

ACT GOVERNING FOOD SANITATION

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Chapter I General Principles

Article 1 This Act is enacted for the governing of food sanitation, safety and quality to protect the health of citizens. Matters not addressed in this Act shall be governed by other applicable acts.

Article 2 For purposes of this Act, the term "foods" shall mean goods provided to people for eating, drinking, or chewing, and the raw materials of such goods. The term "special dietary foods" shall mean the following formulas that are nutritionally balanced or added with nutrients, to be consumed by people with special nutrient requirement:

1. Infant formula and follow-up formula.
2. foods for special medical purposes to be provided to patients with certain disease and with nutritional needs, and to be consumed under the instruction of a doctor, pharmacist or dietitian, with the purpose to sustain the health of the patients; and
3. other foods designed for special subjects designated by the central competent authority in a public notice.

Article 3 For purposes of this Act, the term "food additives" shall mean materials that are added to or brought into contact with foods in the course of manufacturing, processing, preparation, packaging, transportation and storage of foods for the purpose of coloring, seasoning, preserving, bleaching, emulsifying, flavoring, stabilizing quality, enhancing fermentation, increasing viscosity, enriching nutritional value, preventing oxidation or otherwise.

Article 4 For purposes of this Act, the term "food utensils" shall mean instruments, tools, or containers that come into direct contact with foods or food additives in the course of production, transportation or distribution.

Article 5 For purposes of this Act, the terms "food containers" and "food packaging" shall mean containers and packaging materials that come into direct contact with foods and food additives.

Article 6 For purposes of this Act, the term "food cleansers" shall mean materials directly used to disinfect or clean foods, food utensils, food containers and food packaging.

Article 7 For purposes of this Act, 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, food packaging, or food cleansers.

Article 8 For purposes of this Act, the term "labels" shall mean wording, pictures, or symbols affixed to the following articles to indicate the product name or to give explanation:

1. Containers, packaging or instruction sheet of foods, food additives or food

- cleansers; and
2. Food utensils, food containers or food packaging themselves or the exterior thereof.
- Article 9 For purposes of this Act, the term "competent authority" shall mean the Department of Health of the Executive Yuan at the central government level, the municipal governments at the municipality, and the county/city governments at the county/city level.
- Chapter II Food Sanitation
- Article 10 Foods, food cleansers, food utensils, food containers and food packaging being sold shall conform to sanitation, safety and quality standards which are prescribed by the central competent authority.
- Article 11 Foods or food additives under any 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 pathogens;
 5. those with pesticide residue or veterinary drugs 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; or
 9. those that have never been provided for human consumption and proven to be harmless to human health.
- The standards governing the permissible tolerance of pesticide residue or veterinary drugs, and the nuclear fallout or radioactivity shall be prescribed by the central competent authority through consultation with the relevant authorities.
- The first paragraph, that contains substance which is harmful to human health, includes skulls, brains, eyes, spinal marrow, ground beef, internal organ 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.
- Article 12 The product names, specifications, scope of use and maximum allowance of food additives shall conform to the regulations prescribed by the central competent authority.
- Article 13 Hygienic inspection of the slaughtering and cutting of livestock and poultry at the slaughterhouse shall be conducted by the competent agricultural authority in accordance with the Animal Industry Act.
- The sanitation of the manufacture, processing, preparation, packaging, transportation, storage, sale, import or export of carcasses, viscera or meat cuts transported out of the slaughterhouse shall be subject to the governing of the competent authority in accordance with this Act.
- Article 14 None of the foods, food additives, food cleansers, food utensils, food containers and food packaging which are designated by the central competent authority in a public notice shall be manufactured, processed, prepared, repacked, imported or exported without product registration filed with and a license procured from the central competent authority. Any change in the

material facts being registered shall be subject to the prior approval of the central competent authority.

The license referred to in the preceding paragraph shall be valid for a term of one year to five years subject to the decision 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.

Regulations governing the revocation of the approval referred to in the first paragraph, and issuance, replacement, re-issuance, extension, transfer, de-registration, and change in the registered material facts of the license, etc. shall be prescribed by the central competent authority.

