

Guidelines for Risk Assessment
in the Utilisation of
MEDICINAL FAUNA AND FLORA

August 2023

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PREFACE

Traditional medicine represents a valuable cultural heritage and wisdom cherished and shared by humanity. Throughout its thousands of years of history, Traditional Chinese Medicine (TCM) has played a pivotal role in advancing healthcare and promoting well-being, and continues to benefit people not only in China and Asia but across the globe. TCM has garnered increased recognition and acceptance of its clinical efficacy on a global scale following the arduous three-year journey of the COVID-19 pandemic. It will continue to play an important role in safeguarding human life and health in the future.

Plants, animals, and minerals form the basis of ingredients used in traditional medicine to treat diseases and strengthen the body's immune system. With growing demand for pharmaceutical medicines, there is increasing attention in China and internationally on the sustainable use of medicinal bio-genetic resources and conserving biodiversity to ensure supply of ingredients for traditional Chinese medicine practices and prescriptions. The Chinese government attaches great importance to the heritage of traditional Chinese medicine culture. Current government policies are framed by several guidelines and regulations to encourage and support the cultivation of plants and the breeding of animals for medicinal purposes. These efforts aim to promote sustainable development and ensure the continuous and stable supply of commonly used medicinal materials. However, there are still some medicinal materials that rely on plant and animal resources from the wild. Government authorities regulate the use of medicinal plants and animals with a national policy outlining "priority protection, regulated utilization, and strict supervision" of designated medicinal plant and animal resources. A series of associated laws and policies have been issued, and related international Conventions have been signed, making it mandatory for entities and individuals engaged in the production and application of traditional Chinese medicine to strictly comply with these laws, regulations, and international Conventions.

To guide pharmaceutical enterprises in understanding these laws, regulations, and policies, the China Association of Traditional Chinese Medicine, the China Wildlife Conservation Association, and TRAFFIC have jointly compiled the "Guidelines for Risk Assessment in Utilization of Medicinal Fauna and Flora". The Guidelines aims to facilitate pharmaceutical companies in sustainable sourcing and utilization of traditional medicinal ingredients and products, prevent illegal activities, and avoid significant economic losses. It collates relevant national laws, regulations, and international Conventions, and provides a risk assessment process when acquiring, importing and exporting of raw medicinal materials, certification checklists, operational standards, and material inventory to assist enterprises in conducting independent assessments. The legal provisions, regulations, policies, notices, and lists referenced in the guideline are valid at the time of writing. Enterprises should keep up to date with updates and adjustments to relevant legal provisions and implement the latest version.

1. PURPOSE AND SIGNIFICANCE

These guidelines' purpose is to guide Chinese enterprises on risk assessment in obtaining, purchasing, importing and exporting raw materials related to traditional Chinese medicine (TCM). It does this by introducing a risk assessment workflow, providing a clear, sequential set of questions for users to assess risk in utilizing medicinal fauna and flora. The document further outlines all relevant laws, regulations, certification lists, operational standards, and material lists, providing a consolidated document for users' information needs. The Guidelines can help enterprises to carry out risk assessments proactively and independently and come to an outcome on the legitimacy of the medicinal fauna/flora in question, addressing questions of legal compliance and sustainability of usage trends of the industry. The document aims to strengthen the foundations for the long-term sustainability of the TCM industry, foster high-quality traditional medicines, and support global efforts to ensure the security of medicinal ingredients.

2. APPLICATION

This document is a non-binding risk assessment guide for TCM enterprises in raw material acquisition and export adaptability. Documents cited in these guidelines, including laws and regulations, policies, notices and catalogues, are all valid at the time of completion; nevertheless, enterprises should check for and use the most up-to-date versions, as these are living documents that may be amended to reflect the changing development needs of the country. Please consult the relevant authorities for any questions or doubts concerning the assessment process.

PRECIOUS AND ENDANGERED WILDLIFE

Species under legal and regulatory supervision in China. While it does not explicitly refer to species facing extinction in ecological terms, the term applies to all species mentioned as “endangered” in this entire document.

SPECIMEN

The whole, part, exfoliation, secretions, extracts and processed products derived from an individual animal or plant in any life stage of the species. Unless otherwise excluded, the scope of protection for listed species includes all individuals and specimens.

BIOLOGICAL RESOURCES

Fauna and flora as well as taxonomic ranks below species level and their materials containing genetic functions, whether of actual or potential value.

THE LIST OF NATIONAL KEY PROTECTED WILD ANIMALS

The latest list released by the National Forestry and Grassland Administration and the Ministry of Agriculture and Rural Affairs on 1 February 2021. The new list now includes 980 species and eight categories of wild animals, of which 234 species and one category are under Class I protection, and 746 species and seven categories of wild animals are under Class II protection.

THE LIST OF NATIONAL KEY PROTECTED WILD PLANTS

The latest list released by the National Forestry and Grassland Administration and the Ministry of Agriculture and Rural Affairs on 7 September 2021. The new list has a total of 455 species and 40 categories of wild plants under state protection, of which 54 species and four categories are under Class I protection, and 401 species and 36 categories are under Class II protection.

THE LIST OF NATIONAL PROTECTED ANIMALS FOR “THREE VALUES”

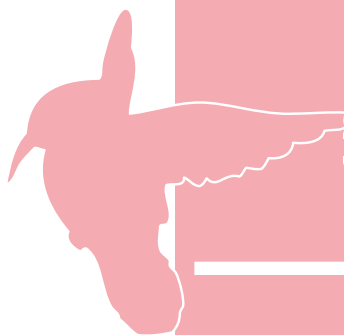
Refers to the *List of Terrestrial Wild Animals with Important Ecological, Scientific and Social Values*. The current list has 1924 species from 177 families, 44 orders of Mammalia, Aves, Reptiles, Amphibians, Insecta, Arachnida, and Oligochaeta.

THE LIST OF LOCALLY KEY PROTECTED WILDLIFE

Key protected wildlife species identified by provincial governments in their respective jurisdictions, in line with the *Wild Animal Protection Law of the People’s Republic of China* and the *Wild Plant Protection Ordinance of the People’s Republic of China*. The List is enforced following local conservation ordinances.

THE CITES APPENDICES

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Appendices accord varying degrees of protection, as in Appendix I, II and III, to a range of species based on the extent to which international trade threatens their survival in the wild.



3. TERMINOLOGY AND DEFINITIONS

THE CATALOGUE OF IMPORTED AND EXPORTED WILD FAUNA AND FLORA

THE APPROVED CATALOGUE

THE CATALOGUE OF CAPTIVE BREEDING

Species listed in CITES Appendix I, II, and III and China's national key protected wild animals and plants. Listed species and their specimens are labelled as "import control" and/or "export control".

In line with the *Wild Animal Protection Law of the People's Republic of China*, the National Forestry and Grassland Administration has approved all national key protected terrestrial wild animals originating from outside China as Class I or Class II species under national protection. Management of these wild animals and their products (including identifiable parts or derivatives) shall follow the same approach as for class-one and class-two protected animals native to China. CITES-listed aquatic species are also managed in line with the approved level of national protection with the release of the *Catalogue of CITES Appendix Aquatic Species Approved as National Key Protected Wild Animals and Plants* released by the Ministry of Agriculture and Rural Affairs (Notice No. 491) on 16 November 2021. Species listed as national key protected wild animals are no longer subject to individual approval but are to be managed based on the corresponding national protection levels. Their import/export shall comply with provisions of the international conventions.

According to the current *Wild Animal Protection Law*, captively bred populations of wild animals using mature and reliable technologies shall be excluded as national key protected wild animals and shall be managed differently from those of natural breeding. All captive breeding shall be licensed, and bred animals will require special labelling in line with the Law. Accordingly, the risks of the wild population of the listed species can be lowered, and the management authorities will keep updating their terrestrial and aquatic wild animal captive breeding lists. The catalogue includes CITES appendix species approved as national key protected species.

WILD MEDICINAL MATERIALS CULTIVATION

An ecological production approach based on the medicinal plants' growth characteristics and the requirements of maintaining ecologically-sound conditions. The cultivation shall take place in their original or similar habitat. The aim of increasing plant production, either artificially or naturally, to levels appropriate for human collection and utilization while maintaining an ecological balance within the plant-growing habitat.

SUSTAINABLE WILD MEDICINAL MATERIALS HARVESTING

Harvesting naturally grown medicinal plants or their parts while not decreasing the plant population, not affecting the long-term survival of the species, not damaging the ecosystems of the target species, and not affecting detrimentally species of fauna or flora.

NATURE RESERVES

Land or sea areas delimited or stipulated by governments at levels in accordance with the law to implement long-term protection of important natural ecosystems, natural relics, and natural landscapes, and to sustain the natural resources, ecological functions and cultural values they possess. There are three types of Nature Reserves, including National Park, Natural Reserved Field, and Nature Park.

PRODUCTION AND OPERATION PROCESS

The entire process of business entities from obtaining raw materials (wildlife commodities for processing or sales), through production processes such as transportation, processing, storage and marketing, to the completion of product sales. The number of steps in this process varies from entity to entity – some may handle all these steps, while others may engage in only some of them.

LEGAL RISK

Risks arising from the failure of entities to comply with the laws and regulations of China, countries of origin, or the countries of (re-)export in the processes of (raw materials/products) procurement, harvesting, capturing, cultivation and breeding, transportation, manufacturing, processing, and import and (re-)export, etc

SAFETY RISK

Health and safety risks that are caused to the business entity's employees, surrounding communities and downstream stakeholders due to imperfect monitoring, prevention, control, and response to zoonotic diseases in the process of (raw materials/products) procurement, harvesting, capturing, cultivation and breeding, transportation, production, processing, and import and (re-)export, and other steps in TCM supply chain management.

