STATUS OF GM CROPS IN INDIA: RESEARCH AND REGULATORY SYSTEM

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MINISTRY OF SCIENCE AND TECHNOLOGY
GOVERNMENT OF INDIA

BIOLOGY----BIOTECHNOLOGY----BIOECONOMY
Today Topics

• Policy and Government
• Research and technology Development
• Regulations
• Are we ready for the future
National Biotechnology strategy (2006---------)

International coop
R&D

BioSafety
1986

Equipment and infrastructure

Human resource Development

1996 Transgenic Research

2002 commercial Bt cotton

IPR
PPP

Technology licensing

Funds

1980

Development Of Biotechnology innovation and development policy In India

2000
National Biotechnology Development and Innovation Strategy 2006

Policy Framework and Strategic Actions

An inter-ministerial / multi-sectoral effort
The strategy

Vision

“To create ecosystem of innovation for development of tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy”
Promotion of excellence innovation and technology development

- Discovery led innovation (2410)
- Centres of excellence (50)
- Networks (52)
- New Institutions (6)
- Grand Challenges (5)
- Global Partnerships (16)
- Bio-clusters (3)
- Translational Platforms (10)
- Public-Private Partnerships (100)
Investments in product range

- Biotherapeutics and cell therapy
- Vaccines and adjuvants – human and animal
- Diagnostics, biomarkers, biosensors
- Transgenic crops and marker-assisted breeding
- Bioenergy
- Nutraceuticals
- Nano-biotechnology
- Bio equipments, implants and devices
- New, greener manufacturing processes and technologies
- Genomics and proteomics science

In the last 5 years about Rs 400 crore (US $100 m) has been invested in transgenic research, human resource, regulation and infrastructure in public sector.
Today Topics

• Policy and Government
• Research and technology Development
• Regulations
• Are we ready for the future
Agricultural Biotechnology
Policies, Priorities and Schemes

**NEEDS**
- Productivity gains
- Enhanced nutrition
- Ensuring quality
- Resistance to pests and diseases
- Resistance to drought
- Salinity, high temperature

**Technology focus:**
- Discover genes
- Genetic engineering
- Molecular marker assisted breeding
- Biofertilisers
- Biopesticides
Agricultural Biotechnology Strategy

Capacity Building
• Human Resource Development
• Creation of Research Facilities
• Institutions Building

Research & Development
• Promoting Basic & High End Research
• International Collaboration
• Translational Research for Product Development
• Public-Private Partnership

Developing Biosafety Regulatory System
Human Resource Development

- 14 State Agricultural Universities offer Post Graduate courses
- PG Diploma on Regulatory Aspects
- Award 100 Doctoral, Postdoctoral & Overseas Associateships

Institutions & Facilities

- National Institute for Plant Genome Research
- Automated high-throughput DNA sequencing facilities at NIPGR, UDSC and IARI, New Delhi.
- National Containment – cum - Quarantine Facility for transgenic planting material established at NBPGP, New Delhi
- National Plant Gene Repository NIPGR, New Delhi.
- Technology Platform for Translational Research on Transgenic Crops set up at ICRISAT
- National Agri-Food Biotechnology Institute (NABI) & Bioprocessing Unit (BPU) in the Agri-food Biotech Park at Mohali, Punjab
R&D Programmes

- Coordinated Network Projects (Approx. 300 Sub-projects)
- Projects under International Collaboration (20 projects) (with US, Canada, Australia, UK, Finland, Switzerland etc.)
- Programme Support for SAUs: 4 Universities/31 Sub-projects
- Centre of Excellence and Innovation in Biotechnology: 3 COEs & programme support for 5 projects
- Public-Pvt. Partnership: For early stage research or late developmental activities (20 projects)

More than 100 projects relate to Basic and product development through transgenics
## Today Of Transgenic Research in India

<table>
<thead>
<tr>
<th>Crops</th>
<th>Traits</th>
<th>Research Institutions</th>
<th>Companies</th>
<th>Total Engaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>18</td>
<td>50</td>
<td>45</td>
<td>235</td>
</tr>
<tr>
<td></td>
<td></td>
<td>140</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Examples Crops & Traits being focussed under Public R&D programmes

Rice: Tolerance/resistance to drought and salinity, tungro virus, gall midge, bacterial leaf blight, biofortification,

Wheat: Breeding for quality traits, heat tolerance, biofortification,
Resistance to leaf and stripe rust, karnal bunt, powdery mildew

Cotton: Fibre strength and oil content, gene stacking in Bt.Cotton

Maize: Quality protein, biofortification,

Brinjal: Resistance against fruit & shoot borer

Mustard: Seed yield and oil content, Low glucosinolate, Aphid resistance

Soybean: Resistant to yellow mosaic virus

Chickpea: Resistance against pod borers

Sorghum: Shoot fly resistance

Groundnut: Resistance against TSV Virus
Biotechnological intervention for improving productivity of Underutilized/orphan crops