The product registration under the first paragraph may be commissioned to another institution in accordance with regulations which are prescribed by the central competent authority.

Article 14-1 When carrying into the territories any foreign food or food additive that has been designed by the central competent authority in a public notice under the concern that such item may be harmful to the body or health of the people, the passenger shall declare the goods with the sanitation certificate issued by the sanitation 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 notice.

Foods or food additives violating the preceding paragraph shall be confiscated and destroyed.

Article 15 Food utensils, food containers, food packaging or 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; or
3. those that are otherwise harmful to health.

Article 16 Upon diagnosing a patient suspected of being associated with foodborne disease outbreak, a medical institution shall report to the local competent authority within 24 hours.

Chapter III Food Labeling and Advertisement

Article 17 Prepackaged foods or food additives shall conspicuously indicate in Chinese and common symbols the following material facts on the container or packaging:

1. product name;
2. name, weight, volume or quantity of the content or, in the case of a mixture of two or more ingredients, each of the ingredients;
3. name of food additive;
4. name, telephone number and address of the company; in the case of imported food, name, telephone number and address of the responsible domestic company;
5. expiry date; if the product is designated by the central competent authority in a public notice, the date of manufacture, shelf life or storage instructions shall also be indicated; and
6. other material facts designated by the central competent authority in a public notice.

Food designated by the central competent authority in a public notice shall be

- conspicuously labeled with its nutrients and the contents thereof in Chinese and common symbols in such format and covering such items as prescribed by the central competent authority.
- Article 17-1 The central competent authority may prescribe restrictions on the vending location and methods of specific bulk foods, or may require food labeling showing country of origin in Chinese.
The central competent shall prescribe in a public notice the restrictions on vending location and methods of the specific bulk foods in the preceding paragraph.
- Article 18 Food cleansers and food utensils, food containers and food packaging which are designated by the central competent authority in a public notice shall conspicuously indicate in Chinese and common symbols the following material facts:
1. name, telephone number and address of the company; in the case of imported products, name, telephone number and address of the responsible domestic company; and
 2. other material facts designated by the central competent authority in a public notice.
- Article 19 The labeling, promotion or advertisement of foods, food additives or food cleansers 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 scope, method and venue of advertising for special dietary foods.
A media business being commissioned by a principal to publish or broadcast an advertisement shall maintain the particulars of its principal, such as its name (corporate or group name), identify number, business license number, domicile (firm or business office) 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 IV Sanitary Control in the Food Industry
- Article 20 The operation sites, facilities or quality assurance system used by a food business for manufacturing, processing, preparing, packaging, transporting, storing, and selling foods or food additives shall meet the Good Hygiene Practice prescribed by the central competent authority; where the food business belongs to a designated category designated by the central competent authority in a public notice, the Hazard Analysis Critical Control Point (HACCP) prescribed by the central competent authority shall also be observed.
The central competent authority shall prescribe the provisions in Good Hygiene Practice and HACCP.
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.
- Article 21 Any food business with definite category and scale designated by the central competent authority in a public notice shall take out product liability insurance. The insured amount and contents of the insurance contract shall be prescribed by the central competent authority through consultation with the relevant authorities.
- Article 22 Food manufacturing factories which are designated by the central competent