SUSTAINABILITY RISK

Includes ecological sustainability risks and the supply sustainability risks, specifically when (a) the utilization of medicinal species is higher than their rate of natural recovery and therefore threatens the sustainability of their survival or supply; or (b) the utilization of the species used has caused significant changes to the environment, adversely affecting the survival of other species in the original environment; or (c) resources of the medicinal species have shown a significant downward trend, or have an adverse impact on the survival of other related species.

ZOOZOSES

Diseases caused by common pathogens in humans and non-human vertebrates capable of natural transmission among and between humans and animals.

ANIMAL WELFARE

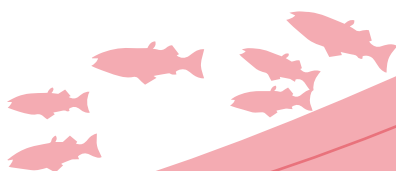
The standards and practices of control and utilization of animals to ensure the animals' basic natural needs are met and without causing psychological discomfort

BIOSECURITY

The potential threats to the natural environment and human health caused by the development and application of modern biotechnology and a series of effective prevention and control measures. Based on the provisions of the Biosecurity Law, the collection, preservation, utilization, and transportation out of China of precious, endangered, and endemic species and their genetic resources, such as individuals, organs, tissues, cells, and genes that can be used for regeneration or reproduction shall abide by relevant laws and regulations

BENEFIT SHARING

The fair and equitable sharing of benefits arising from utilizing biological and genetic resources and related traditional knowledge between the providers and users of biological and genetic resources and related traditional knowledge in accordance with the principle of informed consent and mutual agreement.



4. MAJOR LAWS, REGULATIONS, POLICIES AND INTERNATIONAL CONVENTIONS

4.1 NATIONAL LAWS, REGULATIONS, AND POLICIES ❖

These guidelines are based on the following laws and bylaws:

- ✔ Constitution of the People's Republic of China
- ✔ Wild Animal Protection Law of the People's Republic of China
- ✔ Wild Plant Protection Ordinance of the People's Republic of China
- ✔ Biosecurity Law of the People's Republic of China
- ✔ Animal Quarantine Law of the People's Republic of China
- ✔ Law of the People's Republic of China on the Entry and Exit of Animal and Plant Quarantine
- ✔ Traditional Chinese Medicine Law of the People's Republic of China
- ✔ Medicinal Product Administration Law of the People's Republic of China
- ✔ Criminal Law of the People's Republic of China
- ✔ Forest Law of the People's Republic of China
- ✔ Agriculture Law of the People's Republic of China
- ✔ Grassland Law of the People's Republic of China
- ✔ Seed Law of the People's Republic of China
- ✔ Customs Law of the People's Republic of China
- ✔ Other (see Annex I for more information)

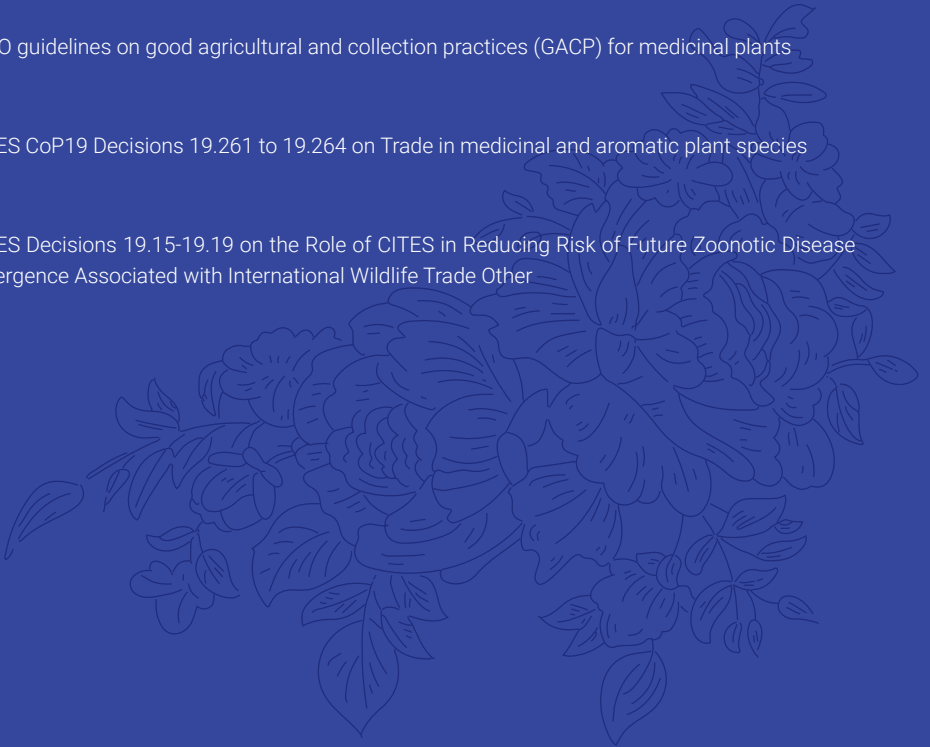


4.2 INTERNATIONAL CONVENTIONS AND STIPULATIONS ❖

These guidelines refer to international conventions, protocols, guidance notes, behavioral norms and other documents pertaining to the administration and import of TCM products, including:

- CITES Appendices and Resolution Conf. 10.19 (Rev. CoP14) Traditional Medicine
- CBD and its Nagoya Protocol on Access to Genetic Resources and Benefit Sharing Arising from Their Utilization, and the Kunming-Montreal Global Biodiversity Framework (GBF), Global Strategy for Plant Conservation 2011-2020, Biodiversity and Human Health programme of work, etc. For more resources, please visit the link: <https://www.cbd.int/health/publications/>
- Guidelines on the Conservation of Medicinal Plants, WHO/IUCN/WWF
- Joint Statement on the Prioritization of Monitoring SARS-CoV-2 Infection in Wildlife and Preventing the Formation of Animal Reservoirs, OIE
- Zoonosis and Food Safety – Improving Collaboration between Animal and Public Health Professionals to Achieve a Better Outcome, OIE
- WHO-FAO-OIE-Tripart Zoonosis Guide

- FairWild Standard Version 2.0--unifying the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) Version 1.0, 2007 and the FairWild Standards Version 1, 2006, The FairWild Foundation
- A WHO guide to good manufacturing practice (GMP) requirements
- WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants
- CITES CoP19 Decisions 19.261 to 19.264 on Trade in medicinal and aromatic plant species
- CITES Decisions 19.15-19.19 on the Role of CITES in Reducing Risk of Future Zoonotic Disease Emergence Associated with International Wildlife Trade Other



5. RISK ASSESSMENT SYSTEM

5.1 RISK CATEGORIES ❖

Enterprises could face a number of risks in the utilization of medicinal plants and animals. Risks covered in these guidelines fall into three categories – legal risks, safety risks, and sustainability risks (see Section 3 for definitions):

- (a) Legal risks of incurring criminal or administrative penalties from the violation of laws, regulations and policies that pertain to the process of production, transport and sale of wildlife products;
- (b) Safety risks due to inadequate surveillance, prevention, control, and response to zoonotic disease risks; and
- (c) Sustainability risk, whereby the use of medicinal species imperils the species' survival due to over-extraction, causes changes to the environment and/or affects the survival of other species.

Among the three categories, legal risks are considered "high risk", with risks along the supply chain—from cultivation and wild sourcing to product sale—that the enterprises shall give considerable attention to. The safety risks of spreading zoonotic diseases have the potential to cause significant economic and health impacts. Such risks are regulated under the Biosecurity Law, and compliance concerns biological resources for medicinal purposes, whether they are endangered species or not. Finally, while sustainability risks are not prescribed in law, nor do they always incur direct economic costs, they can nevertheless, adversely impact enterprises, given the growing attention on the sustainable use of natural resources in China and internationally. It could lead to reputational risks for enterprises and have a cost impact due to supply chain instability.

5.2 FOUNDATION FOR RISK ASSESSMENT ❖

The assessment is established upon species-based protection lists, national and local government conservation policies, catalogues of import/export commodities, catalogues of approved species, captive breeding lists, licensing documents, and other laws and regulations in Annex I.

5.2.1 Species identification and verification

A preliminary step in managing risks is identifying the species used as medicinal materials. The species must be identified and verified as risk levels and requirements for legal proof documentation can vary between species, depending on their protected status under regulation.

The process of *species verification*, or confirming the species name as declared, is more complex than it seems. Species names can vary from one person to another due to language (including dialects), industry, history, traditions, disciplines and other factors resulting in scientific names (Latin names), names in Chinese or English, aliases, common names, local names, medicinal materials and food names, etc. Only the scientific name is unique and universal.

For instance, the Chinese toad, known by the scientific name of *Bufo gargarizans*, is referred to by its Chinese name for Chinese toad in the natural sciences, and as the large

Chinese toad in the *Pharmacopoeia of the People's Republic of China* (from now on referred to as "Pharmacopoeia"). This minor difference in names can easily cause confusion. The difference in the example above is caused by the lack of harmonization in species names in biological science taxonomy, industry standards, and everyday use by practitioners. It is necessary to clarify the exact species being utilized.

