Phytosanitary and Biosafety Measures

(summary of presentation)

I. Relevance to GR managers

The movement of PGRFA typically involves small quantities of living materials – packets and packages as opposed to truck or shiploads. Nevertheless, such transfers are regulated by international and national law designed to prevent the introduction of disease and pests and to minimize the threat posed to native plants and animals from exotic species. GR professionals involved with accessing and distributing PGRFA across national boundaries need to be familiar with the international and national regulations relevant to this transfer. GR professionals who also provide advice to ministries of health and agriculture must also be aware of the sensitivities and issues related, in particular, to biosafety and genetically modified organisms.

There are three principal international agreements in this area that are relevant to genetic resource managers, research directors and national policy-makers: the International Plant Protection Convention, the World Trade Organization's Sanitary and Phytosanitary Agreement, and the Cartagena Protocol on Biosafety. This Chapter looks at each, briefly, and notes instances where policy is fluid and where the relationship between agreements is less than certain. While all of these agreements purport to be based on 'science,' it should be noted that political and economic considerations are never far below the surface in any discussion of how transfers of agricultural produce and products, seeds, planting materials, etc., will be regulated.

II. Phytosanitary measures and why they are important

The distribution of plant genetic resources (PGR) brings with it risks to plant health, biological diversity and potentially human health too. Up to the present day, the overriding concern in the movement of living plant material is the parallel spread of diseases into new areas and their damaging impact on agricultural production. Increasing genetic uniformity in crops has accentuated the potential effect of diseases. The potato famine in Europe and North America in the 19th century is a famous example. The fungus, *Phytophthora infestans,* completely wiped out potato crops and was responsible for the death by starvation of 1 million and the emigration of another 1.5 million poor people in Ireland alone.[1]

In a similarly important vein, the introduction of infections to collections of germplasm can be highly detrimental to the viability of plant material in both the short and long terms. Infected germplasm from genebanks can corrupt the results of research, characterization and evaluation studies, and bring about genetic erosion in genebanks, multiplication plots and

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[1] http://www.geocities.com/willboyne/nosurrender/PotatCom.html. FAO. 1998. The state of the world's plant genetic resources for food and agriculture. FAO, Rome.

other field sites.[2] The consequences of such failures in PGR conservation and research are, of course, grave, especially for important collections containing a large part of the world's diversity of specific crop species.

Although less prominent, alien invasive species are also of concern because of their far-reaching effect on natural ecosystems. Numerous plant species, often crop plants or ornamentals, have been transported throughout the world by humans. Their attractive characteristics frequently include adaptability and hardiness. Invariably as humans have colonized and re-colonized more remote places (oceanic islands are some of the most notable examples) their chosen plants have expanded rapidly into delicately balanced native ecosystems to the detriment of native species. Species of pine, guava, *Passiflora*, *Leucaena*, *Cecropia*, *Rhododendron*, *Rubus, Miconia*, etc., are just a few of the burgeoning numbers of invasive species which have spread around the world and contributed significantly to the loss of biological diversity. As an extension of this phenomenon, genetically modified organisms have been recognized as a vector or a new form by which foreign and potentially invasive genes may be introduced into a new environment.

The benefits of introducing new germplasm to a continent, country or province, therefore, must be weighed against the risks posed and the costs of managing such risk. Levels of risk differ with the origin, age, volume, type and identity of plant material and the characteristics of the receiving territory or body. Vegetative propagules, especially where roots and soil are included, pose a greater risk than seeds in transmitting pathogens.[3] The nature of the packing material also can increase the risk of transmitting disease.

