

3.1 Entry-Exit Inspection for Different Categories of Commodities

3.1.1 Commodities Subject to Mandatory Inspection and Quarantine

The *Catalogue of Import-Export Commodities Subject to Compulsory Inspection and Quarantine* lists the types of commodities requiring entry-exit inspection and quarantine. It also covers the contents of inspection. Provisions for the administration of inspection and quarantine for different commodities promulgated by China set out detailed regulations governing the bases, methods and procedures of inspection and quarantine.

3.1.2 Technical Standards for Inspection and Quarantine

Inspection is conducted by AQSIQ according to the following criteria: for import and export commodities listed in the catalogue, inspection is carried out in accordance with mandatory national standards; where relevant standards are not yet formulated, inspection is carried out with reference to foreign standards specified by the commodity inspection departments.

3.1.3 Supervision and Inspection of Foodstuffs

(a) Inspection of Imported Food

All imported food (including beverages, liquor and sugar), food additives, food containers, packaging materials, and food utensils and equipment must be declared to the inspection and quarantine authorities for health supervision and inspection. Under the management of inspection and quarantine authorities, imported food is classified into different categories by hazard ratings and inspected according to national health standards. Only those foodstuffs that meet requirements can enter China.

(b) Inspection of Exported Food

All food for export (including finished products and raw materials for human consumption and food prepared according to traditional methods with medicinal ingredients) must undergo inspection. Foodstuffs not inspected or not up to standard may not be exported.

(c) Registration of Imported Food and Animal and Plant Products

CIQ is responsible for formulating, revising and publishing the *Catalogue of Imported and Exported Food and Animal and Plant Products Subject to Health Registration*. The products in the catalogue mainly include processed food that can be consumed directly, such as canned food, beverages, liquor and condiments, as well as semi-finished products and raw materials, such as meat, aquatic products and vegetables.

Foreign food manufacturers may apply for registration with CIQ through the local food and hygiene authorities at their resident country. Those that meet CIQ requirements will be added to CIQ's list of countries and enterprises permitted to export food to China and issued special quarantine and health registration codes.

(d) Registration of Exported Food and Animal and Plant Products

All enterprises in China engaged in the processing and storage of food for export as well as the slaughtering of animals and poultry for export must first obtain a health licence from the local health department and then apply to the inspection and quarantine authorities for a registration certificate. Enterprises not granted the registration certificate may not process, produce or store food for export. Where overseas registration or recognition is required, the enterprises must apply to CIQ which is responsible for the unified handling of all the necessary foreign-related procedures. Enterprises failing to

obtain approval or recognition from the importing country may not export food to that country.

3.1.4 Supervision and Inspection of Mechanical and Electronic Products

(a) Scope of Mechanical and Electronic Products

The *Statistical Handbook on the Import and Export of Mechanical and Electronic Products* (1999 Edition) compiled by the Department of Mechanical and Electronic Products Import and Export under the Ministry of Commerce includes a *Catalogue of Mechanical and Electronic Products*, which CIQ uses as the basis for defining the scope of mechanical and electronic products subject to entry-exit inspection and supervision.

(b) Supervision and Inspection of Mechanical and Electronic Products for Export

- Supervision by enterprise category

The inspection and quarantine authorities divide export enterprises into four categories according to their management standard and product quality:

- Enterprises with exemption certificates: the mechanical and electronic products for export of these enterprises are exempt from inspection;
- Category I enterprises: batch inspection rate 10-30%;
- Category II enterprises: batch inspection rate 40-70%;
- Category III enterprises: batch inspection rate 100%.

- Bases for inspection

For mechanical and electronic products subject to mandatory safety, health and environmental protection requirements, their standards must not be below the mandatory requirements set by the state. For other

products, their standards can follow those stipulated in the trade contracts.

- Certification

To facilitate exports, CIQ has introduced interim measures governing export quality licensing for special cases in the implementation of the export quality licensing system for mechanical and electronic products. CIQ also encourages enterprises to seek ISO9000, ISO14000 and other quality certifications. Enterprises awarded certification by institutions approved by the China National Accreditation Board (CNAB) are exempt from factory inspection and such certification may also serve as the basis for categorising the enterprises concerned.

- Registration of production enterprises exporting complete sets of equipment

China requires and encourages enterprises that produce complete sets of equipment for export to register with the local inspection and quarantine authorities. The inspection and quarantine authorities provide technical guidance free of charge to registered enterprises to help them meet foreign technical and quality requirements and comply with international practices in the course of production. Inspection is carried out jointly and is charged accordingly.

(c) Regulations for Inspection of Imported Mechanical and Electronic Products

- Quality licensing for import commodities

China has published a *Catalogue of Import Commodities Subject to the Safety and Quality Licensing System*. Products listed in the catalogue but not granted a safety and quality licence cannot enter the China market.

- Regulations governing the import of second-hand mechanical and electronic products

With the exception of products to be imported for special needs, China forbids the import of used mechanical and electronic products listed in the *Catalogue of Import Commodities Subject to the Safety and Quality Licensing System*, and CIQ would not handle their applications. For the import of such products upon approval, the inspection bases and relevant technical specifications must be stipulated in the contract or agreement. For the import of used mechanical and electronic products and complete sets of second-hand equipment in connection with national safety, environmental protection and public health, the importing enterprise must include in the trade contract provisions for pre-shipment inspection and supervised loading in the exporting country. The importing enterprise (or consignee) should apply to the inspection and quarantine authorities at the port of entry for a *Record for the Import of Used Mechanical and Electronic Products* by presenting original copies of import documents issued by the approving organs together with other relevant trade documents prior to customs declaration. After clearing customs, the importing enterprise (or consignee) should report to the inspection and quarantine authorities at the place of use within a specified period by presenting invoices, packing lists, bills of lading and other necessary documents.