Given the widespread use of scientific names in laws, national protection lists and CITES appendices, the Guideline document adopts its use to encourage uniformity and clarity, and the enterprises shall also use the scientific names to process the risk assessment. In practice, enterprises should consult specialised agencies for clarification when encountering species that are hard to identify. The scientific name of a plant species can be found [via the National Alliance of Medicinal Botanical Gardens](#).

5.2.2 Regulatory approaches for reducing risk

Local governments typically notify the public of

specific measures prohibiting or restricting the use of certain species through announcements, stipulations or explanations. There is a wide range of possible measures, including comprehensive prohibitions, quota limitations, inventory registrations, labelling, etc. A key aspect to note is the species covered under the stipulation and the validity period of the announced measures.

Besides measures that control and restrict the use of protected species, another regulatory approach in reducing threats to species is to set temporal or spatial limits, such as no-take zones or quotas under permit. This is typically utilized in fishery laws, forest laws and instructions on nature reserves. These could include prohibited harvesting, collection, fishing, hunting or mining areas where almost all wild species are protected within the prescribed limit. The key in risk assessment is when and where the raw materials derived from fauna and flora species can be legitimately hunted, fished or harvested.

5.3 PROCESS FOR CONDUCTING RISK ASSESSMENT

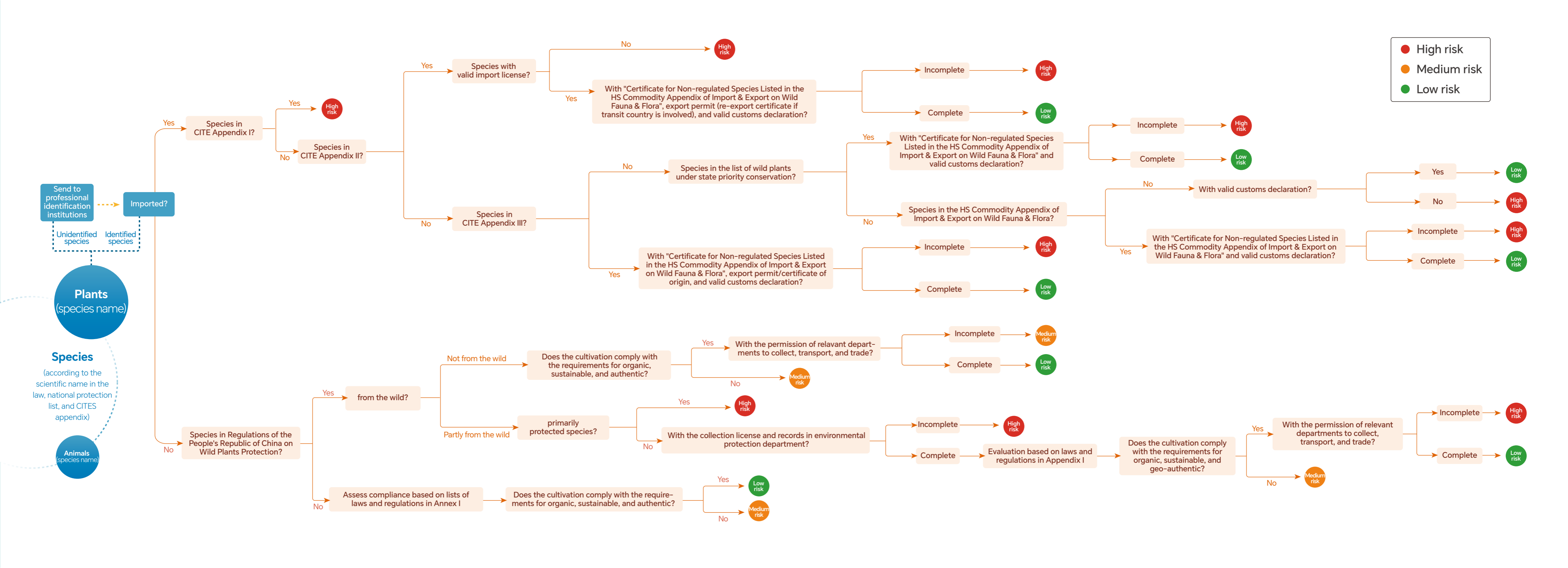
Several key elements should be considered when assessing risks in utilizing medicinal fauna and flora. They include:

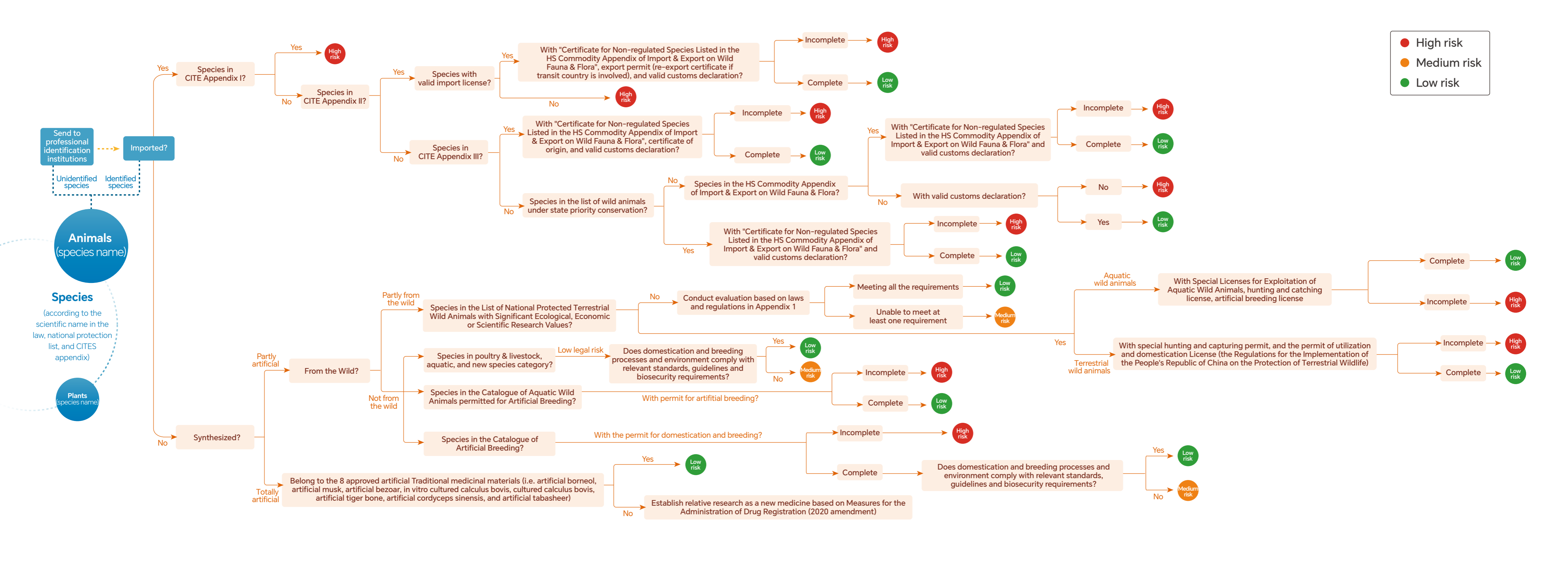
- First, identify the species (including the genus, family, order and other taxonomic units);
- Second, confirm whether the production and business process involve import and/or (re-)export; and
- Check the protection level (i.e., if key protected species and CITES appendix and approval list species).

Enterprises should make use of the Workflow (Section 5.3.1), going from left to right, to identify the potential risks in utilizing the species in question, and whether the necessary documentation for legal proof has been, or can be, obtained. If the workflow indicates

that the material is at high risk, enterprises should stop the procurement/sourcing until all requirements of the low-risk stream are met. Otherwise, enterprises should replace suppliers or sourcing approaches that work on the low-risk stream. If the workflow indicates medium risk or further check/clarification/research is needed, enterprises need to consider their development strategy versus the risk categories in Section 5.1 while undertaking the research for additional information that may facilitate the decision-making.

Due to the differences in local administrative stipulations, these guidelines emphasizes the need for consultation with relevant local authorities for advice in case of any doubt in the assessment process.





5.3.2 MATTERS NEEDING ATTENTION IN MATERIALS AND PRODUCTS EXPORT

When exporting TCM materials and products with animal and plant components, enterprises need to comply with the laws and regulations of China and CITES international trade rules and the corresponding regulations in destination countries/regions. The following briefly outlines how TCM imports are regulated in the USA, the UK and the European Union. Also, links to further information in other countries are provided.



THE USA

- TCM products are classified as dietary supplements in the US under the regulation of the Food and Drug Administration (FDA). For more details, visit <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>. For smoother clearance, enterprises exporting food to the US are encouraged to obtain certification from a third-party body.
- Through the Voluntary Qualified Importer Program (VQIP), participating importers can import their products to the US with greater speed and predictability, avoiding unexpected delays at the point of import entry. In most cases, the FDA identifies and allows immediate entry of food upon VQIP clearance. VQIP website (with information on purposes, application procedures, and qualifications): <https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip>.
- Food importers need to obtain third-party certification before enrolling in the VQIP, while the third-party bodies must be accredited by entities designated by the FDA. See lists of Accreditation Bodies and Third-Party Certification Bodies via: <https://datadashboard.fda.gov/ora/fd/tpp.htm>.
- On special occasions, to prevent the entry of harmful food into the US, the FDA may inquire about third-party certification of imported products.



