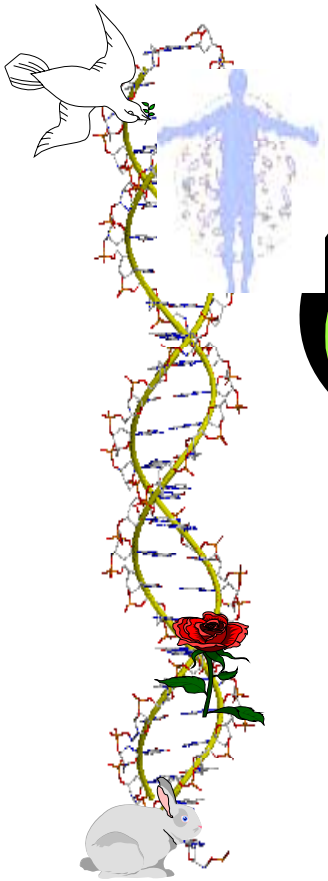
STATUS OF GM CROPS IN INDIA :RESEARCH AND AND REGULATORY SYSTEM

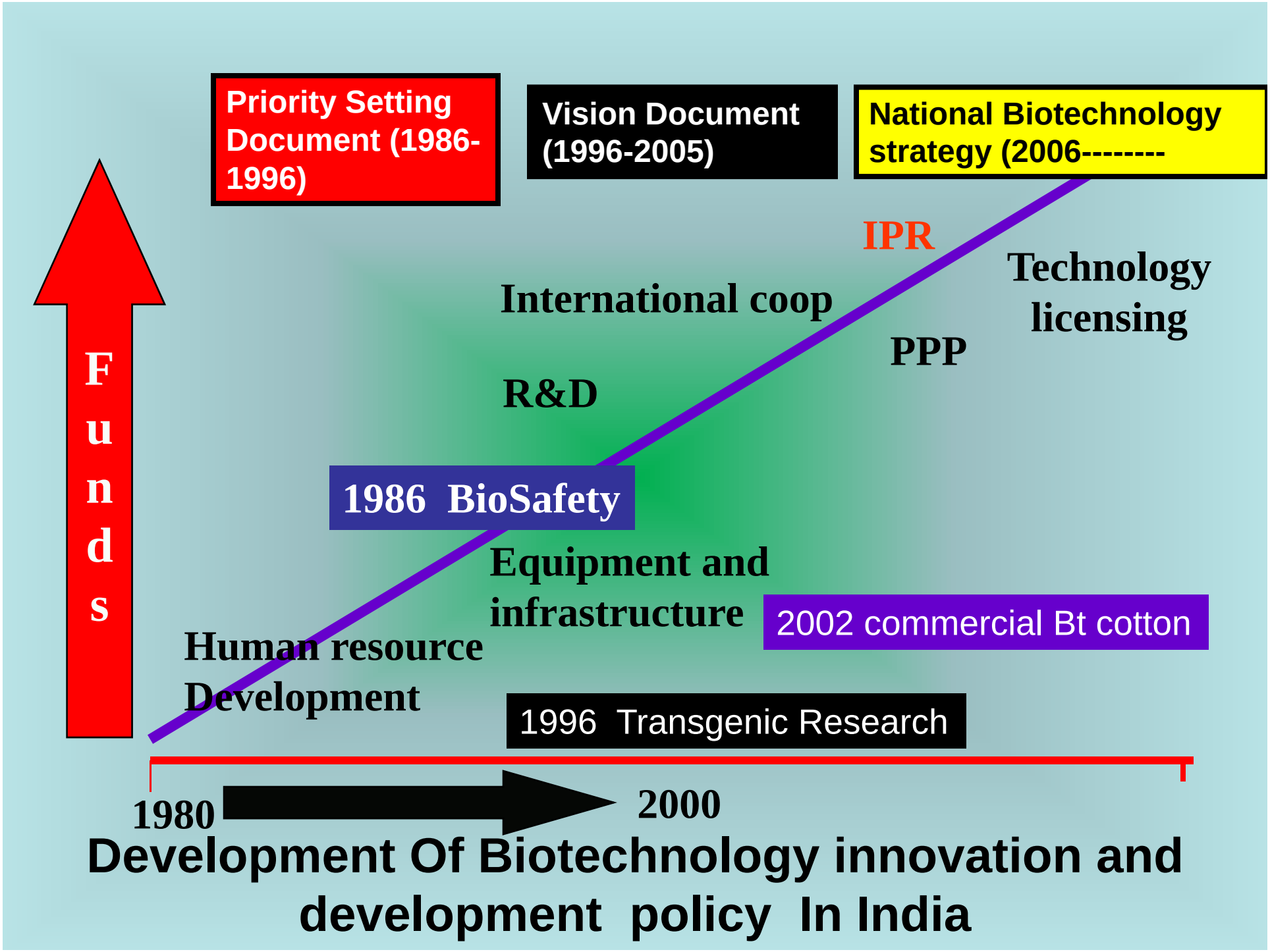


S.R.RAO
ADVISOR
DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE AND TECHNOLOGY
