

The Global Perspective on ERA Regulations for GE Crops and Insects

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ILSI RESEARCH FOUNDATION

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All programs are for public benefit and focus on contributing to long-term solutions. This includes:



Sustainable Nutrition
Security



Environmental
Risk Assessment
of Genetically
Engineered Crops



Environmental
Risk Assessment of
Gene Drives



Genetically
Engineered Food
and Feed Safety
Assessment



Biosafety Capacity
Building

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Disclaimer

This presentation has been pulled together from publicly available resources and interpreted by the presenter

The views expressed are those of the presenter and are not:

- Legal advice for seeking regulatory permissions
- Not necessarily the views of any particular government

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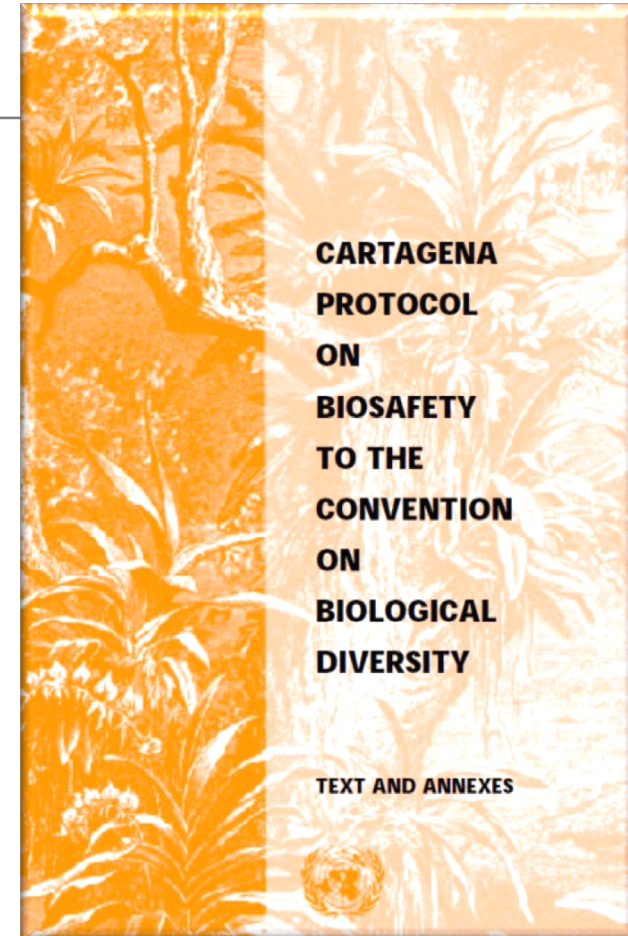
International Agreements

World Trade Organization – Standard Setting Bodies

- IPPC – International Plant Protection Convention
- OIE – Organization Internationale de Zoologique

Convention on Biological Diversity

- Cartagena Protocol on Biosafety

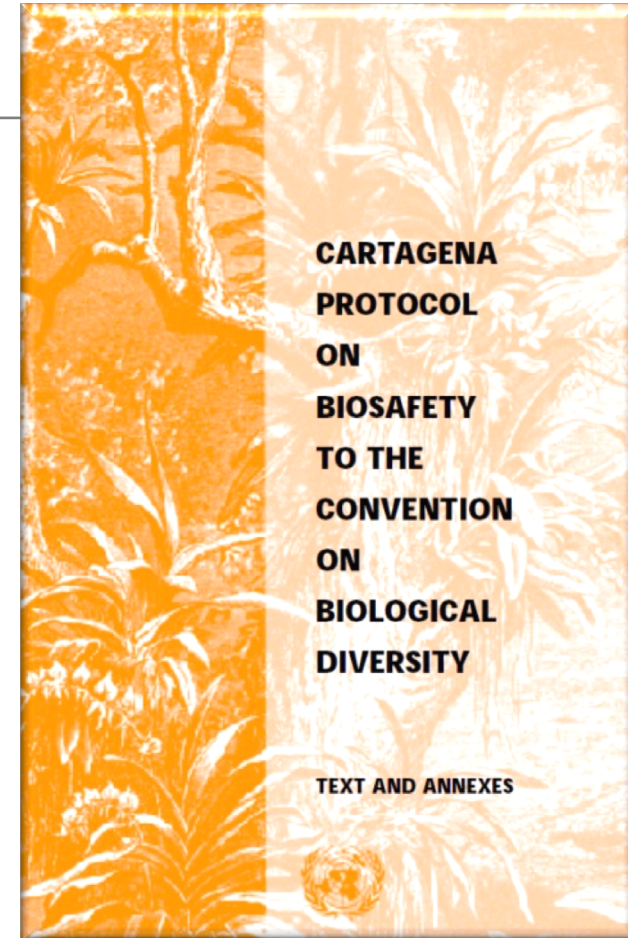


Cartagena Protocol

Small set of functional requirements

- Decisions about transboundary movement of LMO (living modified organisms) must be informed by risk assessment
- Notification of deliberate importation for environmental release
- Notification of accidental transboundary movement

Most countries that have implemented a Biosafety Framework have broadened the scope to domestic LMOs



How Are We Doing So Far?

