HEALTH FOOD CONTROL ACT

Promulgated on February 3, 1999.
Amended and promulgated on November 8, 2000.
Amended and promulgated on January 30, 2002.
Amendments of Articles 2, 3, 14, 15, 24 and 28 pursuant to the President's Order Hua Zong (1) Yi Zi No. 09500069821 promulgated on May 17, 2006.
Amendment to Articles 13 of the Health Food Control Act per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10700007761 dated January 24, 2018.
Amendment to Articles 5 of the Health Food Control Act per Presidential Decree No. Hua-Zhong-Yi-Yi-Zi-10900003941 dated 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 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 issused 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.