GOVERNMENT OF INDIA

Today Topics

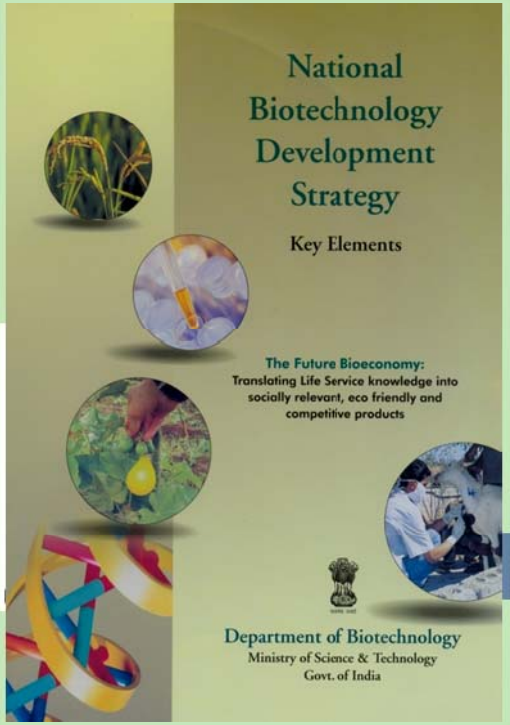
- **Policy and Government**
- **Research and technology Development**
- **Regulations**
- **Are we ready for the future**