**Biotechnological intervention for improving productivity of Underutilized/orphan crops**

**Finger millet**  
*Eleusine coracana*  
widely grown as a cereal in the arid areas by small farmers of India.

**Field bean**  
*Lablab purpureus*  
widely grown as a Pulse in the arid areas small farmers of India.

**Nutritive value (per 100 g)**

<table>
<thead>
<tr>
<th></th>
<th><strong>Finger millet</strong></th>
<th></th>
<th><strong>Field bean</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>7.3 g</td>
<td></td>
<td>22 g</td>
</tr>
<tr>
<td>Fat</td>
<td>1.3 g</td>
<td></td>
<td>2 g</td>
</tr>
<tr>
<td>CHO</td>
<td>72 g</td>
<td></td>
<td>61 g</td>
</tr>
<tr>
<td>Minerals</td>
<td>2.7 g</td>
<td></td>
<td>0.8 g</td>
</tr>
<tr>
<td>Calcium</td>
<td>344 mg</td>
<td></td>
<td>344 mg</td>
</tr>
</tbody>
</table>

**Abiotic stress**  
**Drought**
First demonstration of RNAi-based protection against a plant DNA virus

Only traces of viral DNA were detected in recovered blackgram plants

About 35 projects develop transgenics through RNAi approach out of total 120 projects

Semi-quantitative PCR

Leaf:
- lower
- upper
- lower
- upper
Tackling ‘Hidden Hunger’ by Biofortification

- Micronutrient malnutrition or ‘hidden hunger’ is a global problem
- No single strategy can solve this problem – need for an integrated strategy
- **Biofortification** is a sustainable intervention
  - No additional cost once varieties are adopted
  - Can reach the poor

Fe, Vitamin A and Iodine deficiency (Source: USAID)
DBT Network Project on Biofortification

- Multi-location analysis of genetic variability for kernel micronutrient traits (Fe & Zn) in rice, wheat and maize germplasm
- Identification and validation of molecular markers associated with the target traits
- Molecular marker-assisted breeding for micronutrient enrichment in the target crops
- Analysis of bioavailability
Golden rice - Vitamin A deficiency

**Problem**: Rice is major Staple and does not contain Provitamin A

**Consequences**: 400 million rice eating poor suffer from vitamin A deficiency; 6000 die per day and 500,000 become blind every year

**Answer**: Biofortification: improvement of the micronutrient content of the crops on genetic basis

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**Golden rice** contains genes introduced through genetic engineering required to activate the biochemical pathway leading to accumulation of pro-vitamin A

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Indian Rice lines with 8-25 µg/gram of rice produced by breeding and ready for field testing. Lines with 16µg/gram of rice are enough to meet 50 percent of RDA.
Allium sativum (garlic plant)

Regeneration of transgenic lines
transgenic plant insects

In planta bioassay

Homopteran pests suck plant phloem sap using their stylets

Rice (Oryza sativa)

Mustard (Brassica juncea)

Chickpea (Cicer arietinum)

Discovery led innovation

ASAL (Allium sativum leaf agglutinin) gene isolated from garlic

Chimeric ASAL gene construct in plant transformation vector

Plant expressed lectin bound to the insect gut

Binding of garlic (Allium sativum) leaf lectin to the gut receptors of homopteran pests is correlated to its insecticidal activity
Simultaneous Transfer of Insect Resistance Chickpea Transgenic Technology from public sector to private seed company and Agriculture University for commercial and public good development
## Transgenic crops developed in public sector in regulatory field trials

<table>
<thead>
<tr>
<th>Crop</th>
<th>Organisation</th>
<th>Trait</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brinjal</td>
<td>IARI, New Delhi</td>
<td>Insect Resistance</td>
</tr>
<tr>
<td>Castor</td>
<td>Directorate of Oilseeds Research (DOR), Rajendranagar, Hyderabad</td>
<td>Insect resistance</td>
</tr>
<tr>
<td>Sorghum</td>
<td>National Research Centre for Sorghum (NRCS), Hyderabad</td>
<td>Insect resistance</td>
</tr>
<tr>
<td>Groundnut</td>
<td>ICRISAT, Hyderabad</td>
<td>Fungal disease resistance</td>
</tr>
<tr>
<td>Potato</td>
<td>Central Potato Research Institute (CPRI), Shimla</td>
<td>Leaf blight disease resistance</td>
</tr>
<tr>
<td>Rice</td>
<td>IARI, New Delhi, Tamil Nadu Agricultural University Mahyco, Mumbai</td>
<td>Fungal diseases resistance and drought tolerance</td>
</tr>
<tr>
<td>Tomato</td>
<td>IARI, New Delhi</td>
<td>Virus disease and drought resistance</td>
</tr>
</tbody>
</table>
ICAR Network on Transgenics in Crops