UNITED KINGDOM

- A permit is required to export medicines from non-EU countries to the UK, except for re-exports through the UK or the UK does not have medicines for specific clinical needs, etc. Information on the permits and application procedures can be found at: <https://www.gov.uk/guidance/import-a-human-medicine>.
- Some TCM may be exported to the UK as animal products and high-risk food not of animal origin, for which permits are required for certain products. See the list via: <https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations>.
- Guidance on Importing Live Animals, Animal Products and High-Risk Food and Feed not of Animal Origin (including TCM) from Non-EU Countries to Great Britain: <https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries>.
- Guidance on applying for a traditional herbal registration (THR) in the UK: <https://www.gov.uk/guidance/apply-for-a-traditional-herbal-registration-thr>



EUROPEAN UNION

- EU Guidelines on Imports of Organic Products: https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/guidelines-imports-organic-products_en.pdf
- EU Guidance on Food Biosafety of Imports: https://ec.europa.eu/food/system/files/2016-10/biosafety_fh_legis_guidance_interpretation_imports.pdf/
- EU Guidance on Food and Feed Imports from China: https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/guidelines-addofctrl-china_en.pdf
- EU regulation on Transmissible Animal Diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'): <https://eur-lex.europa.eu/eli/reg/2016/429/oj>
- European Directive on Traditional Herbal Medicinal Products (Directive 2004/24/EC): <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004L0024>
- European Medicines Agency (EMA) on scientific opinions on herbal substances and preparations, along with information on recommended uses and safe conditions: <https://www.ema.europa.eu/en/human-regulatory/herbal-medicinal-products>



OTHER COUNTRIES

- Singapore website on TCM-related laws and regulations: <https://www.hsa.gov.sg/chinese-proprietary-medicines>
- Australia website on TCM-related laws and regulations: <https://www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx>
- Travelers Guide on Bringing Medication into Malaysia (Malaysia): <https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/travellers-guide-bringing-medication-malaysia-personal-use-edited-16012019.pdf>
- Bilateral agreements in FAOLEX database: <https://www.fao.org/faolex/zh/>
- The enterprise shall comply with the laws and regulations of the EU and the destination country when exporting to an EU country.

6. CAPTIVE BREEDING

The current legal framework considers the captive breeding of endangered animals an important avenue in reducing dependence on wild resources and achieving sustainable resource use. For captive breeding, the following basic requirements/conditions must be met:

- Captive breeding permit to be obtained in accordance with the law
- Prevention and control of zoonotic diseases in compliance with regulations
- Ensure the welfare of animals

6.1 PERMIT APPLICATION AND RELATED LISTS

China has promulgated a series of laws and regulations on captive breeding centered on the Wild Animal Protection Law, to conserve endangered wild animals. These regulations specify:

- A *Captive Breeding Permit for National Key Protected Wild Animals* is required for breeding endangered animals within China's territory, according to the requirements in Article 25 of the *Wild Animal Protection Law*, Article 22 of the *Implementation Directory for the Protection of Terrestrial Wild Animal in China* and the *List of National Key Protected Wild Animal*.
- The National Forestry and Grassland Administration manages and endorses the captive breeding, sale, purchase and utilization of 10 categories/

species, including the giant pandas, crested ibis, tigers, leopards, elephants, golden monkeys, gibbons, rhinos, orangutans and bustards. Captive breeding of all other endangered species is subject to approval by provincial, autonomous regions, or municipal forest administration departments, as outlined in the joint notice by the National Forestry and Grassland Administration and the Ministry of Agriculture and Rural Affairs (2017-#14).

- The breeding of sika deer, red deer and reindeer from captive-bred populations shall be managed by the Ministry of Agriculture and Rural Affairs, as stipulated in the *National Catalogue of Livestock and Poultry Genetic Resources* in May 2020.



6.2 PREVENTION AND CONTROL OF ZOOSES

6.2.1 THREAT OF ZOOZOSIS

The three pathogen types typical of zoonotic diseases are bacteria, viruses and parasites, and their transmission patterns include animal-to-human, human-to-human, human-to-animal, and animal-to-animal. About 1,400 human pathogens are in the Human Pathogen Database, of which about 60% are of animal origin. Of all emerging human infectious diseases, 75% are zoonotic diseases transmitted from non-human animals across

species barriers to humans by pathogens such as viruses, bacteria, fungi and parasites. These diseases are closely associated with a range of farmed and/or wild animals as sources, hosts, and/or vectors of transmission. Modes of transmission of zoonotic diseases include direct contact with bodily fluids, excreta, pathogen-contaminated environments, food and water, and insect bites, etc.

6.2.2 LEGAL REFERENCE

This section has referenced the *Biosecurity Law of the People's Republic of China*, the *Animal Disease Prevention Law of the People's*

Republic of China, and the *Law of the Peoples Republic of China on the Entry and Exit Animal and Plant Quarantine*.

6.2.3 PRINCIPLES TO ADOPT

Prevention is key in the control of zoonotic diseases. It is important to adhere to integrated prevention and control principles, focus on hotspots, effective cooperation, and compliance with laws and regulations. Key measures include vaccination, preventative drugs, elimination of transmission medium, cutoff of transmission routes, strengthening food hygiene inspection, and improving food safety. Once a significant animal epidemic

breaks out, the principle of "early detection, rapid response, and strict treatment" should be followed. Authorities in charge shall promptly take technical measures such as lockdown, culling, destruction, disinfection and compulsory immunization to the epidemic area to put the situation under control and prevent further spread, with the aims to reduce losses caused by the epidemic and secure public health to the best possible extent.



6.3 ANIMAL WELFARE

6.3.1 LEGAL REFERENCE

According to Article 26 of the *Wild Animal Protection Law of the People's Republic of China*, captive breeding of wild animals under national protection should be carried out in a manner conducive to species protection and scientific research and should not adversely affect their wild populations. Captive-bred

animals should have adequate space, with facilities and technologies to enhance living conditions and maintain hygiene and health conditions. Compliance to relevant technical standards and epidemic prevention requirements are vital; cruel treatment and abuse of wild animals are prohibited.

6.3.2 PRINCIPLES TO ADOPT

For species with explicit national technical standards for captive breeding, the national standards shall prevail. For species with no

standards yet, relevant laws and regulations shall be followed, and their animal welfare should be improved.



7. CULTIVATION

Medicinal plant resources can come from wild collection, organic farming, wild cultivation (semi-artificial cultivation), mimic-wild cultivation, and artificial cultivation. Sustainable use and development of endangered medicinal plant resources require the conservation of resources, maintaining ecological balance, and preventing adverse environmental impacts. The cultivation (growing) methods of medicinal plants must comply with the *General Principles for Organic Cultivation of TCM Plants*, *General Principles for Wild Cultivation of TCM Plants*, and *General Principles of Mimic-Wild Cultivation of TCM Plants*, all issued by the National Forestry and Grassland Administration (see details in Annex I).

7.1 GERmplasm RESOURCES AND BREEDING MATERIALS ❖❖

Germplasm, or genetic resources (also known as variety resources) of medicinal plants, are the basis for cultivating high-quality and authentic medicinal materials and are of great significance to the sustainable development of the herbal TCM industry. Enterprises should be mindful of protecting germplasm resources. At a minimum, enterprises need to identify the cultivated or wild-collected medicinal plant species (including subspecies, varieties and categories) and record them in their Chinese and scientific names. To comply with relevant national regulations, enterprises should implement inspection and quarantine procedures for seeds, strains and propagation materials in production, storage and transportation. This would help maintain the quality of materials and prevent the spread of pests and weeds. Enterprises are encouraged to participate in and support the collection and preservation of germplasm and establish germplasm resource banks to prevent degradation, carry out the systemic work to optimize varieties selection and breeding of medicinal plants, establish cultivation bases to improve varieties and conserve the germplasm resources of endangered medicinal plants.

7.2 SELECTION OF CULTIVATION ENVIRONMENT — AUTHENTIC MEDICINAL PLANTS, WILD CULTIVATION, AND MIMIC-WILD CULTIVATION ❖

The ecological and environmental conditions of the producing area are key factors in the cultivation of endangered medicinal plants. The quality of the cultivating environment can be an important determinant of the relative quality of cultivated TCM plant products. Therefore, the current environmental quality in and around the producing area must be assessed and understood when selecting the appropriate growing areas for cultivation. Enterprises scouting for the right location should consider the characteristics of the local natural environment, previous environmental monitoring data, community and social conditions, current farming conditions (i.e., use of pesticides and fertilizers), pollution sources around the area, etc. Environmental assessments of this nature are critical for enterprises in order to avoid legal risks and ensure environmental and resource sustainability as well as the safety of human consumption and health.

Recommended principles for the selection of producing areas:

- **Geographic:** Zonality of soil and climate that is identical or close to the natural habitat of the target medicinal plant species. Emphasis shall pay close attention to the development of local medicinal plants, especially the authenticity of the medicinal plants.
- **Safety:** Medicinal materials should be free from contamination. The production areas should be free of pollution sources (i.e., mines, chemical plants, etc.), and the air, soil, and water sources should meet the stipulated quality standards in order for the medicinal materials produced to meet the regulated safety standards.
- **Practicality:** In addition to the ecological environment, adequate infrastructure and a good social environment are also necessary, including local economic conditions, investment environment, cultural conditions, as well as transportation, water and power supply, communications (information about TCM materials and safe usage), etc.
- **Community Support:** medicinal plant cultivation can be a powerful tool for rural development. Enterprises should recognize the capacity of medicine plant cultivation not only in maximizing economic returns for their own, but also the potential for social and community benefits such as poverty reduction.

