
INFORMATION NOTE

Recent Developments in the Regulation of Health Food in Taiwan

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 updated information regarding the research report on "Regulation of Health Food in Taiwan" issued in 2000. In particular, the Bills Committee requested information about the recent developments in the regulation of health claims relating to slimming or fat reduction, the regulation of body immune system and the 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 Taiwan, health food is permitted to carry health maintenance claims (保健功效聲稱) but is prohibited to make any therapeutic claims. Health maintenance claims must be supported by scientific assessments and in principle, the assessment of each health maintenance effect must be conducted in accordance with the assessment methods promulgated by the Department of Health (DOH).

2.2 At present, DOH recognizes seven health maintenance effects, including the regulation of the immune system. Claims relating to slimming or fat reduction and the promotion of detoxification do not fall into the seven types of approved health maintenance claims and are not allowed under the Food Sanitation Control Act (食品衛生管理法).

Regulation of advertisements

2.3 Health food advertisements should not contain information which is false, exaggerated and beyond the health maintenance effects approved by DOH, nor are they allowed carrying any therapeutic claims. Food advertisements should not be false, exaggerated or misleading, and they are prohibited to make any claims of therapeutic effects.

2.4 There is no pre-approval system for the advertisements of both health food and food. Nevertheless, the mass media companies are obliged to keep the particulars of their clients, and should neither evade, impede nor refuse the provision of such information upon requests by the relevant authority. No food product should be advertised or broadcast as health food unless a health food permit has been obtained for such a product.

2.5 Since August 2004, DOH has subsidized selected community groups to implement the "Monitoring of Non-compliant Medical, Pharmaceutical, Cosmetic and Food Advertisements" campaign (「醫療、藥物、化妝品及食品違規廣告監控」計劃), under which the authority will follow up suspected cases of non-compliance reported by the community groups.

Product safety

2.6 A health food product must be assessed and proven safe and to have health maintenance effects before it can be marketed. As at January 2005, DOH approved a total of 55 health food products, including six health food products which regulate immune system functions.

Recent developments

2.7 The Executive Yuan initiated the Health Food Control Amendment Bill in 2004 (健康食品管理法修正草案) which proposes six amendments to the Health Food Control Act (健康食品管理法), and the following two are related to health claims.

2.8 The notion of "specific nutrient" (特殊營養素) in the definition of health food has given rise to enforcement difficulties. Hence, it is proposed that the notion of "specific nutrient" be deleted from the existing legislation and be regarded as a component with health maintenance effects.

2.9 It is also proposed to define the scope of the application of health maintenance effects to help the public distinguish health food products from others, and facilitate the creation/production of labels and advertisements.

3. Definitions

Medicine

3.1 According to Article 6 of the Pharmaceutical Affairs Act (藥事法), medicine refers to any of the following therapeutic raw materials and preparations¹:

- (a) medicines 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 DOH;
- (b) medicines which are not included in the preceding sub-paragraph but are used in diagnosing, curing, alleviating or preventing human diseases;
- (c) other medicines which are sufficient to affect the body structure and physiological functions of human beings; or
- (d) medicines which are used in preparing such medicines set forth in the preceding three sub-paragraphs.

Food

3.2 The Food Sanitation Control Act defines food as "*goods provided to people for eating, drinking, or chewing, and the raw materials of such goods*". The form of food is not only confined to conventional foodstuff such as vegetables, fruit and meat which are consumed daily, but also includes processed food in tablet, capsule, powder or oral liquid forms.

Health food

3.3 The Health Food Control Act defines health food as "*food with specific nutrient or specific health maintenance effects which is especially labelled or advertised, and does not aim at treating or remedying human diseases*". "Health maintenance effects" are effects recognized by DOH which promote the health of citizens or reduce the risk of serious illnesses. They are not therapeutic effects such as treating or remedying human diseases.

