Introduction on the Regulations on Imported Nutrition Supplements of the Republic of China

Preface

With the aging of population in Taiwanese society, the people of Taiwan have become more health-conscious and want to supplement nutrients with nutrition supplement aside from the intake of daily diet. In addition, the types of nutrition supplements nowadays are developed from vitamin products in the early stage to the present products which are intended to provide body organs and parts with different effects. It seems that there is a trend of rapid growth of the nutrition supplements market in Taiwan, and many corporations are eager to export nutrition supplements to Taiwan. As far as the importers are concerned, it is necessary for them to learn and conform to the laws and rules stipulated by Taiwanese government such as procedural requirements on importation, prohibition rules on food additives and ingredients and so on.

The importation of nutrition supplements is mainly subject to the provisions of the Act Governing Food Sanitation and Safety, the Health Food Control Act, the Pharmaceutical Affairs Act, the Products Labelling Act, the Consumer Protection Law, the Fair Trade Act, and so on. This article is intended to briefly describe the regulations of Act Governing Food Sanitation and Safety, and Health Food Control Act.

Regulations on Importation

1. Roadmap

Although many nutrition supplements are packaged and marketed in tablet or capsule forms, unless they fall within the definition of “drug”, they are not classified as drugs[1]under the definition of the Food and Drug Administration

[1] The term "drugs" as used in the Pharmaceutical Affairs Act of the Republic of China refers to any of the following raw materials and preparations: (1) Drugs which are listed in the Chinese Pharmacopoeia, or in the Pharmacopoeia of other countries, the official National Formularies or any of their supplements recognized by the central competent health authority; (2) Drugs which are not included in the preceding Sub-paragraph but are used in diagnosing, curing, alleviating or preventing the diseases

(hereinafter referred to as "TFDA") of the Ministry of Health and Welfare of the Republic of China, the central competent authority in Taiwan. Nutrition supplements are defined as "food products" and subject to the Act Governing Food Sanitation and Safety. Pursuant to paragraph 1 of Article 21 of the Act Governing Food Sanitation and Safety, food products that are designated by TFDA are required to file a production registration application with TFDA and procure the permits from TFDA before importation. The designated foods include **health food**, **special dietary food**, and **packaged tablet or capsule foods**[2]. Due to the length of this article, the following paragraph is only focused on the laws and rules concerning health food and packaged tablet or capsule foods.

2. Health foods

(1) The definition of "health food" in Taiwan

The Health Food Control Act of the Republic of China went into effect as of August 3, 1999. According to the Health Food Control Act of the Republic of China, "health food" is no longer an ordinary usage in Taiwan; instead, it has been transformed into a legal term. The Health Food Control Act prohibits a food product without a health food permit from being labelled or advertised as "health food" in Taiwan. In order to obtain a health food permit, an importer shall submit the information of the product's ingredients, specifications, functions and effects, manufacturing process, methods of analysis and other relevant data and documentations to TFDA for a reviewing and testing application[3]. When the product meets the requirements of the review and test, TFDA would grant a

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of human beings; (3) Other drugs which are sufficient to affect the body structure and physiological functions of human beings; or (4) Drugs which are used in preparing such drugs set forth in the preceding three Sub-paragraphs.
The food additives contained in imported nutrition supplements shall be in compliance with the "Standards for Specification, Scope, Application and Limitation of Food Additives". If the amount of the food additives exceeds the maximum levels of daily intake stipulated in the standard, the nutrition supplement shall be deemed as "drug". According to the Pharmaceutical Affairs Act, if an importer exports drugs to Taiwan without prior approval, he would be sentenced to imprisonment for no more than 10 years and fined no more than NT 10 million dollars.

[2] Based on the "Regulations on Inspection of Imported Foods and Related Products", the designated foods shall obtain product registration permits prior to the procedure of spot check and examination at harbors.

[3] If the imported health food is packaged in tablet or capsule forms, it shall obtain the product registration permit for "packaged tablet and capsule food" prior to applying for the health food permit.

health food permit. Then the product is allowed to be labeled and advertised as "health food". In the event where an importer labels or advertises his product as "health food" without obtaining a health food permit beforehand, he would be subject to sentence of imprisonment for no more than 3 years, and a fine of no more than NT 1 million dollars under Article 21 of the Health Food Control Act.

Based on Article 2 of the Health Food Control Act, the term "health food" refers to a food product which furnishes specific nutrients or has specific health care effects. Moreover, it is also labeled or advertised with such health care effects, however, it is not a medical treatment aimed at treating or remedying human diseases. The two criteria of a health food in accordance with Article 3 of the Health Food Control Act are as follows: (1) its ingredients or substances have definite health care effects and the reasonable amount of intake has been proved by scientific data；(2) it is harmless to human body which is duly supported by scientific assessment of the safety test and health care effects evaluation test and carries definite health care effects. So far, TFDA has announced 13 kinds of health care effects including: regulating blood fat level, adjusting gastrointestinal function, supporting immune system, alleviating allergy symptoms, improving osteoporosis function, maintaining teeth health, managing blood sugar level, protecting the function of liver (for chemical induced liver injuries), preventing from storing body fat, reducing tiredness, anti-aging, managing blood pressure level, promoting the absorption of iron.

