

Biosafety Regulatory Framework and Biosafety Education in Sri Lanka

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Challenges

Human health, wellbeing & Environment

- Increase in human population
- Unprecedented levels of consumption
- Population: 7 billion in 2011.....~ 8-11 b in 2050 (UNFPA, 2011)
- 1.3 billion poorest people (World Bank, 2012)
- Population increase...> Change in age structure
- Migration
- Urbanization
- Increased release of CO₂..... Acidifying oceans & waterways (IAEA, 2011)
- World has warmed by 0.8 C from pre-industrial levels (IPCC, 2007a)
- Melting of snow & ice
- Increased food production.....more land for agriculture
- Decrease in fish stocks.....due to increase in total fish production : 5fold in last 60 years
- Increase in total meat production : 5fold
- Dramatic loss of biodiversity (CBD, 2010) (GBO3:<http://gbo3.cbd>)

3 Pressing Challenges

Royal Society (2012)

- 1. **World's 1.3 billion poorest people**
 - Increase per capita consumption
 - Improve nutrition
 - Improve healthcare
- 2. **Developed countries**
 - Unsustainable consumption...must be reduced
 - Re-use equipment
 - Recycle material
 - Reduce waste
 - Find renewable energy sources
- 3. **Global population growth**
 - Slow and stabilize

Role of Science

- Improve understanding of **cause and effect**
- Limit the most **damaging trends**
- Consider **socio-economic dimensions** of technological deployment
- Show..full, transparent picture of the problems, uncertainties, efficiency of potential solutions, provide trusted source of information for policy-makers and the public
- Must **benefit the people** not only agri-business
- Should be **ecologically positive** (UN, 2011c)
- Solve problems **people care about**

- Everybody...needs access to sufficient food, water and fuel (UNDP, 2011)

- GDP: adopted as primary measure of national prosperity but it does not capture what is more valuable to human life ...freedom, security, health, social relations.....

Sri Lanka

- ‘Small’ island nation – next to ‘large’ nation
- Biodiversity ‘Hot Spot’
- Signatory – CBD, CPB
- Exports: Tea, Rubber, Ornamentals, Spices
- Rice, Corn
- Protect rich culture and values in modern high-tech world- How?

Biological Diversity of Sri Lanka

- One of 25 biodiversity hotspots ! **Millions of genes!**
- 65,610 km², 20 m people
- **Endemic species** – High
- Dragon flies 47%; Fresh water crabs 100%; Land snails 83%; Amphibians 85%; Reptiles 59%; Fresh water fish 54%
- Angiosperms 24%; Ferns 14%; Mosses 11%
- 400 Species of crop wild relatives

What are our needs?

- National Biotechnology Policy – Priorities
- 6 Key Themes
 - **Govt. commitment** for research, development and commercialization of biotechnology
 - Promote **public awareness** and position biotechnology in society
 - **Human resource development** to build capacity
 - Sustainable use of **biodiversity** for biotechnology
 - Enhance opportunities for **biotech-related industries** and entrepreneurship in agriculture, health, industry, energy and environment
 - Establish **Centres of Excellence** and Biotech. Parks

(some relevant) Strategies

- Promote manufacturing of **bio-products**, bio-fertilizer and bio-pesticides and bio-herbicides
- Improve **traditional biotech** processes such as fermenting, retting, composting and garbage recycling
- Establish a **national data bank/information centre** for biodiversity – DNA characterization, Molecular markers etc.
- **Bio-prospecting** of natural resources
- Efficient use of **germplasm in plant breeding** – including molecular breeding
- Promote **novel** breeding technologies
- Develop **value added** new agro-based food products
- Develop **P&D resistant crops** to reduce use of chemicals
- Discover **new genes** in our biodiversity- genes to cope with climate change, salinity, drought, floods

.....some more

- Promote studies on development of **GMOs**
- Improve **nutritional value** of crops & animals
- Improve **animal vaccine** production facilities
- **Develop sectors**: Agriculture & livestock; Fisheries & aquaculture; Plantations; Forestry
- Develop **industrial biotech** sector – mainly microbial sector
- Promote **bio-energy/biofuels**; develop bio-diesel and algal bioenergy; develop plant biomass, optimize biogas reactors; microbial fuel cell systems; conversion of solid waste
- Treatment of household, agricultural and industrial **waste**
- Promote use of **bio-sensors**; develop biofertilizer, biopesticides
- **Bioremediation** of degraded lands and polluted waterways