Enterprises are encouraged to minimize the use of pesticides and chemical fertilizers, to ensure stability and reliable quality of medicinal plants. Despite their use to enhance farm yields, both pesticides and chemical fertilizers can have a negative effect on the environment and ecology. An integrated approach for pest control should be adopted, combining pest monitoring, strengthened natural control measures of pests and diseases, and pesticide reduction through the establishment of pesticide use specifications to minimize the effective dose while recording all uses of pesticides.

The wild cultivation of TCM materials means to artificially or naturally increase the population of the TCM plant in its native or similar environment, which has the advantages of (a) ensuring the natural quality and authenticity of medicinal materials, (b) protecting rare and endangered medicinal materials, and (c) protecting the ecological environment of TCM resources while saving farmland. It is a sustainable utilization approach for TCM materials as it helps achieve the triparted development of ecological environment conservation, resource regeneration and comprehensive utilization, and TCM materials production.

7.3 ENVIRONMENTAL MONITORING AND MANAGEMENT ❖

Given the dependence of high-quality TCM materials on the quality of local air, soil and water it is collected, grown or bred, environmental data must be regularly collected for monitoring and assessment.

The *Technical Specifications of Agriculture Environmental Monitoring* issued by the Ministry of Agriculture and Rural Affairs sets out the environmental monitoring principles for TCM plants producing areas:

- **Optimal site selection for monitoring points:** Collect information that can represent the environmental quality of the monitored area at as little labor and cost as possible;
- **Optimal monitoring:** Based on survey results of pollution sources in the region, monitoring priority shall be given to the most unfavorable plots, river sections, locations and points that may cause pollution to ensure the reliability and representativeness of the evaluation; and
- **Feasibility:** Reliable methodologies and referable and justifiable evaluation standards on pollution impacts.



8. ARTIFICIAL SUBSTITUTION

With the growing demand for medicinal products and the implementation of sustainable harvest limits, wild-sourced medicinal resources can no longer meet the needs of the TCM industry. Experimental research and verification have proved artificial substitutes to be a viable solution. Still, research needs to be expanded and done within the framework of relevant laws and regulations.

8.1 NEW ARTIFICIAL SYNTHETIC CHINESE MEDICINE ❖

In the amended *Administrative Measures for Drug Registration* (2020), the classification of "new substitutes for TCM materials" was removed. The *Requirements for Classification and Application Materials for Registration of Traditional Chinese Medicines* (No. 68 [2020], State Food and Drug Administration) states in Article 1.3, "New medicinal materials and their preparations, that is, medicinal materials and their preparations that have not been included in the State drug standards, drug registration standards and the standards for medicinal materials of provinces, autonomous regions, and municipalities directly under the central government, as well as new medicinal parts of original animals/plants with the above-mentioned standard medicinal materials and their preparations", replacing the term "substitutes". Therefore, substitutes need to be researched as new medicinal materials.

The *Ordinances on the Protection of Varieties of Traditional Chinese Medicines* (effective in

2018) apply to the varieties of TCMs produced in China, including Chinese patent medicines, extracts of natural medicines and their distillations, and artificial Chinese medicine products. The Ordinances divide protected TCM varieties into two grades. For artificial products equivalent to Grade I State-protected wild medicinal species, corresponding Grade I protection applies.

The use of artificial new Chinese medicines and new Chinese decoction pieces for TCM production will need to be approved by the National Food and Drug Administration. China has adopted approval approaches for artificial substituting of Chinese herbal medicines and decoction pieces. Enterprises should purchase artificial substitutes (herbal medicines and decoction pieces) from those with national drug approval licences or local processing standards.

8.2 SYNTHETIC TCM MATERIALS ❖

As of 2021, China has approved nine artificial synthetic TCM materials (see Table 1), including artificial *borneol*, artificial musk, artificial calculus bovis, in vitro cultured

calculus bovis (ICCB), cultured calculus bovis, artificial tiger bone, artificial *Cordyceps mycelium*, artificial tabasheer, and *Cordyceps sinensis* (cultivated).



Table 1. Approved TCM from Artificial Cultivation/Synthetic

Name	Year of Approval	Approval Document No.
artificial borneol	1963	borneol as in Chinese Pharmacopoeia (1963-1995), and borneolum syntheticum (2000-2020)
artificial calculus bovis	1972	MOH Medicine Standards (95) No. 100-1-25
Cultured calculus bovis	1990	MOH Medicine Certificate (90) No. Z-16
artificial musk	1993	MOH Medicine Certificate (93) No. Z-10
In vitro cultured calculus bovis	1997	MOH Medicine Certificate (97) No. Z-125
artificial tiger bone	2003	State Medicine Standards No. Z20030079
artificial <i>Cordyceps mycelium</i>	2020	State Medicine Standards No. Z13022477
artificial tabasheer	1994	Shanghai Municipal Standards for TCM Materials (1994), Ningxia Regional Standards for TCM Materials (2018)
<i>Cordyceps sinensis</i> (cultivated)	2019	Guangdong Provincial Standards for TCM Materials (Vol. 3 2019)

9. WILD CAPTURING AND WILD COLLECTION

Wild capture and collection of animals and plants must comply with the *Wild Animal Protection Law of the People's Republic of China*, the *Ordinances on Wild Plants Protection of the People's Republic of China*, the *List of National Key Protected Wild Animals of the People's Republic of China*, and the *List of National Key Protected Wild Plants of the People's Republic of China*. In addition, the wild capture/collection of medicinal animals/plants must abide by the *Instruction of Nature Reserve* issued by the National Forestry and Grassland Administration. According to the *Instruction*, different regulatory principles are applied based on the land category – all human activities are prohibited in the core zone. In contrast, limited human activities are allowed in the general control zone, which are further regulated by the ordinance and administrative measures of each land type, i.e., National Park, Nature Reserve Field, and Nature Park.

Risk identification and assessment should be carried out for hunting/fishing and collection of wild animals and plants outside the nature reserves, with reference to the flow chart on risk assessment. The hunting/fishing/collection should be managed according to Chapter 3 on hunting wild animals in the *Ordinances on the Protection of Terrestrial Wild Animals, Measures for Special License for*

the Utilization of Aquatic Wild Animals, Ordinances on the Protection and Management of Wild Medicinal Material Resources, and provincial regulations on the protection of wild medicinal materials resources and wild plants protection (see Annex I for more information).

According to the *Notice of the National Forestry and Grassland Administration on Regulating the Collection and Management of National Key Protected Wild Plants* (see Annex I for more details), the collection (including logging, excavation and transplantation) of National Key Protected wild plants (Class-I and Class-II wild plants as stipulated in the *Ordinances on the Protection of Wild Plants of the People's Republic of China*) must have the *National Key Protected Wild Plant Collection Certificate* solely issued by the National Forestry and Grassland Administration. Applicants for the collection of national key protected wild plants shall fill in an *Application Form for Collection of National Key Protected Wild Plants* beforehand. Collectors of Class I protected plants for special purposes such as scientific research, artificial cultivation, or cultural exchange must apply for a *Collection Certificate* from the administrative bodies designated by the National Forestry and Grassland Administration.

Collection of Class I national protected wild plants shall not be used for commercial or trade purposes. Collectors of Class I national protected wild plants shall apply for a *collection certificate* from the provincial forestry and grassland administrative department or the relevant designated administrative body. For collections of Class I or Class II national protected wild plants from urban gardens or scenic spots, consent from urban forestation and tourism administrative bodies must be obtained before a *collection certificate* can be applied from the forestry and grassland administration. Agencies or individuals collecting national key protected wild plants must follow the species, quantity, location, time limit and method specified in the *collection certificate*. The wild plant administrative bodies of county governments are responsible for the supervision and inspection of state-protected wild plant collection activities within its administrative area and promptly report to the wild plant

administrative department or its designated body. The sale or purchase of Class I national protected wild plants is prohibited. The sale or purchase of Class II national protected wild plants must be approved by the wild plant administrative body of the provincial/autonomous region/municipal government or their designated bodies.

In addition to the fundamental laws and regulations that the collectors and companies must obey, it is highly recommended to conduct sustainable measures that mitigate the sustainability risks (ecological and supply sustainability risks) and increase the opportunities for international trade. FairWild is a widely accepted standard with mature good practices for reducing sustainable risks and facilitating market expansion. Some basic principles of FairWild serve as a reference to provide a step-wise approach for companies, including:

1) MAINTAINING WILD PLANT RESOURCES:

Wild collection of plant resources shall be conducted at a scale and rate and in a manner that maintains populations and species over the long term.

- Conservation status of target species: The conservation status of target species and populations is assessed and regularly reviewed.
- Knowledge-based collection practices: Collection and management practices are based on adequate identification, mapping, inventory, assessment and monitoring of the target species and collection impacts.
- Sustainability of collection rate: The rate (intensity and frequency) of target resource collection does not exceed the target species' ability to regenerate over the long term.

2) PREVENTING NEGATIVE ENVIRONMENTAL IMPACTS

Negative impacts caused by collection activities on other wild species, the collection area and neighboring areas shall be prevented.

- Sensitive taxa and habitats: Rare, threatened and endangered species and habitats likely to be affected by the collection and management of the target species are identified and protected.
- Habitat (landscape level) management: Management activities supporting the wild collection of target species do not adversely affect ecosystem diversity, processes and functions.

