism and its transgenes.

### **Article 3**

For use as a food ingredient, the 2'-FL produced by *E. coli* K-12 MG1655 INB000846 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for infant and follow-up formula, and milk powder or similar products for children under 7 years old.
3. The maximum level of 2'-FL is 1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer.
4. The container or external packaging of 2'-FL produced by *E. coli* K-12 MG1655 INB000846 shall be displayed one of the following information: “The 2'-fucosyllactose is produced by genetically modified microorganism” or “The 2'-fucosyllactose is produced by genetically modified microorganism, but

ultimately does not contain any genetically modified microorganism and its transgenes”. Final products containing 2'-FL as one of its ingredients are exempted from this labeling requirement.

## Appendix

### Specifications of the 2'-fucosyllactose produced by genetically modified *Escherichia coli* strain K-12 MG1655 INB000846

Chemical name	: $\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranose
Chemical formula	: C <sub>18</sub> H <sub>32</sub> O <sub>15</sub>
Molecular weight	: 488.44 g/mol
CAS No.	: 41263-94-9
Physical parameter	: 2'-fucosyllactose is a white to off white powder

#### Purity

2'-fucosyllactose	: $\geq$ 94%
D-Lactose	: $\leq$ 3.0%
L-Fucose	: $\leq$ 2.0%
Difucosyllactose	: $\leq$ 2.0%
2'-Fucosyl-D-lactulose	: $\leq$ 1.5%
Sum of 2'-fucosyllactose, D-lactose, L-fucose and Difucosyllactose	: $\geq$ 96%
Genetically modified microorganisms detection	: Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
Water	: $\leq$ 9.0%
Total ash:	: $\leq$ 0.5%
Residual proteins	: $\leq$ 0.01%
Heavy Metals	
Lead	: $\leq$ 0.05 mg/kg
Arsenic	: $\leq$ 0.2 mg/kg

## **Use Restrictions and Labeling Requirements of *trans*-Resveratrol Produced by Genetically Modified *Saccharomyces cerevisiae* Strain EFSC4687 as a Food Ingredient**

Promulgated on June 29, 2023

Effective from June 29, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The *trans*-resveratrol referred to herein is produced by fermentation process using genetically modified *Saccharomyces cerevisiae* strain EFSC4687. The *trans*-resveratrol powder can be purified from the fermentation via a sequence of purification steps including ultrafiltration, washing with water, pH adjustment with sodium hydroxide, diafiltration, precipitation with sulfuric acid, concentration, filtration, dissolution with ethanol, anion-exchange resin, carbon treatment, crystallization with water, filtration and drying etc. The final *trans*-resveratrol powder shall not contain any genetically modified microorganism and its transgenes.

### **Article 3**

For use as a food ingredient, the *trans*-resveratrol produced by *S. cerevisiae* strain EFSC4687 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for food supplements intended for adult population, and the daily intake shall not exceed 150 mg.
3. The container or external packaging of *trans*-resveratrol produced by *S. cerevisiae* strain EFSC4687 shall be displayed one of the following information:  
“The *trans*-resveratrol is produced by genetically modified microorganism”  
or “The *trans*-resveratrol is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its

transgenes” . Final products containing *trans*-resveratrol as one of its ingredients are exempted from this labeling requirement.

#### **Article 4**

The labelling of food products containing the *trans*-resveratrol shall bear the following warning statements: This product can only be used for adult population, pregnant women and lactating women shall avoid consuming. People using medicines shall only consume the product under medical supervision.



## Appendix

### Specifications of the *trans*-resveratrol produced by genetically modified *Saccharomyces cerevisiae* strain EFSC4687

Chemical name	: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol
Chemical formula	: C <sub>14</sub> H <sub>12</sub> O <sub>3</sub>
Molecular weight	: 228.25 Da
CAS No.	: 501-36-0
Physical parameter	: Off-white to slight yellow powder

#### Purity

<i>trans</i> -resveratrol	: $\geq$ 98% (dry weight basis)
Genetically modified microorganisms detection	: Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
Ash	: $\leq$ 0.5%
Water	: $\leq$ 3.0%

#### Heavy Metals

Lead	: < 1 ppm
Arsenic	: < 1.5 ppm
Cadmium:	: < 1 ppm
Mercury	: < 0.1 ppm

## **Use Restrictions and Labeling Requirements of Broccoli (*Brassica oleracea* var. *italica*) Seed Extract as a Food Ingredient**

Promulgated on June 8, 2023

Effective from June 8, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The broccoli seed extract referred to herein is produced from seeds of *Brassica oleracea* var. *italica*. The manufacturing process includes the following steps: hot water extraction, filtration to obtain the liquid extract, decolorization with activated charcoal, centrifugation, filtration, concentration and spray drying etc.

### **Article 3**

For use as a food ingredient, the broccoli seed extract shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for food products intended for adult population, and the daily intake shall not exceed 115 mg.

### **Article 4**

The labelling of food products containing the broccoli seed extract shall bear the following warning statements: This product can only be used for adult population, pregnant women, lactating women and those with thyroid-associated diseases shall avoid consuming. People using anticoagulants and cancer patients shall only consume the product under medical supervision.

## Appendix

### Specifications of the broccoli seed extract

Appearance:	Off-white to tan powder
Glucoraphanin:	13-20%
Moisture:	< 8%
Heavy Metals	
Arsenic:	< 2 ppm
Lead:	< 1.5 ppm
Cadmium:	< 0.5 ppm
Mercury	< 0.5 ppm

## **Use Restrictions and Labeling Requirements of Hen Egg White Lysozyme Hydrolysate as a Food Ingredient**

Promulgated on June 8, 2023

Effective from June 8, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The hen egg white lysozyme hydrolysate referred to herein is obtained from hen egg white lysozyme via sequential steps including enzymatic hydrolysis by subtilisin protease derived from *Bacillus licheniformis*, filtration and spray drying etc.

### **Article 3**

For use as a food ingredient, the hen egg white lysozyme hydrolysate shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for food supplements intended for adult population, and the daily intake shall not exceed 1 g.

### **Article 4**

The labelling of food products containing the hen egg white lysozyme hydrolysate shall bear the following warning statement: This product can only be used for adult population, egg-allergic individuals, pregnant women, lactating women and those with chronic kidney disease shall avoid consuming.

## Appendix

### Specifications of the hen egg white lysozyme hydrolysate

Appearance:	White to light yellow powder
Solubility:	Freely soluble in water
Protein*:	80-90%
Tryptophan:	5-7%
Tryptophan/Large Neutral Amino	0.18-0.25
Acids** ratio:	
Degree of hydrolysis:	19-25%
Moisture:	< 5%
Ash:	< 10%
Sodium:	< 6%
Heavy Metals	
Arsenic:	< 1 ppm
Lead:	< 1 ppm
Cadmium:	< 0.5 ppm
Mercury	< 0.1 ppm

\* : Total Nitrogen  $\times$  5.30

\*\* : Calculated by Phenylalanine, Isoleucine, Leucine, Valine and Tyrosine.

## **Use Restrictions and Labeling Requirements of Liquid Mycelia Culture Powder of Morel Mushroom (*Morchella esculenta*) as a Food Ingredient**

Promulgated on October 5, 2023

Effective from October 5, 2023

### **Article 1**

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

### **Article 2**

The liquid mycelia culture powder of morel mushroom referred to herein is produced from morel mushroom (*Morchella esculenta*) by liquid fermentation with approved food ingredients and food additives as culture medium, and then heating, sterilization and drying.

### **Article 3**

For use as a food ingredient, the liquid mycelia culture powder of morel mushroom shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for food products intended for adult population, and the daily intake shall not exceed 1,200 mg.

### **Article 4**

The labelling of food products containing the liquid mycelia culture powder of morel mushroom shall bear following warning statement: This product can only be used for adult population, pregnant women and lactating women shall avoid consuming.

## Appendix

### Specifications of liquid mycelia culture powder of morel mushroom

Appearance:	Dark brown powder
Morel mycelia content	70-90%
Lovastatin:	< 50 ppb
Ergosterol:	0.80-1.2 mg/g
Total polysaccharide:	9-14%
Moisture:	≤ 8.0%
Heavy Metals	
Arsenic:	≤ 1 ppm
Lead:	≤ 1 ppm
Cadmium:	≤ 1 ppm
Mercury	≤ 1 ppm

## **The Relevant Regulations of Special Dietary Foods**



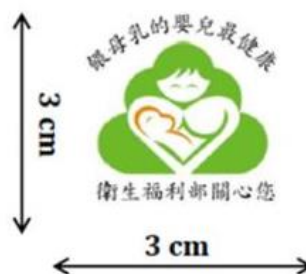
## **The Identification Mark of Infant and Follow-up Infant Formulas as Special Dietary Foods Shall be Conspicuously Labelled by Direct Printing on the Container to Facilitate the Identification by Consumers**

Promulgated on August 11, 2015

Effective from August 11, 2015

### **Article**

1. This rule is formulated in accordance with the provisions of Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.
2. Only infant and follow-up infant formulas those have been reviewed and approved for registration by the central competent authority are allowed to be labelled with this identification mark. The design of the identification mark should have the image promoting breastfeeding presented simultaneously with the promotional text.
3. The specifications of the identification mark are as follows:
  - (1) The phrases "Breastfed babies are the healthiest" and "MOHW cares about you" should be at least Font 8.
  - (2) Colors (CMYK) used on the drawing for promoting breastfeeding: green (Y100C60), orange (Y100M60).
  - (3) The size of the identification mark can be determined by the user as needed, but should not be less than 3 cm (height) x 3 cm (width).



