

## 1. Definition of Category

Natural medicines are cell contents, excretions, extracts or mineral compounds derived animals or plants and used for medicinal purposes. Sometimes these plant or animal parts are consumed raw, and other times they are subjected only to very simple processing such as drying. Some animal or plant parts are used as is for medicinal purposes, while in other cases they are used as raw materials for producing extracts or other processed compounds. Natural medicinal materials have a variety of uses, some of which have no medicinal purpose at all, including:

- 1) Pharmaceuticals.
- 2) Food products (including cassia bark, licorice, wheat, and beefsteak plant).
- 3) Flavor enhancers (including aloe, sandalwood and aristolochia root).

This report focuses on natural materials used for 1) pharmaceutical purposes. For natural medicines treated as a food, refer to the section on “VI-9 Health Foods” in this guidebook. In popular parlance, natural medicines are known in Japan as *kanpoyaku* (“Chinese-style medicines” or “herbal medicines”). There are other terms that also refer to natural medicinal materials (herbal medicines), including the following:

### <Western-style natural medicines>

Natural substances used as part of modern medicine, referred to as “Western-style” because they came to Japan along with Western medical practices. These substances are consumed both processed and unprocessed. (Examples: *uva ursi folium*, *gentianac radix*, *digitalis*, *senegae radix*, *scopoliae rhizoma extract*)

### <Japanese-style natural medicines>

Substances traditionally produced in Japan and are used as raw materials to produce a variety of Chinese-style medicinal compounds. (Examples: *coptidis rhizoma*, *cassia bark*, *rhei rhizoma*, *ginseng*, *ephedrac herbal*)

### <Folk medicines>

These substances have been widely used in Japan for many years and are part of Japanese folk culture. They have some degree of effectiveness, but are often used imprecisely. However, they have few side effects if misused. Most are consumed unprocessed. Some of these materials are also classified as Japanese-style medicines. (Examples: crane’s bill, *swertiae herbal*, *amacha* (naturally sweet tea), and honey)

Because this category encompasses a large number of statistical categories in official trade statistics, HS numbers are omitted herein.

## 2. Import Trends

### (1) Recent Trends in Natural Medicine imports

Almost none of the natural medicines (including some spices, extracts, smoking agents, dye ingredients, gums, resins, etc.) can be produced 100% domestically. Conversely, there are many items that Japan relies 100% on China. Recently, after sharp growth in the early years, the market for Chinese natural medicines is tending to shrink, bringing down imports of natural medicines.

### (2) Imports by Place of Origin

China is the leading exporter of natural medicines to Japan. However, natural medicinal products come from many different countries/regions around the world, including Hong Kong, the Republic of Korea, North Korea, Thailand, Indonesia, Russia, Afghanistan, Pakistan, India, Germany, France, Spain, Hungary, Brazil, Argentina and Australia. Imports from China and other countries/areas in East and Northeast Asia account for about 75% of the total, on both a value and volume basis. Japan imports 85-90% of its supply of Japanese-style medicines, which are used as raw materials to produce a variety of Chinese-style medicinal compounds. Earlier, there were two import routes for Chinese natural medicines, namely, the China to Japan route, and the China - Hong Kong - Japan route. This classification has lost its meaning as Chinese economic reform has progressed. The Guangzhou trade fair still plays a role in imports of Chinese natural medicines because the fair functions as a place to gather information. However, the significance of the fair in import business has substantially declined. Today there is no difference between business with China and business with other countries.

### **(3) Imports' Market Share in Japan**

It is impossible to get exact import values and volumes from customs statistics. Accordingly, the share of imports is unclear. While Japan imports most of its supplies of unprocessed natural medicines, the processed medicinal compounds usually come from manufacturers in Japan.

## **3. Key Considerations related to Importing**

### **(1) Regulations and Procedural Requirements at the Time of Importation**

The Pharmaceutical Affairs Law regulates the import, distribution and sale of natural medicines for use as pharmaceuticals. In some cases, natural medicines are also subject to provisions of the Plant Protection Law, the Domestic Animal Infectious Diseases Control Law, and the Foreign Exchange and Foreign Trade Law under terms of the Washington Convention. Natural medicines imported for use in foods are subject to provisions of the Food Sanitation Law.