3) COMPLYING WITH LAWS, REGULATIONS AND AGREEMENTS

4) RESPECTING CUSTOMARY RIGHTS AND BENEFIT-SHARING

5) PROMOTING FAIR CONTRACTUAL RELATIONSHIPS BETWEEN OPERATORS AND COLLECTORS

6) LIMITING PARTICIPATION OF CHILDREN IN WILD-COLLECTION ACTIVITIES

7) ENSURING BENEFITS FOR COLLECTORS AND THEIR COMMUNITIES

8) ENSURING FAIR WORKING CONDITIONS FOR ALL WORKERS OF WILD-COLLECTION OPERATIONS

9) APPLYING RESPONSIBLE MANAGEMENT PRACTICES

Wild collection of target species shall be based on adaptive, practical, participatory and transparent management practices.

- Species/area management plan: A species/area management plan defines adaptive, practical management processes and good collection practices.
- Inventory, assessment and monitoring: Management of wild collection is supported by adequate and practical resource inventory, assessment and monitoring of collection impacts.
- Implementation of sustainable collection measures by collectors: The wild-collection operation ensures that only trained and competent collectors collect the target resources and monitor the effective implementation of the applicable Collection Instructions by the collectors.
- Training and capacity building: Resource managers and collectors have adequate skills (training, supervision, experience) to implement the management plan's provisions and comply with the requirements of this Standard.
- Transparency and participation Wild-collection activities are carried out transparently with respect to management planning and implementation, recording and sharing information and involving stakeholders.

10). APPLYING RESPONSIBLE BUSINESS PRACTICES

11). PROMOTING BUYER COMMITMENT

10. PROCUREMENT

Enterprises need to ensure that the procurement of medicinal raw materials is informed by risk assessment and follows the requirements of certificates and documentation at each process step (see Table 2). Key aspects of risk management are to ensure the legality and traceability of purchased materials, which is critical in helping enterprises avoid disputes caused by negligence or unclear rights and responsibilities.

The import of TCM materials requires, by law, Customs declaration and entry quarantine, including endangered and non-endangered species. Additional measures and procedures may be necessary as proof of risk mitigation, such as furnishing information/records or employing third-party verification. Enterprises should refuse to purchase medicinal materials or products whose origins cannot be verified, or with potential risk of illegal capture/picking at source.





Table 2. Procurement Information to be Collected

Procurement Information to be Collected	
Type	Information
Product Type	
Name	
Scientific Name	
Quantity	
Place of Origin	
Method of Obtaining specimen(s)	
Attrition Rate	
Supplier at Source	
Trader	
Permit (See section 11.2)	
Species Certificate	
Inspection and Quarantine	
Tax Record	
If the selection of upstream suppliers is in compliance with the laws and regulations of the country	
If needed certificates	
Other	

11.2 (RE-) EXPORT ❖

11.2.1 EXPORT OF ENDANGERED WILDLIFE AND PRODUCTS MUST MEET THE FOLLOWING CONDITIONS:

- Be compliant with biosecurity regulations and public interest requirements
- Legitimately sourced products
- Genuine and adequate materials filed by applicants
- Not in the lists of export restrictions issued by the State Council or its affiliated wildlife administrative authorities
- Meeting other requirements of wildlife administrative authorities under the State Council

Applicants seeking to (import or) export endangered wildlife and their products shall file an application with the department-in-charge of wildlife management under the provincial/autonomous region/municipal government where the applicant is located.

After the import/export approval document is obtained from the department-in-charge, within the validity period of the approval document, the applicant shall seek to obtain an import/(re-)export permit from the CITES-MA.

11.2.2 EXPORT OF ENDANGERED WILDLIFE AND PRODUCTS SHALL COMPLY WITH LAWS AND REGULATIONS OF THE TRANSIT AND DESTINATION COUNTRIES

Unlike in China, TCM materials may not be considered medicines in other countries. As such, enterprises need first to check if the product for export would fall in the category of food, medicines or others before they set out to meet category-specific requirements, procedures and approval processes. Some countries may exempt or accelerate the clearing of products if certified by an officially accredited third-party certification body. Therefore, certification with a reasonable cost is one way to reduce quarantine detention or forfeiture at international borders. A list of accredited third-party certification bodies

can usually be found on the government's official website with outlines of the import and export requirements of the category. Therefore, beyond taking recommendations from local authorities, enterprises should seek relevant information from official websites of the destination country. This document has listed official links to relevant requirements and guidelines for TCM exports to the United States, the United Kingdom and the European Union (see 5.3.2). Still, enterprises are advised to do additional research with destination authorities to ensure the information is up-to-date.

12. ANNEXES

ANNEX I. RELEVANT LAWS, REGULATIONS, CATEGORIES, INDUSTRIAL POLICIES AND STANDARDS OF CHINA, AND RELEVANT INTERNATIONAL CONVENTIONS AND ADVISORY DOCUMENTS

Note: Latest updates of documents listed below should prevail.

1. LAWS

Constitution of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?MmM5MDImZGQ2NzhZjE3OTAxNjc4YmY1YTQ4MzAwNGI%3D
Wild Animal Protection Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwODE2ZjEzNWY0NjAxNmYxY2NlYTE0YjExNDM%3D
Biosecurity Law of the People's Republic of China	http://www.gov.cn/xinwen/2020-10/18/content_5552108.htm
Law on Traditional Chinese Medicine of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?MmM5MDImZGQ2NzhZjE3OTAxNjc4YmY4MzgyODAsYWI%3D
Drug Administration Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwODE2ZjNjYmIzYzAxNmY0NjI0MmQ2MTI3ZWQ%3D
Criminal Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgxODE3OTZhNjM2YTANzk4MjJhMTk2NDJOTi%3D
Forest Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwODE3MmWU5ZTE4MTAxNzI3ZTU1NDM2MjdmNTI%3D
Agriculture Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?MmM5MDImZGQ2NzhZjE3OTAxNjc4YmY3NGUxMTA2YmQ%3D
Grassland Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgxODE3YWlyMml4YTAN2FiZDVhZDI4NjA1N2E%3D
Seed Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgxODE3ZjA3MmEyZTAN2YwYjY2Ml2NDANjY%3D
Law of the People's Republic of China on the Entry and Exit of Animal and Plant Quarantine	http://www.npc.gov.cn/zgrdw/englishnpc/Law/2007-12/12/content_1383874.htm
Customs Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgxODE3YWlyMml4YTAN2FiZDcxOWUwZjA1YzA%3D

2. ADMINISTRATIVE BYLAWS

Ordinances of the People's Republic of China on the Protection of Wild Plants	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNlOTc4NDAXNmY0MjMyMjUzNDZmY0MjM%3D
Ordinances of the People's Republic of China on the Protection of Wild Territorial Wild Animals	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MGUxNDU2MDA4ZTg%3D
Ordinances on the Protection and Management of Wild Medicinal Materials Resources	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MTUxZmQ1YTlxZTE%3D
Ordinances of the People's Republic of China on Import and Export of Endangered Wild Fauna and Flora	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MTM1Zjg0NjFkM2E%3D
Ordinances on the Implementation of the Drug Administration Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNlOTIhZDAXNmY0MjUxY2Q0ZjA0ZjU%3D
Ordinances on the Implementation of the Forest Law of the People's Republic of China	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MTBhN2Q2NjEyZjQ%3D
Instruction on Nature Reserve	http://www.gov.cn/zhengce/2019-06/26/content_5403497.htm
Ordinances of the People's Republic of China on Nature Reserves	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MTNhNTU1NDZmY0MjM%3D
The Administrative Measure (Temporary) of National Parks	http://www.gov.cn/zhengce/zhengceku/2022-06/04/content_5693924.htm
Ordinances of the People's Republic of China on the Origin of Imported and Exported Goods	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MTAyZgyYTExNDY%3D
Ordinances on TCM Varieties Protection	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwO-DE2ZjNjYmlzYzAxNmY0MGYxZjJjNjBkMmU%3D

3. REGULATIONS

Measures for the Administration of Imported Medicinal Materials	https://www.nmpa.gov.cn/xxgk/fgwj/flxzh-fg/20190524110801776.html
Measures for the Administration of Imported Pharmaceutical Products	http://www.yinjiang.gov.cn/jgsz/zfbm/scjdgjl/zcwj/202104/t20210422_67890349.html
Measures for the Administration of Wildlife Import and Export Certificates	http://www.gov.cn/gongbao/content/2014/content_2671529.htm
Directory of Goods Inspection, Verification and Quarantine Procedures	http://gongbei.customs.gov.cn/gongbei_customs/374280/fdzdgnr19/374333/hwtg/2936742/index.html
<Species Certificate> Scope of Application and Import/Export Administration Measures	https://www.forestry.gov.cn/uploadfile/history/data/2008/uploadfile/2008-06-24-504881-%E9%99%84%E4%BB%B6%E7%BC%9A1%E7%BC%8D3.doc
Measures of Agricultural Wild Plants Protection	https://www.waizi.org.cn/doc/127153.html
Measures of the People's Republic of China on Licensing for the Utilization of Aquatic Wild Animals	https://www.gd.gov.cn/zwgk/wjk/zcfgk/content/post_2523995.html
Ordinances for Wetland Conservation and Management	https://www.forestry.gov.cn/main/3951/20171213/635511.html
Measures for Forest Germplasm Resources Management	https://www.forestry.gov.cn/main/3951/content-204689.html
Measures for Crop Germplasm Resources Management	http://www.fgs.moa.gov.cn/flfg/202201/t20220127_6387850.htm
Measures for the Administration of Forest and Wildlife Type of Natural Reserves	https://flk.npc.gov.cn/detail2.html?ZmY4MDgwODE2ZjNjYmlzYzAxNmY0MTAzMmRmZjExNjE%3D
Measures for the Administration of Marine Nature Reserves	https://www.mee.gov.cn/ywgz/fgbz/gz/200609/t20060913_92771.shtml
Measures for Administration of National Forest Parks	http://www.gov.cn/flfg/2011-08/02/content_1918095.htm
Provisions on the Administration of Forest Belts of Special Protection in Coastal Countries	https://www.forestry.gov.cn/main/3951/content-204758.html
Interim Measures for Management of Aquatic Germplasm Resources Conservation	https://www.gd.gov.cn/zwgk/wjk/zcfgk/content/post_2723309.html
Measures for Forest Administration and Management under Natural Forest Resources Protection Projects	https://www.forestry.gov.cn/main/5925/20200414/090421974017245.html
Administrative Measures of Health Food	http://www.nhc.gov.cn/wjw/bmgz/200804/b640ecb56d5c42ccaf241a754b9acd39.shtml
Administrative Measures of Pollution-Free Agricultural Products Labelling	http://www.fgs.moa.gov.cn/flfg/201006/t20100606_6315605.htm
Administrative Measures of Geographical Indication for Agricultural Products	https://nyncw.sh.gov.cn/bmgz/20190704/0009-118000.html
Certification Management Measures of Organic Products	http://amr.sz.gov.cn/xxgk/zcwj/scjgfg/jl/jlfl/content/post_8667514.html
Catalogue Management Measures of Traditional Medicinal Species with Drug-Food Homology (Draft for consultation)	http://www.nhc.gov.cn/sps/s3585/201411/67ac54fb05ed46929adc63f2db31d4bf.shtml