MINISTRY OF SCIENCE & TECHNOLOGY



Development Of Biotechnology innovation and development policy In India

National Biotechnology Development and Innovation Strategy 2006



Policy Framework and Strategic Actions

An inter-ministerial / multi-sectoral effort

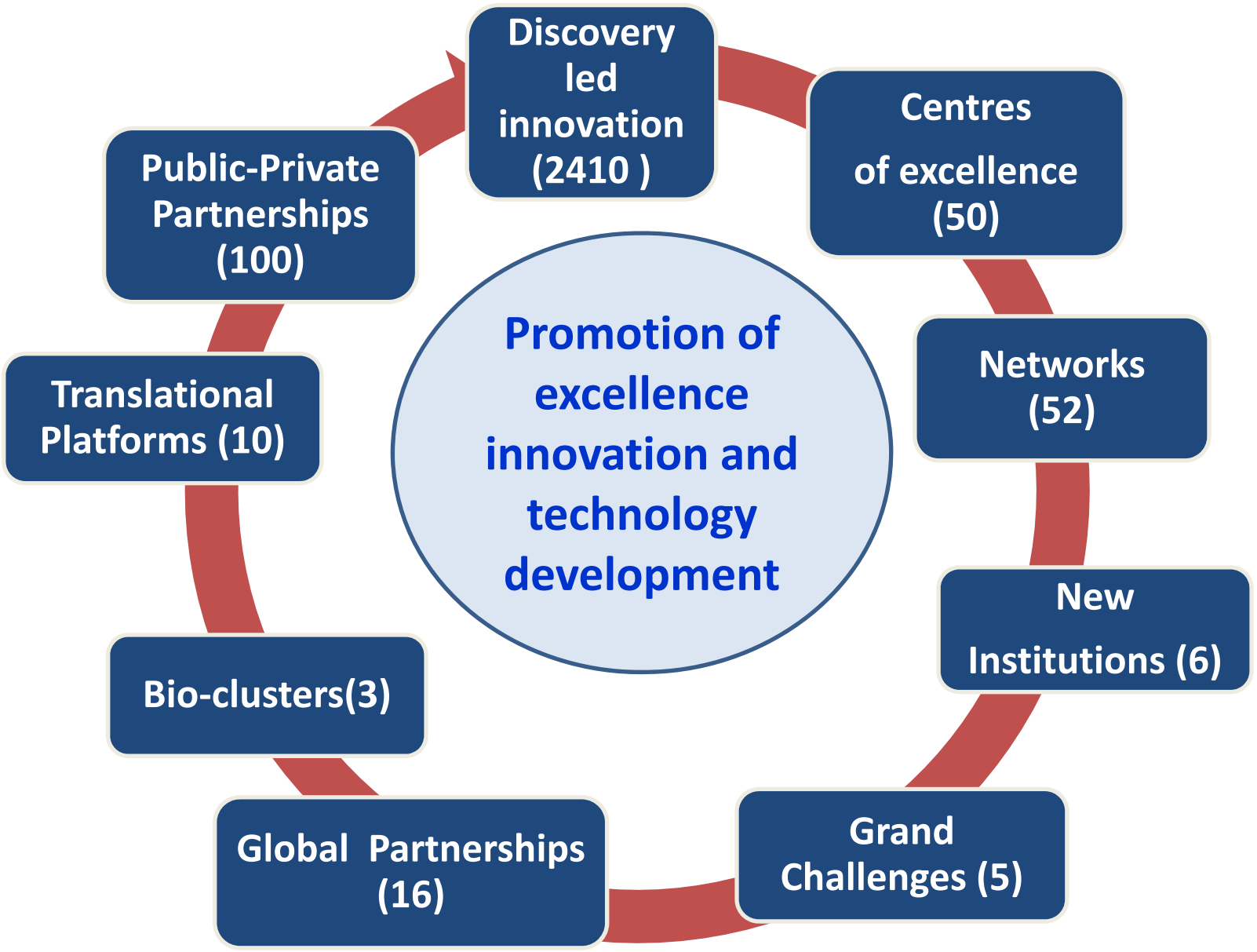
DBT

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"