#### **1) Pharmaceutical Affairs Law**

The importation of natural medicines falling under the category of pharmaceuticals under the Pharmaceutical Affairs Law, such as those including ingredients deemed to be pharmaceuticals or claiming beneficial medicinal effects of a pharmaceutical are subject to the provisions of the Law. Under the Law, anyone desiring to import natural medicines as pharmaceuticals or as raw material for pharmaceuticals in business must first obtain an importer's license for each business location from the governor of the prefecture. If the importer also subdivides or parcels out the natural medicines, a manufacturer's license is also required. However, no manufacturer's license is required if the importer's only role is to add Japanese-language labeling.

The Law also requires to obtain an approval and permit to import for each item from the Minister of Health, Labour and Welfare via the section in charge of pharmaceutical affairs in the prefectural government. Natural medicines included in the Japanese Pharmacopoeia or the Supplemental pharmacopoeia and designated by the Minister of Health, Labour and Welfare and products for which foreign manufacturers have already obtained approval based on the Japanese Pharmaceutical Affairs Law do not require approval (just permit).

But unprocessed pharmaceutical compounds supplied exclusively for use in the manufacture of pharmaceutical products are exempt from this approval requirement. Most of natural medicines are exempt from these requirements when imported as unprocessed material for use in manufacturing other pharmaceutical products. In this case, the product containers are required the labeling "For use in the manufacture." Further, approval is required for these compounds when imported as a processed pharmaceutical for sale to consumers. When an entity obtaining an importer's license desires to import a new pharmaceutical, it may submit a notification of change (addition) of pharmaceuticals and other imported products. Importers of approved pharmaceuticals can complete customs procedures merely by presenting copies of the approval and license forms and paying any customs duties imposed.

#### **2) Plant Protection Law**

Natural medicinal materials derived plants are subject to provisions of the Plant Protection Law, whose purpose is to prevent the spread of any injurious plants into Japan. Upon arrival at the port of entry, the importer must promptly submit to the Plant Protection Station an "Application for Import Inspection of Plants and Import-Prohibited Articles" along with a "Phytosanitary Certificate" issued by the competent government agency of the exporting country. Importers should note that only certain ports of entry equipped with plant quarantine facilities are designated for plant imports. If an infestation is detected, and then the importer will be ordered to decontaminate, discard, or return to the shipper.

#### **3) Domestic Animal Infectious Diseases Control Law**

Natural medicinal materials derived from animals are subject to provisions of the Domestic Animal Infectious Diseases Control Law, whose purpose is to prevent infectious diseases of livestock from being brought into the country. The importer must submit an application for import quarantine inspection along with an inspection certificates issued by the competent government agency of the exporting country to Animal Quarantine Station at the port of entry. Note that animal inspections can only be performed at ports of entry with facilities to carry out required processes. If the product passes inspection, an import quarantine certificate is issued. If the product fails inspection, an order will be issued to destruct, bury, or return to the shipper, depending on the product and the nature of the violation.

#### 4) Food Sanitation Law

Natural medicinal materials may be imported for use as food provided that it is so stated and that no medicinal or health benefit claims are made. In these cases, the natural medicine material is subject to provisions of the Food Sanitation Law.

#### 5) Foreign Exchange and Foreign Trade Law

Natural medicines that fall under provisions of the Washington Convention (CITEC) are classified into three different categories, each of which has its own level of restrictions and its own import requirements. Prospective importers should consult with the Trade Licensing Division, Trade and Economic Cooperation Bureau, Ministry of Economy, Trade and Industry before bringing such items into Japan. Prospective importers must also obtain an export certificate issued by management authority of exporting country.

### (2) Regulations and Procedural Requirements at the Time of Sale

The sale of natural medicines as pharmaceuticals is subject to provisions of the Pharmaceutical Affairs Law. In some cases, when containing special species of tiger bone, etc., it may be subject to the Law for Conservation of Endangered Species of Wild Fauna and Flora. In addition, containers and packaging may be subject to provisions of the Containers and Packaging Recycling Law and the Law for Promotion of Effective Utilization of Resources. For more detailed information about the subject, scope, labeling method, etc., please consult the competent government agencies listed below.

#### 1) Pharmaceutical Affairs Law

Importers may sell natural medicines as pharmaceuticals to another manufacturer, importer, a pharmaceutical product wholesaler, or a drugstore under importer's licenses. However, in order to sell natural medicines as pharmaceuticals directly to consumers or to medical institutions, a pharmaceutical drug dealer's license must also be obtained. In addition, natural medicines sealed in wrappings or containers are subject to labeling requirement under provisions of the Law. (see 4. Labeling) The Law also regulates quality, labeling, advertising, etc.