¹ The term "preparations" refers to medicines which are processed and compounded from therapeutic raw materials into a specific pharmaceutical form and dosage. Preparations are classified into medicines prescribed by physicians, medicines administered under the direction of physicians, pharmacists and/or assistant pharmacists, over-the-counter drugs, and preparations of inherited formulation.

3.4 Products claiming health maintenance effects which have yet to be approved by DOH can only be sold as "food" but not as "health food". Such food products are regulated by the Food Sanitation Control Act instead of the Health Food Control Act.

4. Claims for health food

4.1 In Taiwan, health food is allowed to carry health maintenance claims only. It is prohibited to make any therapeutic claims. Health maintenance claims must be supported by scientific assessments and in principle, the assessment of each health maintenance effect must be conducted in accordance with the assessment methods promulgated by DOH.

Health maintenance claims

4.2 According to the Health Food Control Act, health maintenance claims have to be recognized by DOH. At present, DOH recognizes seven health maintenance effects, namely:

- (a) regulation of blood lipid;
- (b) regulation of gastrointestinal functions;
- (c) regulation of the immune system;
- (d) alleviation of osteoporosis;
- (e) maintenance of dental health;
- (f) regulation of blood sugar level; and
- (g) protection of the liver.

4.3 Only food products with the above approved health maintenance effects are subject to the Health Food Control Act. In addition, health maintenance claims made by such health food products have to be expressed in ways approved by DOH. For example, one of the approved claims is: "help maintain the normal function of the human immune system". If such a claim is extended to having the effect of suppressing tumours or fighting against cancer, it has gone beyond the approved scope.

4.4 Food products claiming to have health maintenance effects other than those seven effects listed above (including slimming or fat reduction and the promotion of detoxification) are regulated by the Food Sanitation Control Act. The labelling and advertisements of such food products cannot contain any therapeutic claims. DOH has also compiled for public information a list of food advertisements and labels containing false or exaggerated presentations or therapeutic claims. It is stated clearly in the list that food advertisements or labels cannot make claims relating to physiological functions (e.g. detoxification) or modification of body outlook (e.g. fat reduction and improving body figure). Appendix I gives some sample phrases of the list.

5. Labelling and advertisement

Contents of the labelling

5.1 The following information shall be conspicuously displayed on the containers, packaging or specification of health food in Chinese and in commonly used symbols² :

- (a) product name;
- (b) name, weight or volume of the contents; separate labelling is required if the health food product is a mixture of two or more ingredients;
- (c) name of food additives³;
- (d) expiry date, method and conditions of preservation;
- (e) name and address of the manufacturer; importer has to supply the name and address of the responsible local business operator;
- (f) the approved health maintenance effects;
- (g) permit number, the legend of "health food" and standard logo;

² Article 13 of the Health Food Control Act.

³ According to Article 3 of the Food Sanitation Control Act, food additives refer to materials that are added to or brought into contact with foods in the course of manufacturing, processing, preparation, packaging, transportation and storage of goods for the purpose of colouring, seasoning, preserving, bleaching, emulsifying, flavouring, stabilizing quality, enhancing fermentation, increasing viscosity, enriching nutritional value, preventing oxidation or otherwise.

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- (h) dosage and important message for consumption of health food and other relevant warnings⁴;
 - (i) nutrient and its content; and
 - (j) other material facts designated by DOH by way of public notice.

Scope of regulation

5.2 It is stipulated under Article 6 of the Health Food Control Act that any food which does not meet the requirements of the Health Food Control Act cannot be labelled or advertised as health food or claim to have health maintenance effects. Any food labelled or advertised as food with specific health maintenance effects is also regulated by the Health Food Control Act.

5.3 Article 14 of the Health Food Control Act provides that the labelling and advertisements of health food should not contain information which is false, exaggerated and beyond the content approved by DOH. Claims of therapeutic effects are not allowed. Examples of cases in contravention of Article 14 of the Health Food Control Act, including non-compliance cases of health food in relation to the regulation of the immune system function, are listed at Appendix II.

