

Proposed requirement for labelling content of caffeine on pre-packaged beverages under the Act Governing Food Sanitation.

Article 17 of the Act Governing Food Sanitation sets out the information to be labelled on food products. In response to requests made by consumers for information on the content of caffeine of beverages, the Department of Health intends to require that pre-packaged caffeine-containing beverages be labelled content of caffeine on the container or packaging in a conspicuous manner and the font shall not be smaller than 2mm in width and length. The followings are detailed requirements:

- (1) Where pre-packed liquid form beverages, contain caffeine, from whatever source, in a proportion equal to or in excess of 20 mg/100mL, labelling of the caffeine content shall be expressed in mg/100mL;
- (2) Where pre-packed liquid form beverages, contain caffeine, from whatever source, in a proportion less than 20 mg/100mL, the following message should be labelled: "less than 20 mg/100mL caffeine";
- (3) Where pre-packed liquid form coffee, tea and cocoa beverages, contain caffeine, in a proportion equal to or less than 2 mg/100mL, labelling of the caffeine content may be expressed as "low caffeine" instead of "less than 20 mg/100mL caffeine"; and
- (4) Where powder form instant coffee products (including plain, 2 in 1 and 3 in 1 coffee products), sold as one serving size, labelling of the caffeine content shall be expressed in mg/serving. This compulsory regulation shall not apply to any other kinds of beverage with powder or dried form.

ACT GOVERNING FOOD SANITATION

Promulgated on January 28, 1975.
Amended and promulgated on November 11, 1983.
Amended and promulgated on May 7, 1997.
Amended and promulgated on February 9, 2000.
Amended and promulgated on January 30, 2002.

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.

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 exceeding the permissible tolerance set by the central competent authority;
6. those that have been contaminated by and contain nuclear fallout or radioactivity exceeding the permissible tolerance set by the central competent authority;
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.

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 Farming 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 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 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.

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 or business name, residence, telephone number, I.D. number or business license number etc., for two 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 food good hygienic practices regulations 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 food safety control system prescribed by the central competent authority shall also be observed.

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 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 may spot check the sanitary condition and record of a food business, and where necessary, conduct random examination of, and seize, the record. Where the food business is suspected of violating Article 11 or the regulations prescribed by the central competent authority in accordance with 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 Article 11 or 15 shall be confiscated and destroyed;

2. Those not conforming to regulations which the central competent authority enacts pursuant to Articles 10 and 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; 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\$40,000 and NT\$200,000. Where the offence is repeated within a year, the business license or factory license may be revoked:

1. violating any of subparagraphs 1 to 7 of Article 11 or Article 15; or
2. violating the ban mentioned in the preceding article.

Article 32

Anyone violating the first paragraph of Article 19 shall be fined between NT\$30,000 and NT\$150,000. 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 third paragraph of Article 19 shall be fined between NT\$30,000 and NT\$150,000 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 shall be fined by the municipal or county/city competent information authority between NT\$60,000 and NT\$300,000 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 Article 10 and failing to cure the violation within the time limit prescribed;
2. violating subparagraph 8 or 9 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 regulations which the central competent authority enacts pursuant to Article 12 or the second paragraph of Article 17;
4. violating regulations which the central competent authority enacts pursuant to the first paragraph of Article 20 or Article 21, and failing to cure the violation within the time limit prescribed;
5. violating regulations which the municipal or county/city competent authority enacts pursuant to Article 23; or
6. 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 three years, detention and/or a fine between NT\$180,000 and NT\$900,000 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 six months, detained or fined NT\$100,000.

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

Subject to paragraph 4, Article 32, fines under this Act shall be imposed by the municipal or county/city competent authority.

Anyone failing to pay the fines within the prescribed time limit after being served a notice demanding payment shall be referred to court for compulsory execution.

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.