# “Herb”, Food or Drug ?

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Many ingredients in Thai food are herbs and Thai people are familiar to take their daily food for health promotion and prevention from illness. From the perspective of food consumer, herbs are not harmful. Even though some herbs, for example, senna leaf, ginger, mint, cardamom, sweet basil, garlic, lemon, are used to alleviate minor illness but they are not popular. Several years ago, the concerning in health, the progressively aging population, the limit of modern drug efficacy, the rising socioeconomic expenditure and the increasing cost for the treatment lead to increasing pressure on public acceptance of herbs as an alternative medication. These consumers perceive that these products from nature are safe.[1-2] There are a lot of medicines derived from plants, such as digoxin, morphine, and vincristine. These examples also demonstrate that natural is not synonymous with innocuous, since these medicines have narrow safety margins.[3] Foods are increasingly taken for health as well as nutritional purposes and the separation between foods and medicines is eroding. In Thailand, herbal products have been promoted as economic products of the community such as “One Tumbon One Product” (OTOP) which their safety are likely emphasized by the government policy. Considering the widespread use of herbal remedies for various medical conditions, many remedies have been shown to be unsafe or potentially unsafe.[4-8] Facing a confusing array of herbal product safety, consideration of the legal status of herbal products is the important issue for consumer’s safety. The objective of this paper is to project the legal regulations of herbal products in different countries. Some countries regulate the herbal products as drug controlling status, some as food products. Consequently, the same product may be bought freely in some countries but may be strictly controlled in others.

## Legal Regulation

### *Legislation of drugs*

Although drugs are benefit to treat illness but drug is not always safe and effective. For protecting public health, the Pharmaceutical Affairs Administration of each countries is responsible for all aspects of drug control, such as control of production and registration of pharmaceutical products, and standard requirements of drug quality.[9-10] The legislation states that drugs deserve to be marketed if they are deemed to be safe and effective.[11] The regulation of medicinal drugs is based on complex risk-benefit assessments.

### *Regulation herbal products*

There are some herbal products of demonstrable efficacy; for example, a standard extract of Hypericum (St. John's wort) was as effective as paroxetine in depression in one trial.[12] For most herbal treatments, however, good trials of efficacy are lacking, and conducting them would be expensive. Without evidence of efficacy, it is hard to judge the safety of herbal medicines, not least because the risk of adverse effect that might be acceptable for an effective treatment will be unacceptable for an ineffective one. A quality of manufacturing is also a serious problem. If the plant itself is used, then the precise chemical content depends on the variety and the growing conditions, processing, and storage.[3] Herbal products, in particular, may contain a wide variety of different compounds, some of which are highly active pharmacologically. Although generally milder than drugs, these products can cause effects or toxicity. For example, the use of any weight loss herbal products containing potentially dangerous stimulant herbs, such as ephedra and guarana, has been linked to hypertension, tachycardia, stroke, and even death.[13]

## Canada[14]

Herbs are classified as either food or drug by Health Canada. They are classified as a drug, because of either a medical claim, or

a pharmacological effect, or both. Herbal medicine must therefore conform to labeling and other requirements as set out in the Food and Drugs Act and Regulations. In contrast to the USA, large numbers of herbal medicines with indication claims are legally on the Canadian market. Some manufacturers of herbal products have been able to avoid much of the regulatory cost associated with medicinal herbs by not classifying them as drugs and making no medicinal claims.

## The United States of America[15]

The United States operate under the Dietary Supplement Health and Education Act of 1994.[7] The dietary supplement is defined as a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constitute, extract, or combination of any ingredient described above. A structure/ function claim for dietary supplement is a statement regarding the effect of nutrient or botanical on a specific physiologic function and the Food and Drug Administration regulation explains the conditions under which such statements can appear on product labels. Claims limited to the maintenance of healthy structure or function are not considered as a disease claim. Advertising for dietary supplement must be truthful, non misleading, and substantiated.