Ministry of Agriculture

Immediate Attention

- **Seed and Planting material** – Development & Distribution
- Increase production: Onions, Pulses, Chilli, Groundnut
- Develop appropriate technology & dissemination – **Rural knowledge revolution**
- Supply chain management, storage, processing and marketing
- **Climate change** and adaptation- sea level, drought, salinity...
- Intervention in **dietary patterns** and consumer behaviour in food
- **3-season** rice cultivation
- **Mid-season** cultivation of other field crops

Mahinda Chinthana – Vision for a New Sri Lanka

Agricultural Sector Policy

- Achieve **food security** – Gene banks, seed banks, grain banks, water banks – import substitution
- Productivity enhancement – **high-tech agriculture**
- Facilitating marketing & related infrastructure
- Adopting stable trade policies
- Providing rural financing
- Reduce **post-harvest losses**
- Enhancing agricultural research – **involve private sector**
- Exchange of **agriculture information** – assist farmers in marketing
- **Technology dissemination**

..... more

- Participation of **community based organizations** (CBO)
- Minimizing **environmental degradation**- e.g. **Bioshield**
- Utilizing and **sharing plant genetic resources** – benefit sharing
- Enhanced **youth involvement** – scientific farming + modern technology
- Ensure **seed and planting material** production – public + private sector interaction
- Encouraging culturally, nutritionally and traditionally important **heritage food crops** – **Traditional Wisdom**
- Enhancing agricultural **export base**
- Transforming current net importer status of foods to **net exporter status**
- **“Economic access to food >>> physical access”**

The CBD

- **Convention on Biological Diversity** – finalized in Nairobi – May 1992
- **CBD** – opened for signature at UN conference in Rio de Janeiro – June 1992
- **CBD** - entered into force – **29 December 1993**

CBD addresses **Biosafety** issues

- Conservation of biological diversity
- Sustainable use of natural resources
- Fair & equitable sharing of benefits derived from the use of **genetic** resources/**biological** resources
- **BIOSAFETY** – the need to protect human health and environment from possible adverse effects of products of modern biotechnology

Modern Biotechnology –Twin Aspects

- * Benefits & Concerns

- Article 16, para 1:
 -
 - Each Contracting Party, recognizing that technology includes **biotechnology**, and that both **access** to and **transfer** of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to **provide and /or facilitate access for and transfer to other Contracting Parties** of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of **genetic resources** and do not cause significant damage to the environment.
- * Biological / Genetic resources
- * Technologies : ‘owned’ by private sector - price
- Biological resources: ‘owned’ by public

CBD – Article 19, para 1 & 2

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in **biotechnological research activities** by those Contracting Parties, especially developing countries, which provide the **genetic resources** for such research, and where feasible in such Contracting Parties
2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the **results and benefits arising from biotechnologies** based upon **genetic resources** provided by those Contracting Parties. Such access shall be on mutually agreed terms.

CBD - Article 8 (g) – National Level

Establish or maintain means to regulate, manage or control the **risks** associated with the use and release of living modified organisms resulting from **biotechnology** which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

CBD - Article 19, para 3 –The Parties shall consider the need for and modalities of a **protocol** setting out appropriate procedures, including, in particular, **advance informed agreement**, in the field of the safe transfer, handling and use of any living modified organism resulting from **biotechnology** that may have adverse effect on the conservation and sustainable use of biological diversity.



**CARTAGENA
PROTOCOL
ON
BIOSAFETY
TO THE
CONVENTION
ON
BIOLOGICAL
DIVERSITY**

TEXT AND ANNEXES

Cartagena Protocol on Biosafety

- Finalized and adopted – Montreal, 29 Jan. 2000
- *“ensure an adequate level of protection in the field of the safe transfer, handling and use of LMO resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movement (importation)”*
- Based on **Precautionary principle** ;
- *“Lack of scientific certainty of the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity, on the environment and human health may be due to insufficient, relevant scientific information and knowledge. This shall not prevent a country from taking appropriate steps/precautions with regards to the import of GMOs, in order to avoid or minimize such potential adverse effects”*
- **2006: > 140 countries signed CP**

National Biosafety Framework

Focal Point ?