ABIOTIC STRESS TOLERANCE
## World’s Top Ten Seed Companies doing business in India

<table>
<thead>
<tr>
<th>S.N</th>
<th>Seed companies</th>
<th>Seed sale (US $ million) 2004</th>
<th>Seed sale (US $ million) 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monsanto (USA)</td>
<td>2,803</td>
<td>1,800</td>
</tr>
<tr>
<td>2</td>
<td>Dupont (USA)</td>
<td>2,600</td>
<td>1,835</td>
</tr>
<tr>
<td>3</td>
<td>Syngenta (Novartis)(SWD)</td>
<td>1,239</td>
<td>1,000</td>
</tr>
<tr>
<td>4</td>
<td>Groupe Limagrain (France)</td>
<td>1,044</td>
<td>733</td>
</tr>
<tr>
<td>5</td>
<td>KWs AG (Germany)</td>
<td>622</td>
<td>370</td>
</tr>
<tr>
<td>6</td>
<td>Land O’ lakes (USA)</td>
<td>538</td>
<td>370</td>
</tr>
<tr>
<td>7</td>
<td>Sakata (Japan)</td>
<td>416</td>
<td>349</td>
</tr>
<tr>
<td>8</td>
<td>Bayer crop science (Germany)</td>
<td>387</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>Taikii (Japan)</td>
<td>366</td>
<td>300</td>
</tr>
<tr>
<td>10</td>
<td>DLF Trifolium (Denmak)</td>
<td>320</td>
<td>-</td>
</tr>
</tbody>
</table>
Foreign R&D Centres

Foreign Centers in Seed Research

- 33 companies having R&D centres in sectors.
  - Genetic diversity and good mix of heterogeneous market segments.
  - Good mix heterogamous market segment.
  - Export potential in tropical to subtropical to some extent temperate.
  - Changes in the stock of knowledge generate new techno-economic opportunities that stimulate and encourage the private sector to undertake developmental research.
  - Regulations, IPR
Next Generation Challenge Programme on Chickpea Genomics

National Institute of Plant Genome Research

Gene/allele discovery

Genetic enhancement for stress tolerance, yield and nutrition
International Tomato Genome Sequencing Project

The diagram illustrates the sequencing project involving 12 countries, each represented by a flag. The project aims to sequence the tomato genome. The lengths of the bars represent the amount of DNA sequenced by each country, measured in millions of base pairs (Mb). The scale at the bottom indicates the range from 0.0 μm to 70.0 μm, with specific measurements shown for each country's contribution.
The International Wheat Genome Sequencing Consortium (IWGSC)

An internationally coordinated sequencing of bread wheat genome for accelerating wheat improvement

Indian Partners

DBT, NIPGR, UDSC and IARI (ICAR)
Wealth of Genes and DNA markers from Genome Research

✓ 15 genes in 12 reproduction and vegetative stages of rice
✓ 500 stress response genes in rice
✓ 1000 EST sequences from Jatropha
✓ 150 SSR markers in 200 stress patic EST database in coffee
✓ 400 EST in mulberry
✓ 4000 buffalo EST markers
✓ 100 SNP markers for buffalo
✓ 4 genes for alkaloid synthesis in pepper
✓ SaltGenes from Mangroves
✓ Genes for alkaloid in sandal wood
✓ 35500 ESTs in silkworm
✓ Garlic lectin gene for sucking pests
✓ 15000 STMS markers in chickpea
Complexity with Research Development and Commercialization of Bt cotton Transgenics

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Development</th>
<th>Commercia-</th>
<th>Public acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASIC RESEARCH</td>
<td>APPLIED RESEARCH</td>
<td>VERIFICATION AND VALIDATION</td>
<td>FIELD TRIALS</td>
</tr>
<tr>
<td>DEVELOPMENT</td>
<td>BREEDING LINE DEVELOPMENT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **EPA Act/rule**
- **Industry Act**
- **Patent Act**
- **Insecticides Act, 1968**
- **Plant variety protection and farmer rights**
- **Liability & redress**
- **Labeling**

- **Seed Act and rules**
- **PFA/food safety Acts**
- **Consumer Act**

**Gene delivery**

**Transgenics**

**Molecular analysis**

**Sd t d l b**

**environmental impact**

**coordination**

**ICAR/SAUs**

**certification of seeds**

**Ls t d t d l a b testing**

**Green house testing**

**PFA/food safety Acts**

**Consumer Act**
Shared Infrastructure, Facilities And Services For Translational Research And Product Development

Translational Platform Model

- Technologies from Indian Research & Academic Institutes Universities and ICRISAT
- Filter
  - Scientific Advisory Board
  - Evaluation Panel
  - Recommendations
- Projects
  - Traits
  - Events
  - Technology
  - Other
  - Evaluate
  - Advance “events”
  - Advance traits
  - Development
  - Product Dossier
- Select
  - Focus
  - Criteria
  - Need
  - Value
  - Biosafety