In essence, the so-called "nutrition supplements" on the market refer to the ordinary nutritional products which do not have health food permits granted by TFDA. Therefore, it is not allowed to be labeled or advertised as "health food" or with any definite health care effects as mentioned above for the health food.

Pursuant to Article 7 of the Health Food Control Act, no health food shall be imported until an application for "review and testing registration" to TFDA and a product registration permit (health food permit) is issued by TFDA. An importer who labels or advertised his product as "health food" without a prior health food permit and exports it to Taiwan would be subject to sentence of imprisonment for no more than 3 years and a fine of no more than NT 1 million dollars.

(2) The procedure of review and testing registration of health foods

The procedure of review and testing registration of health foods is a double-track system. The first track is the review of an individual case. In the event that an importer files an application for review and testing registration with TFDA in accordance with subparagraph 1 of paragraph 1 of Article 3 of the Health Food Control Act, he shall submit experiment results and scientific evidence and other required documentations to TFDA. It takes TFDA 180 working days to check and verify whether the product does no harm to human body and the health care effects have been proved by scientific evidence. The application fee is NT 166,000 dollars.

The second track is the review of specification standards. A product containing ingredients in conformity to the "Health Food Specification Standards"[4] regulated by TFDA is exempted from the health care effects evaluation test since its health care effects has been verified by academic theories. It takes TFDA 120 working days to check and verify the application. The application fee of this kind of product is NT 54,000 dollars.

(3) The term of a health food permit and the renewal

The term of a health food permit is 5 years. Application for renewal shall be filed within 3 months prior to the expiration of the term with TFDA if continued importation after the expiration is desired. The term of each renewal shall not exceed 5 years. The original permit shall become void and null if the application for renewal is not filed in time or renewal is not granted.

3. Packaged tablet or capsule foods

According to the current laws, the importer of packaged tablet or capsule foods shall file product registration application and obtain a registration permit for packed tablet and capsule food. It takes TFDA 60 working days to review the application. The application fee is NT 2,000 dollars. The term of a product registration permit is 5 years. Application for renewal shall be filed within 3 months prior to the expiration of the term with TFDA if continued importation

[4] TFDA has announced two specific standards regulations for red yeast rice products and fish oil products.

after the expiration is desired. The term of each renewal shall not exceed 5 years. The original permit shall become void and null if the application for renewal is not filed in time or renewal is not granted.

4. **Nutrition supplements packaged in other forms**

   The nutrition supplements which are not packaged in tablet or capsule forms such as collagen drinks are not required to obtain a product registration permit. Another example is, according to the announcement of TFDA, effervescent tablet which is designed to dissolve into a solution or water is not required to obtain a product registration permit either.

Regulations on Ingredients

When we analyze the composition of a food, it can be roughly divided into two categories: **raw materials for food** and **food additives**. Raw materials for food refer to (1) fresh products made from plants, animals and microorganisms and minerals, or (2) materials artificially processed from food but not purified or decomposed the specific substances inside, or (3) chemical synthetic substances which do not have properties of food additives and are not used as food additives. Based on subparagraph 3 of Article 3 of the Act Governing Food Sanitation and Safety, food additives refer to the 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.

TFDA has promulgated "Standards for Specification, Scope, Application and Limitation of Food Additives" (hereinafter referred to as "Standards for Food Additives"). Only the substances listed in the Standards for Food Additives are allowed to be added to nutrition supplements and health foods. Moreover, the manufacturers of nutrition supplements and health foods shall comply with the daily maximum and minimum levels set forth in the standard. As for raw materials for food, TFDA also has promulgated "Lists of Edible Raw Materials for Food".[5]

[5] If a material is not listed in the "Standards for Food Additives" or the "Lists of Edible Raw Materials for Food", it could be a lawful ingredient such as a kind of food like, for example, corn dextrin. However, it could also be deemed to be an illegal additive and not allowed to be added to any food

If a health food contains materials detrimental to human health, the importer would be fined between NT 60,000 dollars and NT 300,000 dollars according to Article 22 of the Health Food Control Act. If the illegal materials have caused harm to human health, the importer would be sentenced to imprisonment for no more than 3 years and be fined no more than NT 1 million dollars.