#### 2) Law for Conservation of Endangered Species of Wild Fauna and Flora

The Law established a comprehensive legal framework of protection for species considered to be in danger of extinction. Any materials containing species designated as those specially identified for protection may not be sold or transferred in Japan. However, species that are being raised for commercial purposes may be distributed in Japan, provided that proper registration procedures with the Minister of the Environment are completed. For more details, please consult the Wildlife Division, Nature Conservation Bureau, Ministry of the Environment.

### (3) Competent Agencies

- Pharmaceutical Affairs Law

General Affairs Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Pharmaceutical Affairs Law in general)

Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Import approval procedures)

TEL: 03-5253-1111

<http://www.mhlw.go.jp>

- Plant Protection Law

Fruit and Flower Division, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

Plant Protection Division, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

TEL: 03-3502-8111

<http://www.maff.go.jp>

- Domestic Animal Infectious Diseases Control Law

Animal Health Division, Livestock Industry Department, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

TEL: 03-3502-8111

<http://www.maff.go.jp>

Planning and Coordination Division, Department of the Planning and Coordination, Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries

TEL: 045-751-5921

<http://www.maff.go.jp>

Animal-Products Inspection Division, Department of the Quarantine, Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries

TEL: 045-201-9478

<http://www.maff.go.jp>

- Foreign Exchange and Foreign Trade Law (Washington Convention)  
Trade Licensing Division, Trade and Economic Cooperation Bureau, Ministry of Economy, Trade and Industry  
TEL: 03-3501-1511 <http://www.meti.go.jp>
- Law for Conservation of Endangered Species of Wild Fauna and Flora  
Wildlife Division, Nature Conservation Bureau, Ministry of the Environment  
TEL: 03-3581-3351 <http://www.env.go.jp>
- Containers and Packaging Recycling Law / Law for Promotion of Effective Utilization of Resources  
Recycling Promotion Division, Industrial Science and Technology Policy and Environment Bureau,  
Ministry of Economy, Trade and Industry  
TEL: 03-3501-1511 <http://www.meti.go.jp>  
Recycling Promotion Division, Waste Management and Recycling Department, Ministry of the Environment  
TEL: 03-3581-3351 <http://www.env.go.jp>

## 4. Labeling

### (1) Legally Required Labeling

#### 1) Pharmaceutical Affairs Law

The Pharmaceutical Affairs Law regulates the content of labeling and advertising for natural medicinal materials imported for use as pharmaceuticals. The Law requires that the container and any accompanying written materials list certain items of information. The purpose of this requirement is to make sure products are used correctly, that they are high in quality, and that it is clear where responsibility for the product resides. The product container or wrapper labeling must contain the following items:

- Name and address of the manufacturer or importer
- Product name
- Product number or product code
- Weight, volume, and number of units in the package
- Name of active substance

Accompanying written materials must describe the chemical contents, the proper way to use the product, the recommended dosage, and any other instructions or warnings needed to properly use the product. Because of the potential danger to human health from such practices, the inclusion of false or misleading information on the container or in accompanying material is prohibited.

#### 2) Law for Promotion of Effective Utilization of Resources

When paper or plastic is used as a packaging material for wrapping of individual product items, or for labels, tags, external packaging or elsewhere, a material identifier mark must be displayed with information where the material is used.

< Example >



External  
packaging



Label

### (2) Voluntary Labeling based on Provisions of Law

There is no voluntary labeling based on provisions of law for natural medicines.

### (3) Voluntary Industry Labeling

There is no voluntary industry labeling for natural medicines.

## 5. Taxes

### (1) Customs Duties

Most natural medicines are duty free. For more detailed information, contact customs authorities.

### (2) Consumption Tax

(CIF + Customs duty) x 5%

## 6. Product Characteristics

### (1) Comparison with Japanese Products

Some natural medicinal materials are domestically produced, while others are imported. Three general patterns are discernible in terms of product characteristics:

1) Natural medicines that are only imported

Plant or animal species grow wild over a vast area. Most come from tropical or subtropical regions.

2) Natural medicines that can be produced in Japan, but are primarily imported

Imported materials are cheaper than those from Japan, though Japanese materials are often higher in quality.

3) Natural medicines that come primarily from Japan

In the category of Japanese-style natural medicines, material from Japan is generally more consistent in quality than imported material.

