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Regulation of Health Food in Overseas Places: Overall Comparison

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C O N T E N T S

Regulation of Health Food Products in Hong Kong

Hong Kong has no legal definition of 'health food'. Different terms such as dietary supplements, functional foods, nutraceuticals, designed foods and natural health products are used to refer to health foods. There is also no specific legislation governing health food products in Hong Kong. Health food products in Hong Kong are regulated under different ordinances depending on their ingredients. For example, if the product contains western medicines, it is subject to the regulation of the Pharmacy and Poisons Ordinance. If the product contains Chinese medicines, it is regulated under the Chinese Medicine Ordinance. However, the relevant subsidiary legislation to regulate health food products containing Chinese medicines has not been introduced yet. If the product is considered as a general food product, it is subject to the regulation of the Public Health and Municipal Services Ordinance. Since this paper aims to compare the regulatory mechanism of health food products (not food or medicinal products), Hong Kong is therefore excluded.

Table 1 - Terminology

Jurisdiction	Health food	Other related terminology
Australia	• No legal definition of 'health food'.	• There are interface products between food and drugs called complementary medicines. • Complementary medicines are low risk products which include herbal medicines, traditional medicines, vitamins, etc. • Complementary medicines are in the form of pills, capsules, tablets or powder and may carry claims of health benefits.
Taiwan	• Health food is defined as 'food with specific nutrient or health maintenance effects which are especially labelled or advertised, and do not aim at treating or remedying human diseases'.	• Not applicable.
United States	• No legal definition of 'health food'.	• There is a subset of foods called dietary supplements. • Dietary supplements are products which contain vitamins, herbs, minerals, extracts or concentrates, etc. • Dietary supplements are in the form of pills, capsules, tablets or powder and may carry claims of health benefits.

Table 2 - Types of Health and Related Claims Permitted to be Carried by Health Food or Related Products

Jurisdiction	Health claims - claims which show a link between a substance and a disease or a health related condition	Other health-related claims
Australia Complementary medicines	♦ Not permitted to carry such claims.	♦ Permitted to carry medium and general level therapeutic claims, i.e. claims relating to minor conditions such as health enhancement claims, health maintenance claims, etc.
Taiwan Health food	♦ Not permitted to carry such claims.	♦ Permitted to carry seven DOH-approved health maintenance claims.
United States Dietary supplements	♦ Four FDA-approved health claims.	Permitted to carry the following claims of health benefits: ♦ FDA-defined nutrient content claims; ♦ Structure / function claims; ♦ Claims of general well-being; and ♦ Claims of benefits related to classical nutrient deficiency disease.

DOH - Department of Health, Taiwan.
FDA - Food and Drug Administration, United States.

Table 3 - Main Legislation and Guidelines Regulating Health Food or Related Products

Jurisdiction	Any specific legislation governing health food or related products?	Main legislation and guidelines
Australia Complementary medicines	Yes.	• Therapeutic Goods Act - provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods including complementary medicines. • Therapeutic Goods Regulations - prescribes matters in respect of the manufacture, supply, advertising, registering or listing of medicines so as to make it necessary or convenient to carry out or give effect to the Therapeutic Goods Act. • Therapeutic Goods Advertising Code - governs all advertising of complementary medicines which carry therapeutic claims. • Code of Good Manufacturing Practice - sets out the principles and practices which are necessary to follow in order to provide assurance that each complementary medicine is safe and reliable.
Taiwan Health food	Yes.	• Health Food Control Act - governs matters relating to health food such as setting out qualifying requirements on the manufacture and import of health food, safety and sanitation control, labelling and advertising, inspection and sanction, awards for reporting and detecting non-compliance cases, etc.
United States Dietary supplements	Yes.	• Dietary Supplement Health and Education Act - broadens the definition of dietary supplements, deems dietary supplements to be a food, places the responsibility for ensuring the safety of dietary supplements on manufacturers, specifies labelling requirements, provides for the establishment of Good Manufacturing Practice regulations for dietary supplements, creates the Office of Dietary Supplements and the Commission on Dietary Supplement Labels.