FACTS SHEET 11TH PLAN ---------- OUTCOMES 2007-2011------

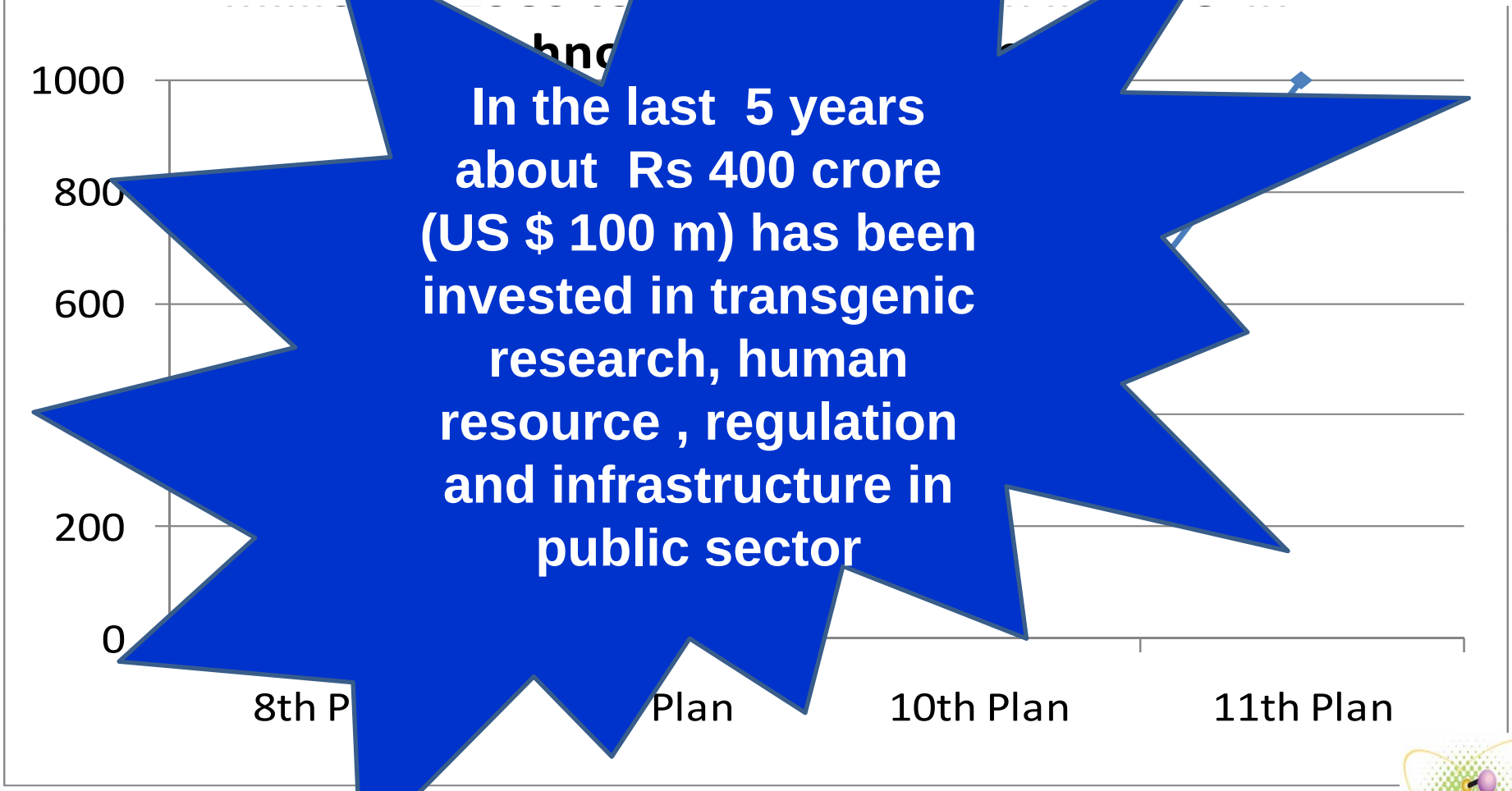


DBT

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

Government investments in ased from US 20 in 1989 to 60 $ n in 20 0 in



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

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Today Topics

- Policy and Government
- **Research and technology Development**
- Regulations
- Are we ready for the future

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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

DBT

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

DBT

- **14 State Agricultural Universties 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 NBPGR, 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** (~App 200 Sub-projects)
- **Projects** **(20 projects)**
  (with US, zerland etc.)
- **Program** es/31 Sub-projects
- **Centre of** **iotechnology:**
- 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

Crops 36	Traits 18
Research Institutions	Companies engaged
Universities	50
Research Institutions	45
Companies	140
Total	235

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Examples Crops & Traits being focussed under Public R&D programmes

DBT

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

Finger millet

Eleusine coracana

widely grown as a cereal in the arid areas by small farmers of India.

Protein 7.3 g
Fat 1.3 g
CHO 72 g
Minerals 2.7 g
Calcium 344 mg

Field bean

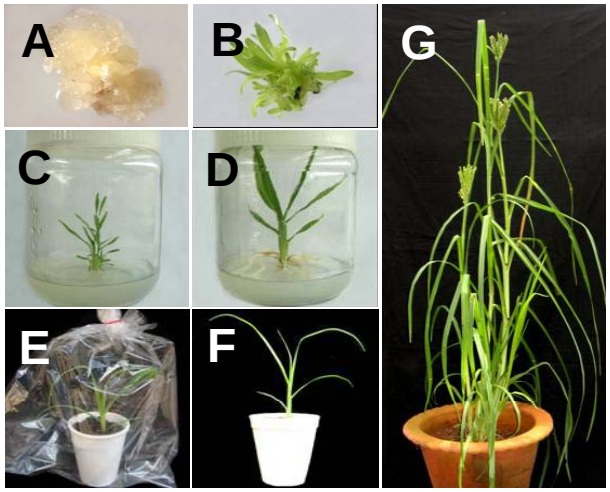
Lablab purpureus

widely grown as a Pulse in the arid areas small farmers of India.

Protein 22 g
Fat 2 g
CHO 61 g
Minerals 0.8 g

Nutritive value (per 100 g)