DBT-ICRISAT
Platform for translational Research on transgenic Crops

Commercial Advancement

Public Sector Advancement

NARS
Seed Companies
Farmers
Translational SMEs Biotech Programme
With new Governance

National Clinical Development Services Agency
with multiple functions, and Phase I – IV capacity
To be set up in NCR Biotech Cluster

- CRO for agri-biotech translation and field trials
  Established in partnership with ICRISAT, Hyderabad
Encouraged proactive funding to promote SME R&D

A biotechnology finance life cycle

1. Start-up Prototype
2. Early Stage/ patenting
3. Development and trails
4. Expansion & Growth

SBIRI  BIPP NIMTLI ; TDB;

Grants
3 F’s, joint research
Informal VC (Business Angels) & seed corn, some formal VC, corporate venturing
VC and corporate venturing
IPO and /or Buyout
Public-Private partnerships

Small Business Innovation Research Initiative (SBIRI)

Eighty nine projects supported Seventy six companies have been benefitted

Technologies developed

- Foligraf (Recombinant Follicle Stimulating Hormone)
- Kit for RBC phenotyping
- Packed Bed Bioreactor’ (PBBR) & ‘Suspended Bed Bioreactor (Nitrifying Bioreactor),
- Rapidec (Automated Dispensing system)
- Rasburicase (Recombinant Uricase)
- Corel C++ (Non-Porous Drug Eluting Stent)
- Automated Cell Counter
- Seriheal (Silk Protein blend film for wound management)
- Pelrich Plus, Soil Nxt (Planting medium)
- Chitin (biopolymer), Astaxanthin (carotenoid)

More success stories on the way…. 
Projects category and products from SBIRI

- Healthcare: 46, 51%
- Agriculture & allied areas: 13, 14%
- Industrial products and processes: 22, 24%
- Instrumentation & Devices: 6, 7%
- Bioinformatics: 3, 3%
- Environmental: 1, 1%

Rapidec: An auto-dispenser

FOLIGRAF: Recombinant human follicle stimulating hormone (commercialized)
BIOTECHNOLOGY INDUSTRY PARTNERSHIP PROGRAMME (BIPP)
An Advanced Futuristic Technology Scheme (ATS)
to support Discovery and Innovation in Industry

Scheme Launched: November 2008
First Call Launched: December 2008
Total Rounds of Proposals processed: 14
Total Proposals Received: 450
Process automated 6th Batch onwards (Feb 2010)

Approved Projects: 60
Agreements Executed: 60
Beneficiary Companies: 51

Area wise distribution of BIPP Projects’ funds

- Health-care: 40%
- Agriculture: 32%
- Industrial products and processes: 14%
- Bio-energy: 9%
- Clinical Trials: 4%
- Field Trials: 1%

% Supported Projects

- Clinical Trials: 42%
- Agri-culture: 8%
- Field Trials: 8%
- Energy & Environment: 18%
- Industrial products, processes & Infrastructure: 15%
HUMAN ACTIVITY TAKES PLACE IN CLUSTERS

PUNJAB AGRI-FOOD CLUSTER

NATIONAL AGRI-FOOD BIOTECHNOLOGY INSTITUTE

Experimental Field Plots

Transgenic
And other Greenhouse facilities

Industry Researcher Tenants
R&D Units
Core Facilities

BIOPROCESS UNIT
Contract Service For start-ups

Ancillary Facilities

KNOWLEDGE PARK WITH START-UP AGRI- OR FOOD COMPANIES
Indian GMO Research Information System (IGMORIS) is a web based database on activities involving the use of GMOs and products thereof in India.

make available objective and realistic scientific information relating to GMOs and products thereof under research, trials and commercial use pertaining to agriculture, pharmaceuticals, environment and industrial products to all stakeholders including scientists, regulators, industry and the public in general.
Today Topics

• Policy and Government
• Research and technology Development
• Regulations
• Are we ready for the future
Recombinant DNA Safety Guidelines, 1990

Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998

Standard Operating Procedures for confined field trials 2008

Guidelines for the conduct of confined field trials of regulated, GE crops, 2008

Guidelines and protocols for food and feed safety assessment of GE crops, 2008
## STUDIES TO BE COMPLETED BEFORE INITIATING BRL-1

<table>
<thead>
<tr>
<th>STUDIES TO BE COMPLETED</th>
<th>Food &amp; Feed Safety Assessment</th>
<th>Environmental Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before first field trial</td>
<td>Field studies</td>
</tr>
<tr>
<td>Description of the genetically engineered plant</td>
<td>Red</td>
<td></td>
</tr>
<tr>
<td>Biology of the non-transgenic host plant</td>
<td>Red</td>
<td></td>
</tr>
<tr>
<td>Donor organism information</td>
<td>Red</td>
<td></td>
</tr>
<tr>
<td>Bioinformatic analysis: potential toxicity and allergenicity</td>
<td>Red</td>
<td></td>
</tr>
</tbody>
</table>