Table 4 - Main Authorities Involved in the Regulation of Health Food or Related Products

Apart from government agencies which are responsible for the regulation of health food or related products, there are also committees, established either by statute or by government, which help monitor the regulation of such products.

Government Agency

Jurisdiction	Government Agency	Responsibilities
Australia Complementary medicines	• Therapeutic Goods Administration	• Administers the Therapeutic Goods Act; • Issues licences of manufacturers; • Conducts pre-market assessment of complementary medicines; and • Conducts post-market vigilance of complementary medicines.
Taiwan Health food	• Department of Health of the Executive Yuan	• Administers the Health Food Control Act; • Issues permits to manufacturers and importers of health food products; • Prescribes standards for health food products; and
	• Local Health Departments	• Conducts post-market vigilance of health food products.
United States Dietary supplements	• Food and Drug Administration	• Administers the Dietary Supplement Health and Education Act; and • Oversees the safety, manufacturing and labelling of dietary supplements.
	• Federal Trade Commission	• Regulates the advertising of dietary supplements.
	• Office of Dietary Supplements	• Co-ordinates, sponsors or organizes workshops to promote scientific study of and research on dietary supplements.

Committees

Jurisdiction	Committee	Membership	Responsibilities
Australia Complementary medicines	♦ Complementary Healthcare Consultative Forum which was established by the Parliamentary Secretary for Health and Aged Care	♦ Chaired by the Parliamentary Secretary for Health and Aged Care. ♦ Members include representatives of: ~ Consumer organizations; ~ Complementary medicines marketing organizations; ~ Industry; ~ Complementary medicine practitioners; ~ Therapeutic Goods Administration; and ~ State / territory governments.	♦ Examines complementary healthcare research, regulation and education as well as industry, consumer and practitioner issues.
	♦ Complementary Medicines Evaluation Committee, a statutory expert committee.	♦ 11 members appointed by Parliamentary Secretary for Health and Aged Care.	♦ Makes recommendations about complementary medicines and substances for the Australian market.
	♦ Therapeutic Goods Advertising Code Council which was established under the Therapeutic Goods Regulations (Amendment) 1997 No. 400.	♦ Members include representatives of : ~ Manufacturers; ~ Industry; ~ Consumer organizations; ~ Healthcare professionals; and ~ Therapeutic Goods Administration.	♦ Reviews the Therapeutic Goods Advertising Code.

Jurisdiction	**Committee**	**Membership**	**Responsibilities**
Australia Complementary medicines	♦ External Reference Panel on Interface Matters, an advisory panel to the Therapeutic Goods Administration and the Australia New Zealand Food Authority	♦ Members include representatives of: ~ Therapeutic Goods Administration; ~ Australia New Zealand Food Authority; ~ State / territory and New Zealand health authorities; ~ Australian Quarantine Inspection Service; ~ Industry; and ~ Consumers.	♦ Determines whether a product is a 'food' or a 'therapeutic good'.
Taiwan Health food	♦ Nil.		
United States Dietary supplements	♦ Commission on Dietary Supplement Labels, an independent experts panel mandated by the Dietary Supplement Health and Education Act.	♦ Seven presidential appointees with expertise in the manufacture, regulation, distribution, and use of dietary supplements.	♦ Make recommendations on the regulation of label claims and statements for dietary supplements.

Table 5 - Regulation of Health Food or Related Products

	Australia **Complementary medicines**	**Taiwan** **Health food**	**United States** **Dietary supplements**
Imported products	• Comply with the same legislation and guidelines as locally manufactured products.	• Comply with the same legislation and guidelines as locally manufactured products. • Importers are required to apply to DOH for a permit in order to import products.	• Comply with the same legislation and guidelines as locally manufactured products.
Registration of Products	• Required to be registered in the Australian Register of Therapeutic Goods (ARTG). • Listed in ARTG if low risk products; • Registered in the ARTG if high risk products.	• No registration is required.	• No registration is required.
Good Manufacturing Practice (GMP)	• Comply with the Code of GMP.	• Comply with the GMP promulgated by the product's manufacturing country.	• Until separate dietary supplements GMP regulations are established, products are subject to food GMP regulations.