5.4 Claims relating to slimming or fat reduction as well as promotion of detoxification are prohibited under the Food Sanitation Control Act. This Act stipulates that the food labelling or advertisements should not be false, exaggerated or misleading. Claims of therapeutic effects are not allowed. Examples of cases where food products for slimming or fat reduction as well as promotion of detoxification contravening the relevant requirements under the Food Sanitation Control Act are listed at Appendix III.

Pre-approval for and monitoring of advertisements

5.5 There is no pre-approval system for health food and food advertisements. Nevertheless, the mass media companies are obliged to keep the particulars of their clients, and should not evade, impede or refuse the provision of such information upon requests by the relevant authority. No food product should be advertised or broadcast as health food if it has not been granted a health food permit.

⁴ Examples of such warnings:

- (a) "Not to be taken by persons with severe, infectious or liver diseases or those undergone surgical operations";
- (b) "Medical advice on the applicability of this product for the regulation of cholesterol should be sought beforehand"; and
- (c) "This product shall not be taken as a substitute for any pharmaceutical product".

5.6 DOH initiated "The Community-wide Monitoring of Non-compliant Medical, Pharmaceutical, Cosmetic and Food Advertisements Campaign" (全民監控醫療、藥物、化粧品及食品違規廣告計劃) in 2001. Volunteers participating in this campaign would report to the authority any suspected cases of non-compliant advertisements they noticed after attending the "Seminar on Monitoring of Non-compliant Advertisements" (違規廣告監控講習會). The authority would then follow up such cases.

5.7 DOH replaced the campaign mentioned in paragraph 5.6 with the "Monitoring of Non-compliant Medical, Pharmaceutical, Cosmetic and Food Advertisements" campaign in August 2004, and subsidized selected community groups to take charge of the monitoring work for a period of three years. The selected community groups would perform their tasks according to the requirements drawn up by DOH and report to DOH on suspected cases of non-compliant advertisements for the relevant authority to take follow-up actions.

6. Assessment of product safety and health maintenance effects

6.1 A health food product must be assessed and proven safe and to have health maintenance effects before it can be marketed. As at January 2005, DOH approved a total of 55 health food products, including six health food products which regulate immune system functions.

Product safety assessment

6.2 Tests on product safety have to be conducted in accordance with the "Methods of Safety Assessments of Health Food" (健康食品安全評估方法) promulgated by DOH. There are four categories of safety assessments and six types of toxicity tests, all aiming at assessing and measuring the safety of long term consumption and the manufacturing and processing of health food products. Factors taken into consideration include the intended purpose of the health food product, its method of consumption, the method and procedure of food manufacturing and processing, the form of the final product and the amount to be consumed.⁵

Assessment of health maintenance effects

6.3 As regards the health maintenance effects of a product, they must conform to the seven health maintenance effects approved by DOH. Tests of the relevant health maintenance effects have to be conducted in accordance with the following principles:

⁵ Clause 10, Methods of Applying for a Health Food Permit (健康食品申請許可辦法).

- (a) the health maintenance effects must be substantiated by scientific studies or proven by academic principles to be harmless and carrying definite and stable health maintenance effects⁶;
- (b) the reasonable intake of the product must be supported by scientific evidence; and
- (c) the assessment of the health maintenance effects must be conducted in accordance with the "Methods of Assessing the Health Maintenance Effects of Health Food" (健康食品保健功效評估方法) promulgated by DOH. For studies that are not conducted in accordance with the promulgated methods, scientific evidence on the study method has to be submitted for assessment of the appropriateness of the method.⁷

7. Law enforcement

7.1 As at 31 January 2005, a total of 55 health food products were approved by DOH under the Health Food Control Act.⁸ The following table is a breakdown of those 55 health food products by health maintenance effects:

Table 1 – Breakdown of Health Food Products Approved by the Department of Health

Health Maintenance Effect	Number of Approved Health Food Products
Regulation of blood lipid	18
Regulation of gastrointestinal functions	23
Regulation of the immune system	6
Alleviation of osteoporosis	1
Maintenance of dental health	1
Regulation of blood sugar level	1
Protection of the liver	5
Total	55

Source: List of Health Food Permits issued by the Department of Health.

