



Life Sciences 2017

Key issues for senior
life sciences executives

Importing plants into India: processes and challenges

Essense Obhan and Charul Yadav
Obhan & Associates



OBHAN & ASSOCIATES

Advocates and Patent Agents

N - 94, Second Floor, Panchshila Park, New Delhi 110017, INDIA
tel: +91 11 40200200 fax: +91 11 40200299 email: email@obhans.com
www.obhanandassociates.com

Importing plants into India: processes and challenges

By Essene Obhan and Charul Yadav, Obhan & Associates

Plants and plant materials may be imported into India for a number of reasons, including for research purposes, commercial release, consumption or registration of plant varieties under the Protection of Plant Varieties and Farmers' Rights Act 2001. The laws and regulations governing the import of plants and plant materials into India vary depending on the reason for import and the type of material being imported. This legislative and regulatory framework is designed to safeguard plant biosecurity, which is essential to ensure agricultural sustainability, food safety and environmental protection. Plant biodiversity in India is particularly critical, as the country is home to one of the world's most biodiverse ecosystems. As international trade of plants and plant materials increases, the risk of introducing exotic pests and diseases along with imported material also rises. Plant biosecurity seeks to prevent, minimise and control the introduction and spread of these pests in the course of international trade.

The volume of trade in plants and plant materials in India continues to grow. According to the statistics, the National Bureau of Plant Genetic Resources (NBPGR) – one of several regulatory authorities in this space – has processed for quarantine clearance 642,671 samples of various crop plants comprising seeds, vegetative propagules, *in vitro* and transgenic materials, of which 499,796 (including 2,447 samples of transgenics) were imported and 142,875 were intended for export. With trade in such material likely to increase in the coming years, it is worth reviewing the legal and regulatory framework governing the import of plants and plant materials into India.

Legislative and regulatory framework

International history

The earliest plant biosafety laws were enacted in France in the 17th century in order to control the spread of wheat stem rust. Other countries, including Germany and the United States, were among the first to establish plant quarantine services. The Phylloxera Convention – the first international plant protection convention – was signed in 1881 by five countries to control the spread of Phylloxera, a North American aphid accidentally introduced into continental Europe around 1865, which subsequently devastated much of Europe's grape-growing regions. The 20th century saw much more action on this front. The International Convention for the Protection of Plants was signed in 1929, followed by the International Plant Protection Convention (IPPC) in 1951. The IPPC, which India joined in 1956, superseded all previous international agreements on plant protection and continues to govern the issue today. The IPPC seeks to develop international cooperation among countries to prevent the introduction and spread of pests through international trade and movement of plant materials. It requires each country to establish a national plant protection organisation to discharge certain defined functions. The 1989 Uruguay Round of the General Agreement on Tariffs and Trade recognised the IPPC as a standard-setting organisation for the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which facilitates the global movement of plants and plant materials and encourages members of the World Trade Organisation to base their phytosanitary measures on IPPC standards.

In parallel with the developments regarding the

IPCC and the SPS Agreement, the Convention on Biological Diversity (CBD) was adopted in 1992. The CBD recognises the sovereign rights of all members over their biodiversity and has three key objectives:

- the conservation of biological diversity;
- the sustainable use of the components of biological diversity; and
- the fair and equitable sharing of the benefits arising from the use of genetic resources.

The Cartagena Protocol on Biosafety, a supplementary agreement to the CBD, was adopted in 2000 and is designed to protect biological diversity from potential risks posed by living modified organisms. It establishes an advance informed agreement procedure to provide countries with relevant information before agreeing to the import of living modified organisms. India is a signatory to both the CBD and the Cartagena Protocol.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is also relevant to the import of plants, as it aims to ensure that international trade in specimens of wild animals and plants does not threaten their survival. India became a member of CITES in 1979.

Indian framework

In India, the Destructive Insects and Pests Act 1914 (as amended) provides for plant protection and quarantine regulatory measures. The import of plants and plant materials is regulated under the Plant Quarantine (Regulation for Import into India) Order 2003 issued under the act. This order replaced the earlier Plants, Fruits and Seeds (Regulation of Import into India) Order 1989. Besides harmonising India's regulatory framework with the IPPC and the SPS Agreement, the Plant Quarantine Order addresses gaps in the previous Plants, Fruits and Seeds Order regarding the import of germplasm, genetically modified organisms (GMOs), transgenics, biocontrol

agents and similar specimens. The Directorate of Plant Protection, Quarantine and Storage under the Ministry of Agriculture carries out plant quarantine operations in India.