*run concurrently with field trials

Contd/-
Recommendations for staged completion of specific information and data requirements for the safety assessment of GE plants

<table>
<thead>
<tr>
<th>STUDIES TO BE COMPLETED</th>
<th>Food &amp; Feed Safety Assessment</th>
<th>Environmental Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Field studies</td>
<td>Non-field studies*</td>
</tr>
<tr>
<td>Acute oral safety limit study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pepsin digestibility assay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein thermal stability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subchronic feeding study in rodents (if required)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Livestock feeding study (if required)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular characterization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inheritance of introduced trait</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stability of introduced trait</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expression of introduced protein(s)</td>
<td></td>
<td></td>
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<tr>
<td>Compositional analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive and survival biology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact on non-target organisms: Tier I testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact on non-target organisms: Tier 2 testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*run concurrently with field trials
## GMOs approved so far in India

| Agriculture | Bt Cotton from Monsanto, USA  
|            | Bt Cotton from IIT, Kharagpur  
|            | Bt Cotton from Biocentury, China  
|            | Bt Cotton from Metahelix, Bangalore  
|            | Bt Cotton from CICR, Nagpur  
| Healthcare (Recombinant Therapeutics) | A Total of 20 products including  
|                                             | - Human insulin for diabetes  
|                                             | - Hepatitis B Vaccine  
|                                             | - Human growth hormone  
|                                             | - Streptokinase for acute myocardial infraction  
|                                             | - Teriparatide (Forteo) for Osteoporosis  
|                                             | - Platelet Derived Growth Factor (PDGF) for Bone marrow induction & Osteoblasts proliferation  
|                                             | - Follicle Stimulating Hormone for reproductive disorders  

VARIOUS GENES/EVENTS OF UNDER CULTIVATION AND Advanced EVALUATION IN INDIA

OLD GUIDELINES

Five Approved Events
MON 531 (cry1Ac gene),
MON 15985 (cry1Ac & cry2Ab)
GFM Cry 1A (cry1Ab –cry1Ac),
JK-1 (cry1Ac)
CICR (cry1Ac)

NEW GUIDELINES

Events Under Biosafety Evaluation

Cotton
- Round-up Ready Flex (RRF) cry1Ac & cry2Ab (Event MON15985) & CP4 EPSPS (Event MON 88913)
- WideStrike™ (cry1Ac & cry1F) Event 3006-210-23 and Event 281-24-236
- JK Stack- cry1Ac (Event -1) and cry1EC (Event-24)
- cry1C (Event 9124)
- Brinjal Event EE1
### Transgenic Planting Material Imported

<table>
<thead>
<tr>
<th>Crops</th>
<th>No of samples</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brassica</td>
<td>199</td>
<td>Australia, Belgium</td>
</tr>
<tr>
<td>Chickpea</td>
<td>34</td>
<td>Australian, Scotland</td>
</tr>
<tr>
<td>Cotton</td>
<td>46</td>
<td>China, USA</td>
</tr>
<tr>
<td>Maize</td>
<td>50</td>
<td>USA, South Africa</td>
</tr>
<tr>
<td>Paddy</td>
<td>6898</td>
<td>Belgium, Germany, Philippines, Singapore, Switzerland, UK, USA, Vietnam</td>
</tr>
<tr>
<td>Potato</td>
<td>10</td>
<td>USA</td>
</tr>
<tr>
<td>Soybean</td>
<td>359</td>
<td>USA</td>
</tr>
<tr>
<td>Tobacco</td>
<td>3</td>
<td>Canada</td>
</tr>
<tr>
<td>Wheat</td>
<td>43</td>
<td>Germany</td>
</tr>
</tbody>
</table>

50:50 Public: Private
<table>
<thead>
<tr>
<th>S.No.</th>
<th>Crop</th>
<th>Gene/event</th>
<th>Event selection</th>
<th>Biosafety Research Level-I</th>
<th>Biosafety Research Level-II</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Brinjal</td>
<td>cry1Ac</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cry1Aa &amp; cry1Aabc</td>
<td>Green</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Cabbage</td>
<td>cry1Ac</td>
<td></td>
<td>Blue</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cry1Ba &amp; cry1Ca3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cauliflower</td>
<td>cry1Ac</td>
<td></td>
<td>Blue</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cry1Ba &amp; cry1Ca3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Corn</td>
<td>cry1Ac + cp4epsp4</td>
<td></td>
<td>Blue</td>
<td></td>
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<tr>
<td>5</td>
<td>Groundnut</td>
<td>Chitinase gene</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6</td>
<td>Okra</td>
<td>cry1Ac</td>
<td></td>
<td>Blue</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Potato</td>
<td>RB gene</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>8</td>
<td>Rice</td>
<td>cry 1 Ah, cry 1C &amp; bar</td>
<td></td>
<td></td>
<td>Blue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cry1Ac</td>
<td></td>
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<tr>
<td>9</td>
<td>Tomato</td>
<td>unedited NAD9</td>
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</tbody>
</table>
GM foods have regulatory implication from Lab to Markets even after processing.