## The European Union

The European Union has now taken a hand on the regulation of herbal products. Directive 2004/24/EC envisages a special, simplified registration procedure for certain medicinal products, particularly herbal ones, that have long traditional uses. In this context, a long tradition of use is the one that goes back to 30

years, of which at least 15 years are within the EU.[3] In the United Kingdom, there are also another regulation for new herbal product, and Herbal Medicine Advisory Committee that would advise ministers on all medicinal products for human use. To receive a marketing authorization (product license), herbal medicines are required to meet safety, quality and efficacy criteria in a similar manner to any other licensed medicines. Therefore, Standard marketing authorisations could be granted for herbal products having reliable data. Herbal remedies are exempt from licensing requirements; the exemption applies where herbal remedies meet conditions set out in Section 12 of the Medicines Act 1968, such as relying on folklore[3].

## Belgium[16]

In Belgium, herbs are regulated as food under the Belgian Herbal Law (1997). The products sold under food law could be sold in any retail outlet. The law included a list of 365 herbs that could be sold as foods and there was a further list of toxic herbs which could not be sold. Of the 365, 100 were under scrutiny for possible toxic effects. Notification to the Ministry of Health was necessary before marketing any herbal products. The composition of the product had to be justified and proof had to be provided that it was manufactured according to good manufacturing practice (GMP) standards and the manufacturer had to include a label and any proposed advertising material. In the future, sellers of herbal products would have to be qualified according to an accredited programme.

## Germany[16]

In Germany, almost all herbals were medicines, although many were registered according to a "simplified registration procedure." This procedure had arisen as a result of the German Medicines Law of 1978 in which all medicines on the market at that time had to be

assessed and re-registered. However, this procedure was slow - and for herbs the required efficacy data did not always exist - that in 1994 the scope of the law was widened, such that preparations with a long history of use could be registered according to a simplified procedure. These "traditional use" products included many herbs, and about 1,700 of these had now been registered. The other routes to registration of herbals in Germany were as prescription medicines, in which case robust clinical trial data were needed, or as over-the-counter medicines using what was known as a standard authorisation procedure, which cited official monographs as "evidence". However, only products on the market before 1978 and the containing prophylactic or mildly effective herbs were regarded as "traditional use" products. These could also be registered as medicines. Few herbals were foods, which had to be presented as foods - not pharmaceutical products - and could not make medical claims.

## Spain[16]

An important issue to the industry in Spain was the channel of distribution for herbals. There were two categories of herbs in Spain: medicinal herbs, which legally could be sold only in the pharmacies, and phytotraditional products, which could be sold in other outlets. However, there was a problem in distinguishing between medicinal herbs and traditional products. There were also products containing mixtures of herbs with other ingredients, which did not fall into either category. Moreover, in practice, herbalists and health food shops actually sold all kinds of herbs - both medicinal and traditional. The industry preferred herbals to be classified either as food or as a special category and be able to make claims for their uses. If they were categorized as medicines, they could not be sold outside of pharmacies.

## Sweden[16]

Special legislation for herbal products had existed in Sweden since 1978, and in 1993 they were classified by the regulatory authorities as medicines. Earlier legislation had not allowed claims for herbals, but current regulations allowed for 64 claims to be applied to particular products. Thus, both garlic and echinacea could make a claim for "traditional use for soothing symptoms of coughs and colds" and Ginkgo biloba for "treatment of prolonged symptoms in elderly persons such as failing memory, dizziness and tinnitus." More than 100 herbal remedies had now been registered as medicines by the Swedish medical agency, and all these products could make claims. However, huge "grey areas" still existed, including the 200 or so natural products that had been regulated according to older legislation, and a number of products marketed as foods, for which no claims could be made.

## Netherlands[16]

In Holland, herbals could be either foods or medicines. Most were foods, which were sold mainly through drug stores, with only a small amount being sold in pharmacies. However, the situation was more complex than it seemed in that there were new regulations for foods, which covered issues of safety and claims. In terms of safety, there was now a negative list of herbs which were considered to be too toxic to be sold as foods. A list of allowable health claims had also been developed. Although the statement "splitting hairs," and "promotes blood flow" were considered to be a health claim, while "promotes the production of white blood cells" was a medicinal claim. "Breathe more freely" was judged to be a health claim, while "breathe freely" was a medicinal claim. "Used for inner anxiety" was a health claim and "for difficulty in concentrating" a medicinal claim.