Although the Cartagena Protocol requires signatory states to set up a regulatory body for GMOs in agriculture and food, India has yet to introduce a law or create a regulatory body for this purpose. Instead, the manufacture, import, use, research and release of GMOs are controlled and regulated by the Ministry of Environment, Forests and Climate Change and the Department of Biotechnology of the Ministry of Science and Technology, pursuant to the 1989 rules notified under the Environment (Protection) Act 1986. The Ministry of Environment, Forests and Climate Change regulates the commercial release of GMOs through the Genetic Engineering Appraisal Committee.

The Department of Biotechnology deals with all aspects of transgenics research. It reviews, permits and monitors experiments which use GMOs and recombinant DNA products. There were plans to legislate on the regulation of modern biotechnology in India through the Biotechnology Regulatory Authority of India Bill – which was introduced to Parliament in 2013 – but this legislation has since lapsed.

Import permissions and restrictions

The import of plant materials into India is regulated based on the purpose of import (eg, research or commercial release) or the type of plant materials (eg, vegetables or fruits, or propagating materials such as seeds, saplings or germplasm). The plant materials can be transgenic or non-transgenic. The regulatory framework applies regardless of whether the plant materials are being imported in bulk for propagation or consumption, or in small quantities for research or registration of plant varieties.

Schedules IV, V, VI and VII of the Plant Quarantine Order list the plant species whose import is regulated:

“Although the Cartagena Protocol requires signatory states to set up a regulatory body for GMOs in agriculture and food, India has yet to introduce a law or create a regulatory body for this purpose”

“Despite some improvements in regulatory processes, the system in India remains ill equipped to handle the challenges associated with plant protection and biosafety, such as the risks of new agricultural production technologies, the emergence of transboundary diseases, climate change and bioterrorism”

- Prohibited plant species – Schedule IV lists the plant species that are prohibited from being imported from specified countries.
- Restricted plant species – Schedule V lists restricted plants and plant materials, whose import is permissible only on the recommendation of authorised institutions along with additional declarations and special conditions (eg, fumigation, pre-shipment cold treatment and post-entry quarantine for a specified period).
- Regulated plant species – Schedule VI lists the plants and plant materials that may be imported with additional declarations and special conditions.
- Other plant species – Schedule VII lists plant species intended for consumption for which no additional declarations are specified.

No consignment of seed or grain contaminated by quarantine weeds listed in Schedule VIII may be imported. To import new commodities that are not mentioned in the Plant Quarantine Order, importers must apply to the plant protection adviser for a pest risk analysis request form.

Import process

Applications for the import of plant germplasm, transgenics or GMOs for research or experimental purposes must be submitted to the NBPGR. An import permit for transgenics or GMOs is issued subject to the approval of the Review Committee on Genetic Manipulation (established by the Department of Biotechnology under the 1989 rules and subject to their relevant restrictions and conditions). The NBPGR is responsible for ensuring that imported transgenic material is free from pests and terminator gene technology.

The bulk shipment of transgenic plants, plant products and GMOs is regulated by the Genetic Engineering Appraisal Committee under the provisions of the 1989 rules or the mechanism

established under the Biosafety Protocol of the Ministry of Environment, Forests and Climate Change.

The importer must ensure that no prohibited or restricted plant species are imported (with the exception of those imported by authorised institutes). The importer must also ensure that every imported consignment of plant species is accompanied by a phytosanitary certificate from the country of origin, containing additional declarations as indicated for that particular plant species. Where the import of certain plants is subject to the prior approval of authorised institutions, the importer should apply for such approval well in advance. For example, certain imports require prior approval of the EXIM Committee of the Department of Agriculture and Cooperation (under the Ministry of Agriculture). The committee meets once every 30 to 45 days to approve such applications. The importer should also ensure that all provisions of CITES are complied with. If any conditions or restrictions under the Plant Quarantine Order are not complied with, the imported plants or plant materials may be deported or destroyed, although the importer may be allowed a one-off relaxation, at the discretion of the plant quarantine officer, on payment of five times the import sampling fees.

Where the imports require post-entry quarantine, the importer must arrange for an appropriate quarantine facility, such as an isolated field or nursery or a greenhouse that is certified by the inspection authorities in accordance with the Plant Quarantine Order. Such facilities should be established sufficiently in advance so that they are ready for use when the imports arrive.

How efficient is the import process?

The past few years have seen considerable improvement and simplification of the import regulatory framework. The Plant Quarantine Information System (PQIS) has been introduced

for online issuance of phytosanitary certificates and import release orders to importers and exporters. The PQIS is now being integrated with the customs gateway (ICEGATE) for single window facilitation. However, the PQIS has not been modified in six years and needs urgent updating.