⁶ The degree of stability of the health maintenance effects forms the basis for evaluating the effective period of a health food product.

⁷ Clause 11, Methods of Applying for a Health Food Permit.

⁸ Please refer to the List of Health Food Permits issued by the Department of Health (衛生署核發健康食品許可證一覽表) for detailed information of those 55 health food products.

7.2 According to the information provided by DOH, DOH referred 273 cases that contravened the Health Food Control Act to the courts in 2004.

7.3 DOH also publicizes non-compliance cases detected and handled by county/city health authorities each month. Between August and November 2004, there were 146 (August), 210 (September), 215 (October) and 118 (November) cases respectively in relation to violation of the provisions on advertisement and labelling. Among those cases, the highest fine imposed on a non-compliant case of advertisement or labelling was NT\$150,000 (HK\$36,777).

8. Recent legislative development

8.1 In Taiwan, the Health Food Control Act was passed on 3 February 1999 and came into effect on 3 August of the same year. Three amendments to the Health Food Control Act have been introduced since it was implemented. They were introduced respectively for correcting a misprint, compatibility with the revamping of the government's organizational structure and revising the terms used to bring them in line with the provisions under the Administrative Procedure Act (行政程序法).

8.2 DOH summed up its experience in implementing and enforcing the Act and proposed the fourth amendment to it. The Executive Yuan submitted the Health Food Control Amendment Bill to the Legislative Yuan for deliberation in 2004. At the moment, the Legislative Yuan has not yet started on deliberating this amendment bill, which proposes to:

- (a) amend the definition of health food and restructure the regulation regime;
- (b) revise the inspection, registration and re-examination system;
- (c) regulate strictly the safety and sanitation control of health food products;
- (d) specify that matters not addressed under the Health Food Control Act should be governed by the Food Sanitation Control Act;
- (e) step up the inspection and sanction of health food products; and
- (f) revise the penal provisions.

8.3 Since the Health Food Control Act was implemented, the notion of "specific nutrient" in the definition of health food has given rise to different understandings of it due to the lack of a scientifically or internationally recognized definition for this notion⁹. To reduce the difficulties in law enforcement, it is proposed in the Health Food Control Amendment Bill that the notion of "specific nutrient" be deleted from the existing legislation, and be regarded as a component with health maintenance effects and be regulated in the context of health maintenance effect.

8.4 At present, it is difficult to differentiate between the claims for health maintenance effects made by health food products and those by conventional food products due to the ways of making product specification and the wording used. To help the public distinguish health food products from others, it is proposed under the Health Food Control Amendment Bill that DOH determine the scope of health maintenance effects and promulgate it to the public. Labelling and advertisements relating to health maintenance effects of health food products should also comply with the content inspected by and registered with DOH and may not go beyond the approved scope.

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⁹ The General Summary of the Health Food Control Amendment Bill (健康食品管理法修正草案總說明).