NFGA Notice on Regulating the Collection and Management of National Key Protected Wild Plants	https://www.forestry.gov.cn/main/5925/20200414/090421787586225.html
NFGA Notice on Regulating the Collection and Management of National Key Protected Wild Plants Measures for the Collection and Administration of Licorice and Ephedra	http://www.zfs.moa.gov.cn/flfg/201006/t20100606_6315597.htm
Measures for the Administration of Regenerative Felling of Forests	https://www.forestry.gov.cn/main/3950/content-459873.html
Scope of Special Labels for National Key Protected Terrestrial Wildlife and Their Products (Batch 1)	https://www.forestry.gov.cn/html/main/main_4461/20220506185547300525856/file/20220507152240498537894.pdf

4. INDUSTRIAL POLICIES

State Council Opinions on Supporting and Promoting TCM Development	http://www.gov.cn/zwgg/2009-05/07/content_1307145.htm
State Council Notice on Prohibition of the Collection and Sale of Notice and Stopping the Rampant Digging of Licorice and Ephedra	http://www.gov.cn/gongbao/content/2000/content_60307.htm
State Council Opinions on Promoting the Development of Public Health Services	http://www.gov.cn/zwgg/2013-10/14/content_2506399.htm
State Council Notice on Deepening Public Health and Medication System Reforms during the 12th FYP and Program of Action	http://www.gov.cn/zwgg/2012-03/21/content_2096671.htm
State Council Opinions on Strengthening Environmental Protection Work in Key Areas	http://www.gov.cn/zwgg/2011-10/20/content_1974306.htm
State Council Notice on Turning Low-Yield Farmland Back into Forests	http://www.gov.cn/zwgg/2007-08/14/content_716617.htm
CPC Central Committee Decision on Major Issues related to Comprehensively Promoting the Rural Law	https://www.audit.gov.cn/n4/n18/c60263/content.html
State-Owned Forest Reform Plan	http://www.gov.cn/gongbao/content/2015/content_2838162.htm
Opinions on Reforming Key State-Owned Forest Regions	http://www.gov.cn/gongbao/content/2015/content_2838162.htm
Joint Notice by the Food and Drug Inspection and Administrative Bureau and Others on Further Strengthening the Management of TCM Materials	https://www.nmpa.gov.cn/xxgk/gwjw/gzwyj/gzwyyp/20131009120001949.html
State Council General Office Notice on Further Strengthening Species Resource Biodiversity Conservation and Management	http://www.gov.cn/xxgk/pub/govpublic/mrlm/200803/t20080328_32361.html
Ministry of Health Notice on Restricting the Production of Health Foods Using Wild Animals and Plants and Their Products as Raw Materials	https://www.waizi.org.cn/doc/95780.html
Notice of the State Endangerment Wild Fauna and Flora Management Office on Strengthening the Management of Non-Profit Cultivation and Utilization of Wild Animals and Plants	https://www.forestry.gov.cn/main/5925/20200414/090421953944788.html

Ministry of Health Notice on Restricting the Production of Health Foods using Licorice, Ephedra, Cistanche, Snow Lotus and their Products as Raw Materials	http://www.cnhfa.org.cn/fagui/show.php?itemid=128
Urgent Notice on Further Strengthening Taxus Resource Management	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1068
Notice on Strengthening the Supervision of Prohibited Collection and Sale of Notice	https://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172206.htm
Response from the Ministry of Health on now allowing the use of Astragalus and other items as ordinary food raw materials	http://www.nhc.gov.cn/cms-search/xxgk/getManuscriptXxgk.htm?id=38058
Letter from the Office of the Import and Export Administration of Endangered Species of the People's Republic of China on Seeking Assistance in the Administration of the Export of Economic and Medicinal Wildlife and their Products	https://www.customslawyer.cn/index.php/portal/fgk/detail/id/28943.html
State Council Notice on Strengthening Wetland Conservation and Management	http://www.gov.cn/zwgk/2005-08/15/content_22930.htm
Notice on Forcefully Strengthening Forest Resources Conservation and Management	http://www.law-lib.com/law/law_view.asp?id=58173
Circular of the State Management Office of Endangered Fauna and Flora, the General Administration of Customs, and the State Administration for Industry and Commerce on Prohibiting the Display and Sale of Precious Animals, Rare Plants and their Products in Stores in the Quarantine Zones of Ports of Import and Export	https://www.forestry.gov.cn/main/5925/20200414/090421488151449.html
Ministry of Health Notice on Further Regulating the Administration of Health Food Raw Materials	http://www.nhc.gov.cn/wjw/gfxwj/201304/e33435ce0d894051b15490aa3219cdc4.shtml
Clarification by the National Health and Family Planning Commission on Issues Related to New Raw Materials for Food, Ordinary Food and Health Food	http://www.nhc.gov.cn/sps/s3586/201404/32830cde058b413e87b82119caf89c3f.shtml
Notice of the State Food and Drug Administration on Further Strengthening the Quality Supervision of the Specialized TCM Materials Market	https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwj-yp/20150209230001599.html
Circular of the State TCM Administration, State Administration of Public Health & Medication, Ministry of Health, and the State Administration of Industry & Commerce on Strictly Implementing the 'Standards for Specialized TCM Materials Market Rectification', and Strengthening the Management of the Specialized Market for TCM Materials	http://www.law-lib.com/law/law_view.asp?id=12145
Circular of the State TCM Administration, State Administration of Public Health & Medication, Ministry of Health and the State Administration of Industry & Commerce on Issuance of the Standards for Specialized TCM Materials Market Rectification	http://www.law-lib.com/Law/law_view.asp?id=15894

Circular of the State TCM Administration, Ministry of Health, and the State Administration of Industry & Commerce on the Issuance and Approval of Certificates for Long-Term Operators to Enter and Rent Booths in the Specialized Market of TCM Materials	http://www.law-lib.com/law/law_view.asp?id=65339
Notice of the State Food and Drug Administration on Strengthening the Administration of Online Drug Sale	https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwj-yp/20131029152901595.html
Notice of the State Food and Drug Administration on Strengthening Administration of extraction and extract in TCM manufacturing	https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwj-yp/20140729120001758.html
Notice of the General Administration of Customs and the State Food and Drug Administration on Opening Heihe and other 20 Border Ports as Customs Clearance Ports for TCM Materials Import (Extremely Urgent)	https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwj-yp/20050508010101546.html
State Food and Drug Administration General Office Notice on Strengthening Management of Local Medicinal Materials Standards	https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwj-yp/20150116120001842.html
State Forestry Administration Notice on Strengthening Irrigated Forest Cultivation and Utilization in the Returning Farmlands to Forests Program	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1349
Guiding Opinions on Promoting Sustainable Development of Wild Fauna and Flora	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1079
MOFCOM General Office Notice on Guiding Opinions on Accelerating Modern TCM Logistics System Development	http://www.mofcom.gov.cn/article/h/redht/201501/20150100859755.shtml
Notice on Further Strengthening Retailers and Suppliers Transactions Supervision	http://www.mofcom.gov.cn/article/h/redht/201502/20150200885348.shtml
National Forestry Administration Opinions on Further Strengthening Forest Resources Administration	http://www.law-lib.com/law/law_view.asp?id=122940
National Forestry Administration Notice on Further Strengthening Natural Resources Management in Natural Parks	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=243
National Forestry Administration Guiding Opinions on Further Strengthening the Management and Protection of Public Welfare Forests in Tianbao Project areas	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1986
National Forestry Administration Response Letter on Some Issues Concerning the Felling Management of Cultivated Previous Tree Species	https://www.forestry.gov.cn/main/5925/20200414/090421356746802.html
National Forestry Administration Guiding Opinions on Forcefully Strengthening the Development of the Wild Plants Utilization Training Industry	http://www.law-lib.com/law/law_view.asp?id=485766
Notice on Further Strengthening the Implementation and Management of the Returning Farmland to Grazing Project	https://www.moa.gov.cn/govpublic/XMYS/201006/t20100606_1534930.htm
Notice on Further Strengthening Biological Conservation Work	https://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172454.htm