All such risks are alleviated through quarantine measures: regulating the form and nature of incoming material, eliminating high-risk material or subjecting it to quarantine and therapy. These controls are exerted at a national level. However, policy has existed at an international level, since at least the 19th century, with the aim of coordinating phytosanitary measures to improve biosafety over wider areas. Existing legislation is largely focused on transboundary movement and quarantine procedures. In terms of plants, there are three main agreements of relevance: the International Plant Protection Convention (IPPC) which is, to date, the most important and the oldest international agreement, the World Trade Organization (WTO)–Sanitary and Phytosanitary (SPS) agreement, and the Cartagena Protocol on Biosafety. Invasive species are poorly regulated but their control is a requirement of signatories to the Convention on Biological Diversity (CBD).

The aims and main features of national and international regulations are summarized below. In brief, the IPPC provides an international framework for the harmonization of national phytosanitary measures to prevent the spread and introduction of pests of plants and plant products. The WTO-SPS aims at preventing the misuse of phytosanitary regulations as a barrier to trade and works closely with the IPPC. The Cartegena Protocol on Biosafety has a wholly different function. Its aim is very specific: to safeguard biodiversity from the potential dangers of genetically modified organisms (GMOs).

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2 Frison, E.A. 1991. Phytosanitary aspects of genebank management. Pp. 53-59 *in* Proc. Inter-Centre Meeting on Germplasm Health and Movement, October 1990, Rome. International Board for Plant Genetic Resources, Rome.

3 Kahn, R.P. 1977. Plant quarantine: Principles, methodology and suggested approaches. *In* W.B. Hewitt and L. Chiarappa (eds), Plant health and quarantine in international transfer of genetic resources. CRC Press, Cleveland, OH, USA.

III. National and international plant protection regulations

A. National phytosanitary regulations

Almost all countries regulate incoming plant material because of the risk of pests and pathogens for agriculture. National phytosanitary regulations are in place in compliance with the IPPC. They usually:

1. Specify prohibitions
2. Grant exceptions for scientific purposes
3. Require import permits
4. Require phytosanitary certificates and/or certificates of origin
5. Stipulate inspections upon arrival
6. Prescribe treatment upon arrival to eliminate risks
7. Prescribe quarantine, post-entry quarantine, isolation or other safeguards[4]

Both small assignments of germplasm and bulk shipments of commercial material involve a potential risk. There are, however, important differences between the two. Germplasm assignments are generally small and have a relatively high value. The costs of applying therapy and testing procedures are, therefore, more reasonably absorbed. However, additional precautions may be necessary where either the germplasm itself or the area of origin is poorly studied from a pathological perspective. Detection of poorly characterized pathogens, particularly viruses, requires specialized tools. The procedure of exporting germplasm should, therefore, be specific to the species. A joint FAO/IPGRI programme is set up to generate crop-specific guidelines for disease-indexing and other phytosanitary measures, including the listing of important pests and diseases of concern. The guidelines are focused specifically on the movement of germplasm and are intended to provide scientific information to national quarantine authorities and to scientists wishing to exchange germplasm (Table 4.10.1). They are not intended for commercial shipments of seeds or other plant material and they have no officially recognized status.

B. International Plant Protection Convention

This legally binding convention aims to promote legislative and other measures to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. Its application is much wider than the protection of cultivated plants, and extends to the protection of wild flora. The range of pests covered by the IPPC extends to pests affecting directly plants, but also weeds and other species that have indirect effects on plants. Provisions cover not only plants and plant products, but also conveyances, storage places, soil and other objects or material capable of harbouring pests.

The IPPC came into force in 1952, and was amended twice. Latest amendments were adopted at the FAO Conference in 1997, which take account of the role of the IPPC in relation to the WTO-SPS Agreement. Under the Convention, provisions exist for the following:

- A national organization for plant protection (with responsibilities such as issuing certificates, conducting surveillance, inspecting plants, conducting risk analyses)
- Phytosanitary certification
- Phytosanitary measures
- Regulation of pests
- International cooperation

[4] *Ibid.*

As a result of the 1997 amendments, a Commission with a Secretariat is now formally established with the role of developing and adopting international standards and conducting other activities on technical assistance and information exchange. The secretariat is hosted by FAO, and 132 governments are party to the Convention.