Appendix I

食品廣告標示詞句涉及虛偽、誇張或醫藥效能的例句

一、詞句涉及醫藥效能：

- (一) 宣稱預防、改善、減輕、診斷或治療疾病或特定生理情形：
例句：治療近視。恢復視力。骨鈣流失及骨關節退化之治療及修補。健胃整腸。防止便秘。利尿。改善過敏體質。壯陽。強精。減輕過敏性皮膚病。治失眠。防止貧血。降血壓。改善血濁。清血。調整內分泌。防止提早更年期。
- (二) 宣稱減輕或降低導致疾病有關之體內成分：
例句：解肝毒。降肝脂。抑制血糖濃度上升。
- (三) 宣稱產品對疾病及疾病症候群或症狀有效：
例句：改善更年期障礙。消渴。消滯。平胃氣。降肝火。防止口臭。改善喉嚨發炎。祛痰止喘。消腫止痛。消除心律不整。解毒。
- (四) 涉及中藥材之效能者：
例句：補腎。溫腎(化氣)。滋腎。固腎。健脾。補脾。益脾。溫脾。和胃。養胃。補胃。益胃。溫胃(建中)。翻胃。養心。清心(火)。補心。寧心。瀉心。鎮心。強心。清肺。宣肺。潤肺。傷肺。溫肺(化痰)。補肺。瀉肺。疏肝。養肝。瀉肝。鎮肝(熄風)。潤腸。潤腸。活血。
- (五) 引用或摘錄出版品、典籍或以他人名義並述及醫藥效能：
例句：「本草備要」記載：冬蟲夏草可止血化痰。「本草綱目」記載：黑豆可止痛、散五臟結積內寒。

二、詞句未涉及醫藥效能但涉及虛偽誇張或易生誤解：

- (一) 涉及生理功能者：
例句：增強抵抗力。強化細胞功能。增智。補腦。增強記憶力。改善體質。解酒。清除自由基。排毒素。分解有害物質。
- (二) 未涉及中藥材效能而涉及五官臟器者：
例句：保護眼睛。保肝。增加血管彈性。
- (三) 涉及改變身體外觀者：
例句：豐胸。預防改善乳房下垂。減肥。塑身。增高。使頭髮烏黑。延遲衰老。防止老化。改善皺紋。美白。
- (四) 涉及引用本署相關字號，未就該公文之旨意為完整之引述者：
例句：衛署食字第88012345號。

資料來源：節錄自《食品廣告標示詞句涉及虛偽、誇張或醫藥效能之認定表》。

Appendix II

違反《健康食品管理法》的廣告或標示內容的案例

違反情節	內容
調整免疫功能 的保健功效	XXX含維他命C可以提高免疫力
	XXX在增強身體免疫能力及調養體內功能正常的功效早已認識
	加強免疫氣血循環、提昇免疫、增強免疫
	添加...β-胡蘿蔔素 — 可以提高寶寶的免疫力
	增強抵抗力
	免疫增強作用
	可維持細胞內的GSH含量,支持人體的免疫反應,同時並述及GSH能提高免疫力、維持體內免疫系統的正常活化
	促進免疫系統的發展
	為最佳強化免疫力之強力天然免疫物質...活化免疫細胞...凡因免疫功能衰退所引起的各種病症...皆有出奇的效果
	XXX為唯一通過美國FDA檢定為每天可服用的安全健康食品,並稱高境界免疫乳漿蛋白具有增進體液免疫反應,增強人體免疫機能之功效
	含有三種能提高人體免疫力的醣蛋白、天然抗生素及抗癌成分、干擾素等物質等
	本產品經中國大陸保健食品批准第食健字:(1997)第569號保健功效:免疫調節,調節血脂
調節血脂 的保健功效	有清血防栓成份
	預防及減輕高血脂症、血栓病
	能乳化及清理體內膽固醇和三酸甘油脂。長期服用,可降低體內膽固醇及脂肪,防止血管硬化
	紅酒單寧酸物質存在於葡萄中之天然抗氧化物質,可防止血液中壞的膽固醇氧化
	含OMEGA 3,有助於降低膽固醇之作用,可預防心臟血管疾病
	可降低膽固醇、促進心臟及循環系統順暢
	能有效降低膽固醇,和預防冠狀動脈心臟病、減少動脈硬化的機率
	降膽固醇、淨血、促血液循環、清血
	可幫助維持血液循環...降低動脈硬化指數
	抑制膽固醇形成的因子
	治療高血脂症,可使總膽固醇、甘油三脂下降,高密度脂蛋白上升
	改善血濁、清血
	品名諧音清脂及標示上有人體上半身佈滿血管及心臟等器官之圖案
具淨血作用...促進血液循環	
蒟蒻可平衡體內的膽固醇含量	