標誌 3 cm x 3 cm

字體大小 8 號字體

Mark Size: 3cm\*3cm

Character font size: 8

## **Regulations Governing the Labeling which shall be labeled of Infant and Follow-up Formula**

Promulgated on February 1, 2023

Effective from January 1, 2025

### **Article**

1. The Regulations are established under the provisions of Article 22 Paragraph 1 Subparagraph 10 of the Act Governing Food Safety and Sanitation.
2. Infant and Follow-up formula shall have container or external packaging labeled with the following information, as required in addition to general information of the packaged food requirements:
  - (1) Products with iron content less than 1 milligram per 100 kilocalories shall be labeled with the warning statement "For infants, additional iron may be necessary", or the synonyms.
  - (2) Products with iron content of 1 milligram per 100 kilocalories or more shall be labeled with the warning statement "Infant formula with iron", or the synonyms.
  - (3) Instructions of storage before and after opening.
  - (4) Directions for product preparation and amount of using.
    - i. Products in powder form shall be labeled with the weight of a spoonful filled with the attached measuring spoon, and the amount of the product and water required for preparation.
    - ii. Concentrated products in liquid form shall be labeled with the warning statement "Must be prepare with water before feeding" or the synonyms, and the amount of the product and water required for preparation.
  - (5) The warning statement "Prepare and dilute with water that has been boiled and then cooled to warm and in totally sterilized containers only", or the synonyms.
  - (6) The warning statement "Inappropriate preparation will cause health hazard of the baby", or the synonyms.

- (7) Products in liquid form shall be labeled with the warning statement "Shake the bottle till the solution is evenly mixed before feeding", or the synonyms.
  - (8) The warning statement "From the age over six months, infant shall receive complementary foods in addition to the formula", or the synonyms.
  - (9) The warning statement "User shall follow the advice of health care worker and nutritionists to determine whether the need for infant formula and the proper method of use", or the synonyms.
  - (10) The recognized label shall be clearly printed on the container or external packaging. The image and specifications are regulated in the Appendix.
  - (11) Infant formula in liquid form shall be labeled with the warning statement, "For hospital use only".
3. In addition to the foregoing requirements, the container or external packaging shall be labeled with the following information depending on the product categories:
- (1) Infant formula:
    - i. The phrase "infant formula" shall be labeled.
    - ii. A statement of the superiority of breastfeeding shall be labeled.
    - iii. The baby's weight shall be added in the feeding table.
  - (2) Follow-up infant formula: The phrase "follow-up infant formula " shall be labeled.
  - (3) Infant formula for special medical purposes: The characteristics of the products and applicable users.
4. Phrases like "humanized", "maternalized" or other similar phrases suggesting superiority to breast milk shall not be labeled on the container or external packaging of infant and follow-up formula. Nor shall there have pictures of infants or phrases and pictures which may idealize the use of product.
5. The label contents specified in Articles 2 and 3 shall follow the specifics approved by registration review of the products. For any changes, applications shall be filed in

accordance with the Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products. The changes can be made only with the approval granted.

6. If the labeling of the product does not comply with this regulation, and appears to be false, exaggerated or misleading, it shall be fined in accordance with the relevant regulations of this law.

## Appendix

### Image and Specifications of the recognized label on the container or external packaging of Infant and Follow-up Formula:

#### 1. Image:



#### 2. Specifications:

- (1) The words of the image "Breast milk is the best food for your baby" and "Ministry of Health and Welfare cares for you" shall be printed using at least font size 8.
- (2) The image shall be printed using CMYK colors: green (Y100C60) and orange (Y100M60).
- (3) The size of the image may be determined by the user, but shall not be smaller than 3 cm (height) × 3 cm (width).

## Regulations Governing the Labeling of Formula for Certain Disease

Promulgated on February 6, 2020

1. The Regulations are established under the provisions of Article 22 Paragraph 1 Subparagraph 10 of the Act Governing Food Safety and Sanitation.
2. Formula for certain disease shall have container or external packaging labeled with the following information, as required in addition to general information on regulations of prepackaged food requirements:
  - (1) The applicable subjects.
  - (2) Storage instructions before and after the package is opened.
  - (3) Usage and dosage instructions.
  - (4) Warning statement: "This product is a formula food for certain disease, and it is not suitable for the general population and must be taken under the instruction of a doctor or registered dietitian", or the synonyms. Text shall appear bold and be distinct from the background color.
  - (5) Warning statement: "Increasing dosage will not help improve this type of disease", or the synonyms.
  - (6) Warning statement: "This product is not for intravenous use", or the synonyms.
  - (7) Tube-feeding formulas must specify the osmotic pressure.
  - (8) Other precautions related to nature thereof and characteristics of product.
3. In addition to the foregoing requirements, different categories shall have the following additional information printed on the container or package:
  - (1) Nutritionally complete food with balance formula:

All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products.
  - (2) Nutritionally complete food with customized formula:

- A. All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products.
  - B. Products with adjusted nutrients/ingredients must specify the “increased” “reduced” or “eliminated” nutrient/ingredient, or the synonyms.
- (3) Nutrition adjusted supplementary formula food:
- A. All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products.
  - B. Products with nutrients/ingredients adjusted must specify the “increased”, “reduced” or “eliminated” nutrient/ingredient, or the synonyms.
  - C. Where a product does not contain the essential fatty acids, such must be stated on the product (e.g. “This product does not contain the essential fatty acids.”). Where a product does not contain one of the essential fatty acids, Linoleic acid (LA) or  $\alpha$ -Linolenic acid (ALA), such must be stated on the product (e.g. “This product does not contain Linoleic acid, an essential fatty acid” or “This product does not contain  $\alpha$ -Linolenic acid, an essential fatty acid”).
  - D. “This product should not be used as the sole source of nutrients” label in bold.
- (4) Special modular formula food:
- A. Products with a specific nutrient or ingredient must specify the nutrient and nutrient content on the label.
  - B. “This product should not be used as the sole source of nutrients” label in bold.
4. The label of the two foregoing requirements with particularity is set after approving the application through examination procedure. In the event of changes in the information of the label, the application of modification according to Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products shall be submitted for approval.

## **Amendment to Article 2 of Regulations Governing the Labeling of Formula for Certain Disease**

Promulgated on February 6, 2020

Amended on October 9, 2022

Effective from January 1, 2025

2. Formula for certain disease shall have container or external packaging labeled with the following information, as required in addition to general information on regulations of prepackaged food requirements:
  - (1) “Formula for Certain Disease” shall appear prominently and conspicuously on the principal display panel of container or external packaging. The characters of the labeling shall not be less than 0.4 centimeters in length and width and shall be of equal size. The color of the font shall be clearly distinguishable from the background color of the product packaging.
  - (2) The applicable subjects.
  - (3) Storage instructions before and after the package is opened.
  - (4) Usage and dosage instructions.
  - (5) Warning statement: "This product is a formula food for certain disease, and it is not suitable for the general population and must be taken under the instruction of a doctor or registered dietitian", or the synonyms. Text shall appear bold and be distinct from the background color.
  - (6) Warning statement: "Increasing dosage will not help improve this type of disease", or the synonyms.
  - (7) Warning statement: "This product is not for intravenous use", or the synonyms.
  - (8) Tube-feeding formulas must specify the osmotic pressure.
  - (9) Other precautions related to nature thereof and characteristics of product.



# **The Relevant Regulations for Labeling of Food Utensils, Food Containers**

## **The Items of Food Utensils, Food Containers or Packaging shall be Labelled as Required**

Promulgated on April 18, 2016

Effective from July 1, 2017

1. Food utensils, food containers or packaging with plastics on their food contact surface, shall be labelled as required by Article 26 of the Act Governing Food Safety and Sanitation before sale.
2. Products shall follow the regulation if produced on or after the date when the regulation came into force.

## **Regulations on the Labeling of Food Utensils, Food Containers, or Packaging**

Promulgated on April 18, 2016

Effective from July 1, 2017

1. The regulations are promulgated according to Subparagraph 8, Article 26 of the Act Governing Food Safety and Sanitation.
2. Food utensils, food containers or packaging shall be labelled with “for food contact use” or the words with equivalent meaning.
3. Food utensils, food containers or packaging with plastics on their food contact surface, shall be labelled as reusable or disposable, or the words with equivalent meaning.
4. Food utensils, food containers or packaging with polyvinyl chloride (PVC) or poly(vinylidene chloride) (PVDC) on its food contact surface, shall be labelled with the note that the products shall not directly contact with high-fat and high-temperature food, or the words with equivalent meaning.

## **Principles for Labelling the Names of Plastic Materials in Food Utensils, Containers and Packaging**

Promulgated on December 10, 2019

Effective from December 10, 2019

### **1. Legal basis**

In compliance with Article 26 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act), “food utensils, food containers or packaging<sup>1</sup> that contain plastic materials on food contact surfaces” announced by the central competent authority in a public announcement shall conspicuously indicate in Chinese and common symbols the material names etc. Those composed of two or more materials shall indicate the material names separately. In compliance with Subparagraph 1 of Article 21 of the Act, the content of the labelling should be printed, embossed, stamped or labelled on the packaging or body of the smallest sales unit, and it should be conspicuously visible during sales and circulation. Plastic utensils and containers for repeated uses which are regulated by the central competent authority<sup>2</sup>, the material name of the main body and heat resistance temperature should be marked through printing, embossing, or stamping on main body.

### **2. Principles for Labelling the Names of Plastic Materials**

- (1) Names of the materials should be marked with "the Chinese terms or generally recognized symbols." For the principles for identifying the generally recognized symbols, refer to Appendix 1. Those composed of two or more plastic materials shall indicate the material names separately.
- (2) Other than the regulation that "plastic materials generally understood to contain specific fillers and reinforcing materials should be marked in the manner listed in Appendix 2", marking is not required for "material characteristics", "additives", "fillers and reinforcing materials" on plastic

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<sup>1</sup> MOHW Public Announcement No. Bu-shou-shi-zi-di-1041304937 of April 18, 2016.

<sup>2</sup> MOHW Public Announcement No. Bu-shou-shi-zi-di-1041302075 of September 18, 2015.

materials. Voluntarily marking should comply with the rules specified in Appendix 2 and Appendix 3. In addition to this, the general name is not regarded as the material name.

- (3) For assembly parts or laminated materials, the labelling should at least include the materials<sup>3</sup> of the "food contact surface" and "main constituent". Otherwise, labelling by legends or in an outward sequence is recommended to present the material names of each part or laminated materials.

### **3. Miscellaneous**

- (1) The principles are used for illustration purposes only in determining the compliance with the rules governing the labelling the names of plastic materials in food utensils, containers, and packaging. These are not to be construed as relevant materials already being used in products, nor indicating the application and sanitation safety, etc. of any materials. Business operators are advised to exercise discretion to ensure the compliance of their products with relevant provisions of the Act, including Article 16 of the said Act and the "Sanitary Standards for Food Utensils, Containers and Packaging" stipulated based on Article 17 of the Act.
- (2) With regard to the contents of the appendices and schedules of these principles, FDA will make compilations, updates, reviews, amendments, and announcements from time to time.