Documentation of field history

Segregation of field

Planting

Field inspection

Harvesting

On-farm storage

Transport

Central Warehousing corporation (CWC)

Export terminal

Testing

Importers

Testing

Wholesalers & retailers

Testing

Public Distribution System & subsidized grain shops

Testing

Processing

Testing

Testing

Testing
PILS – SCIENCE VERSUS PROCESS

Some important judgments of Supreme Court of India

May 1 2009- Impact of poverty is more dangerous that supposed side effects of GM crops

September, 2008- Courts do not give judgment on science it should be left to scientists

Courts can deal with process of approval as per law and streamlining it if needed

September 2007: Do not waste time of court.

March 2006 : LOD at 0.001 %
Evolution of GM debate vs policy leading to setting up of National Biotechnology Regulatory authority

- US GM Rice escape
- Burning of Bt-rice trial field, 28 October 2006, Haryana
- Burning of Bt-cotton trial field, 28 November, Karnataka 1998
- Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro organisms and Genetically Engineered Organisms or Cells, 1989 (Secondary legislation)

- Environmental Protection Act, 1986 (Parent legislation)
- Mashelkar Committee (Task Force on agricultural biotechnology) to April 2004
- Revised Guidelines for research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998
- recombinant safety guidelines, 1990
Some concerns in public consultations for Commercial release of Bt Brinjal
Moratorium Till such independent scientific studies establish, to the satisfaction of both public and professionals, the safety of the product from the point of long term impact on human health, environment including rich genetic wealth existing in brinjal.

Jairam Ramesh
MOS(I/C)E&F; February 9th, 2010
“WHAT’LL IT BE — ONE LARGE RISK OR SEVERAL SMALL ONES?”

State of mind of GEAC
Today Topics

- Policy and Government
- Research and technology Development
- Regulations

- Are we ready for the future!
Lessons learnt.....

Regulatory Framework

PUBLIC POLICY

Public concerns

Science of risk assessment
Several lessons around 12 topics in 10 years

- Regulatory Experience and Evaluation of Policy
- Science and Process of Biosafety Assessment
- Post-Release & Science of Resistance Management
- Dynamics of Seed Industry, Pricing and Markets
- Evolution of Anti-GM Activists and Their Agenda
- Public Perception and Response
- Plight of Agricultural Extension and Communication
- Inter-Ministerial Coordination
- Center-State Relations
- PILS – Science versus Process
- Human Resource Development
Effective regulation is an essential component of any innovation process.

Serious re-evaluation of the existing regulatory framework in the light of accumulated evidence and experience reveals its reforms since the days of Bt cotton release.
My Government is in the process of setting up of a National Biotechnology Regulatory Authority which will be the nodal authority for release, import and post-release monitoring of GM crops and seeds. The quality control of GM seeds is an important issue and it is proposed to strengthen the State Seed Testing Laboratories.
Government Directives

- Directive from PMO for DBT to act as a nodal agency for establishment of NBRA in Nov. 2006

- Meeting of Committee of Secretaries in October, 2007 to consider National Biotechnology Development Strategy. Directive regarding NBRA was:
  - NBRA would be set up under DBT to provide a single window mechanism for genetically modified/engineered products and processes
  - Existing mechanisms may continue till a full-fledged body is created with the required infrastructure and fully functional autonomy.
ADDRESS BY THE HON'BLE PRESIDENT OF INDIA TO PARLIAMENT
New Delhi, February 21, 2011,

“Scientific and technological competence of a high order is essential for sustained economic growth.
A **Biotechnology Industry Research Assistance Council** will be set up to augment efforts on food security, promote industrial research and development and facilitate innovation in biotechnology.
A **national programme for Crop Genetic Enhancement Network** will be launched to develop improved varieties.
A **Biotechnology Regulatory Authority of India Bill** is proposed to be introduced in this session. “
### Approaches to Regulatory Implementation

<table>
<thead>
<tr>
<th>Characteristic of Regulatory Framework</th>
<th>Argentina</th>
<th>Australia</th>
<th>Canada</th>
<th>Philippine</th>
<th>Japan</th>
<th>S. Africa</th>
<th>EU</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>New laws were passed to specifically address gene technology</td>
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<tr>
<td>Statutory instruments are employed</td>
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Presence of an “X” indicates conformity with the first alternative in each dichotomous comparison.
Setting up NBRA will require the promulgation of new legislation, namely the:

