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## INFORMATION NOTE

### Regulation of Health Food in the Mainland

#### 1. Background

1.1 The Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004, at its meeting on 17 January 2005, requested the Research and Library Services Division to provide information regarding the regulation of health food in the Mainland. In particular, the Bills Committee requested information about the regulation of health claims relating to blood sugar, blood pressure, blood lipids, slimming or fat reduction, regulation of body immune system and promotion of detoxification. This information note provides such information to the Bills Committee.

#### 2. Highlights of the regulatory framework for health food

##### Claims for health food

2.1 In the Mainland, according to the Health Food Regulations (保健食品管理辦法) (HFR), food products that claim to have certain health functions must undergo human or animal functional tests. Health food products can be marketed for sale only after they have obtained an approved health food certificate and a code number issued by the relevant authority.

2.2 At present, health food can apply for certification of 27 types of health functions, which are divided into two main groups. The first group comprises 16 types related to prevention of diseases, relief of symptoms and assisting in drug treatment, including assisting blood pressure reduction, assisting blood sugar reduction, assisting blood lipids reduction, facilitating digestion, improving constipation and facilitating lead excretion. The other group comprises 11 types related to enhancing physical health and strengthening bodily conditions, such as enhancing immune function, stamina, controlling obesity, improving skin moisture, improving skin oil content and improving growth and development function. Each health food product can apply for certification of no more than two health functions.

### Regulation on labels and descriptions

2.3 Descriptions of health food products shall be examined and approved by the relevant authority. In addition to fulfilling the requirements for general food products, such descriptions shall also state the health maintenance effects of the health food products, the suitable target users, the methods of consumption, the recommended intake portion, the functional components, the names of ingredients, the code number and a special health food label issued by the relevant authority. The supervision of labels and descriptions focuses on whether the relevant product briefs contain false and exaggerated advertising elements regarding their functions; whether the indicated contents are complete, and whether such contents are in line with the requirements set during the product evaluation and approval procedure.

### Regulation on advertisements

2.4 There is no pre-approval system for health food advertisements in the Mainland. The Provisional Rules on Food Advertising (食品廣告發佈暫行規定) (PRFA) stipulate that the contents of health food advertisements shall be in line with those of the descriptions and labels as approved by the administrative department of public health under the State Council. The advertisements shall not extend beyond the approved scope arbitrarily and the code number of the approved health food shall also be promulgated. In addition, functional comparison shall not be drawn between health food products and other health care instruments or pharmaceutical products, and the promotion of health food shall not make use of feudal and superstitious elements.

### Recent developments

2.5 A comprehensive review on the regulatory framework for health food in the Mainland is underway but the details of the relevant laws and regulations have not been promulgated. The scope of the review covers various aspects including the application, examination and approval procedures, as well as the manufacturing and supervision, of health food products. Moreover, the State Food and Drug Administration (SFDA) is now drafting the Administrative Provisions for Examination of Health Food Advertisements (保健食品廣告審查管理辦法), which cover the procedure, mechanism and content of the examination.

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### 3. Definitions

#### Food

3.1 The essential legal basis for regulation of food hygiene in the Mainland is the Food Hygiene Law of the People's Republic of China (中華人民共和國食品衛生法) (FHL). According to this law, food *"means any finished product or raw materials provided for people to eat or drink, as well as any product that has traditionally served as both food and medicament, with the exception of products used solely for medical purposes"*.<sup>1</sup>

#### Health food

3.2 Articles 22 and 23 of FHL provide general rules on the definition of, requirements for as well as examination and approval of health food.<sup>2</sup> These rules constitute the legal basis for drafting laws and regulations as well as standard requirements for health food.

3.3 The Ministry of Health (MOH) under the State Council set out in detail the administration of health food in HFR, which was formulated and implemented in 1996. According to HFR, health food is *"food indicated to have specific health functions, which is suitable for the consumption by specific groups of people and has the effect of regulating human body functions, but is not used for the purpose of treating diseases"*.<sup>3</sup>

3.4 At present, the manufacture, marketing, examination and approval of health food in the Mainland are supervised and managed by SFDA. No health food product shall be manufactured, marketed or imported unless it obtained an approved code number issued by SFDA.

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<sup>1</sup> Article 54 of FHL.

<sup>2</sup> Article 22 of FHL stipulates that *"with regard to the food product indicated to have specific health functions, the product and its description must be submitted to the administrative department of public health under the State Council for examination and approval, its hygiene standards and the measures for control of its production and marketing shall be formulated by the administrative department of public health under the State Council."* Article 23 stipulates that *"food indicated to have specific health functions shall not be harmful to human health; the content of the product description shall be true, and the functions and ingredients of the product shall be identical with the information given in the product description and there shall be no false information."*

<sup>3</sup> Article 2 of HFR.