- Signed Biosafety Protocol : 24 May 2000
- Ratified: 28 April 2004
- National Focal Point: Ministry of Environment & Natural Resources
- NBFSL Project : May 2003
- UNEP/GEF
- 5 Main Elements: Precautionary principle + Advance Informed Agreement
- Regulatory Regime
- Administrative System
- Risk Assessment & Management
- Public Participation
- National Biosafety Policy

Elements of the Framework

- 1. Regulatory system
- 2. Administrative structure
- 3. Risk Assessment & Management
- 4. Mechanism for public participation
- 5. Biosafety Policy

I. Regulatory System

- National Biosafety Law
- Existing regulations
- Food Act : Ministry of Health
- Plant Protection Act of 1999 : Ministry of Agriculture

Legal background for the risk assessment of GMOs, GM Food

- **Food (Control of Import, Sale and Labelling of Genetically Modified Foods) Regulations 2006**

- Published in Gazette No 1456/22 –
August 03, 2006

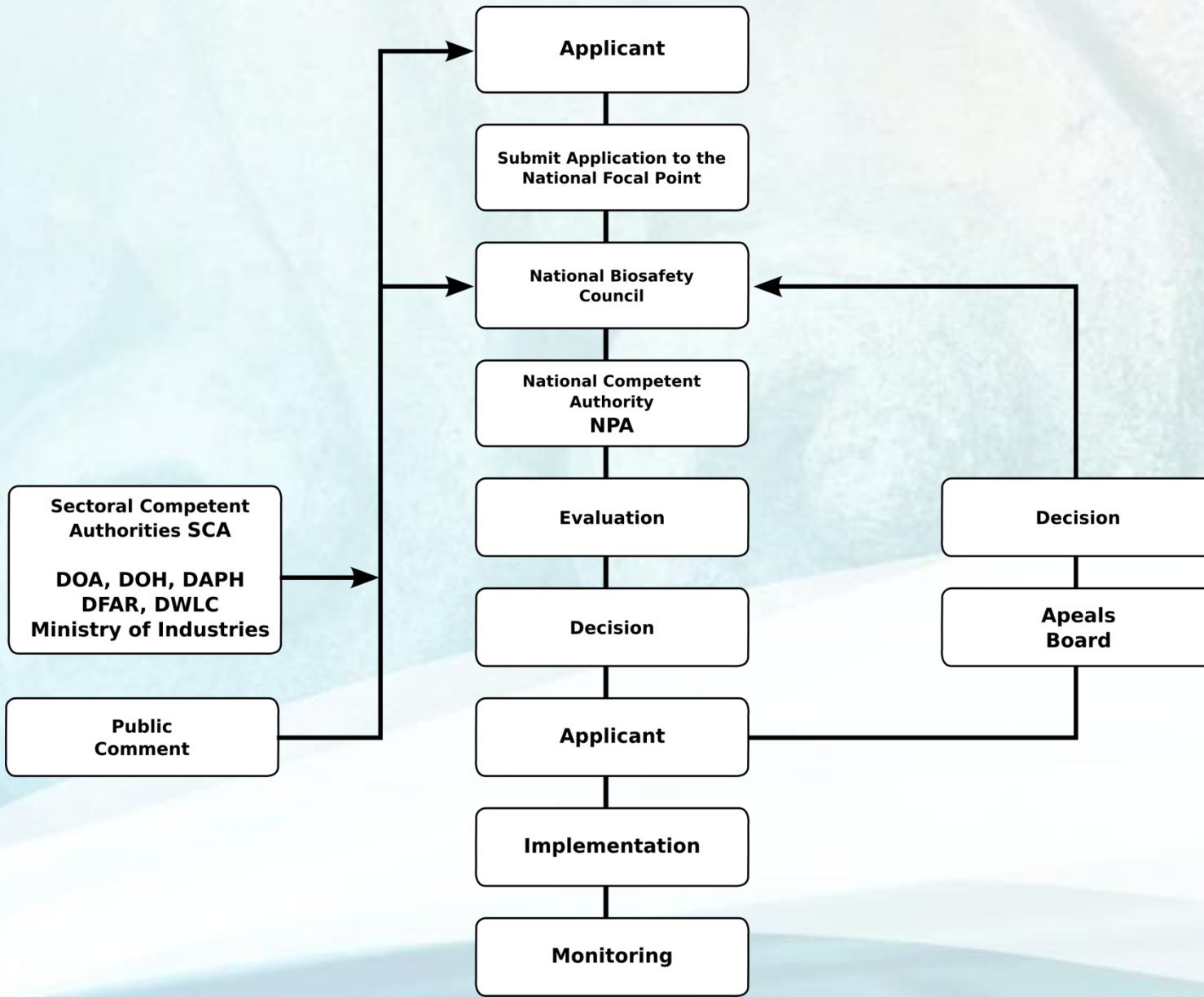
How it works.....