Pursuant to Article 49 of the Act Governing Food Sanitation and Safety, where a nutrition supplement or a health food is added in food additives not listed in the "Standards for Food Additives", the importer would be subject to sentence of imprisonment for no more than 5 years and a fine of no more than NT 8 million dollars. If a nutrition supplement or a health food has endangered human health, for example, toxic materials or substances detrimental to human health are added to a health food or a nutrition supplement, or the food additives it used are not conformity with the "Standards for Food Additives", the importer would be sentenced to imprisonment for no more than 7 years and be fined no more than NT 10 million dollars. If the illegal nutrition supplement or the illegal health food has caused death, the importer would be sentenced to a life imprisonment or imprisonment for no less than 7 years and fined no more than NT 20 million dollars.

As for the administrative punishment, TFDA may fine the violator a fine between NT 60,000 dollars and NT 50 million dollars. In the event that the profits gained from the illegal conduct above exceed the amount of NT 50 million dollars and if the violation is deemed to be a severe violation by TFDA, TFDA has the right to increase the amount of the fine within the amount of interests a violator has obtained therefrom.

Regulations on Labeling and Advertisement[6]

1. Health foods

The Health Food Control Act states that the following material facts shall be

products.

[6] The advertisement of health foods or nutrition supplements is not subject to a prior approval. Based on the announcement of TFDA, whether the content of the advertisement of health foods or nutrition supplements is involved in misrepresentation, exaggeration, or deception depends on all the information the company conveys. TFDA would make a decision based on the wordings, descriptions, the product's name, images, pictures and symbols used in the advertisement.

shown conspicuously on the containers, packaging or written instruction of health foods in Chinese and in commonly used symbols: (1) product name; (2)name, and weight or volume of the contents; in case of a health food which is a blend of two or more ingredients, the ingredients shall be separately labeled; (3) name of food additives; (4) expiration date, methods and conditions of preservation; (5)name and address of the responsible business operator; the name and address of the importer shall be specified if the health food is imported; (6) the approved health care effects; (7) reference number of the permit, the legend of "health food" and standard logo; (8) amount of intake and important messages for consumption of the health food and other necessary warnings; (9) nutrient component and its volume; and (10) other material facts designated by the central competent authority. As such, TFDA has promulgated “Regulations on Nutrients and Contents Labeling for Health Food”.

The labeling or advertisement of a health food shall not misrepresent or exaggerate, and the health claim shall not extend beyond the approved scope and shall not claim or refer to medical efficacy. For instance, if the approved claim allows the health food to claim “the product helps to maintain the normal function of immune system”, the seller is not allowed to extend the scope and claim of things which are not permitted by TFDA such as “the product can restrain the growth of tumor” or “the product is helpful to fight cancer cells”.

In the event of a misrepresentation or exaggeration on a health food’s labeling or advertisement or where a health claim of a health food extends the approved scope, the seller of the health food would be fined between NT 100,000 dollars and NT 500,000 dollars. If a labeling or an advertisement of a health food claims medical efficacy, the seller of the health food would be fined between NT 400,000 dollars and NT 2 million dollars. TFDA may fine the violator for each violation till the publication or broadcast stops. In the event of a severe violation, TFDA may revoke the health food permit. In the event of repeated violation within one year, the competent authority may terminate the business registration of the corporation.

2. Nutrition supplements

Pursuant to Article 22 of the Act Governing Food Sanitation and Safety, the

following material facts shall be shown conspicuously on the container or packaging of a food product in Chinese and in commonly used symbols:
(1) product name; (2) name of the ingredients or, in the case of a mixture of two or more ingredients, each of the ingredients shall be indicated separately; (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 additives separately; (5) name, telephone number and address of the manufacturer and the responsible domestic company; (6) place (or country) of origin; (7) expiration date; (8) nutrition label; (9) if any, modified food ingredients; (10) other matters designated by the central competent authority in a public announcement. TFDA has enacted the "Regulations on Nutrition Labeling for packaged tablet or capsule foods containing vitamins and minerals". The labeling on other types of nutrition supplements such as liquid type shall comply with the "Regulations on Nutrition Labeling for Packaged Food" promulgated by TFDA.

Based on Article 28 of the Act Governing Food Sanitation and Safety, the labeling, promotion or advertisement of food shall not misrepresent, exaggerate, mislead or claim any medical efficacy. If the labeling, promotion or advertisement of a nutrition supplement misrepresents, exaggerates or misleads, the importer would be fined between NT 40,000 dollars and NT 4 million dollars. If the labeling, promotion or advertisement of a nutrition supplement claims medical effects, the importer would be fined between NT 40,000 dollars and NT 5 million dollars. TFDA may fine the violator for each violation till the publication or broadcast stops. In the event of repeated violation, the competent authority may order to terminate, suspend the violator's business, or revoke all or part of the items listed in the company registration, business registration or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration within one (1) year would be prohibited.

Accordingly, TFDA has promulgated a standard on the wordings used in food products' labeling, promotion and advertisement for food corporations' reference.