3.1.5 Supervision and Inspection of Drugs

(a) Supervision and Inspection of Imported Drugs

- Registration of imported drugs

China implements a registration and approval system for imported drugs. All imported drugs must obtain a registration certificate from the State Drug Administration (SDA). Manufacturers of the imported drugs must meet the drug production and quality control standards in the producing country as well as China's GMP requirements. Imported drugs applying

for registration in China must be registered with the drug administration department and granted approval for public sale in the producing country, and must pass inspections by SDA-authorised port-of-entry drug laboratories.

The China office or registration agent of the foreign drug manufacturer is responsible for applying for imported drug registration. They have to submit the *Imported Drug Registration Certificate Application Form* together with other required documents to SDA for examination and approval. These offices or agents must be legitimate establishments registered with the State Administration for Industry and Commerce (SAIC).

After reviewing the quality and performing the necessary clinical tests, SDA will grant an *Imported Drug Registration Certificate* to the imported drugs in question. This certificate is the official document for the registration, import, sale and use of foreign drugs in China.

- Filing of imports

Drugs must be imported through designated ports of entry and the importer must register and file the import with the drug administration at the port of entry. Any change in the packaging as well as the form and content of labeling must be reported to SDA.

- Application for inspection

Inspection organs: The port-of-entry drug laboratories set up by SDA are the inspection authorities for imported registered drugs. Drugs must be imported through port cities where port-of-entry drug laboratories are located. These laboratories would not inspect drugs imported via other ports of entry.

Application procedures: After the imported drugs have arrived at the port of entry, the importing enterprise has to complete the *Imported Drug Inspection Form* and submit it to the local port-of-entry drug laboratory

together with the *Imported Drug Registration Certificate* (original or copy) and other relevant documents. After inspection, the port-of-entry drug laboratory will prepare an *Imported Drug Inspection Report* and issue an *Imported Drug Customs Clearance Note* if the drugs are up to standard. A negative report will be prepared if the drugs do not meet requirements.

Re-inspection and arbitration: The importing enterprise may apply to the original port-of-entry drug laboratory for re-inspection within 30 days of receiving the inspection report if it objects to the results of inspection. If it still objects to the results of the re-inspection, it may apply to the National Institute for the Control of Pharmaceutical and Biological Products for arbitration within 30 days of receiving the results of re-inspection.

(b) Supervision and Inspection of Exported Drugs

- Supervision of drug production

Production licence: Drug manufacturers in China must be approved and issued a drug production licence by the local provincial-level drug administration, and must register with SAIC by presenting the drug production licence.

Quality certification: Drug manufacturers must undertake production in accordance with the *Quality Control Standards for Drug Production* formulated by SDA. SDA is responsible for certifying whether or not an enterprise complies with these standards and will issue a certificate to those that are qualified.

- Export inspection

Enterprises may request a drug laboratory established by the Ministry of Health to prepare a report on the inspection of drugs for export. The criteria of inspection are generally in accordance with the export contract.

3.1.6 Import Control on GM Agricultural Bioproducts

(a) Definition

Genetically modified (GM) agricultural bioproducts refer to plants, animals, microbes and associated products genetically modified through genetic engineering techniques for the purpose of agricultural production or agricultural produce processing. Import control on GM agricultural bioproducts varies according to their usage, i.e. whether they are for research and experiment, production, or processing as raw materials. GM agricultural bioproducts include the following:

- GM animals and plants (including seeds, stud stocks, and aquatic fries) and microbes;
- Products of GM animals, plants and microbes;
- Products directly processed from GM agricultural products;
- Seeds, stud stocks, aquatic fries, pesticides, vet medicines, fertilisers and additives containing the elements of GM animals, plants, microbes or associated products.

(b) Safety Rating

GM agricultural bioproducts are classified into the following four categories according to their risks to mankind, animals and plants, microbes, and the ecological environment:

- Safety Rating I: no existing risk
- Safety Rating II: low risk
- Safety Rating III: medium risk
- Safety Rating IV: high risk

(c) Labelling

China adopts a labelling system for the management of GM agricultural bioproducts and publishes a catalogue

accordingly. All GM bioproducts listed in the catalogue must be properly labelled if they are to be sold in the China market. Those not labelled or not labelled according to requirements may not be imported or sold.

The following is the first batch of GM agricultural bioproducts subject to labelling management.

- Soy bean seeds, soy bean, soy bean powder, soy bean oil and bean dregs
- Corn seeds, corn, corn oil, corn powder (including corn powder under tariff numbers 11022000, 11031300 and 11042300)
- Seeds of rape, rapeseed, rapeseed oil and rapeseed dregs
- Cotton seeds
- Tomato seeds, fresh tomatoes and tomato paste

(d) Entry Inspection

For the import of GM agricultural bioproducts, it is necessary to apply to the Office for Safety Management of Genetically Modified Agricultural Bioproducts for a safety certificate and import approval by submitting the relevant documents. The types of documents to be submitted depend on the usage of the GM agricultural bioproducts, namely whether they are for research and experiment, production, or processing as raw materials. Imports not accompanied by the relevant approval documents or safety certificate, or imports not compliant with the descriptions in the approval documents or safety certificate, will be returned or destroyed.

Inspection and quarantine authorities will carry out entry inspection against the approval documents and issue a clearance note upon satisfactory inspection and quarantine, to be presented to customs for clearance.