Notice on Strengthening Cultivation and Utilization of Shrub Forests in the Returning Low-Yield Farmland Back to Forests Program	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1349
Guiding Opinions on Strengthening the Ex-situ Conservation of Plant Species Resources in Botanical Gardens	http://www.law-lib.com/law/law_view.asp?id=399869
National Forestry Administration Guiding Opinions on Effectively Strengthening the Forest Cultivation in Tianbao Project Areas	http://www.law-lib.com/law/law_view.asp?id=408304
National Forestry Administration Opinions on Accelerating the Development of Characteristic Economic Forest Industry	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=2119
National Forestry Administration Guiding Opinions on Improving Degraded Shelter Forest Rejuvenation Work	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=2134
National Council General Office's Opinions on Strengthening the Management of Tree Seedlings	http://www.gov.cn/zwgk/2012-12/28/content_2301323.htm
National Council General Office's Opinions on Accelerating the Development of Under-the-Forest Economy	http://www.gov.cn/zwgk/2012-08/02/content_2197041.htm
National Council General Office's Opinions on Further Improve the Three-North Shelter Forest Program	http://www.gov.cn/zhengce/content/2009-08/21/content_2741.htm
National Council General Office's Response Letter on Enlisting the Coastal Basal Forest Belt as a Special Protected Forest Belt	http://www.gov.cn/xxgk/pub/govpublic/mrlm/201012/t20101202_63027.html
National Forestry Administration General Office Notice on the Establishment of National Forest Biodiversity Conservation Commission	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=2102

5. DEVELOPMENT PLANNING OUTLINES

TCM Materials Conservation and Development Plan (2015-2020)	http://www.gov.cn/zhengce/content/2015-04/27/content_9662.htm
Outline for TCM Innovation and Development (2006-2020)	http://www.gov.cn/zwgk/2007-03/22/content_557466.htm
TCM and Health Service Development Plan (2015-2020)	http://www.gov.cn/zhengce/content/2015-05/07/content_9704.htm
China Biodiversity Conservation Strategy and Program of Action (2011-2030)	https://www.mee.gov.cn/gkml/hbb/bwj/201009/t20100921_194841.htm
China Early 21st Century Sustainable Development Program of Action	http://www.gov.cn/zhengce/content/2008-03/28/content_2108.htm
China Program of Action for the Conservation of Aquatic Biological Resources	http://www.gov.cn/zwgk/2006-02/27/content_212335.htm
Program of Action for National Biological Species Resources Conservation and Utilization	https://www.mee.gov.cn/gkml/zj/wj/200910/t20091022_172479.htm
Guideline on Sustainable Management and Utilization of Forest	https://www.forestry.gov.cn/sites/main/main/gov/content.jsp?TID=1291

Outline of National Afforestation and Greening Plan (2011-2020)	https://www.forestry.gov.cn/portal/main/govfile/13/govfile_1837.htm
National Forestry Administration (NFA) Outline on Comprehensive Law Enforcement in Forest Management	http://www.law-lib.com/law/law_view.asp?id=87343
The 12th Five-Year Plan for Traditional Chinese Medicine (TCM) Development	http://gcs.satcm.gov.cn/gongzuodongtai/2018-03-24/2169.html
The 12th Five-Year Plan for Public Health Development	http://www.gov.cn/zwgk/2012-10/19/content_2246908.htm
The 12th Five-Year Plan for Ecological Conservation	http://www.gov.cn/gongbao/content/2013/content_2396624.htm
The 12th Five-Year Plan for Forestry Development	http://www.gov.cn/gzdt/2011-10/10/content_1965517.htm
Regional Planning Layout of Agriculture with Special Characteristics (2013-2020)	https://www.moa.gov.cn/nybgb/2014/dsanq/201712/t20171219_6105530.htm
The 12th Five-Year Plan for Environmental Protection	http://www.gov.cn/zwgk/2011-12/20/content_2024895.htm
National Plan of Modern Agriculture Development (2011-2015)	http://www.gov.cn/zwgk/2012-02/13/content_2062487.htm
The 12th Five-Year Plan for Health and Pharmaceutical Industry	http://www.gov.cn/gzdt/2012-01/19/content_2049023.htm
Circular Economy Development Strategy and Near-Term Action Plan	http://www.gov.cn/zwgk/2013-02/05/content_2327562.htm
China Plant Conservation Strategy	http://kbg.kib.cas.cn/kxyj/zlxz/wxzl/201912/P020191225503637386567.pdf

6. STANDARDS AND TECHNICAL SPECIFICATIONS

Green Foreign Trade Industry Standards for Import and Export of Medicinal Plants and Products	http://www.satcm.gov.cn/fajiansi/gongzuodongtai/2018-03-24/2394.html
Good Manufacturing Practices for Pharmaceutical Products (2010 Revision)	https://www.nmpa.gov.cn/xxgk/fgwj/bmgzh/20110117120001434.html
Good Supply Practices for Pharmaceutical Products	https://www.nmpa.gov.cn/xxgk/fgwj/bmgzh/20160720102601205.html
Chinese Pharmacopoeia	http://www.gov.cn/xinwen/2020-11/28/content_5565608.htm

7. INTERNATIONAL REGULATIONS

Joint Statement on the Prioritization of Monitoring SARS-CoV-2 Infection in Wildlife and Preventing the Formation of Animal Reservoirs	https://www.who.int/zh/news/item/07-03-2022-joint-statement-on-the-prioritization-of-monitoring-sars-cov-2-infection-in-wildlife-and-preventing-the-formation-of-animal-reservoirs (Chinese)
Zoonosis and Food Safety – Improving Collaboration between Animal and Public Health Professionals to Achieve a Better Outcome	https://www.woah.org/app/uploads/2021/03/2019-asi1-isoda.pdf (English)
Joint Risk Assessment Operational Tool: Operational Tool for the Tripartite Guidelines on Zoonotic Diseases - Adopting a multisectoral, integrated approach to health: a tripartite guide for countries to combat zoonotic diseases	https://apps.who.int/iris/bitstream/handle/10665/340005/9789240033559-chi.pdf?sequence=17 (Chinese)
Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	https://cites.org (English)
	www.cites.org.cn (Chinese)
Guidelines on the Conservation of Medicinal Plants	https://apps.who.int/iris/bitstream/handle/10665/41651/2831701368_en.pdf?sequence=1&isAllowed=y (English)
CITES Appendices and Resolution Conf. 10.19 (Rev CoP14) Traditional Medicine	https://cites.org/sites/default/files/document/E-Res-10-19-R14_0.pdf (English)
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity	https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (English)
the Kunming-Montreal Global Biodiversity Framework (GBF)	https://www.cbd.int/gbf/ (English)
Global Strategy for Plant Conservation 2011-2020	https://www.bgci.org/files/Plants2020/GSPCbrochure/gspc_english.pdf (English)
Biodiversity and Health: the WHO-CBD Joint Work Programme	https://www.who.int/news/item/01-01-2020-biodiversity-and-health-the-who-cbd-joint-work-programme (English)
Guidelines on the Conservation of Medicinal Plants	https://portals.iucn.org/library/sites/library/files/documents/1993-027.pdf (English)
Taking a Multisectoral One Health Approach: A Tripartite Guide to Addressing Zoonotic Diseases in Countries	https://www.fao.org/3/ca2942en/CA2942EN.pdf (English)
FairWild Standard Version 2.0--unifying the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) Version 1.0, 2007 and the FairWild Standards Version 1, 2006	https://www.wwf.or.jp/activities/data/FairWild-Standard-V2.pdf (English)
A WHO guide to good manufacturing practice (GMP) requirements	https://apps.who.int/iris/handle/10665/64465 (English)
WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants	https://www.who.int/publications/i/item/9241546271 (English)
CITES CoP19 Decisions 19.261 to 19.264 on Trade in medicinal and aromatic plant species	https://cites.org/eng/dec/index.php/44300 (English)

ANNEX II. RELATED PROTECTION LISTS

List of National Key Protected Wild Animals	http://www.gov.cn/xinwen/2021-02/09/content_5586227.htm
List of National Key Protected Wild Plants	http://www.gov.cn/zhengce/zhengceku/2021-09/09/content_5636409.htm
List of Terrestrial Wild Animals with Important Ecological, Scientific and Social Values	http://www.forestry.gov.cn/u/cms/www/202306/30153816dzk1.pdf
Catalogue of Imported and Exported Species of Wild Fauna and Flora	https://www.customslawyer.cn/index.php/portal/fkg/detail/id/65852.html
National Key Protected Wild Medicinal Species List	http://www.law-lib.com/law/law_view.asp?id=48829
List of Protected New Varieties of Agricultural Plants of the People's Republic of China (Batch 1, 2, 3, 4 & 5)	https://nyncw.sh.gov.cn/bmgz/20190715/0009-118209.html
List of Main Forest Tree Varieties of the People's Republic of China (Batch 1 & 2)	http://www.linan.gov.cn/art/2022/2/21/art_1377192_59065518.html
List of Traditional Medicinal Species with Drug-Food Homology	http://www.zyczjzx.cn/html/2546131936.html
Summary List of New Food Raw Materials and Ordinary Foods	http://www.nhc.gov.cn/sps/pztq/201612/712553a-5f7554e0e9ec1dfdbcc91e99a.shtml
CITES Appendices	http://www.cites.org.cn/citesgy/fl/