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<sup>3</sup> For example, marking of "PE-coated paper" is not accepted. Required marking format is like: PE (food contact surface) and "paper" (main body of the material).

**TABLE 1: TABLE OF ABBREVIATIONS OF GENERAL PLASTIC MATERIALS**

Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
AB		acrylonitrile-butadiene plastic	丙烯腈-丁二烯塑膠	[A]
ABAK	ABA	acrylonitrile-butadiene-acrylate plastic	丙烯腈-丁二烯-丙烯酸酯塑膠	[A]
ABS		acrylonitrile-butadiene-styrene plastic	丙烯腈-丁二烯-苯乙烯塑膠	[A]
ACS	ACPES	acrylonitrile-chlorinated polyethylene-styrene	丙烯腈-氯化聚乙烯-苯乙烯	[A]
AEPDS	AEPDMS	acrylonitrile-(ethylene-propylene-diene)-styrene plastic	丙烯腈-(乙烯-丙烯-二烯)-苯乙烯塑膠	[A]
AMMA		acrylonitrile-methyl methacrylate plastic	丙烯腈-甲基丙烯酸甲酯塑膠	[A]
ASA		acrylonitrile-styrene-acrylate plastic	丙烯腈-苯乙烯-丙烯酸酯塑膠	[A]
CA		cellulose acetate	乙酸纖維素	[A]
CAB		cellulose acetate butylate	乙酸丁酸纖維素；或纖維素乙酸丁酸酯	[A]
CAP		cellulose acetate propionate	乙酸丙酸纖維素；或纖維素乙酸丙酸酯	[A]
CEF		cellulose formaldehyde	甲醛纖維素	[A]
CF		cresol-formaldehyde resin	甲酚-甲醛樹脂	[A]
CMC		carboxymethyl cellulose	羧甲基纖維素	[A]
CN		cellulose nitrate	硝酸纖維素	[A]
COC		cycloolefin copolymer	環烯烴共聚物	[A]
CP		cellulose propionate	丙酸纖維素；或纖維素丙酸酯	[A]

<sup>4</sup> The "abbreviations" in the first column of the table are the preferred abbreviations, and the "other abbreviations" in the second column are those that should be gradually converted into the preferred abbreviations in the future. Considering the general applications in the relevant industries, these are taken as the generally recognized symbols of the respective materials.

<sup>5</sup> [A] indicates ISO 11469. [B] indicates the information submitted by the food industry operators when referring to the materials on the "Registration Platform for Food and Pharmaceutical Enterprises". [C] indicates the wording principles announced in the "Sanitary Standards for Food Utensils, Containers and Packaging" of the Ministry of Health and Welfare.

Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
CTA		cellulose triacetate	三乙酸纖維素；或纖維素三乙酸酯	[A]
EAA		ethylene-acrylic acid plastic	乙烯-丙烯酸塑膠	[A]
E/B		ethylene-1-butene plastic	乙烯-1-丁烯塑膠	[B]
EBAK	EBA	ethylene-butyl acrylate plastic	乙烯-丙烯酸丁酯塑膠	[A]
EC		ethyl cellulose	乙基纖維素	[A]
EEAK	EEA	ethylene-ethyl acrylate plastic	乙烯-丙烯酸乙酯塑膠	[A]
EMA		ethylene-methacrylic acid plastic	乙烯-丙烯酸甲酯塑膠	[A]
EP		epoxide; epoxy resin or plastic	環氧化物；或環氧樹脂（或環氧塑膠）	[A]
E/P	EPM	ethylene-propylene plastic	乙烯-丙烯塑膠	[A]
ETFE		ethylene-tetrafluoroethylene plastic	乙烯-四氟乙烯塑膠	[A]
EVAC	EVA	ethylene-vinyl acetate plastic	乙烯-乙酸乙烯酯塑膠	[A]
EVOH		ethylene-vinyl alcohol plastic	乙烯-乙烯醇塑膠	[A]
FEP	PFEP	perfluoro (ethylene-propylene) plastic	全氟(乙烯-丙烯)塑膠	[A]
FF		furan-formaldehyde resin	呋喃-甲醛樹脂	[A]
HBV		poly(3-hydroxybutyrate)-co-(3-hydroxyvalerate)	聚羥基丁烷酸-羥基戊烷酸共聚物	[A]
MABS		methyl methacrylate-acrylonitrile-butadiene-styrene plastic	甲基丙烯酸甲酯-丙烯腈-丁二烯-苯乙烯塑膠	[A]
MBS		methyl methacrylate-butadiene-styrene plastic	甲基丙烯酸甲酯-丁二烯-苯乙烯塑膠	[A]
MC		methyl cellulose	甲基纖維素	[A]
MF		melamine-formaldehyde resin	三聚氰胺-甲醛樹脂	[A]
MP		melamine-phenol resin	三聚氰胺-酚樹脂	[A]
MSAN		$\alpha$ -methylstyrene-acrylonitrile plastic	$\alpha$ -甲基苯乙烯-丙烯腈塑膠	[A]
PA <sup>6</sup>		polyamide	聚醯胺；或尼龍	[A], [C]

<sup>6</sup> Types of nylon should be marked in complete terms, such as: PA6, PA66, PA11, PA12, PA610, PA

Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
PAA		poly(acrylic acid)	聚丙烯酸	[A]
PAEK		polyaryletherketone	聚芳基醚酮	[A]
PAI		polyamideimide	聚醯胺醯亞胺	[A]
PAK		polyacrylate	聚丙烯酸酯	[A]
PAN		polyacrylonitrile	聚丙烯腈	[A]
PAR		polyarylate	聚芳酸酯	[A]
PARA		poly(arylamide)	聚芳基醯胺	[A]
PB		polybutene	聚丁烯	[A]
PBAK		poly(butyl acrylate)	聚丙烯酸丁酯	[A]
PBD		1,2-polybutadiene	1,2-聚丁二烯	[A]
PBN		poly(butylene naphthalate)	聚對萘二甲酸丁二酯	[A]
PBS		poly(butylene succinate)	聚丁二酸丁酯	[A], [B]
PBSA		poly(butylene succinateadipate)	聚丁二酸丁酯己二酸共聚物	[A]
PBT		poly(butylene terephthalate)	聚對苯二甲酸丁二酯	[A], [C]
PC		polycarbonate	聚碳酸酯	[A], [C]
PCCE		poly(cyclohexylene dimethylene cyclohexane dicarboxylate)	聚環己二亞甲基環己二甲酸酯	[A]
PCL		polycaprolactone	聚己內酯	[A]
PCO		polycycloolefin	聚環烯烴	[A]
PCT		poly(cyclohexylenedimethylene terephthalate)	聚對苯二甲酸二亞甲基環己二基酯	[A], [C]
PCTFE		polychlorotrifluoroethylene	聚氯三氟乙烯	[A]
PDAP		poly(diallyl phthalate)	聚鄰苯二甲酸二烯丙酯	[A], [C]
PDCPD		polydicyclopentadiene	聚二環戊二烯	[A]
PE		polyethylene	聚乙烯	[A], [C]
PEC		polyestercarbonate	聚酯碳酸酯	[A]
PEEK		polyetheretherketone	聚醚醚酮	[A]
PEEST		polyetherester	聚醚酯	[A]
PEI		polyetherimide	聚醚醯亞胺	[A]
PEK		polyetherketone	聚醚酮	[A]
PEN		poly(ethylene naphthalate)	聚萘二甲酸乙二酯	[A]

612, PA1010, PA46, PA7, PA9, PA13, PA6T, PA9T, etc.



Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
PEOX		poly(ethylene oxide)	聚環氧乙烷；或聚氧化乙烯	[A]
PESTUR		polyesterurethane	聚酯胺酯	[A]
PESU	PES	polyethersulfone	聚醚砵	[A], [C]
PET	PETE	poly(ethylene terephthalate)	聚對苯二甲酸乙二酯	[A], [C]
PEUR		polyetherurethane	聚醚胺酯	[A]
PF		phenol-formaldehyde resin	酚甲醛樹脂	[A]
PFA		perfluoroalkoxyalkane resin	全氟(代)烷氧基鏈烷樹脂	[A]
PHA		polyhydroxyalkanoate	聚羧基烷酸酯	[B]
PI		polyimide	聚醯亞胺	[A]
PIB		polyisobutylene	聚異丁烯	[A]
PIR		polyisocyanurate	聚異氰脲酸酯；或聚三聚異氰酸酯	[A]
PK		polyketone	聚酮	[A]
PLA		polylactic acid	聚乳酸	[C]
PMI		polymethacrylimide	聚甲基丙烯醯亞胺；或聚異丁醯亞胺	[A]
PMMA		poly(methyl methacrylate)	聚甲基丙烯酸甲酯	[A], [C]
PMMI		poly(N-methylmethacrylimide)	聚-N-甲基丙烯醯亞胺	[A]
PMP		poly-4-methylpent-1-ene	聚甲基戊烯	[A], [C]
PMS		poly- $\alpha$ -methylstyrene	聚甲基苯乙烯	[A]
POM		poly(oxymethylene); polyacetal; polyformaldehyde	聚氧亞甲基；或聚縮醛； 或聚甲醛	[A]
PP		polypropylene	聚丙烯	[A], [C]
PPC		polypropylene carbonate	聚丙烯碳酸酯	[B]
PPE		poly(phenylene ether)	聚伸苯基醚	[A]
PPOX		poly(propylene oxide)	聚環氧丙烷；或聚氧化丙烯	[A]
PPS		poly(phenylene sulfide)	聚伸苯基硫醚；或聚苯硫醚	[A]
PPSU		poly(phenylene sulfone)	聚伸苯基砵；或聚苯砵	[A], [C]
PS		polystyrene	聚苯乙烯	[A], [C]
PSU		polysulfone	聚砵	[A]

Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
PTFE		polytetrafluoroethylene	聚四氟乙烯；或鐵氟龍	[A]
PTT		poly(trimethyleneterephthalate)	聚對苯二甲酸丙二酯	[A], [C]
PUR	PU	polyurethane	聚胺基甲酸酯；或聚胺酯	[A]
PVAC	PVA	poly(vinyl acetate)	聚乙酸乙烯酯	[A]
PVAL	PVOH	poly(vinyl alcohol)	聚乙烯醇	[A]
PVB		poly(vinyl butyral)	聚乙烯醇縮丁醛	[A]
PVC		poly(vinyl chloride)	聚氯乙烯	[A], [C]
PVDC		poly(vinylidene dichloride)	聚偏二氯乙烯	[A], [C]
PVDF		poly(vinylidene difluoride)	聚偏二氟乙烯	[A]
PVF		poly(vinyl fluoride)	聚氟乙烯	[A]
PVFM		poly(vinyl formal)	聚乙烯醇縮甲醛	[A]
PVK		poly(N-vinylcarbazole)	聚-N-乙烯基咔唑	[A]
PVP		poly(N-vinylpyrrolidone)	聚-N-乙烯基吡咯烷酮	[A]
SAN		styrene-acrylonitrile plastic	苯乙烯-丙烯腈塑膠	[A]
SB		styrene-butadiene plastic	苯乙烯-丁二烯塑膠	[A]
SI		silicone plastic	矽氧塑膠；或矽膠	[A], [B]
SMAH	SMA	styrene-maleic anhydride plastic	苯乙烯-順丁烯二酐塑膠	[A]
SMMA		styrene-methyl methacrylate plastic	苯乙烯-甲基丙烯酸甲酯塑膠	[B]
SMS		styrene- $\alpha$ -methylstyrene plastic	苯乙烯- $\alpha$ -甲基苯乙烯塑膠	[A]
UF		urea-formaldehyde resin	尿素-甲醛樹脂	[A]
VCE		vinyl chloride-ethylene plastic	氯乙烯-乙烯塑膠	[A]
VCEMAK	VCEMA	vinyl chloride-ethylene-methyl acrylate plastic	氯乙烯-乙烯-丙烯酸甲酯塑膠	[A]
VCEVAC		vinyl chloride-ethylene-vinyl acetate plastic	氯乙烯-乙烯-乙酸乙烯塑膠	[A]
VCKAK	VCMA	vinyl chloride-methyl acrylate plastic	氯乙烯-丙烯酸甲酯塑膠	[A]
VCMAA		vinyl chloride-methyl methacrylate plastic	氯乙烯-甲基丙烯酸甲酯塑膠	[A]
VCKAK	VCKA	vinyl chloride-octyl acrylate plastic	氯乙烯-丙烯酸辛酯塑膠	[A]

Abbreviations	Other Abbreviations <sup>4</sup>	Names in English	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>5</sup>
VCVAC		vinyl chloride-vinyl acetate plastic	氯乙烯-乙酸乙烯酯塑膠	[A]
VCVDC		vinyl chloride-vinylidene dichloride plastic	氯乙烯-偏二氯乙烯塑膠	[A]
VE		vinyl ester resin	乙烯酯樹脂	[A]
改質PCT		1,4-benzenedicarboxylic acid, dimethyl ester, polymer with 1,4- cyclohexanedimethanol and 2,2,4,4-tetramethyl -1,3-cyclobutanediol; Tritan™ (TX1000、TX1001、TX1500HF、TX1501HF、TX2000、TX2001、TX3000、TX3001、TX1800、TX1801)	(1,4-環己烷二甲醇與2,2,4,4-四甲基-1,3-環丁二醇)及對苯二甲酸二甲酯合成之共聚酯	

**TABLE 2: TABLE OF ABBREVIATED NAMES OF PLASTIC MATERIALS**

Abbreviations <sup>7</sup>	Description of Form	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>8</sup>
ACM Rubber	copolymer of ethyl acrylate and monomer for vulcanization (acrylic rubber)	丙烯酸酯橡膠；或壓克力橡膠	[A], [B]
AEM Rubber	copolymer of ethyl or other acrylates and ethylene	乙烯丙烯酸橡膠	[A], [B]
ANM Rubber	copolymer of ethyl or other acrylate and acrylonitrile	丙烯酸乙酯-丙烯腈共聚橡膠	[A], [B]
BIMSM Rubber	brominated polymers derived from a copolymer of isobutylene and <i>p</i> -methylstyrene	溴化異丁烯-對甲基苯乙烯共聚橡膠	[B]
CM Rubber	chloro-polyethylene	氯化聚乙烯橡膠	[B]
CFM Rubber	polychloro-trifluoro-ethylene	聚氯三氟乙烯橡膠	[B]
CSM Rubber	chloro-sulfonyl-polyethylene	氯磺化聚乙烯橡膠	[A], [B]
EBM Rubber	copolymer of ethylene and butene	乙丁橡膠	[A]
EOM Rubber	copolymer of ethylene and octene	乙己橡膠	[A], [B]
EPDM Rubber	terpolymer of ethylene, propylene, and a diene with the residual unsaturated portion of the diene in the side chain	三元乙丙橡膠	[A], [B]
EPM Rubber	copolymer of ethylene and propylene	乙丙橡膠	[A], [B]
EVM Rubber	copolymer of ethylene and vinyl acetate	乙烯-乙酸乙烯酯橡膠	[A], [B]
FEPM Rubber	fluoro-rubber of the polymethylene type only containing one or more of the monomeric alkyl, perfluoroalkyl, and/or perfluoroalkoxy groups, with or without a cure site monomer	四丙氟橡膠	[A], [B]
FFKM Rubber	perfluorinated rubber of the polymethylene type having all fluoro, perfluoroalkyl, or perfluoroalkoxy substituent groups on the polymer chains	全氟橡膠	[A], [B]

<sup>7</sup> The word “Rubber” of each abbreviation should not be deleted.

<sup>8</sup> [A] represents ISO 1629, and [B] represents ASTM D1418.

Abbreviations <sup>7</sup>	Description of Form	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>8</sup>
FKM Rubber	fluoro-rubber of the polymethylene type that utilizes vinylidene fluoride as a comonomer and has substituent fluoro, alkyl, perfluoroalkyl or perfluoroalkoxy groups on the polymer chain, with or without a cure site monomer	氟橡膠	[A], [B]
IM Rubber	polyisobutylene	聚異丁烯橡膠	[B]
NBM Rubber	hydrogenated acrylonitrile-butadiene rubber (saturated)	氫化丁腈橡膠	[A]
SEBM Rubber	terpolymer of styrene, ethylene and butene	苯乙烯橡膠	[A]
SEPM Rubber	terpolymer of styrene, ethylene and propylene	苯乙烯橡膠	[A]
CO Rubber	polychloromethyl oxirane	聚醚橡膠	[A], [B]
ECO Rubber	copolymer of ethylene oxide and chloromethyloxirane		[A], [B]
GECO Rubber	epichlorohydrin-ethylene oxide-allylglycidylether terpolymer		[A], [B]
GPO Rubber	polypropylene oxide and allyl glycidyl ether		[A], [B]
ABR Rubber	acrylate-butadiene rubber	丙烯酸-丁二烯橡膠	[A], [B]
BIIR Rubber	bromo-isobutene-isoprene rubber	溴化丁基橡膠	[A], [B]
BR Rubber	butadiene rubber	順丁橡膠	[A], [B]
CIIR Rubber	chloro-isobutene-isoprene rubber	氯化丁基橡膠	[A], [B]
CR Rubber	chloroprene rubber	氯丁橡膠	[A], [B]
ENR Rubber	epoxidized natural rubber	環氧化天然橡膠	[A], [B]
HNBR Rubber	hydrogenated acrylonitrile-butadiene rubber (unsaturated)	氫化丁腈橡膠	[A], [B]
IIR Rubber	isobutene-isoprene rubber (butyl rubber)	丁基橡膠	[A], [B]
IR Rubber	isoprene rubber, synthetic	異戊二烯橡膠	[A], [B]
MSBR Rubber	copolymer of $\alpha$ -methylstyrene and butadiene	$\alpha$ -甲基苯乙烯-丁二烯橡膠	[A]
NBIR Rubber	terpolymer of acrylonitrile, butadiene and isoprene	丁腈異戊橡膠	[A]
NBR Rubber	acrylonitrile-butadiene rubber (nitrile rubber)	丁腈橡膠	[A], [B]
NIR Rubber	acrylonitrile-isoprene rubber	丙烯腈-異戊二烯橡膠	[A], [B]
NR Rubber	natural rubber	天然橡膠	[A], [B]

Abbreviations <sup>7</sup>	Description of Form	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>8</sup>
NOR Rubber	norbornene rubber	降冰片烯橡膠	[A]
PBR Rubber	vinylpyridine-butadienerubber	丁吡橡膠	[A], [B]
PSBR Rubber	vinylpyridine-styrene-butadiene rubber	丁苯吡橡膠	[A], [B]
SBR Rubber	styrene-butadiene rubber	丁苯橡膠	[A], [B]
SIBR Rubber	terpolymer of styrene, isoprene and butadiene	苯乙烯-異戊二烯-丁二烯橡膠	[A]
SIR Rubber	styrene-isoprene rubber	苯乙烯-異戊二烯橡膠	[B]
XBR Rubber	carboxylic-butadiene rubber	羧基丁二烯橡膠	[A], [B]
XNBR Rubber	carboxylic-acrylonitrile-butadiene rubber	羧基丁腈橡膠	[A], [B]
XSBR Rubber	carboxylic-styrene-butadiene rubber	羧基丁苯橡膠	[A], [B]
FMQ Rubber	silicone rubber with methyl and fluorine groupson the polymer chain	甲基氟基矽橡膠	[A], [B]
FVMQ Rubber	silicone rubber with fluorine, vinyl and methyl groupson the polymer chain	氟矽橡膠	[A], [B]
MQ Rubber	silicone rubber with only methyl groupon the polymer chain	矽橡膠	[A], [B]
PMQ Rubber	silicone rubber with methyl and phenyl groupson the polymer chain		[A], [B]
PVMQ Rubber	silicone rubber with methyl, phenyl and vinyl groupson the polymer chain		[A], [B]
VMQ Rubber	silicone rubber with methyl and vinyl groups on the polymer chain		[A], [B]
AFMU Rubber	terpolymer of tetrafluoroethylene, trifluoronitrosomethaneand nitrosoperfluorobutyric acid	亞硝基橡膠	[A], [B]
AU Rubber	polyester urethane	聚酯尿烷橡膠	[A], [B]
EU Rubber	polyether urethane	聚醚尿烷橡膠	[A], [B]
OT Rubber	rubber with either a -CH <sub>2</sub> -CH <sub>2</sub> -O-CH <sub>2</sub> -O-CH <sub>2</sub> -CH <sub>2</sub> group or occasionally an -R-group, where R is an aliphatic hydrocarbon between the polysulfide linkages in the polymer chain	聚硫橡膠	[A], [B]
EOT Rubber	rubber with either a -CH <sub>2</sub> -CH <sub>2</sub> -O-CH <sub>2</sub> -O-CH <sub>2</sub> -CH <sub>2</sub> group and Rgroups that are usually -CH <sub>2</sub> -CH <sub>2</sub> but occasionally otheraliphatic hydrocarbon between the polysulfide linkages		[A], [B]