- Applicant.....> Chief Food Authority.....**acknowledge <=15days**



National Biosafety Framework

continues



E.g. Safety Assessment of GM Food

- Description of **rDNA plant** – crop, type/purpose of modification
- Taxonomic **classification** – history of cultivation, known toxicity...
- Description of **Donor** organism-...pathogenicity, history of safe use..
- Description of genetic **modification** – characterization of cassette, sequence data, open reading frames, no. of inserted sites.....
- Description of **transformation** process – method, helper plasmids?.....
- Characterization of all **DNA** transferred- marker genes, regulatory elements, orientation of sequences.....
- **Safety assessment:**
- **Expressed products**, phenotype of new trait, level and site of expression, levels in edible portions, rearrangements after insertion, post-translational modifications of proteins. Inheritance and stability through several generations, effect on other genes.....
- Compare with **non-transformed plant** in growing environments
- Evaluation of **metabolites** – potential for accumulation in food
- Food **processing** – effect on protein in home preparations
- Nutritional **modification** – intake for population groups such as infants, children, pregnant/lactating mothers, elders, with chronic diseases...

At present only six Institutes were identified as Competent Authorities .

Category	Competent Authority	Contact Details
1. Wild Animals	1. Director General, Department of Wildlife Conservation	Department of Wildlife Conservation, 18, Gregory's Road, Colombo, Sri Lanka Tel: + 94 112 695043; 698086 Fax: + 94 112 698556 e-mail:
2. Domesticated Animal and Animal Medicines	2. Director General, Department of Animal Production and Health	Department of Animal Production and Health, 1120, Kandy Road, Peradeniya, Sri Lanka Tel: + 94 812 388195 Fax: + 94 812 388619 e-mail:
3. Fish and other Aquatic Organisms	3. Director General, Department of Fisheries and Aquatic Resources	Department of Fisheries and Aquatic Resources, New Secretariat, Maligawatta, Colombo 10, Sri Lanka Tel: + 94 112 449170; 442187 Fax: + 94 112 449170 e-mail:
4. Plants and Plant Materials	4. Director General of Agriculture, Department of Agriculture	Department of Agriculture, Peradeniya, Sri Lanka Tel: + 94 812 388157 Fax: + 94 812 388333 e-mail:
5. Food and Pharmaceuticals	5. Director General of Health Service, Department of Health Service	Department of Health Services, 385, Suwasiripaya, Colombo 10, Sri Lanka Tel: + 94 112 698543; 694860 Fax: + 94 112 693869 e-mail:
6. Industrial Products	6. Secretary, Ministry of Industries	Ministry of Industries, 356, NPC Building, Second Floor, Union Place, Colombo 2, Sri Lanka Tel: + 94 112 343937 Fax: + 94 112 432783

Risk Management

- Identify the risk – what, when, how
- Analyze the risk – magnitude & frequency of occurrence
- Evaluate the risk – compare with pre-determined standards, target risk levels
- Assess the risk – overall analysis & evaluation
- Treat the risk – Selection & implementation of appropriate options to deal with risk

National Biosafety Policy

Sri Lanka

1. Ensure the highest possible level of biosafety in transfer, handling and use of genetically modified organisms on the basis of the precautionary approach.
2. Develop the national biosafety framework and all its components.

I The **major policy objectives** are as follows:

- *Implementation of biosafety measures in order to ensure that there will be no significant adverse effects on human health, the environment and biodiversity.
- *Ensure effective regulation and management of GMO/FFP that may be imported to Sri Lanka, based on the Advance Informed Agreement.
- ***Regulate and manage any locally produced GMO/FFP.**
- *Promote dissemination of knowledge in the safe use and probable hazards of modern biotechnology.
- *Emphasize biosafety and bioethical considerations in the development and application of modern biotechnology
- *Provide an institutional framework for national decision-making, networking, monitoring R&D, and international cooperation in all matters relating to biosafety.
- *Promote public participation in the decision making processes of all matters related to biosafety in order to maintain transparency in the process.