Appendix II(cont'd)

違反情節	內容
腸胃道功能改善的保健功效	促進乳酸菌復活、活化腸道細菌
	有效抑制腸道有害菌繁殖
	健胃整腸
	宣稱為健康食品並具有調整胃，小腸，大腸三合一效果
	將腸內有害細菌一起排除
	整腸、防腸胃問題
	可增加腸內有益菌叢的數量...促進腸內有益菌的繁殖
	讓寶寶體內的比非得氏菌大幅增加，使腸道中益菌增殖害菌減少
	可有效活化比菲德氏菌，攝取幾天後腸內菌增加10-100倍
	抑制腐敗菌繁殖
	阻斷病原菌的繁殖
	分泌的瑞特素能幫助益菌繁殖，抑制害菌生長
	乳酸菌...其產生的乳酸、醋酸、過氧化氫等抗菌物質，可有效抑制腸內腐敗菌的生長
	特別添加維持幼兒腸道健康的人體免疫腸道菌...對幼兒能有提升消化及吸收功能，並可維持幼兒體內有益菌多於有害菌數，因而能夠使幼兒體內的好菌更活潑的繁殖且在體內充分發揮作用
	幫助腸內有益菌的增生
增加體內的好菌數量，幫助孩子增加抵抗力	
XXX OLIGO產品宣稱為健康食品及「BIFIDUS是最佳有益菌，OLIGO促進BIFIDUS繁殖」	
預存骨本	
改善骨質疏鬆的保健功效	增加骨密
	保骨本...中老年後骨質密度才結實，優酪奶粉更使鈣的吸收性更佳
	抑制骨質中鈣質之流失，預防骨質疏鬆症
	具有幫助減緩骨質流失、增加骨骼中鈣的含量與密度
	增加自己的骨本
	預防骨質疏鬆症及骨折
骨鈣流失之治療及修補	
調節血糖的保健功效	糖尿病完全根治
標示「健康食品」字樣	本產品為天然健康食品，含豐富蛋白質等
	XXX是最近被發現具有非常滋補成果的健康食品等
涉及誇張易生誤解	許可之健康食品宣稱完全無任何肝、腎副作用

資料來源：節錄自《食品廣告標示解釋案例》。

Appendix III

**違反《食品衛生管理法》第19條規定有關纖體或減肥以及
促進排毒食品的案例**

飯前30分鐘飲用「效果更佳」(瘦身產品)
雕塑理想身材，瘦的更健康
與其他瘦身產品做比較
吸附油脂效果最好
能使你清除油脂
英文品名「FAT-CUT」
增強脂肪代謝能力...且可清腸
立即塑
XXX是一減肥食品，可讓粗臂肥臀不見...促進肥胖部位血液循環、燃燒脂肪...達到瘦身效果
雕塑體型
吃出身材
幫助您保持好身材
減肥消脂茶包...活化細胞...使你『輕』鬆愉快
解決減肥時因缺鈣而引起的焦躁感...讓自己輕盈苗條起來
病人用之控制體重特殊營養食品，搭配「××××錠」(食品)可使效果相乘、加倍
「購買XXX蕃茄汁一打，即可獲得蕃茄減肥健康法乙冊」、「讀蕃茄減肥健康法得大獎」
排泄有害物質
分離有害物質排出體外...
幫助清除腸內有害物質、體內毒素及宿便
清除體內宿便、強力淨化健康
BIFIDUS是最佳有益菌，它是體內廢棄物之環保清道夫
慣性便秘，容易導致皮膚粗糙，腰腹肥胖
排除毒素、改善體質
吸收雜質及毒素、清腸、消除脹氣
排出體內堆積毒素，促進全身血液流通之效果

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