- authority in a public notice shall have sanitation control personnel.
The rules for establishment of the sanitation control personnel of the preceding paragraph shall be prescribed by the central competent authority.
- Article 23 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 regulations promulgated by the central competent authority.
- Chapter V Inspection, Analysis and Prohibition
- Article 24 The municipal or county/city competent authority shall spot check the sanitary condition and record of a food business, and where necessary, shall conduct random examination of, and seize, the record. Where the food business is suspected of violating the first paragraph of Article 11, Article 15, or the sanitation, safety and quality standards prescribed by the central competent authority pursuant to Article 10, or the product names, specifications, scope of use and maximum allowance of food additives to be prescribed pursuant to Article 12, the municipal or county/city government may order such food business to suspend its operations and seal the articles concerned.
The central competent authority may commission the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs to execute the above measures at the ports of entry with respect to foods, food additives, food utensils, food containers, food packaging or food cleansers.
Where necessary, the central competent authority may execute the measures described in the first paragraph with respect to articles listed in the preceding paragraph that are available on the market.
- Article 25 The method of food sanitation examinations shall be prescribed by the central competent authority in a public notice; in the absence of such prescription, an internationally recognized method may govern.
- Article 26 Food sanitation examinations shall be performed by the food sanitation analysis institution of the particular level of competent authority. Where necessary, such examination may be commissioned in whole or in part to other analysis institution, academic organization or research institution in accordance with regulations prescribed by the central competent authority.
- Article 27 Regulations governing the spot check and examination under this Act shall be prescribed by the central competent authority, provided, where the inspection and examination involves the jurisdiction of other authorities, such regulations shall be established in conjunction with those authorities.
The central competent authority may accreditate a domestic or overseas certifying institution with respect to food sanitation inspection and examination. The items to be accredited and regulations governing the accreditation shall be prescribed by the central competent authority.
The central competent authority may authorize its subordinate organization or commission relevant organization (institution) to deal with the accreditation referred to in the preceding paragraph. Regulations governing the commissioning shall be prescribed by the central competent authority.
- Article 28 The competent authority shall keep strictly confidential the particulars of, and grant reward to, anyone informing against foods, food additives, food utensils, food containers, food packaging, food cleansers, labels, promotional materials, advertisements or food businesses that are found to have violated this Act. Regulations governing the granting of the above reward shall be prescribed by the central competent authority.
- Chapter VI Penal Provisions

Article 29 The local competent authority shall impose the following punishment based on inspection or examination results for foods, food additives, food utensils, food containers, food packaging or food cleansers that have been spot-checked or examined in accordance with Article 24:

1. Those under any of the circumstances listed in the first paragraph of Article 11 or Article 15 shall be confiscated and destroyed;
2. Those not conforming to the sanitation, safety and quality standards prescribed by the central competent authority pursuant to Article 10, or the product names, specifications, scope of use and maximum allowance of food additives to be prescribed pursuant to Article 12, or those violating the second paragraph of Article 13 or the first paragraph of Article 14, shall be confiscated and destroyed. However, if those can be used or reconditioned for use 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 Article 17, 18, or the first paragraph of Article 19, 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 cured; in case the notice is not complied with within the prescribed time limit or the second paragraph of Article 19 is violated, those goods shall be confiscated and destroyed; and
4. The punishment with respect to goods which are subject to a suspension on operation and are sealed pursuant to the first paragraph of Article 24 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 above shall immediately announce the termination of use or consumption of such goods and recall and destroy those said goods. Where necessary, the local 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 local competent authority shall officially publish the company name, address, name of the responsible person, and product name of, and circumstances of the violations by, any food business manufacturing, processing, preparing, packaging, transporting, selling, importing or exporting goods under subparagraph 1 or 2 of the first paragraph above.

The central competent authority shall restrict the importation of goods under the first paragraph above which are inspected at the ports of entry and found to be failed to conform to regulations, and may also impose the punishment under any of the subparagraphs of the first paragraph, or the second or preceding paragraph, with respect to such goods.

Article 29-1 The municipal and the county/city competent authority shall keep the remaining bodies of the specimens that failed the examination, including the containers, packages and labels for a term of six months, and dispose the stuff thereafter. For those items that will deteriorate within six months, however, the storage period will depend on the length they can be stored. Where a food business disagrees on examination results, it may apply for a

re-examination from the original sampling agency within fifteen days upon the receipt of the relevant notification. The agency receiving the case shall re-examine the remaining specimens in storage within seven days. The application for re-examination may be filed only once with the re-examination fees.

Article 30 In addition to being handled pursuant to Article 29, foods, food additives, food utensils, food containers, food packaging or food cleansers which are found to be under any of the circumstances described in subparagraph 1 or 2 of the first paragraph of Article 29 may be subject to a ban on manufacture, sale, import or export by the central competent authority per a public notice. Where the article subject to a ban under the preceding paragraph was registered and licensed by the central competent authority, the relevant license will be revoked.