Biotechnology Regulatory Authority of India Act, 2011” or the BRAI Act.
**METHODOLOGY ADOPTED BY DBT FOR ESTABLISHMENT OF BRAI**

**Step 1**
- Review of the structure and governance of other autonomous agencies in India
- Review of international models for the regulation of biotechnology
- Review of India’s international obligations pertinent to the BRAI’s mandate

**Development of a model for the BRAI that addresses:**
1. Scope of the regulatory mandate of the BRAI
2. Structure of the BRAI: programs and operations
3. Legal framework and other issues

**Step 2**
- Preparation of a preliminary establishment plan for the BRAI
- Stakeholder interviews to obtain feedback on the preliminary plan
- Preparation of a revised, draft plan incorporating stakeholder feedback

**Step 4**
- Preparation of draft legislation for establishing the BRAI

**Step 5**
- Consultative process with various stakeholders
Elements of Biotech regulatory System

Legislation
Rules & procedures

SOPs

Guidelines

People

Biosafety Review Process

Decision

Communication

Infrastructure

Notified Testing Labs

Monitoring Cells

Field sites

MULTIDISCIPLINARY HUMAN RESOURCE

Feedback
PROCESS OF TAKING FORWARD BRAI BILL

- Preparation of draft Bill and establishment plan through a consultative process.
- High level advisory committee to review and recommend.
- Placing on the DBT’s websites and advertisements in leading newspapers for comments.
- Consultation with state governments for consensus and feedback.
- Six countrywide consultation meetings with various stakeholders in Delhi, Chennai, Bangalore, Hyderabad, Mumbai and Kolkata.
- Special consultation with Media & legal experts.
- Finalization of the draft Bill and establishment plan.
- Inter-ministerial consultation.
- Roundtable with international regulators (USA, Canada, Australia, Philippines).

- After 3 more COS meetings the cabinet approved the bill in November 2010 and further amendments and NOC.
- Bill TABLED IN LOKSABHA for introduction in parliament on 27th July 2011.
GLIMPSES OF THE REGIONAL CONSULTATIONS

at Mumbai

Chennai

Kolkatta

at Delhi

HYDERABAD
KEY FEATURES OF BRAI BILL, 2011

- The proposed statutory independent regulator that is the Biotechnology Regulatory Authority of India (BRAI) would be a nodal agency of the Government of India to ensure comprehensive safety assessment of organisms and products of modern biotechnology.

- Commercialization of biotechnology products in agriculture and healthcare would be subject to all other laws whether Central or State, for the time being in force and rules and regulations made thereunder.

- The organizational plan of the Authority also provides collaborative arrangements, co-ordination and mechanisms with other existing regulatory agencies.
ORGANIZATION STRUCTURE OF BRAI

Chairperson, BRAI and two whole time and two part time members

Inter-Ministerial Governing Board

Product Rulings Committee

Chief Regulatory Officer, Agriculture, Fisheries & Forestry Division

Regulatory & Policy Unit

Scientific Advisory Panels (as needed)

Risk Assessment Unit

Core Characterization: Molecular biologist; Microbiologist; Biochemist; Toxicologist; Bioinformatics; Biostatistics
Animal Biotechnology: Physiologist; Pathologist; Nutritionist; Animal breeder; Veterinary scientist; Fisheries/aquaculture scientist
Plant Biotechnology: Physiologist; Pathologist; Entomologist; Agronomist; Plant breeder
Human Health Biotechnology: Immunologist; Epidemiologist; Pharmacologist; Clinical scientist
Industrial & Environmental Biotechnology: Ecologist; Environmental biologist; Industrial microbiologist; Analytical chemist

Chief Regulatory Officer, Industrial & Environmental Applications Division

Regulatory & Policy Unit

Scientific Advisory Panels (as needed)

Cross-Sectoral Offices

National & International Policy Coordination Unit

Communications & Outreach Unit

Legal Unit

Monitoring, Compliance & Accreditation Unit

Capacity Building & Training Unit

Economic Analysis Unit

State Biotechnology Advisory Committees

Chief Regulatory Officer, Human & Animal Health Division

Regulatory & Policy Unit

Scientific Advisory Panels (as needed)

National Biotechnology Advisory Council

Environment Appraisal Panel
PROPOSED MANAGEMENT STRUCTURE:
REGULATORY BRANCHES

- **Agriculture, Forest and Fisheries Branch (AFFB)** to regulate GM plants, animals, and micro-organisms used in agriculture, forestry, or fisheries, including aquaculture.

- **Human and Animal Health Branch (HAHB)** to regulate genetically modified organisms with applications in human and veterinary health, such as assessing the potential environmental risks and benefits associated with the application of GMOs in pharmaceutical development or recombinant livestock vaccine production.

- **Industrial and Environmental Applications Branch (IEAB)** to regulate GMOs used in industrial manufacturing and in environmental applications, such as the use of GMOs for bioremediation of contaminated sites or oil spills.