Import procedures have also been simplified. Most critically, timelines have been stipulated for import clearance of plants and plant products and other regulated articles in order to facilitate trade. This provides greater certainty for importers and increases accountability for regulatory authorities. Another crucial procedural change is the closure of the permit system for importing plants other than those regulated by the NBPGR.

Despite some improvements in regulatory processes, the system in India remains ill equipped to handle the challenges associated with plant protection and biosafety, such as the risks of

new agricultural production technologies, the emergence of transboundary diseases, climate change and bioterrorism. Further, India has been unable to keep up with its international obligations under various multilateral agreements. The Destructive Insects and Pests Act is over a century old and is inadequate to deal with the fast pace of change in this domain. The Core Committee of the Department of Agriculture and Cooperation (established in 2008) pointed out that:

the Destructive Insects and Pests Act, 1914 and the Livestock Importation Act, 1898 are age old legislations and are subsidiary to the Customs Act, 1962 which does not give direct powers to the quarantine officers to deport or destroy or confiscate the consignment or lodge complaints under the Indian Penal Code. Inadequate or obsolete definitions in these Acts need to be updated.



Essense Obhan

Managing partner
essense@obhans.com

Essense Obhan is the founding partner of Obhan & Associates. An IP attorney and patent agent with a degree in mechanical engineering, he has extensive expertise in the mechanical, industrial, software and telecoms sectors. Mr Obhan regularly advises clients – which include Fortune 500 companies, as well as some of India’s leading businesses – on IP strategy and portfolio management. He has extensive experience in drafting and prosecuting patents, and also focuses on patent litigation and opposition proceedings before various courts, the Patent Office and the Intellectual Property Appellate Board. Mr Obhan is a frequent speaker on patent protection and enforcement issues in India and abroad.



Charul Yadav

Principal associate
charul.yadav@obhans.com

Charul Yadav is an advocate registered with the Bar Council of India and a patent agent. She has a master’s degree in biotechnology. She strategises, manages and executes patent matters related to patents in the domain of life sciences and biotechnology, particularly molecular biology, nutraceuticals, food, biopharmaceuticals, probiotics and transgenics. She advises clients on patent strategy. Her work includes prior art searching, patentability assessment, freedom-to-operate and validity opinions, legal opinions on various aspects of Indian patent law, patent prosecution, patent drafting, infringement, opposition and revocation proceedings.

Adequate provisions for regulating plants, livestock and aquatics and powers for inspecting transport vehicles and seizure and destruction of infested or infected plants and livestock or their products have to be incorporated. Punishment or penalty on the importer or custom house clearing agents or other defaulters for violation of provisions of the legislation has to be provided. Provisions for effective domestic quarantine have to be incorporated. The enabling legislation for the proposed biosecurity authority would have to be enacted.

The complex inter-ministerial bureaucratic and regulatory machinery designed to regulate imports and exports further complicates matters and slows down the process. India's biosecurity has been breached on several occasions, leading to the introduction of exotic pests (eg, coffee berry borers, coconut eriophyid mites, bunchy top virus in bananas from Sri Lanka, warts on potatoes from the Netherlands, parthenium weed with wheat from the United States and *Argemone mexicana* weed with mustard seed from the United States and Mexico). Many plant, animal and marine diseases and pests have been introduced into India through imports of seeds, plant materials, livestock and livestock products. Many weeds (eg, parthenium, *Phalaris minor* and *Lantana camara*) have become established in the country's ecosystem and continue to cause heavy economic losses every year.

Various taskforces and committees have highlighted the need for an integrated system in India. The Department of Agriculture and

Cooperation Core Committee recommended the establishment of a National Agriculture Biosecurity System, while also suggesting that a new law is needed which is more relevant to the present situation. However, subsequent attempts to legislate on the issue through the Agricultural Biosecurity Bill 2013 ultimately failed.

Many other countries have implemented strict measures for the import of plants and plant materials. The United States, Australia and New Zealand have stringent legislative and regulatory requirements for imports and integrated biosecurity systems for plant protection and biosecurity. India likewise needs a robust integrated system that not only meets these challenges, but is also consistent with international obligations. **iam**

OBHAN & ASSOCIATES

Advocates and Patent Agents

Obhan & Associates

Advocates and Patent Agents

N - 94, Second Floor

Panchshila Park

New Delhi 110017

India

Tel +91 11 4020 0200

Fax +91 11 4020 0299

Web www.obhanandassociates.com