Article 31 Anyone committing any of the following shall be fined between **NT\$60,000 and NT\$6,000,000. In severe circumstances, the enterprise may be ordered to terminate business for a certain period of time, suspend business or revoke the company registration, business registration or factory registration:**

1. violating any of subparagraphs 1 to 7 of the first paragraph of Article 11 or Article 15;
2. violating the first paragraph of Article 20, and failing to cure the violation within the time limit prescribed; or
3. violating the ban mentioned in the preceding article.

Article 32 Anyone violating the first or third paragraph of Article 19 shall be fined between NT\$40,000 and NT\$200,000. Anyone violating the second paragraph of such article shall be fined between NT\$200,000 and NT\$1 million. Where the offense is repeated within a year, the business license or factory license may be revoked. The punishment may be consecutively imposed for each violation until the publication or broadcast of the advertisement is suspended. A media business violating the fourth paragraph of Article 19 shall be fined between NT\$60,000 and NT\$300,000 and may be consecutively fined for each violation.

The competent authority shall notify the media business and the municipal or county/city competent information authority in writing of the punishment under the first paragraph upon imposing such punishment. The media business shall suspend the broadcast or publication of the advertisement concerned from the day following its receipt of the above notification.

A media business continuing to publish or broadcast, against the preceding paragraph, the advertisement which violates the first or second paragraph of Article 19, or the public notice prescribed by the central competent authority pursuant to the third paragraph of Article 19, shall be fined between NT\$120,000 and NT\$600,000 and may be consecutively fined by such authority for each violation until the publication or broadcast is suspended.

Article 33 Under any of the following circumstances, a fine between NT\$30,000 and NT\$150,000 shall be imposed. Where the offense is repeated within a year, the business license or factory license may be revoked:

1. violating the sanitation, safety and quality standards prescribed by the central competent authority pursuant to Article 10, and failing to cure the violation within the time limit prescribed;
2. violating subparagraph 8 or 9 of the first paragraph of Article 11, the second paragraph of Article 13, the first paragraph of Article 14, the first paragraph of Article 17, Article 18, or the first paragraph of Article 22;

3. violating the product names, specifications, scope of use and maximum allowance of food additives prescribed by the central competent authority pursuant to Article 12, or violating the regulations concerning nutrition labeling prescribed by the central competent authority pursuant to the second paragraph of Article 17;
4. violating the public notice prescribed by the central competent authority pursuant to Article 17-1;
5. violating regulations concerning product liability insurance prescribed by the central competent authority pursuant to Article 21, and failing to cure the violation within the time limit prescribed;
6. violating the regulations governing the sanitation of public food service sites prescribed by the municipal or county/city competent authority pursuant to Article 23; or
7. failing to comply with an order of recall and destruction as given by the competent authority pursuant to the second paragraph of Article 29.

- Article 34 If any of the acts described from Article 31 to the preceding article are committed to the detriment of human health, imprisonment of not more than **seven years, detention and/or a fine NT\$10,000,000 shall be imposed.** 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 of the preceding paragraph in the operation of duties, not only shall the wrongdoer be punished but the legal entity or natural person shall also be fined as in the preceding paragraph.
Anyone committing any of the offenses described in the first paragraph out of negligence shall be imprisoned for not more than **one year**, detained or fined **NT\$6,000,000.**
- Article 35 Anyone refusing, impeding or evading a spot-check, random examination or seizure, or unable or not agreeing to provide the source of articles which do not conform to this Act, or failing to observe a suspension on operation, shall be fined between NT\$30,000 and NT\$150,000. Where the violation is material or repeated within a year, the business license or factory license may also be revoked.
- Article 36 Fines under this Act shall be imposed by the municipal or county/city competent authority.
- Chapter VII Supplementary Provisions
- Article 37 The provisions of this Act regarding food utensils and food containers shall apply mutatis mutandis to the governing of toys that are directly contacted and placed into the mouth of children.
- Article 38 The central competent authority shall charge a review fee, examination fee, and license fee with respect to applications by a food business for review, examination and permits. The respective amount of such fees shall be prescribed by the central competent authority.
- Article 39 The enforcement rules of this Act shall be prescribed by the central competent authority.
- Article 40 This Act shall be implemented as of its being promulgated.