There are 193 Countries in the World

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA)

- 23 countries growing GE crops
- 43 countries have issued some kind of decision (i.e. cultivation or food/feed import)
- Meaning 150 countries have yet to make a single decision about GE crops

Many countries have issued only one or two decisions

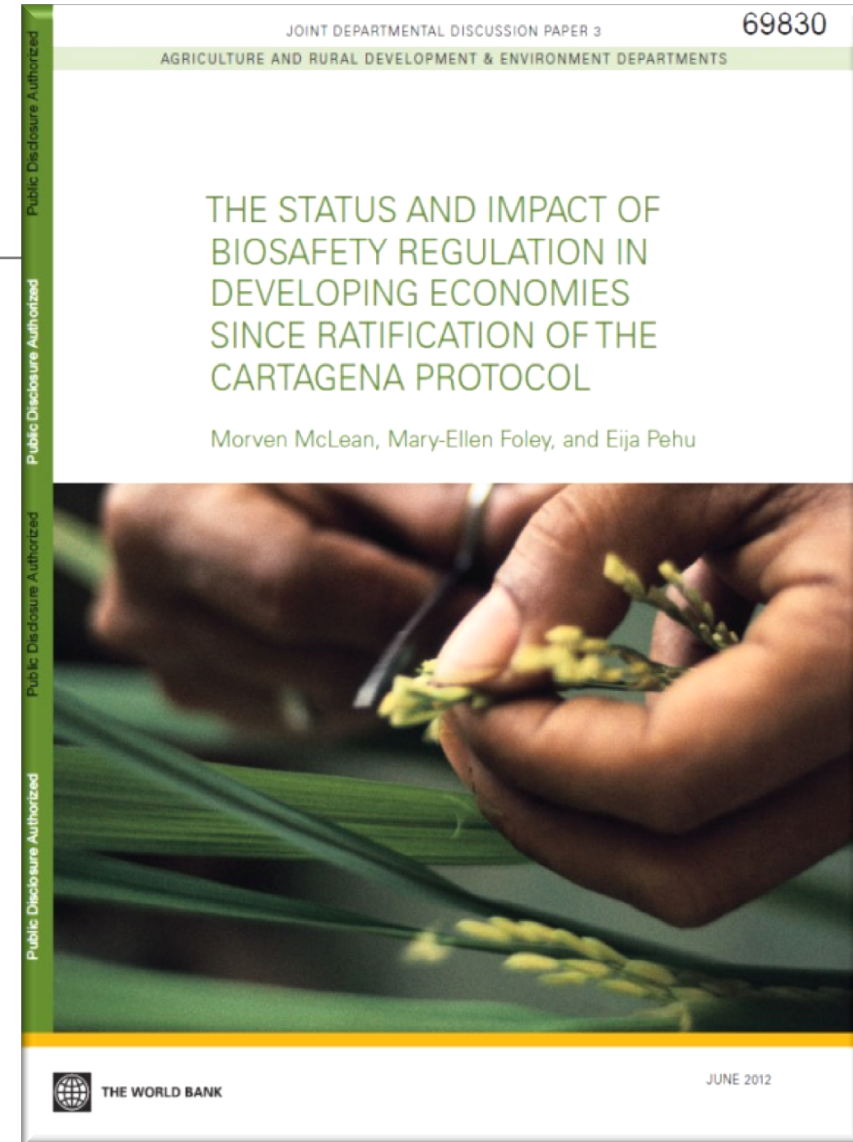
- After 25 years of commercial deployment and 18 since the finalization of the Cartagena Protocol, this doesn't seem great.

Implementation of Biosafety Frameworks

UNEP Global Environment Facility

- National Biosafety Framework Development Projects
 - 123 countries participated
- National Biosafety Framework Implementation
 - 65 countries participated

Most have never issued any decision



Typical National Biosafety Framework

National Biosafety Committee

- Policy level committee that is responsible for decision-making on individual importations and releases of GE organisms
- Also with approving regulations, guidance etc.

Technical Advisory Committee

- Academic advisors responsible for reviewing technical submissions and preparing an opinion to inform the National Biosafety Committee

Size and composition of these committees varies considerably, and there are many variations on this theme

National Biosafety Frameworks Globally

On paper, these should be more than adequate to develop guidance, receive and review applications, and issue decisions

In reality, very few of these frameworks are truly functional

There are a variety of reasons for this

- Including lack of national interest in the technology
- Availability of expert technical committee members
- Other national priorities for government officials

Moving a Biosafety Framework from paper to practice can take a while

Challenges for the Future

Many of the 150 countries that have not made any decision on GE crops (or insects) have serious agriculture and pest problems

- Climate change
- Global spread of pests and pathogens

Discussions under the Convention on Biological Diversity and Cartagena Protocol have not been very constructive

- Ad Hoc Technical Expert Groups
 - Spent ten years producing guidance that has not been endorsed by the Parties

A Note of Optimism

The interest in public health applications for GE insects in particular has the potential to change the dialogue

- Benefits to the public are direct, measurable and meaningful

Countries that are motivated to adopt the technology can adopt functional biosafety systems comparatively quickly

- Paraguay is one example

We have a significant knowledge base for structuring regulatory risk assessments

- Biocontrol activities
- Sterile insect releases

Narrative Summary

We have lengthy experience with GE crops demonstrating that they pose a low risk to the environment

AND

We have international legal frameworks to facilitate regulation

BUT

Most countries, and especially developing countries do not have FUNCTIONAL regulatory risk assessment

THEREFORE

If we want to see access to potentially beneficial technologies increase, we need to provide more impactful assistance

Thanks!

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