Abbreviations <sup>7</sup>	Description of Form	Names in Chinese (Not limited to terms listed)	Sources of Reference <sup>8</sup>
	in the polymer chain		
FZ Rubber	rubber with a -P(CxN)-chain and with fluoroalkoxy groups attached to the phosphorus atoms in the chain	氟化磷腈橡膠	[A], [B]
PZ Rubber	rubber with a -P(CxN)-chain and with aryloxy groups attached to the phosphorus atoms in the chain	聚磷腈橡膠	[A], [B]

**TABLE 3: TABLE OF CLASSIFICATIONS AND SUBCLASSIFICATIONS OF THERMOPLASTIC ELASTOMERS<sup>9</sup>**

Names of Classification	Names of Subclassification	Description of Form	Names in Chinese (Not limited to terms listed)
TPA thermoplastic elastomer		A block copolymer composed of interlaced hard segments of amide bonds and soft segments of ether and/or ester bonds	聚醯胺類熱塑性彈性體
	TPA-EE Thermoplastic elastomer	Soft segment formed of Polyether and polyester	醚酯-聚醯胺類熱塑性彈性體
	TPA-ES Thermoplastic Elastomers	Soft segment formed of polyester	酯-聚醯胺類熱塑性彈性體
	TPA-ET Thermoplastic Elastomers	Soft segment formed of Polyether	醚-聚醯胺類熱塑性彈性體
TPC thermoplastic elastomer		Copolymer with the main chain consisting of ether and (or) ester bonds	共聚酯類熱塑性彈性體
	TPC-EE Thermoplastic Elastomers	Soft segment formed of Polyether and polyester	醚酯-共聚酯類熱塑性彈性體
	TPC-ES Thermoplastic Elastomers	Soft segment formed of polyester	酯-共聚酯類熱塑性彈性體
	TPC-ET Thermoplastic Elastomers	Soft segment formed of Polyether	醚-共聚酯類熱塑性彈性體
TPD thermoplastic elastomer		Compound of polyolefin and rubber	聚烯烴類熱塑性彈性體
	TPO-(EPDM+PP) Thermoplastic Elastomers	Mixture of EPDM and polypropylene	[三元乙丙橡膠-聚丙烯]熱塑性彈性體
TPS thermoplastic elastomer		Tertiary block copolymer composed of hard segments at both ends of polystyrene, and inner soft segments of polydiene or hydrogenated polydiene	苯乙烯類熱塑性彈性體
	TPS-SBS Thermoplastic Elastomers	[Styrene-butadiene-styrene] block copolymer	
	TPS-SEBS Thermoplastic Elastomers	[Styrene-ethylene-butylene-styrene] block copolymer	
	TPS-SEPS Thermoplastic Elastomers	[Styrene-ethylene-propylene-styrene] block copolymer	
	TPS-SIS Thermoplastic Elastomers	[Styrene-isoprene-styrene] block copolymer	

<sup>9</sup> Sources of Reference: ISO 18064



TPU thermoplastic elastomer		A block polymer composed of hard segment of urethane bond, ester, ether or (and) soft segment of carbonic acid bond	聚氨酯類熱塑性彈性體
	TPU-ARES Thermoplastic Elastomers	[Aromatic hard segment, polyester soft segment] Polyurethane thermoplastic elastomer	
	TPU-ARET Thermoplastic Elastomers	[Aromatic hard segment, polyether soft segment] Polyurethane thermoplastic elastomer	
	TPU-AREE Thermoplastic Elastomers	[Aromatic hard segment, polyester ether soft segment] Polyurethane thermoplastic elastomer	
	TPU-ARCE Thermoplastic Elastomers	[Aromatic hard segment, polycarbonate soft segment] Polyurethane thermoplastic elastomer	
	TPU-ARCL Thermoplastic Elastomers	[Aromatic hard segment, polycaprolactone soft segment] Polyurethane thermoplastic elastomer	
	TPU-ALES Thermoplastic Elastomers	[Aliphatic hard segment, polyester soft segment] Polyurethane thermoplastic elastomer	
	TPU-ALET Thermoplastic Elastomers	[Aliphatic hard segment, polyether soft segment] Polyurethane thermoplastic elastomer	
TPV thermoplastic elastomer		Vulcanized mixture of thermoplastic and rubber	動態硫化類熱塑性彈性體
	TPV-(EPDM+PP) Thermoplastic Elastomers	[Mixing of EPDM rubber and polypropylene] Dynamic Vulcanized thermoplastic elastomer	
	TPV-(NBR+PP) Thermoplastic Elastomers	[Mixing of nitrile butadiene rubber and polypropylene] Dynamic Vulcanized thermoplastic elastomer	
	TPV-(NR+PP) Thermoplastic Elastomers	[Mixing of natural rubber and polypropylene] Dynamic vulcanization thermoplastic elastomer	
	TPV-(ENR+PP) Thermoplastic Elastomers	[Mixing of Epoxidized Natural Rubber and Polypropylene] Dynamic Vulcanization thermoplastic elastomer	
	TPV-(IIR+PP) Thermoplastic Elastomers	[Mixing of Butyl Rubber and Polypropylene] Dynamic Vulcanization Thermoplastic Elastomer	
TPZ thermoplastic elastomer		Not the TPA, TPC, TPO, TPS, TPU, and TPV listed above	雜類熱塑性彈性體
	TPZ-(NBR+PVC) Thermoplastic Elastomers	[Mixing of acrylonitrile-butadiene rubber and polyvinyl chloride] Miscellaneous thermoplastic elastomers	

**TABLE 4: TABLE OF PREFIX CODES COMMONLY USED FOR COATING FILM MATERIALS**

Prefix Code	Name of Coating Film which the Prefix Code Represents
A	PVAC
K	PVDC
VM	aluminum metalized

**TABLE 5: LIST OF MATERIALS GENERALLY KNOWN AS CONTAINING SPECIFIC FILLING MATERIALS AND REINFORCING MATERIALS**

<b>General Terms of the Materials</b>	<b>Composition overview</b>
Stone paper	Certain plastics, calcium carbonate or other filler materials
Pearl paper	Specific plastics, paper
Fiberglass plastic	Specific plastics, fiberglass and/or carbon fiber and/or boron fiber

**TABLE 6: CODES OF FILLING AND REINFORCING MATERIALS<sup>10</sup>**

Code	Material (in English)	Material (in Chinese)	Code	Material (in English)	Material (in Chinese)
B	boron	硼	N	natural organic (cotton, sisal, hemp, flax, etc.)	天然有機物 (棉、瓊麻、大 麻、亞麻等)
C	carbon	碳	P	mica	雲母
D	alumina trihydrate	三水合氧化鋁	Q	silica	二氧化矽(矽 石，矽土)
E	clay	白土(瓷土、黏 土)	S	synthetic organic	合成有機物
G	glass	玻璃	T	talcum	滑石
K	calcium carbonate	碳酸鈣	W	wood	木材
L	cellulose	纖維素	X	not specified	未規定
M	mineral	礦物，金屬*	Z	others not included in this list	本表以外者

<sup>10</sup> Source of Reference: ISO 1043-2 (summarized in National Standards of the Republic of China CNS 5346-1)

**TABLE 7: CODES OF FORMS OF FILLING AND REINFORCING MATERIALS<sup>11</sup>**

Code	Form and structure (in English)	Form and structure (in Chinese)	Code	Form and structure (in English)	Form and structure (in Chinese)
B	beads, spheres, balls	珠狀物、球形物、中空球形物	P	paper	紙
C	chips, cuttings	碎片，切片	R	rovings	粗紗(紗束)
D	fines, powders	細粒，粉末	S	flakes	鱗片狀
F	fiber	纖維	T	twisted yarn or braided fabric, cord, tube	假捻或編織布，繩索
G	ground	磨碎	V	veneer	合板
H	whisker	晶鬚	W	woven fabric	織物
K	knitted fabric	針織布	X	not specified	未規定
L	layer	層狀	Y	yarn	紗線
M	mat (thick)	氈(厚)	Z	others not included in this list	本表以外者
N	non-woven (fabric, thin)	非織物(布，薄)			

<sup>11</sup> Source of Reference: ISO 1043-2 (summarized in the National Standards of the Republic of China CNS 5346-1)

**TABLE 8: TABLE OF ABBREVIATIONS OF SPECIFIC MATERIALS  
COMMONLY USED**

Abbreviations	English Name	Chinese Name	Sources of Reference <sup>12</sup>
BOPP	biaxially oriented polypropylene	雙軸延伸聚丙烯	[B]
CPE	chlorinated polyethylene	氯化聚乙烯	[B]
CPP <sup>13</sup>	cast polypropylene	流延聚丙烯；或 未拉伸聚丙烯	[C]
EPP, or PP-E	expandable polypropylene	發泡性聚丙烯	[A], [B]
EPS, or PS-E	expandable polystyrene	發泡性聚苯乙烯	[A], [B]
HDPE, or PE-HD	high-density polyethylene	高密度聚乙烯	[A], [B]
HIPP	high-impact polypropylene	耐衝擊性聚丙烯	[B]
HIPS, or PS-HI	high-impact polystyrene	耐衝擊性聚苯乙烯	[A], [B]
LDPE, or PE-LD	low-density polyethylene	低密度聚乙烯	[A], [B]
LLDPE, or PE-LLD	linear low-density polyethylene	線性低密度聚乙烯	[A], [B]
MDPE, or PE-MD	medium-density polyethylene	中密度聚乙烯	[A], [B]
OPP	oriented polypropylene	定向聚丙烯	[B]
UHMWPE, or PE-UHMW	ultra-high-molecular weight polyethylene	超高分子量聚乙烯	[A], [B]
VLDPE, or PE-VLD	very-low-density polyethylene	極低密度聚乙烯	[A], [B]

<sup>12</sup> [A] indicates ISO 1043-1 (summarized in the National Standard of the Republic of China CNS 5346). [B] indicates the information submitted by the food industry operators when referring to the materials on the "Registration Platform for Food and Drug Industry Operators". [C] indicates the information based on communication and research in the related industries.