In addition, medicinal material comes from many different parts of China, each of which has its own distinctive flora, fauna and dialect pattern. Thus, different materials sometimes have the same name in different areas, while sometimes different names refer to materials that actually are the same.

## **(2) Characteristics of Products from Different Countries / Regions**

Natural medicines differ considerably in quality depending on the place of origin and on the processing methods applied. For example, Australian bezoar bovis is generally rated the best in color and condition (ratio of whole to broken), followed by bezoar bovis from North America, South Africa and Europe. Mid-range products come from Brazil (the quantitative leader) and Argentina, while products from India are said to have many problems with product quality. About 70% of China's production of natural medicines comes from the four provinces of Sichuan, Guangxi, Yunnan and Gueijou. It is customary in China for the product name to be prefixed with the name of the province where it was produced, this serving as a mark of product quality.

## **(3) Market Prices**

The natural medicine market is perpetually unstable due to changing weather conditions and political conditions in exporter countries or areas. Prices fluctuate in response to supply imbalances that occur in the marketplace. For example, a 10% shortage can cause prices to double even as quality goes down. Conversely, if there is an oversupply in the marketplace, prices can drop to half of normal with the same level of quality. However, if prices go much lower it removes the incentive to produce, and quality tends to deteriorate.

## **7. Domestic Distribution System and Business Practices**

### **(1) Domestic Market Conditions**

Compared to Western medicines, natural medicine does not give immediate effects, but the effects are stable. Furthermore, there is little concern about side effects. For these reasons, demand for natural medicines had grown remarkably. In recent years, however, the market for natural medicines is showing a shrinking trend due to the following reasons: (a) prescriptions for Chinese natural medicines are difficult to obtain, (b) people are now aware that Chinese natural medicines can have side effects, (c) due to a series of measures by the government to cut expenditures on medicines used by hospitals, demand is shifting to chemical medicines that can provide quick results. As a consequence, use of Chinese natural medicines has declined because it is necessary to use such medicines for long periods. Today, there is a sign that the drop in demand for Chinese natural medicines will soon end.

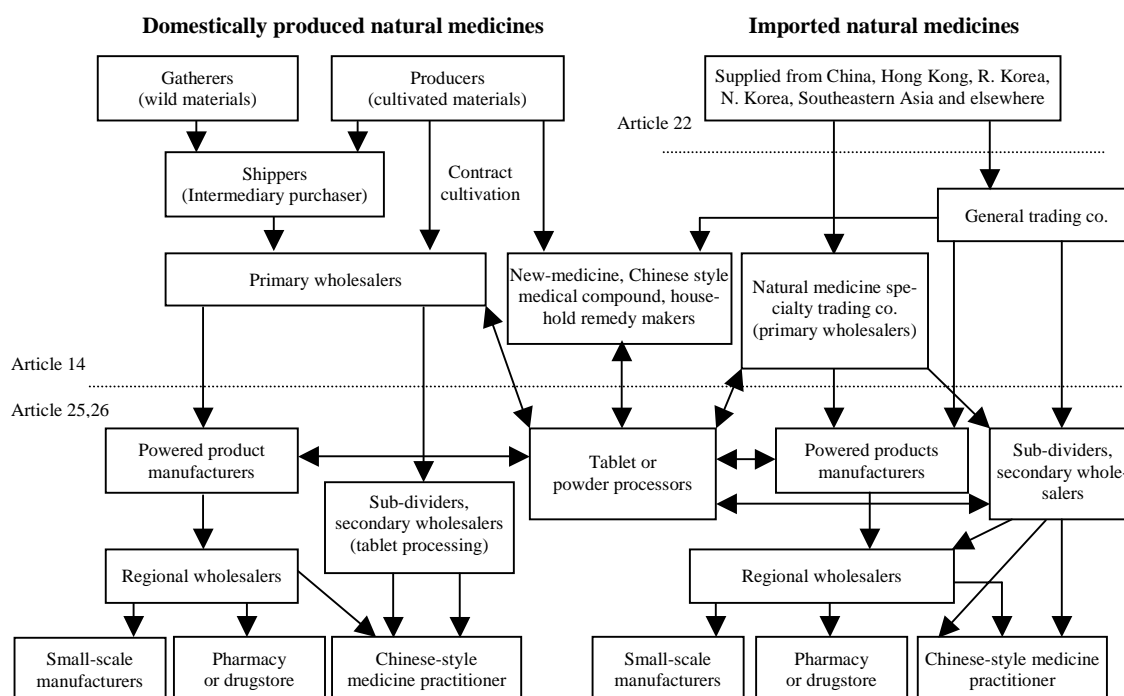
The market for Chinese natural medicines that once grew to ¥140 billion is now estimated to have fallen to the level of about ¥100 billion. Of total medicine production, which surpassed ¥6 trillion a year in value, Chinese natural medicine is estimated to account for about 2%. Including other natural medicines, natural medicines' share is estimated at below 5%.