## Regulation of herb products in Thailand

In Thailand, as mention above, herbs can be used in form of food and drug. But foods and drugs are different in regulation by Thai law. Drugs are regulated by the Drug Act 1967(B.E. 2510) and four more revisions[17] but foods are under the Food Act 1979 (B.E. 2522). Herbal products are under both the Drug Act and the Food Act. Definition of drugs by Drug law; "drugs" means substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness and shall not include those intended for use as food for human. Licensing for manufacturing, importation and sale of drugs are required by law. Licensees must register the drugs before they can manufacture or import them to ensure efficacy, safety and effectiveness. Drugs are classified into two groups- modern and traditional drugs. Traditional drugs are the group of those intended to be used in indigenous treatment as monographed in the official pharmacopoeia of traditional medicines or those declared by the Minister of Public Health as traditional drugs or those permitted to be registered as traditional drugs. The control and registration of drugs in this group are less stringent than those of the modern drugs such as no application for an approval of analytical methods. Herbal medicines are classified to be traditional drugs that must be applied for permission to manufacture only. However, marketing herbal medicines are freely permitted by law.

Definition of foods by Food law; "food" means edible item and those which sustain life or substance can be eaten, drunk, sucked or gotten in to the body either by mount or by other means, no matter in what form, but not including medicine, psychotropic substances, narcotic under the law as the case may be. To guarantee the quality and safety of food under the Food Act B.E.2522 (1979), an importation or production from factories* of food products must be

* Start from 7 workers and up or equipments start from 5 horse-powers and up

applied for permission. Some foods must meet Thai Food and Drug Administration's food standard and specification as well as hygienic and labeling requirements. Any form of advertisement for food through any media is subjected to be approved by Thai FDA. False or deceptive advertisement on quality or benefit of food is prohibited. If a food product, either manufactured or imported, is categorized as Specific-Controlled Food, it must be registered. Analysis of the product as well as details of the process and ingredients are required for the registration process and the standard of these food products have to meet the standard specified in the Ministerial Notification. Imported foods are required to bear labels containing Thai language and subjected to be approved by Thai FDA prior to sell in the market. For food products, in general, labelling must follow the Notifications of the Ministry of Public Health No.194 (B.E.2544). But all food manufacture must be processed under Good Manufacturing Practice Guidelines.

Most of herbal products are classified in Category 2 (Prescribed Food with quality or standard), for example, Herb teas[18] and Category 3 (Prescribed Food with label) of the Food Law, for examples, Garlic Products[19] And Gingko products[20]

Regulation of food is minimal in comparison with regulation of traditional medicines. Herbal foods can be produced or sold freely in Thai market, but herbal medicines (traditional drugs) must be approved by Thai FDA before distributing in market and were sold only by those with licenses to sell traditional drugs.

What is the difference between herbal food and herbal medicine in Thai current situation? Both of them may have similar ingredients, dosage forms, and packages. Sometimes it is hard for consumer to distinguish between food and drug, especially the borderline herbal products. Under Thai FDA regulations, these products are categorized by the purposes for which the products are intended.[21] If producer's claims are to use in the diagnosis, treatment, relief, cure or prevention of human or animal diseases or

illness, those products have to be classified as drugs and to be controlled under the Drug Act. Food products cannot be labeled for medicinal indication. If herbs had never been used as food ingredients, they cannot be claimed as food products except having an evidence of safety in such manner.

## Conclusion

Herbal products are differently regulated in each country. It is not important that herbal products are considered as foods or drugs. Governments have developed systems to regulate the herbal products, which ascertain whether herbal products are safe and efficacious enough to be permitted on the market, because they have responsibility to protect public health. So there may be a different category for the same herbal product in different countries. Consumers should get information that these products carry some risk, although they are the natural products. Without evidence of efficacy, it is hard to judge the safety of herbal products, not least because the risk of an adverse effect that might be acceptable for an effective treatment will be unacceptable for an ineffective one.

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