<sup>13</sup> Terms with further distinctions (e.g. GCPP[general], MCPP[metalized], RCPP[retort]) which are considered too detailed are not accepted. More general terms, e.g. PP and CPP, or in Chinese terms should be used.

**TABLE 9: CODES OF FORMS OF PLASTIC MATERIALS<sup>14</sup>**

Codes of Form	Meaning in English	Meaning in Chinese	Codes of Form	Meaning in English	Meaning in Chinese
A	acid (modified)	酸(改質)	N	normal	正常的
A	amorphous; atactic	非晶形(非規)，雜排	N	novolak	線型酚醛樹脂(可溶，可融)
B	biaxial	雙軸	O	oriented	定向的
B	block	嵌段	P	plasticized	塑化的
B	brominated	溴化的	P	thermoplastic	熱塑性的
C	chlorinated	氯化的	R	raised	隆起的
C	crystalline; isotactic	晶態，順排	R	random	隨機的
D	density	密度	R	resol	A階酚醛樹脂
E	elastomer	彈性體	R	rigid	硬質的
E	expanded; expandable	發泡；可發泡的	S	saturated	飽和的
E	epoxidized	環氧化的	S	sulfonated	磺化
F	flexible	可撓的	S	syndiotactic	對排(間規)
F	fluorinated	氟化的	S	thermosetting	熱固性
F	fluid	流體	T	temperature	耐溫性
G	glycol (modified)	乙二醇(改質)	T	toughened	韌化的
H	high	高	U	ultra	超
H	homo	同元	U	unplasticized	未塑化的
I	impact	衝擊	U	unsaturated	不飽和的
L	linear	線性	V	very	極
L	low	低	W	weight	重量
M	medium	中	X	crosslinked; crosslinkable	交聯的(交連的)，可交聯的
M	molecular	分子的			

<sup>14</sup> Based on ISO 1043-1 (summarized in the National Standard of the Republic of China: CNS 5346).

## **Appendix 1: Principles for Identifying the Generally Recognized Symbols for Names of Plastic Materials**

For general plastic materials, the abbreviated names listed in [Table 1](#) are regarded as generally recognized symbols. For rubber materials, the abbreviated names listed in [Table 2](#) are regarded as generally recognized symbols. For thermoplastic elastomers, one of the following: "Thermoplastic elastomer", "TPE", "names of category" or "names of sub-category" as listed in [Table 3](#) are regarded as generally recognized symbols.

For substrates coated with films of other materials, the names of materials of the coating and the substrates should be marked separately, or the prefix codes as listed in [Table 4](#) should be added to the names of the material of the substrates.<sup>15</sup>

Other abbreviations or names not set in accordance with these Principles<sup>16</sup> are not regarded as material names unless one of the following conditions is met:

1. The abbreviated material names are found used in documents of the Chinese National Standards (CNS), the International Organization for Standardization (ISO), the Japanese Industrial Standards (JIS), the American Society for Testing and Materials (ASTM) and/or those found in other internationally circulated documents but are not coined by the business operators themselves, and do not contradict these Principles, provided that the evidence of the use of the names has been presented by the business operators to FDA for reference before the products are sold in market.
2. The products are marked with other abbreviations or names but, at the same time, clearly provide links of reference to the Chinese names or generally recognized symbols of the materials referred to by the marked content".<sup>17</sup>

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<sup>15</sup> For example, "KPET" means PET coated with PVDC, and it can also be marked with "PVDC, PET".

<sup>16</sup> Including only "plastic", "rubber", trademark names such as Tritan, simple foreign transliteration or other names that cannot clearly refer to the material, whether in Chinese or foreign languages.

<sup>17</sup> The types of links are not limited, nor are they limited to the links operated by the business operators themselves (such as citing documents from other agencies). The links should be clear and continuously available. If presented on a web page, they should directly open viewable webpages, should not be hidden among other links with unclear click paths, and should not be invalid. Otherwise, it is not considered a legitimate provision of web links.



## **Appendix 2: Guidelines on the Mandatory and Voluntary Marking of Fillers and Reinforcing Materials on Plastic Materials**

For materials "generally known to consist of specific fillers and reinforcing materials" and listed in Table 5, one of the following manners should be adopted (with stone paper cited as an example). In addition to this, it is considered a case of marking violation that leads to misunderstanding:

1. Expanded marking of the "names of plastic materials" and "names of generally known fillers and reinforcing materials", for example: "polyethylene, calcium carbonate", or
2. Juxtaposed marking of the "general name in Chinese" listed in Table 5 and the name of the plastic materials contained, for example: "stone paper (polyethylene)".

For the materials not listed in Table 5, marking of fillers and reinforcing materials is not mandatory. Voluntary marking should be done in one of the following methods. In addition to this, the abbreviations or names are not regarded as the material names:

1. Fillers and reinforcing materials marked in Chinese; or
2. Information of the fillers and reinforcing materials<sup>18</sup> is marked with the "category mark" listed in Table 6 and the "form mark" listed in Table 7. The name of the material and the mark are connected by a hyphen " – ". A link of reference to the meaning of the mark should be provided.

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<sup>18</sup> The number indicating the mass fraction of the filling materials and the reinforcing materials is recommended after the mark. For filling materials and reinforcing materials that are metals, the symbols of metal elements are recommended in brackets. For example: label "PE-MD(Al)60", with a link on the product stating that the label refers to "polyethylene containing 60% of aluminum powder"

### **Appendix 3 Guidelines on the Voluntary Marking of Material Characteristics on Plastic Materials**

Marking of material characteristics is not mandatory. Voluntary marking should be done in one of the following methods. In addition to this, the overall names are not regarded as the material names:

1. For materials commonly with characteristics marked, the "abbreviated names" listed in Table 8 may be regarded as generally recognized symbols, or
2. Material characteristics are marked in Chinese on the material names, or
3. "Special marks" as listed in Schedule 9 are used to mark the material properties. The name of the material and the mark are connected by a hyphen " – ". A link of reference to the meaning of the mark should be provided.

**“PRINCIPLES FOR LABELLING THE NAMES OF PLASTIC  
MATERIALS IN FOOD UTENSILS, CONTAINERS AND PACKAGING”  
REVISED VERSION**

Version	Remarks	Date
1	Formulated “Principles for Labelling the Names of Plastic Materials in Food Utensils, Containers and Packaging”	Sept. 18, 2018
2	1. Revised "CNS 11469" to "ISO 11469" in Note 9 on Page 7 2. Added "Modified PCT" on Table 1.	Dec. 10, 2019

## **The Relevant Regulations for Labeling of Food Cleaners**

## Principles for Labeling Food Cleaners

Promulgated on May 18, 2017

Effective from May 18, 2017

### Announcements:

Interpretation of the principles for labelling food cleaners is hereby made in compliance with Article 27 and Paragraph 1 of Article 28 of the Act Governing Food Safety and Sanitation (hereinafter referred to as the Act), which takes effect immediately.

1. As for the chemical names of the primary ingredients specified in Subparagraph 2 of Article 27 of the Act, those with ingredients of a single compound should be named with their chemical names (in Chinese), and those with natural ingredients undergoing chemical processing can be named with their common names (in Chinese). Those with natural ingredients but without undergoing chemical processing can be named with individual raw materials (in Chinese).
2. Any of the following labeling methods of food cleaners may constitute a violation of Paragraph 1 of Article 28 of the Act:
  - (1) Labeling with the marking of "natural" and meet any of the following conditions:
    - A. All raw materials in the product are not "natural materials processed without changing their natural properties", but the marking of the word "natural" or its equivalent meaning is made in the Chinese or other languages in the product name or in any text, picture, mark, or in the attached manual.
    - B. Only a part of the raw materials in the product are "natural materials processed without changing their natural properties", but the marking of the word "natural" or its equivalent meaning is made in the Chinese or other languages in the product name, picture, or mark.
    - C. Only a part of the raw materials in the product are "natural materials processed without changing their natural properties", and the marking of the word "natural" or its equivalent meaning is made in the Chinese or other languages in any text, except for the product name, picture, and mark, and

the content percentages of those raw natural materials in the product are not indicated.

(2) Labeling with the marking of "organic" and meet any of the following conditions:

A. All raw materials in the product are not approved as organic by the central agricultural competent authority, but the marking of the word "organic" or its equivalent meaning is made in the Chinese or other languages in the product name or in any text, picture, mark, or in the attached manual.

B. Only a part of the raw materials in the product are approved as organic by the central agricultural competent authority, but the marking of the word "organic" or its equivalent meaning is made in the Chinese or other languages in the product name, picture, or mark.

C. Only a part of the raw materials in the product are approved as organic by the central agricultural competent authority, and the marking of the word "organic" or its equivalent meaning is made in the Chinese or other languages in any text, except for the product name, picture, and mark, but the content percentages of those raw materials in the product are not indicated.

(3) Labeling with the marking of "food grade" or "non-toxic" or its equivalent meaning is made in the Chinese or other languages.

3. Violations which do not fall into the above-mentioned manners should be judged according to the actual conditions.

4. Except for Item 3, Sub-paragraph 1 (2. (1) C.) and Item 3, Sub-paragraph 2 (2. (2) C.) of Article 2, which are to be implemented on January 1, 2018, all the other provisions are to be implemented when the interpretation takes effect.

## **The Relevant Regulations of the Health Food**

# Health Food Control Act

Promulgated on February 3, 1999.

Amended on December 22, 1999.

Amended on November 8, 2000.

Amended on January 30, 2002.

Amended on May 17, 2006.

Amended on July 19, 2013.

Amended on January 24, 2018.

Amended on January 15, 2020.