	Australia **Complementary medicines**	**Taiwan** **Health food**	**United States** **Dietary supplements**
Pre-market assessment of products	• Yes. • Listed products are evaluated by manufacturers and TGA for safety and quality. • Registered products are evaluated by TGA for safety, quality and efficacy.	• Yes. • Products are evaluated by DOH for safety of products and validity of health maintenance effects.	• No. Manufacturers have the responsibility for checking the safety of products.
Post-market vigilance	• Mostly problem driven. • Post-market activities include investigating problems, laboratory testing of products on the market and monitoring of market activities.	• Post-market activities are conducted regularly and they include inspecting the premises, facilities and business of health food operators, and conducting random testing of products.	• Mostly problem driven. • Post-market activities include monitoring safety through voluntary dietary supplement adverse event reporting, and checking product information such as labelling, package inserts, etc.
Substantiation of health and related claims	• Yes, by scientific evidence or evidence of traditional use.	• Yes, by scientific evidence.	• Yes, by evidence.
Regulation of advertisement	• Pre-approval of advertisements is required.	• No pre-approval of advertisement.	• No pre-approval of advertisement.

	Australia **Complementary medicines**	**Taiwan** **Health food**	**United States** **Dietary supplements**
Regulation of labelling:- information contained in a label includes:			
♦ Name of the goods	Yes	Yes	Yes
♦ Quantity of the goods	Yes	Yes	Yes
♦ Names and quantities of active ingredients	Yes	Yes	Yes
♦ Dosage forms, batch number, expiry date, storage condition	Yes	Yes	Yes
♦ Name and address of manufacturer or responsible business operator	Yes	Yes	Yes
♦ Warning statements	Yes	Yes	Yes. A disclaimer statement if a structure/function claim is made.

	Australia **Complementary medicines**	**Taiwan** **Health food**	**United States** **Dietary supplements**
Regulation of labelling:- information Contained in a label includes:			
• Others	• Statement of purpose of use of the products. • "Aust R#" for registered products or "Aust L#" for listed products.	• Approved health maintenance effects. • A permit number.	• Statement of purpose of use of the products.
Problems reporting	• Reports of suspected adverse reactions of the products are made voluntarily.	• Anyone who reports cases in contravention of the relevant act will be awarded a sum equivalent to 5% of the amount of fine imposed.	• Reports of suspected adverse reactions of the products are made voluntarily.

DOH - Department of Health, Taiwan.
TGA - Therapeutic Goods Administration, Australia.

Table 6 - Sale of Health Food or Related Products

Jurisdiction	Sale of health food or related products
Australia Complementary medicines	♦ Step 1: the sponsor (manufacturer or importer) is required to determine the nature of the product (as food or a therapeutic good). ♦ Step 2: the manufacturer is required to possess a valid licence for manufacturing the product. ♦ Step 3: the sponsor needs to submit the product to the TGA for a pre-market assessment. ♦ Step 4: the sponsor is required to list or register the product in the Australian Register of Therapeutic Goods before marketing.
Taiwan Health food	♦ Step 1: the manufacturer or importer submits documents and information to DOH for examination and registration. ♦ Step 2: DOH conducts an initial assessment upon receiving the application and documents. ♦ Step 3: the Health Food Evaluation Committee under DOH will further examine the documents to ensure the safety of the products and the validity of the health maintenance effects made. ♦ Step 4: if the application is successful, the manufacturer or importer will be granted a permit valid for five years to sell or import health food products.
United States Dietary supplements	♦ If the product carries a nutrient content claim or health claim, the manufacturer or the importer is required to notify the FDA 120 days prior to using the nutrient content claim or the health claim. ♦ If the product contains a new dietary ingredient, the manufacturer or the importer is required to notify the FDA at least 75 days before marketing. ♦ If the product carries a structure / function claim, the manufacturer or the importer is required to notify the FDA within 30 days after marketing.

DOH - Department of Health, Taiwan.
FDA - Food and Drug Administration, the United States.
TGA - Therapeutic Goods Administration, Australia.

Table 7- Distribution Channels of Health Food or Related Products

Jurisdiction	Distribution channels
Australia Complementary medicines	♦ Widely available through direct marketing, pharmacies, health food stores and supermarkets.
Taiwan Health food	♦ Widely available in pharmacies chartered under the National Health Insurance Programme, chain pharmacies, supermarkets, and approved direct sale companies.
United States Dietary supplements	♦ Widely available in health food stores, grocery, drug and national discount chain stores, mail-order catalogues, TV programmes, the internet, and direct sales.