Although the International Standards on Phytosanitary Measures (ISPM) (Table 4.10.2) are not legally binding, it is largely through their adoption that SPS measures are shaped. In applying phytosanitary measures, contracting parties have an obligation to comply with the Convention's principles, including necessity, technical justification and transparency.

Among ISPMs, several standards cover the analysis of pest risk (in particular ISPM No. 11: *Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*). These standards provide details for assessing risk and selecting risk-management options. These processes cover the assessment of the pest risk of all organisms. In particular, they take account of risks to the environment and biological diversity (including risks from weeds and invasive plants). They also include guidance on evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs, i.e., living GMOs).

C. The WTO and SPS

Since the creation of the General Agreement on Tariffs and Trade (GATT), international legislation has existed to protect plant, animal or human health where it is under risk from the introduction of traded goods. However, the concern that this legislation was open to abuse as an unnecessary barrier to trade gave rise to more recent agreements on Technical Barriers to Trade (TBT) and SPS measures. The two are complementary: the first sets down relevant technical requirements including labelling and inspection requirements, the second obliges parties to base SPS measures on science-based risk assessment. Parties are able to define their own SPS measures, but they should conform to standards adopted by the commission of the IPPC. Any more restrictive measures must be consistent and justifiable scientifically.

D. The Biosafety Protocol

In January 2000, in response to the nature of the debate about GMOs, Parties to the CBD adopted a supplementary agreement, the Cartagena Protocol on Biosafety. This agreement is devoted solely to the safe transfer, handling and use of LMOs, particularly concentrating on their transboundary movement across nations. The Protocol does not cover the introduction of exotic species in general, nor other products of biotechnology that have not been genetically modified. Like the CBD, the Biosafety Protocol is focused on safeguarding biological diversity, taking human health and safety into consideration.

The Cartagena Protocol covers all LMOs that are new or meant for intentional introduction in a country that is a signatory to the Protocol. The two major elements of the protocol are (1) the Advanced Informed Agreement (AIA) procedure, whereby importing countries agree to receive LMOs from exporting countries, and (2) the Biosafety Clearing House Mechanism; which will act as a resource for information exchange. The AIA process (Articles 7–12) differentiates procedures for LMOs for intentional introduction into the environment and those intended for direct use as food, feed or for processing (LMO-FFPs). Under the AIA, prior informed consent is needed for the first movement of LMOs for intentional introduction into the environment. The exporter must provide detailed information in advance of first shipment. The importer may then authorize or refuse shipment, depending on risk assessment. There is also a simplified procedure that allows importing countries to accept specified LMOs and to bypass the AIA procedure.

AIA procedure		
Notification by party of export ➔ (max 90 days)	Acknowledgement of receipt ➔ (max 270 days)	Communication of decision

The AIA mechanism involves notification, decision making and, if needed, review of decisions by countries exchanging LMOs that are destined for anything other than direct use as food, feed, processing or for contained use. The decision-making process, particularly risk assessment, is highly specific and should be conducted as per Annex III of the Protocol on Risk Assessment. Importing countries may take up to a year after notification by the exporter to come to some kind of decision. The exporter may be liable for the costs of the decision-making process.

The transboundary movement of LMO-FFPs (Article 11) is monitored and documented through a considerably less demanding process. Shipment of all LMOs, including those in transit or destined for contained use, are to be identified, and details on the taxonomy, origin and characteristics of donor and parent organisms, and other data on handling and storage, may also be demanded.

Article 20 of the Protocol establishes the Biosafety Clearing House to facilitate information exchange on LMOs, including scientific, technical, environmental and legal information, and sharing of experiences. It has been set up to assist Parties in implementing the Protocol. A pilot phase of the Biosafety Clearing House is currently operational. When fully functional, Clearing House will contain the following:

- National laws, regulations, guidelines
- Bilateral, regional, multilateral agreements
- Risk-assessment summaries
- Final decisions on importation or release
- Reports

The protocol emphasizes capacity building (Article 22 and 28), recognizing the need for and dearth of capacity, especially in developing countries. Capacity building includes strengthening regulatory, technological and institutional capabilities. It also includes training in safe management of biotechnology, risk assessment and risk management.