## Chapter I General Provisions

Article 1 This Act is enacted to enhance the management and supervision of matters relating to health food, protect the health of the people of the republic and safeguard the rights and interests of consumers. Matters not addressed herein shall be governed by other applicable laws.

Article 2 For the purposes of this Act, the term "health food" shall denote food with health care effects, having been labeled or advertised with such effects.

The term "health care effects" shall mean an effect that has been scientifically proven to be capable of improving people's health, and decreasing the harms and risks of diseases. However, it is not a medical treatment aimed at treating or remedying human diseases; such "health care effects" shall be announced by the central competent authority.

Article 3 A health food permit shall be issued only if one of the following requirements is met under the purpose of this Act.

1. Duly supported by scientific assessment of the safety and health care effects of food that they are harmless and carry definite, certain health care effects; if current technology cannot identify ingredients contributing to such effects, the ingredients with the relevant health care effects and supporting literature shall be enumerated and provided to the central competent authority for



evaluation and verification.

2. Ingredients conforming to the Health Food Specification Standards set by the central competent authority.

The methods by which health care effects and safety are assessed, and by which standards are determined in the preceding paragraph shall be determined by the central competent authority. If the central competent authority has not yet determined a method to assess the health care effects, a method submitted by academics shall be reviewed and approved by the central competent authority.

Article 4 The health care effects of health food shall be described in any of the following ways:

1. claiming the effect of preventing or alleviating the illness relating to nutrients when deficient in the human body if intake of the health food can make up said nutrients;
2. claiming the impact on human physiological structure and functions by the specified nutrients or specific ingredients contained in a health food or the food itself after the health food has been taken;
3. furnishing the scientific evidence to support the claim that the health food can maintain or affect human physiological structure and functions; and/or
4. describing the general advantages of taking the health food.

Article 5 For the purposes of this Act, the term "competent authority" shall mean the Ministry of Health and Welfare at the central level, the municipal governments at the municipality, and the county/city governments at the county/city level.

## Chapter II Health Food Permit

Article 6 No food shall be labeled or advertised as health food unless it is registered as such in accordance with this Act.

This Act shall govern any food that is labeled or advertised as food furnishing specific nutrient or specific health care effects.

Article 7 No health food shall be manufactured or imported unless and until an application for review and testing registration supported by information on its ingredients, specifications, functions and effects, a summary of the manufacturing process, specifications and methods of analysis, other relevant data and documentation, as well as label and sample are submitted along with permit fee, review and testing fees to, and a product registration permit is issued by, the central competent authority or the organization commissioned thereby.

The permit fee referred to in the preceding paragraph means the fee for the issuance, replacement, or supplementary issuance of the health food permit against the application for review and testing registration. The review and testing fees mean the fees for the review and testing. The relevant fee amount shall be prescribed by the competent authority.

An application for change of the registered items of the health food after permit is issued must be filed with the relevant review fee to the central competent authority.

The central competent authority may, where necessary, commission relevant organization (institution), school or group to deal with the review and testing referred to in the first paragraph. The relevant regulations shall be prescribed by the central competent authority.

Regulations of the application for permit referred to in the first

paragraph shall be prescribed by the central competent authority.

Article 8 A health food manufacture or import permit is valid for five years. Application for renewal shall be filed within three months prior to the expiration of the term with the central competent authority if continued manufacture or importation after the expiration is desired. The term of each renewal shall not exceed five years. Such permit shall automatically become null and void if the above application for renewal is not filed within the prescribed period or renewal is not granted.

If the above permit is stained, damaged or lost, an application shall be filed, with reasons stated, with the original issuing authority for a replacement or new permit, and the original permit shall at the same time be surrendered for cancellation or canceled by the issuing authority by public notice.

Article 9 The central competent authority may re-evaluate approved health food during the validity of the health food permit for any of the following reasons:

1. where scientific research raises doubts about the effects of the product;
2. where the ingredients, formula, or method of production of the product is subject to doubt ; or
3. where the re-evaluation is considered necessary by the competent food sanitation authority.

Where the health food does not pass re-evaluation, the central competent authority shall request the company concerned to make improvement within a prescribed period, and may revoke the permit if the improvement is not made within such period.

### **Chapter III Management of Safety and Sanitation of Health Food**

Article 10 Health food shall be manufactured in accordance with good manufacturing practices.

Imported health food shall conform to the good manufacturing practices of the country of origin.

Standards for the good manufacturing practices mentioned in the first paragraph shall be prescribed by the central competent authority.

Article 11 Health food as well as its containers and packaging shall conform the sanitation standards which are prescribed by the central competent authority.

Article 12 No health food or raw materials thereof shall be manufactured, prepared, processed, sold, stored, imported, exported, offered as gift, or publicly displayed if the health food or raw materials thereof:

1. deteriorate or become rotten;
2. are contaminated by pathogens;
3. contain any residual pesticide exceeding the permissible tolerance set by the central competent authority;
4. are contaminated by nuclear fallout or radioactivity exceeding the permissible tolerance set by the central competent authority;
5. are adulterated or counterfeited;
6. exceed the shelf life; or
7. contain other substances or foreign matters detrimental to human health.

### **Chapter IV Labeling and Advertisement of Health Food**

Article 13 The following material facts shall be conspicuously displayed on the containers, packaging or written instruction of health food in Chinese and in commonly used symbols:

1. product name;
2. name of the ingredients; those that contain two or more ingredients shall indicate the respective ingredients in descending order of proportion;
3. net weight, volume or quantity;
4. name of food additives; in the case of a mixture of two or more food additives which are named according to its function shall indicate the name of each additive separately;
5. expiry date, method and conditions of preservation;
6. name and address of the responsible business operator; the name and address of the importer shall be specified if the health food is imported;
7. the approved health care effects;
8. reference number of the permit, the legend of "health food" and standard logo;
9. amount of intake and important message for consumption of the health food, possible side effect and other necessary warnings;
10. nutrient and its content; and
11. other material facts designated by the central competent authority.

The format and contents of the labeling described in subparagraph 10 above shall be prescribed by the central competent authority.

Article 14 No health food labeling or advertisement shall misrepresent or

exaggerate, and the health claims shall not extend beyond the approved scope and shall be limited to the content registered at the central competent authority.

No labeling or advertisement of health food shall claim or refer to medical efficacy.

Article 15 No mass communication business shall publish or broadcast advertisements for health food in respect of which no permit is obtained in accordance with Article 7 hereof.

A mass communication business retained to publish or broadcast a health food advertisement shall keep the name, ID number or reference number of business registration, residence (place of business or operations), and telephone number of the person (or legal person or name of organization) who retains the advertising services for six months from the date the advertisement is published or broadcasted and shall neither evade, impede or refuse to provide the above information for inspection upon being so requested by the competent authority.

## **Chapter V Inspection of and Enforcement on Health Food**

Article 16 The competent health authority shall assign officers to inspect the premises, facilities and relevant business of health food manufacturers and vendors, and to conduct a random testing of their health food, which shall not be refused by such manufacturers or vendors without good cause shown; provided the health food subject to random testing shall be of such quantity sufficient for the testing.

The competent health authority at each level may order a business suspected of violating Articles 6 to 14 to suspend its manufacture, preparing, processing, sale or display, and seal up the product

concerned for a prescribed period to be temporarily held in custody by such business against a certificate of custody.

Article 17 The central competent authority shall from time to time by public notice ban the manufacture and importation of any approved health food which is found to be materially harmful to human health, and also revoke the permit in respect of such food. If such health food has been manufactured or imported, the exportation, offering for sale, transport, consignment storage, introduction, transfer or display with the intent of offering for sale of such food shall be banned for a prescribed period; where necessary, the above health food shall be confiscated and destroyed.

Article 18 A health food manufacturer or importer shall forthwith notify its downstream businesses upon the occurrence of any of the following events and recall all products from the market within a prescribed period and dispose of such products along with any inventory according to this Act:

1. where a food is labeled or advertised as health food without official approval;
2. where manufacture or importation of the health food with a permit is banned by public notice;
3. where no application for renewal of the existing permit is filed or such application is rejected;
4. where Article 10 is violated;
5. where Article 11 is violated;
6. where any of the events under Article 12 arises;
7. where any of the events under Article 13 arises;

8. where Article 14 is violated; or
9. where health food shall be recalled from the market per the public notice of the central competent health authority.

The downstream businesses shall lend their support and assistance to any manufacturer and importer recalling the health food pursuant to the preceding paragraph.

Article 19 The local competent authority shall have the authority to take any of the following official actions against health food based on the results of random inspection or testing:

1. where a food that is labeled or advertised as health food without official approval or any of the events under Article 12 arises with any health food, the particular food shall be confiscated and destroyed;
2. health food not meeting the standards prescribed in Articles 10 and 11 shall be confiscated and destroyed. If after disinfection or the enforcement of appropriate safety measures such health food is usable or can be used after reconditioning, request shall be made for such disinfection, reconditioning or enforcement of safety measures within a prescribed period; if such request is not complied with within said period, the health food shall be confiscated and destroyed;
3. health food labeled in violation of Article 13 or 14 hereof shall be recalled for labeling correction within a prescribed period, otherwise such food shall be confiscated and destroyed; or
4. the official action shall be revoked and the sealed health food shall be unsealed if none of the situations under any of the above three subparagraphs arises but the manufacture, preparing,



processing, sale and display of the food is suspended and the food sealed up and held in custody per an order under the second paragraph of Article 18(sic).

The local competent authority shall publicize the company name and address of the business manufacturing, preparing, processing, selling, importing or exporting the health food under subparagraph 1 or 2 of the first paragraph, the name of its responsible person, the product name and the story of violation.

Article 20      Anyone informing against or discovering any health food not meeting the requirements set forth in this Act shall be rewarded by the competent authority. The reward regulations shall be prescribed by the competent authority.

## **Chapter VI      Penal Provisions**

Article 21      Whoever is guilty of manufacturing or importing health food without official approval or violating the first paragraph of Article 6 hereof shall be imprisoned for not more than three years and may additionally be fined not more than NT\$1,000,000.

Whoever is guilty of knowingly offering for sale, supplying, transporting, storing, introducing, transferring, labeling, advertising, or displaying with the intent of offering for sale the above food shall be punished pursuant to the preceding paragraph.

Article 22      Whoever is guilty of violating Article 12 hereof shall be fined between NT\$60,000 and NT\$300,000.