Pharmaceuticals makers or extract makers use about 80% of all the natural medicinal materials distributed in Japan. The remaining 15-20% is sold in tablet, powder, liquid or tincture form to end-users by Chinese-style medicinal compounds companies, Chinese-style medicine practitioners, pharmacies and drugstores. Chinese-style medicinal compounds companies buy from trading companies that specialize in natural medicines, from general trading companies, or sometimes direct from producers in other countries. However, it takes many years of experience in the business to accurately judge the quality of natural medicinal materials. This makes it unprofitable for the major general trading companies to deal in natural medicines unless the transaction involves a very large volume or very large sum of money.

## (2) Distribution Channels

Years of experience with the system and entrenched business customs mean that distribution patterns have changed little over the years. The following figure illustrates the distribution channel for natural medicines.

**Fig. 1 Distribution channels for natural medicines**



## (3) Key Considerations for entering the Japanese Market

### 1) Import considerations

When doing business with a new business partner in another country, importers have to be on the lookout for possible problems caused by different perceptions of product quality and by inexperience with international trading practices. Natural medicines are primary industry products that mostly come from developing countries or areas. Accordingly, it is important to do business under contract.

### 2) Import procedural considerations

In practice it is impossible for an individual to import and market large quantities of natural medicinal materials. It is hypothetically possible that an individual could satisfy all the facility, storage and specialized personnel requirements of the Pharmaceutical Affairs Law and obtain license to import natural medicines. However, individuals should give the matter very careful consideration before undertaking to do so.

## 8. After-Sales Service

Natural medicines are treated as a kind of fresh produce, so no special comments on after-sale service are required. Ministerial Ordinance Regulations for Manufacturing and Quality Control for Pharmaceutical (Article 8) require manufacturers to investigate the cause of any health problem suspected of resulting from product quality or side effects, and to take measures needed to rectify any problem identified. If any person suffers health problems as a result of taking a natural medicinal product, the manufacturer must report that fact to the appropriate division of the nearest prefectural government office.

## 9. Related Product Categories

Operative criteria for determining whether a particular material is a pharmaceutical or whether it may be distributed as a health food product, a nutritionally enhanced food product, a food flavoring, a food flavor enhancer, or an ordinary commodity are contained in a pair of memoranda from the Ministry of Health, Labour and Welfare to prefectural governors across Japan. Please also refer to the section on “VI-9 Health Foods” in this guidebook.

Prospective importers should note that depending on the determination made based on the criteria in the memoranda, natural medicinal material may be subject variously to provisions of the Pharmaceutical Affairs Law, the Food Sanitation Law, the Nutrition Improvement Law, the Plant Protection Law or the Foreign Exchange and Foreign Trade Law.

## 10. Direct Imports by Individuals

By definition, direct imports by individuals should be intended for personal use only. In general the quantity deemed appropriate to import for personal use is at most a 1 - 2 month supply. For specific information, consult with the Ministry of Health, Labour and Welfare's pharmaceuticals specialist at the port of entry. However, if a pharmaceutical contains ingredients obtained from a plant or animal species identified as endangered by the Washington Convention (CITES), imports of that product are subject to any applicable restrictions under terms of the Foreign Exchange and Foreign Trade Law, and certain types of documentation may be required, even though the quantity is within normally permissible limits. Individuals should check with customs officials and with the Trade Licensing Division, Trade and Economic Cooperation Bureau, Ministry of Economy, Trade and Industry regarding the permissibility of particular ingredients.

Regarding imports of natural medicines used by individual physicians for the purpose of treatment of patients, please refer to the section on "Medical Equipment" (VI-1) in this guidebook.

## 11. Related Organizations

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|---|---|
| • Japan Medical Plant Federation                  | TEL: 06-6202-7898   |
| • Japan Kampo-Medicine Manufacturers' Association | TEL: 03-3662-5757 <a href="http://www.nikkankyo.org">http://www.nikkankyo.org</a> |