Analysis

1. Three different jurisdictions, Taiwan, Australia and the United States, are selected in this study because each of them adopts a regime that is unique for the regulation of health food or related products. First, among these three jurisdictions, only Taiwan has legally defined 'health food'. There is no legal definition of 'health food' in Australia and the United States and the terms used in Australia and the United States to refer to 'health food' are 'complementary medicines' and 'dietary supplements' respectively. Secondly, Taiwan has set up a regulatory framework specifically designed for health food. Australia makes use of an existing regulatory framework for therapeutic goods to regulate complementary medicines. Although the United States has created a new regulatory framework for dietary supplements, similarities can be found between the regulatory framework for dietary supplements and that for food as dietary supplements are deemed as food.

Regulation of Claims

2. Different jurisdictions impose different degrees of control on the types of claims permitted to be carried by health food or related products. Under certain circumstances, dietary supplements are allowed in the United States to carry FDA-approved health claims - claims which show a link between a substance and a disease or a health related condition. In Australia and Taiwan, health food or related products are not allowed to carry such claims.

3. Moreover, dietary supplements are allowed to carry structure/function claims without FDA prior approval in the United States. They can make any structure/function claims provided that there is evidence to substantiate them. However, the FDA does not specify what constitutes adequate substantiation. The mandatory requirement to make such claims is that a disclaimer statement on FDA responsibility must be included in the product label. On the other hand, in Australia and Taiwan, sponsors or manufacturers of health food or related products are required to provide specified types of evidence before they are allowed to make such claims about their products. In addition, there is also restriction on the wordings of the claims made about health food or related products in both Australia and Taiwan.

Authorities Involved in the Regulation

4. In Taiwan and the United States, the main authorities governing the regulation of health food or related products are government agencies/departments. However, in Australia, committees which include members who are non-government officials play an equally important role as a government agency in the regulation of health food or related products. These committees usually comprise members from various backgrounds: healthcare practitioners, professionals, industry representatives and consumers. With this wide range of expertise available in the regulatory system, the Australian government is able to respond quickly to the rapidly growing industry of health food or related products.

Manufacture and Import

5. All three jurisdictions require manufacturers of health food or related products to comply with Good Manufacturing Practice, and meet similar labelling standards. Imported products are required to comply with the same legislation and guidelines as locally manufactured products. In Taiwan, importers of health food are in addition required to apply to the Department of Health for a permit in order to import health food products.

Registration and Advertisements

6. In Australia, complementary medicines must first be registered before they can be marketed. However, there is no such registration system in either Taiwan or the United States. Moreover, advertisements of complementary medicines in Australia are required to seek approval prior to publishing. There is no such requirement in either Taiwan or the United States although advertisements of health food or related products in these two jurisdictions are required to comply with the relevant legislation.

Pre-Market and Post-Market Activities

7. In Australia and Taiwan, health food or related products are required to undergo pre-market assessments. However, no pre-market assessment is required in the United States; manufacturers of dietary supplements in the United States are only required to notify the FDA within 30 days after marketing. Regarding post-market activities, they tend to be problem-driven in Australia and the United States but they are conducted regularly in Taiwan.

Conclusion

8. In sum, it seems that the degree of control of health food or related products is higher in Taiwan and Australia but lower in the United States. However, in Taiwan, the Health Food Control Act has only been implemented since 1999 and only six health food products have been approved. Whether the existing framework can successfully safeguard the safety and interests of consumers in Taiwan has yet to be observed. The Legislative Yuan is now deliberating on the Health Food Control Amendment Bill which seeks to improve the regulatory regime in Taiwan. While in Australia, rigid control has been placed by the government on both the pre-marketing and post-marketing of complementary medicines, in the United States, only notification to the relevant authority is required; the FDA places the responsibility for checking the safety of dietary supplements products on their manufacturers. Therefore, between Australia and the United States, the Australian government is required to spend more resources in maintaining such a regime than that of the United States government.

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