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## Medicine

3.5 Under Article 102 of the Drug Administration Law of the People's Republic of China (中華人民共和國藥品管理法), drug "*refers to materials that are used for preventing, treating, or diagnosing diseases of the people, and regulating the physiological functions, with prescribed applicable diseases, main functions, usage, and dosage, including Chinese traditional medicinal materials, Chinese medicine crude slices, prepared Chinese medicines, chemical raw material pharmaceuticals and their preparation, antibiotics, biochemical pharmaceuticals, radioactive pharmaceuticals, blood serum, vaccine, blood products, and diagnosis pharmaceuticals, etc.*"

## **4. Claims for health food**

4.1 A total of 24 acceptable health functions were promulgated by MOH in 1996 and 1997 respectively. Subsequently, it was announced that MOH would not accept the two health functions of "improving sexual function" and "assisting in suppressing tumor" for the moment, reducing the number of acceptable health functions to 22. On 1 May 2003, MOH issued the "Technological Specifications for Inspection and Evaluation of Health Food" (保健食品檢驗與評價技術規範). Under the specifications, certain aspects which had been included under other functions were listed out individually, making the number of acceptable health functions increased from 22 to 27 (details of which are at the Appendix).

4.2 The 27 health functions can be divided into two main groups. The first group includes 16 functions related to prevention of diseases, relief of symptoms and assisting in drug treatment. Among these 16 functions, 12 of them are related to commonly encountered diseases with complicated causes and diseases caused by particular life styles. Examples of such functions are assisting blood pressure reduction, assisting blood sugar reduction, assisting blood lipids reduction, facilitating digestion, and improving constipation. The other four are related to diseases with single cause and protection from the effects of exogenic noxious factors. Examples of such functions are facilitating lead excretion, improving endurance during anoxia, assisting protection against irradiation and assisting protection against chemical liver injury.

4.3 Another group comprises 11 health functions related to enhancing physical health and strengthening bodily conditions. Such functions include enhancing immune function, stamina, controlling obesity, improving skin moisture, improving skin oil content, increasing milk secretion and improving growth and development. Among these 27 health functions, each health food product shall apply for certification of not more than two health functions.

4.4 Apart from those food products with the abovementioned specific health functions can apply for certification to be health food products, nutritional products are also placed under the health food control as nutritional supplements. For instance, products containing vitamins and minerals as their main ingredients or food products aiming at supplementing human body nutrients can apply for certification to be health food.

4.5 MOH promulgated the "Notification on Problems Concerning the Regulation of Nutritional Supplements" (關於營養素補充劑管理有關問題的通知) in 2002 with a view to enhancing the regulation of nutrient products and standardizing the evaluation of nutritional supplements. The notification clearly states that nutritional supplements refer only to products which supplement vitamins and minerals. It also stipulates that nutritional supplements cannot make claims relating to the provision of energy. The recommended daily intake of nutrients added to a nutritional supplement product should also fall within the range specified in the List of Nutrients and Recommended Intake for Nutrient Supplements (營養素補充劑中營養素名稱及用量表).

## **5. Functional evaluation**

5.1 As stipulated in HFR, food products that claim to have certain health functions must undergo human or animal functional tests and obtain the approval of health food certificate with a code number issued by MOH. SFDA has been responsible for the evaluation and approval of the application and acceptance for health food since 10 October 2003.

5.2 A series of technological regulations on functional evaluation, examination and approval, as well as technical operation of health food have been formulated since the promulgation of HFR in 1996. Such regulations include Functional Evaluation Procedures and Test Methods for Health Food (保健食品功能學評價程式和檢驗方法), Technical Specifications for Inspection of Health Food (保健食品評審技術規程), Authorization and Regulation of Institutions for Functional Tests on Health Food (保健食品功能學檢驗機構認定與管理辦法), Requirements for Application and Acceptance for Health Food (保健食品的申報與受理規定), Toxicological Evaluation Procedures for Food Safety Analysis (食品安全性毒理評價程式) and Regulations for Hygienic Control of Food Nutrition Enriching Substances (食品營養強化劑衛生管理辦法).

## 6. Labelling and advertisement

### Labels and descriptions

6.1 In the Mainland, the labelling of health food is regulated by HFR and the Regulations on Health Food Labelling (保健食品標識規定). According to HFR, the labels and descriptions of health food shall comply with relevant standards and requirements and contain the following information<sup>4</sup>:

- (a) health maintenance effects and suitable target users;
- (b) methods and appropriate amount of consumption;
- (c) storage methods;
- (d) name and amount of functional ingredients;
- (e) code number of the approved health food;
- (f) the health food symbol; and
- (g) other labelling information as stipulated by the relevant standards or requirements.