- Other branches as per need in future.
GOVERNING BOARD AND ADVISORY COUNCIL

BRAI Bill provides for:

i. Constitution of **Inter-Ministerial Governing Board** to oversee the performance of the Authority. The Board will include high level representations from key line ministries.

ii. Constitution of **Biotechnology Advisory Council** to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India. The Council members will include representatives from the scientific community, private sector and civil society.
HOW APPLICATION WILL BE PROCESSED

Risk Assessment Unit

Internal Risk Assessment Report

Product Rulings Committees

Environmental Appraisal Panel

Organized Public Review

Authority
OTHER UNITS

BRAI to have units for cross-sectoral support including:

- Enforcement, Compliance and Accreditation Unit
- National and International Policy Coordination Unit
- Communications and Outreach Unit
- Legal Unit
- Economic analysis unit
- Capacity building and training unit
NOTIFICATION OF LABORATORIES

- Provides for notification by the Authority of accredited laboratories and research institutions for the purposes of proposed legislation.

- Provides for recognizing any organisation or agency for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities as may be specified.
ROLE OF STATE GOVERNMENTS

- Statutory State Biotechnology Regulatory Advisory Committees (SBACs) have been envisaged for interaction between the state governments and the Authority regarding regulatory matters.
- To ensure functioning of SBACs, the Authority will provide technical and financial assistance.
- Each SBAC will have two members nominated by the Authority.
- There will be at least one annual meeting of the Authority with all SBACs.
- Coordination Cells supported (both technical and financially) by the Authority in one state agricultural university in each state have been proposed.
Harmonization with other acts/policies/systems/authorities

- Central / state seed systems of varietal registration / sale/ quality control
- PVP&FR
- EXIM policy for import of GM food
- Plant quarantine notification
- Import permit NBPGR for R&D
- Customs ACt
- Import clearance online
- Biodiversity Authority
- Food safety Authority 2006
- Labeling
- Process

Cultivation

BRAI

Safety and efficacy certification

- Planting
- Cultivation
Biotechnology Industry Research Assistance Council (BIRAC)- End-to-end Services

Started as a pilot project and EFC ready for circulation under I&M sector

<table>
<thead>
<tr>
<th>Stage 01</th>
<th>Stage 02</th>
<th>Stage 03</th>
<th>Stage 04</th>
<th>Stage 05</th>
<th>Stage 06</th>
<th>Stage 07</th>
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</thead>
<tbody>
<tr>
<td>Sourcing ideas</td>
<td>IP Protection</td>
<td>Proof of Concept</td>
<td>Licensing</td>
<td>Formation and incubation of technology businesses</td>
<td>Investment</td>
<td>Exits</td>
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<tr>
<td>Market application</td>
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<td>Product Development</td>
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*Images for each stage are shown in the diagram.*
Phenotyping - the new bottleneck in plant science

Phenotyping centres will come up

• Genomics is accelerating gene discovery
  Discovering candidate genes for stress tolerance

• High throughput growth analysis now the factor limiting discovery of new traits
  Need more technology
to elucidate function
to support forward genetics

• Need to measure effects of gene manipulations on plant function - ‘phenotyping’
Traits relevant in the changing climate priority

- Water Use Efficiency
- Nitrogen Use Efficiency
- Thermo-tolerance
- C3 to C4 Photosynthesis

Understanding genetic and molecular basis of tolerance

Genes/QTLs

Improved crop genotypes
Post harvest biotechnology will be new priority

Pre-harvest & Post harvest

Losses are phenomenal

Affecting productivity and quality of cereals / pulses

Predicted loss 9.5% overall
Upto 30% in some crops like pulses
What are the major constraints?

- **Preharvest:**
  - Precocious germination
  - Seed shattering

- **Post harvest:**
  - **Biotic:** Mycotoxin
  - **Abiotic:** Seed deterioration

- **Anti-nutritional factors**
  - [Protein digestibility]
R&D on Second Generation of Biotech Crops

- Farmer
- Consumer
- Processor

- Fortified Food
- Healthy Oils
- Pharma
- Biofuel
- Feed Enhanced
- Industrial Processes

- Drought
- Nitrogen
- Yield

Second Generation of Biotech

First Generation of Biotech

- Insect / Virus Protection
- Herbicide Tolerance
Challenges

While the bill takes some time to become ACT, we have to act now to strengthen the system.

- GM crop Technology Development policy is urgently needed.
- Human resource for risk assessment, review, management and communication at all levels.
- State of art Laboratories (new or Existing) to meet future challenges of technology complexities.
- Funding for regulatory science and socio economic studies.
- System for Continual education and research resources for regulation.
- A sustainable Long term communication system for promoting Public understanding of Science.
Future is bright if Public Policy, Science and public understanding are addressed and linked.

MORE SUGGESTIONS WELCOME

www.dbtindia.nic.in

Thanks