The protocol proposes basis requirements for Parties to ensure that measures are in place to manage risks to biodiversity posed by any LMOs. This could include a period of observation on newly developed or newly introduced LMOs, according to the life cycle of the organisms involved, before they are put to use. The protocol also calls for taking into account in the decision-making process those socio-economic conditions that arise from the impact of LMOs on biological diversity.

The protocol came into force in September 2004. To date, it has been signed by almost 100 countries, but some of the major exporters of GM crops, like the USA, Uruguay and Australia, have not signed the agreement. The relationship of the Protocol with other forms of international regulations (e.g., the WTO) is not very clear, although the preamble of the Protocol states that obligations to other international regulations remain unaltered and that the protocol should not be considered subordinate to other agreements.

IV. Conclusions

Controls on the movement of germplasm are mainly geared to prevent the spread of pests and diseases and are exerted through phytosanitary regulation at the national level. International policy attempts to harmonize these controls and ensure that their use is not employed as a barrier to trade. More recently conceived policy, in the form of the Cartagena Protocol, will govern the movement of LMOs through clear identification of shipments and a system of the notification and decision-making between importers, exporters and an information clearinghouse mechanism.

Addresses to the Websites of the Conventions	
Convention on Biological Diversity	http://www.biodiv.org
Cartagena Protocol on Biosafety	http://www.biodiv.org/biosafety
International Plant Protection Convention	http://www.fao.org/ag/agp/agpp/pq/default.htm
World Trade Organization–Sanitary and Phytosanitary Measures	http://www.wto.org/english/tratop_e/sps_e/sps_e.htm
World Trade Organization–Technical Barriers to Trade	http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

Table 4.10.1. Crops covered in the series of published FAO/IPGRI technical guidelines for the safe movement of germplasm

Allium spp.	*Eucalyptus*	Small grain temperate cereals
Cacao	Grapevine	Stone fruits
Cassava	Legume	Sugarcane
Citrus	*Musa*	Sweet potato
Coconut	Potato	*Vanilla*
Edible aroids	Small fruits	Yam

Table 4.10.2. International Standards for Phytosanitary Measures (ISPMs)

No.	Title	Date of Adoption/Status
ISPM 1	Principles of Plant Quarantine as Related to International Trade	1995, under revision (2005)
ISPM 2	Guidelines for Pest Risk Analysis	1996, under revision (2005)
ISPM 3	Code of Conduct for the Import and Release of Exotic Biological Control Agents	1996, under revision (2005)
ISPM 4	Requirements for the Establishment of Pest Free Areas	1996
ISPM 5	Glossary of Phytosanitary Terms	2004
	Glossary Supplement No. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests.	2001
	Glossary Supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations.	2003
ISPM 6	Guidelines for Surveillance	1997
ISPM 7	Export Certification System	1997
ISPM 8	Determination of Pest Status in an Area	1998
ISPM 9	Guidelines for Pest Eradication Programmes	1998
ISPM 10	Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites	1999
ISPM 11	Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms	2004
ISPM 12	Guidelines for Phytosanitary Certificates	2001
ISPM 13	Guidelines for the Notification of Non-Compliance and Emergency Action	2001
ISPM 14	The Use of Integrated Measures in a System Approach for Pest Risk Management	2002
ISPM 15	Guidelines for Regulating Wood Packaging in International Trade	2002
ISPM 16	Regulated Non-Quarantine Pests: Concept and Application	2002
ISPM 17	Pest Reporting	2002
ISPM 18	Guidelines for the Use of Irradiation as a Phytosanitary Measure	2003
ISPM 19	Guidelines on Lists of Regulated Pests	2003
ISPM 20	Guidelines for a Phytosanitary Import Regulatory System	2004