Whoever is guilty of repeating the above act within one year shall be fined between NT\$90,000 and NT\$900,000; in addition, its business/factory license may be revoked.

Whoever is guilty of committing the act under the first paragraph of

this Article to such extent detrimental to human health shall be imprisoned for not more than three years, detained and/or fined not more than NT\$1 million; in addition, its business/factory license may be revoked.

Article 23 Whoever is guilty of committing any of the following acts shall be fined between NT\$30,000 and NT\$150,000:

1. violation of Article 10;
2. violation of Article 11; or
3. violation of Article 13.

Whoever is guilty of repeating the above act within one year shall be fined between NT\$90,000 and NT\$900,000; in addition, its business/factory license may be revoked.

Whoever is guilty of committing the act under the first paragraph of this Article to such extent detrimental to human health shall be imprisoned for not more than three years, detained and/or fined not more than NT\$1 million; in addition, its business/factory license may be revoked.

Article 24 Violation of Article 14 will Result in the Following Fines and Penalties:

1. A fine of NT\$100,000 to NT\$500,000 shall be imposed when the first paragraph of Article 14 hereof has been violated.
2. A fine of NT\$400,000 to NT\$2,000,000 shall be imposed when second paragraph of Article 14 hereof has been violated.
3. The fines imposed by the preceding paragraphs shall be imposed consecutively according to the number of violations committed until the advertisement or broadcasting has been suspended; in case of a serious violation, the Health Food permit shall be

revoked.

4. The business or factory registration certificate shall be revoked if violation is repeated within one year of the penalties imposed by the preceding paragraphs.

A mass communication business guilty of violating the second paragraph of Article 15 thereof shall be fined NT \$60,000 and NT \$300,000 and such fine may be consecutively imposed according to the number of violations committed.

By taking the official actions in accordance with the first paragraph, the competent authority shall by letter inform both the mass communication business and the competent information authority of the municipal/city/county government. The mass communication business shall cease and desist from publishing or broadcasting immediately on the next day of the receipt of the letter.

A mass communication business guilty of violating the first paragraph of Article 15 thereof or violating the Article 14 by continuously broadcasting the advertisement shall be fined NT \$120,000 and NT \$600,000 by the municipal/city/county government and such fine may be consecutively imposed according to the number of violations committed.

Article 25      Whoever is guilty of violating Article 18 hereof shall be fined between NT\$300,000 and NT\$1,000,000 and such fine may be consecutively imposed from day to day.

Article 26      If the representative of a legal entity, or the agent or employee of a legal entity or a natural person commits any of the offenses under Articles 21 to 22 in his/her occupational capacity, not only shall the culprit be penalized, but the particular legal entity or natural person shall be fined

pursuant to the article(s) concerned.

Article 27 Whoever is guilty of refusing, impeding or deliberately evading the random inspection or testing under Article 16 or 17 hereof or refusing to comply with a suspension order or ban on manufacturing, preparing, processing , offering for sale or display shall be fined between NT\$30,000 and NT\$300,000, and such fine may be consecutively imposed.

The business/factory license of the culprit may be revoked if the violation is material or is repeated within one year.

Article 28 The competent municipal/county/city authority shall impose the fines, except those provided in the fourth paragraph of Article 24 hereof.

Article 29 If a vendor is guilty of violating any of Articles 7 and 10 to 14, the buyer may return the goods and claim refund of the purchase price from the vendor. If the vendor knowingly commits such violation, it shall refund twice the amount of the purchase price. If the buyer suffers any other damage, the court shall have the authority to order vendor to pay the buyer punitive damages not more than three times the retail price or the value of the damage, whichever is chosen by the buyer, unless the buyer is aware of such violation.

Any manufacturer, importer or vendor who knowingly commits the above violation or is jointly liable with the vendor in negligence shall be held jointly and severally liable.

## **Chapter VII Supplementary Provisions**

Article 30 The enforcement rules of this Act shall be prescribed by the central competent authority.

Article 31 This Act shall take effect six months after its being promulgated.

The amendment of this Act shall be implemented as of its being promulgated.

## Enforcement Rules of Health Food Control Act

Promulgated on August 1, 1999.

Amended and promulgated on July 2, 2002.

Amended and promulgated on October 30, 2006.

Amended and promulgated on June 9, 2015.

Amended on January 17, 2019.

- Article 1     These Rules are enacted in accordance with Article 30 of the Health Food Control Act (hereinafter referred to as "Act")
- Article 2     For the purposes of paragraph 2 of Article 6 of the Act, the term "specific nutrient" shall denote substance with definite health care effects and so identified by the central competent authority.
- Article 3     (Deleted)
- Article 4     (Deleted)
- Article 5     (Deleted)
- Article 6     (Deleted)
- Article 7     Where the name, label, packaging, design, labeling etc. of health food is suspected, during the processing of the application for product registration or after a permit has been issued, of counterfeiting or insinuating another person's registered trademark, the central competent authority shall order that correction be made or other necessary measures be taken within a prescribed time limit.
- Article 8     For the purposes of the second paragraph of Article 10 of the Act, the phrase "conform to good manufacturing practices of the country of origin" shall denote that imported health food shall conform to the good manufacturing practices set by the competent authority of the country of origin.
- Such practices shall be equivalent to that mentioned in the first paragraph of the same article.
- Article 9     For the purposes of Article 11 of the Act, the term "sanitation standards"

as in the phrase "health food containers and packaging shall meet the sanitation standards" shall denote the relevant standards prescribed by the central competent authority in accordance with the Act Governing Food Safety and Sanitation.

- Article 10 The contamination by pathogens as in subparagraph 2, permissible tolerances of residual pesticides as in subparagraph 3, permissible tolerances of nuclear fallout or radioactivity as in subparagraph 4, and substances or foreign matters detrimental to human health as in subparagraph 7 of Article 12 of the Act shall be governed by the Act Governing Food Safety and Sanitation and the relevant regulations.
- Article 11 For the purposes of subparagraph 6 of Article 12 of the Act, the phrase "exceed the shelf life" shall denote that the shelf life has passed the expiry date mentioned in subparagraph 4 of the first paragraph of Article 13 of the Act.
- Article 12 The material facts to be labeled on health food pursuant to subparagraphs 1 to 5 and 9 of the first paragraph of Article 13 of the Act shall be governed by the Act Governing Food Safety and Sanitation and the relevant regulations.
- The characters to be labeled pursuant to subparagraphs 6 to 8 of the first paragraph of Article 13 of the Act shall be governed by the Act Governing Food Safety and Sanitation and the relevant regulations.
- Article 13 These Rules shall be implemented as of their being promulgated.

## Principles for Labeling the Items of Health Claim of Health Food

Promulgated on June 10, 2015

Effective from June 10, 2015

### Article

1. Scope of Application: Health foods with the health food permit
2. Principles of Labelling:
  - (1) Health foods may be labelled on the packaging with the items of health claim that have been inspected and registered with permission (See Note).
  - (2) The items of health claim labelled on the health foods should be visually clear and complete, of the same color, font and size as the description of the health care effects approved for labelling.
  - (3) In case the "items of health claim" are labelled in more than one place in the same block of the label, the parts using the largest font should be clearly made in the same color, font and size for the description of the health claim approved for labelling.
  - (4) Products with more than one effect marked with "items of health claim" should not have only one of them marked. All the effects should be marked in full.

Note: The items of health claim of health foods, as specified in the announcement of “Items of Health Claim under Health Food Control Act” by Ministry of Health and Welfare with No. Bu-shou-shi-zi-di-1031304312 of December 26, 2014, include: Liver protection; Fatigue resistance; Regulation of blood lipids, blood glucose, and immunity; Care of bone health and teeth; Postponing senility; Facilitating iron absorption; Regulation of gastrointestinal functions and blood pressure; Prevention of body fat accumulation and Allergies amelioration.



## Regulations Governing The Labeling of Health Food

Promulgated on January 17, 2019

Amended on November 8, 2022

Effective from January 1, 2023

### Article 1

The Regulations are set forth pursuant to the subparagraph 11 of paragraph 1 of Article 13 of the Health Food Control Act (hereinafter referred to as "Act").

### Article 2

The containers or packages of health food shall be labeled with the related ingredients with health care effect and its content, but it shall be labeled by ingredients with quality control criteria if the related ingredients with health care effect are unapproved.

### Article 3

The containers or packages of health food shall be labeled the approved description of health care claims to meet the following requirements:

- (1) The product conforming to the subparagraph 2 of paragraph 1 of Article 3 of the Act shall be stated "the health care effects of the product is known from academic theory but not approved by product experiments" or other similar statements with the same meaning in the behind of the description of "health care claims".
- (2) The experiments using animal model to assess the health care effect of the health food shall be stated "Based on the testing results from animal model, the product can help to..." or other similar statements with the same meaning in the front of the description of health care claims.

### Article 4

The containers or packages of health food shall be labeled the following precautions at least:

- (2) Health food in capsule and tablet form
  - i. This product is not a drug, for health care only. Patients still need medical treatment.

- ii. Please eat according to the recommended intake, excessive intake does not benefit health.
- (3) Health food in other than capsule and tablet form:  
This product is for health care only, without therapeutic efficacy.

#### **Article5**

Health food with additional refined sugar over 17 grams of the recommended daily intake shall be labeled “The additional refined sugar will reach ○○ grams when eating the product in accordance with the recommended daily intake ○○ grams (g)/milliliter (mL) and be care of the caloric intake.” or other similar statements with the same meaning.

#### **Article6**

Health food with fish oil shall be labeled “Infants, pregnant women, patients with diabetes mellitus or the people with abnormal blood coagulation taking anticoagulant are suggested to ask doctor’s recommendations before eating.” or other similar statements with the same meaning in the warnings on containers or packages.

#### **Article7**

Health food with red yeast rice shall be labeled “Eating this product combined with statin- and fibrate-derived hypolipidemic agents or grapefruit may result in liver and kidney hurt or rhabdomyolysis.” or other similar statements with the same meaning in the warnings on containers or packages.

#### **Article8**

The above four points that related the precautions and statements in the warnings on containers or packages of health food shall be displayed distinct color from the background color.

#### **Article9**

The domestic and foreign products based on their manufacturing and import date before the promulgation date, respectively, can still sell continuously until their expiry date.