

Health Food Governing 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 foods, protect public health, and safeguard consumers' rights and interests. 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, labeled or advertised with such effects.

The term "health care effects" shall mean effects scientifically substantiated to improve people's health, and reduce disease risks. However, it is not a medical treatment aimed at treating or curing 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 this Act.

1. Supported by scientific assessment of the safety and health care effects of food, demonstrating it is harmless to human health and contains specific health care effects; if current technology cannot identify ingredients contributing to such effects, the applicant shall list the ingredients with the relevant health care effects and

provided supporting literature to the central competent authority for evaluation and verification.

2. Ingredients conform to the Health Food Specification Standards set by the central competent authority.

The methods by which health care effects and safety are assessed, and the standards specified 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 academic institutions 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 that the health food can prevent or alleviate conditions related to nutrient deficiencies if it supplements nutrients lacking in the human body;
2. describing the effect of specific nutrients, ingredients, or the food itself on human physiological structure or function 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 level, 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 in compliance with this Act.

This Act shall govern any food that is labeled or advertised as providing specific nutrients or having specific health care effects.

Article 7 No health food shall be manufactured or imported unless and until an application for inspection and registration supported by information on its ingredients, specifications, functions and effects, a summary of the manufacturing process, testing specifications and methods, other relevant data and documentation, as well as labels and samples are submitted along with certificate fees and inspection fees, and a product registration permit is issued by, the central competent authority or its commissioned organization.

The certificate fees referred to in the preceding paragraph means the fee for the issuance, replacement, or supplementary issuance of the health food permit based on the application for inspection and registration. The inspection fees mean the fees for the examination and testing. The relevant fee amount shall be prescribed by the competent authority.

An application for modification of the health food after a permit is issued must be filed with the relevant examination fee to the central competent authority.

The central competent authority may, where necessary, commission relevant organization, institution, school or group to conduct the inspection and registration referred to in the first paragraph. The relevant regulations shall be prescribed by the central competent authority.

Regulations for application of permit referred to in the first paragraph shall be prescribed by the central competent authority.

Article 8 A health food manufacturing 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 manufacturing or importation after the expiration is desired. The term of each renewal shall not exceed five years. The permit shall automatically become null and void if renewal application 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 reissuance, 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. if scientific research raises doubts about the efficacy of the product;
2. if the ingredients, formula, or production method of the product is subject to doubt; or
3. if 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 notify the company concerned to make improvements 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 comply with 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 to the sanitation standards which are prescribed by the central competent authority.

Article 12 No health food or its raw materials thereof shall be manufactured, prepared, processed, sold, stored, imported, exported, offered as a gift, or publicly displayed if the health food or its raw materials thereof:

1. deteriorate or become rotten;
2. are contaminated by pathogens;
3. contain any residual pesticide exceeding the safe permissible tolerance set by the central competent authority;
4. are contaminated by nuclear fallout or radioactivity exceeding the safe permissible tolerance set by the central competent authority;
5. are adulterated or counterfeited;
6. have exceeded the shelf life; or
7. contain other substances or foreign materials detrimental to human health.

Chapter IV Labeling and Advertisement of Health Food

Article 13 The following information 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; for mixtures of two or more ingredients, the ingredients shall be list in descending order of proportion;
3. net weight, volume or quantity;
4. name of food additives; if a mixture of two or more food additives is named by its function, the name of each additive must be listed 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. permit number, the legend of "health food" and standard logo;
9. recommended intake and important message for consumption of the health food, possible health risks, and other necessary warnings;
10. nutritional components and their content; and
11. other information 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 contain false or exaggerated claims, and the health claims shall not exceed

the approved scope and must align with the content registered with the central competent authority.

Health food labeling or advertisement shall not imply or suggest any medical efficacy.

Article 15 No mass communication business shall publish or broadcast advertisements for health food for which no permit has been 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, address (place of business or operations), and telephone number of the person (individual or entity) who retains the advertising services for six months from the date the advertisement is published or broadcast and shall neither evade, impede nor 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 reasonable cause; provided the health food subject to random testing shall be limited to the quantity sufficient for the testing purposes.

The competent health authority at each level may order a business suspected of violating Articles 6 to 14 to suspend its manufacture, preparation, processing, sale or display, and temporarily seal up the product concerned for a prescribed

period to be temporarily held in custody by such business upon issuance of a certificate of custody.

Article 17 The central competent authority shall, as necessary, issue a public notice to ban the manufacture and importation of any approved health food which is found to be materially harmful to human health, and revoke its permit. If such health food has been manufactured or imported, the exportation, offering for sale, transport, consignment for storage, promotion, 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 may also be subject to confiscation and destruction.

Article 18 A health food manufacturer or importer shall immediately notify its downstream businesses upon the occurrence of any of the following events and recall all products from the market within the specified period and dispose of such products along with any inventory according to this Act:

1. where health food is labeled or advertised as health food without official approval;
2. where the manufacture or importation of permitted health food is banned by public notice;
3. where an application for renewal of the existing permit is not filed or 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 is required to be recalled from the market per the public notice of the central competent health authority.

The downstream businesses shall cooperate with 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 health food that is labeled or advertised as health food without approval as health food or where 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 can still be used or reconditioned for use, 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 this 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 specified period; if the recall is not complied with within this period 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 in any of the above three subparagraphs applies, but the manufacture, preparation, processing, sale and display of

the food was suspended and the food was sealed in accordance with an order under the second paragraph of Article 16.

The local competent authority shall publicly announce 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 details of the violation.

Article 20 Anyone reporting or seizing any health food not meeting the requirements set forth in this Act shall be rewarded by the competent authority. The regulations for rewards 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.