6.2 The name of health food should be precise and scientific. The name of a person or a place, codes, exaggerating or misleading names, as well as the name of a functional ingredient that does not constitute a major component of the product shall not be used. The information on the label, in the description and advertisement of a health food product shall be true and in compliance with its quality requirements. It shall not contain any publicity materials implying that such product can cure diseases.<sup>5</sup>

6.3 At the same time, according to the Regulations on Health Food Labelling, the labels and product descriptions of health food shall comply with the following basic principles:

- (a) The labels of health food shall not be separated from the packaging containers. Product descriptions should be placed inside the packaging of the products.

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<sup>4</sup> Article 21 of HFR.

<sup>5</sup> Articles 22 and 23 of HFR.

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- (b) The labels should be placed in the corresponding space in accordance with this Regulation. When the space is insufficient, they can be placed in another "information space".
  - (c) The texts, diagrams and symbols on the label and product description of health food shall be clear, eye-catching, directly perceivable through senses as well as easy to identify and read. A contrasting colour should be used for the background.
  - (d) The texts, diagrams and symbols on the label and product description of health food shall be securely in place and long-lasting. The label and product description shall not become blurred or even detached during circulation and in the process of consuming the health food product.
  - (e) The main text shall be written in standard Chinese characters. Chinese pinyin, languages of minorities or foreign languages may be used at the same time. However, they shall be directly corresponding to the text written in Chinese characters and spelled correctly. The Chinese pinyin or foreign languages used shall not be larger in size than the corresponding Chinese characters.

#### Pre-approval for and monitoring of advertisements

6.4 At present, there are no specific laws or regulations for the regulation of health food advertisements in the Mainland. The advertisements of such products are mainly regulated by PRFA and HFR. PRFA stipulates that food advertisements shall not: carry any expressions that may cause confusion with drugs; directly or indirectly publicize therapeutic effects; and state or hint at the therapeutic effects of the food product through publicizing the functions of certain ingredients. In addition, food advertisements shall not make use of the name or image of experts and consumers to testify to specific efficacy.<sup>6</sup>

6.5 There is no pre-approval system for health food advertisements in the Mainland. PRFA stipulates that the contents of health food advertisements shall be in line with those of the descriptions and labels as approved by the administrative department of public health under the State Council. It shall not be extended beyond the approved scope arbitrarily and the code number of the approved health food shall also be shown in the advertisement.<sup>7</sup> In addition, functional comparison shall not be drawn between health food products and other health care instruments or pharmaceutical products<sup>8</sup>, and the promotion of health food shall not make use of feudal and superstitious elements.<sup>9</sup>

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<sup>6</sup> Articles 7 and 9 of PRFA.

<sup>7</sup> Articles 10 and 12 of PRFA.

<sup>8</sup> Article 11 of PRFA.

<sup>9</sup> Article 24 of HFR.

## 7. Recent development of the regulatory framework

7.1 A comprehensive review on the regulatory framework for health food in the Mainland is underway but the details of the relevant laws and regulations have not been promulgated. In April 2004, SFDA issued the draft Regulation for the Registration of Health Food for consultation (保健食品註冊管理辦法(徵求意見稿)), to seek comments from relevant departments in different parts of the country. Moreover, SFDA is now drafting the Administrative Provisions for Examination of Health Food Advertisements, which cover the procedure, mechanism and content of the examination.

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## Appendix

## 內地保健食品可以申報的保健功能

(根據《保健食品檢驗與評價技術規範(中華人民共和國衛生部2003年版)》規定)

增強免疫力功能
輔助降血脂功能**
輔助降血糖功能**
抗氧化功能**
輔助改善記憶功能**
緩解視疲勞功能*
促進排鉛功能**
清咽功能**
輔助降血壓功能**
改善睡眠功能
促進泌乳功能**
緩解體力疲勞#
提高缺氧耐受力功能
對輻射危害有輔助保護功能
減肥功能**#
改善生長發育功能**
增加骨密度功能
改善營養性貧血**
對化學肝損傷有輔助保護功能
祛痤瘡功能*
祛黃褐斑功能*
改善皮膚水份功能*
改善皮膚油份功能*
調節腸道菌群功能**
促進消化功能**
通便功能**
對胃粘膜損傷有輔助保護功能**

註：\* 人體試食試驗

\*\* 動物試驗 + 人體試食試驗

# 增加興奮劑檢測

## References

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