- **Policy Principles**

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- Sri Lanka shall ensure that biosafety regulations are established based on the precautionary principle and the advanced informed agreement.
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- Sri Lanka shall place utmost importance on developing its own capabilities in all aspects of biosafety
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- The manufacture, use, import, export, sale or trans-boundary movements of modern biotechnology applications, practices and products shall conform fully to all relevant national legislations.
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- Public awareness, education and participation in the decision-making processes shall be made essential for ensuring the judicious use of modern biotechnological applications, practices and products for socio-economic development, without jeopardizing the environment, biodiversity and human health.
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- Risk assessment and management of GMO/FFP shall be carried out according to national biosafety regulations. Where scientific risk evaluation of a biotechnology product, application or procedure gives rise to a negative recommendation, this shall not be overruled.
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- As a matter of public health protection and democratic governance, the industries involved in the use of modern biotechnology shall reveal information on organisms used and all other relevant data in order that consumers are aware of the substances they are exposed to. Safety test data, especially for agricultural biotechnology and human genetic testing, manipulations and applications, shall be fully disclosed and made public.
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- Some international fora favour commercial considerations over public health, environmental and safety interests. Decisions on biosafety issues shall be made in fora that do not suffer from this structural orientation.
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– Policy Statements

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- Recognizing the importance of protecting its people, environment and biodiversity while promoting a sustainable social and economic development through the safe use of modern biotechnology,
- Recognizing the human and environmental health risks that may be incurred by careless or unscrupulous development of modern biotechnology and the use of its products for agriculture, health, waste management and other purposes,
- Realizing the need for developing our own capabilities in biosafety through research & development and training and
- Reaffirming the commitment to the obligations of the CBD and CP
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- 2.3.1 **An Apex Body** [termed The National Council for Biosafety (NCB)] shall be appointed by the Ministry of Environment and Natural Resources, which is the National Focal Point for Biosafety. It shall be the controlling authority for all issues relating to biosafety in Sri Lanka, including R&D, development of industry linkages, establishment of relevant legislations, protocols and guidelines.
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- 2.3.2. **Labeling of genetically modified products** shall be made mandatory. Compulsory labeling will be required for all products resulting from modern biotechnology, at all stages of the production process, from raw material to final product, in order that the demands of consumers for a free and informed choice regarding food are fulfilled.

- 2.3.3. **National safety guidelines** and implementation practices shall be adopted by industries using modern biotechnology. The guidelines shall cover all related aspects, including material handling, equipment, storage, waste disposal, laboratory safety, etc.
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- 2.3.4. **GM detection and analytical food safety laboratories** to generate scientific data, as well as resources for risk assessment and management, shall be identified, established and supported. They shall be accredited under the NCB.
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- 2.3.5. Priorities in **Human Resource Development** in Biosafety shall be assessed identified and developed.
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- 2.3.6. **Public awareness** of modern biotechnology and potential risks/benefits, risk assessment and management techniques shall be enhanced, involving the community at large, including policy makers, legislators, administrators, the private sector and biotechnology industries. Special courses in natural sciences, technology and ethics at academic level shall be offered to personnel, who in their professional activities come into contact with biosafety issues and their ethical applications.
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- 2.3.7. **Research** into the risks to the environment and human health that can be caused by modern biotechnology shall be supported. Adequate funds shall be allocated to implement such programmes.
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- 2.3.8. **Safety standards** shall be reviewed and updated at appropriate intervals to incorporate local or global changes in modern biotechnology.
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- 2.3.9. Appropriate knowledge bases and infrastructure for **information exchange** on biosafety shall be established and developed.
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- 2.3.10. A **Master Plan** for Biosafety shall be established and used to implement the strategies and to develop the infrastructure and instruments outlined in this policy.
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Public Awareness

Biosafety Education

- **Public Awareness** : actively participate in decision-making procedure
- What is a gene? Relationship to characters; What is DNA? Control of gene expression/regulation; What is a GMO? Present global status What are the risks & concerns?
- Production of GMO/FFPs : Plants, Animals, Microbes
- Risks & Concerns: Human health; Biodiversity; Environment; Socio-economic; IPR etc
- Public: Science-based – scientists; undergrads/postgrads; Doctors
- Non-science based – Lawyers; farmers; teachers; school children; consumers; media

Biosafety Education

- Secondary
- Tertiary
- Postgraduate
- Training programmes - teachers
- Publications

Postgraduate Course

- AB 5229 Genetically Modified Organisms, Food, Feed and Processed Products and Biosafety (1)
- Convention on Biological Diversity – CBD and its relation to Biotechnology, Status of Genetically Modified Organisms (GMO), Food, Feed and Processed Products (FFPs), Advantages, Risks and Concerns, Cartagena Protocol, Risk Assessment and Management, Biosafety Policy, Detection of GMO and FFP, Legislations

- Transparent in what we know
- Need to know what we don't know
- Freedom of choice to the public
 - Gross Domestic Happiness

Thank you