Abiotic stress
Drought



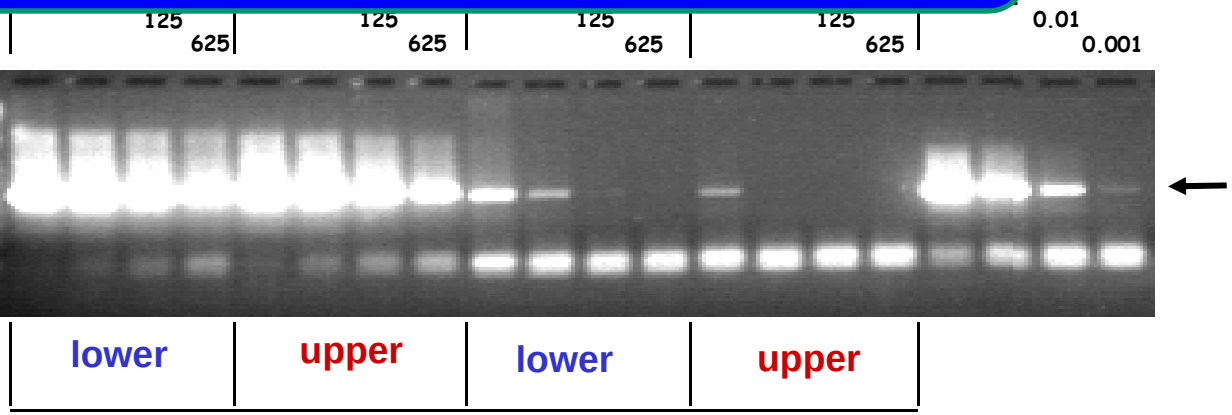
First demonstration of RNAi-based protection against a plant DNA virus

Only traces of viral DNA were detected in recovered blackgram plants

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

lasmid
NA A
anograms)

ld):



Semi-quantitative PCR

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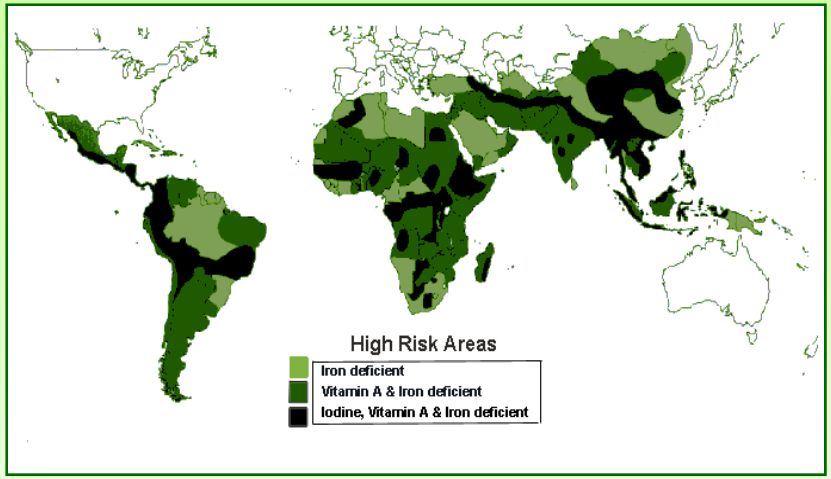
Tackling 'Hidden Hunger' by Biofortification



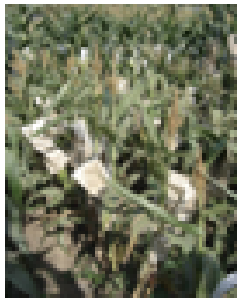
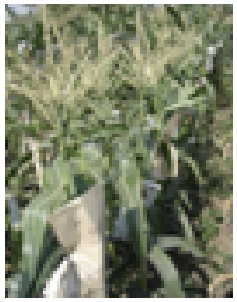
Fe, Vitamin A and Iodine deficiency (Source: USAID)

- 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

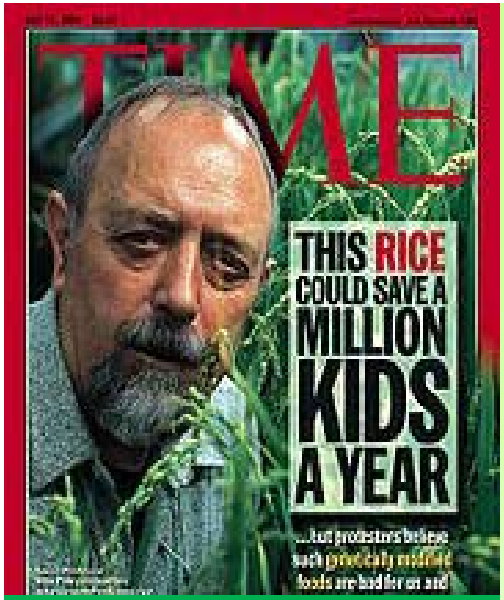
DBT Network Project on Biofortification

- 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



Ingo Potrykus
co inventor

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

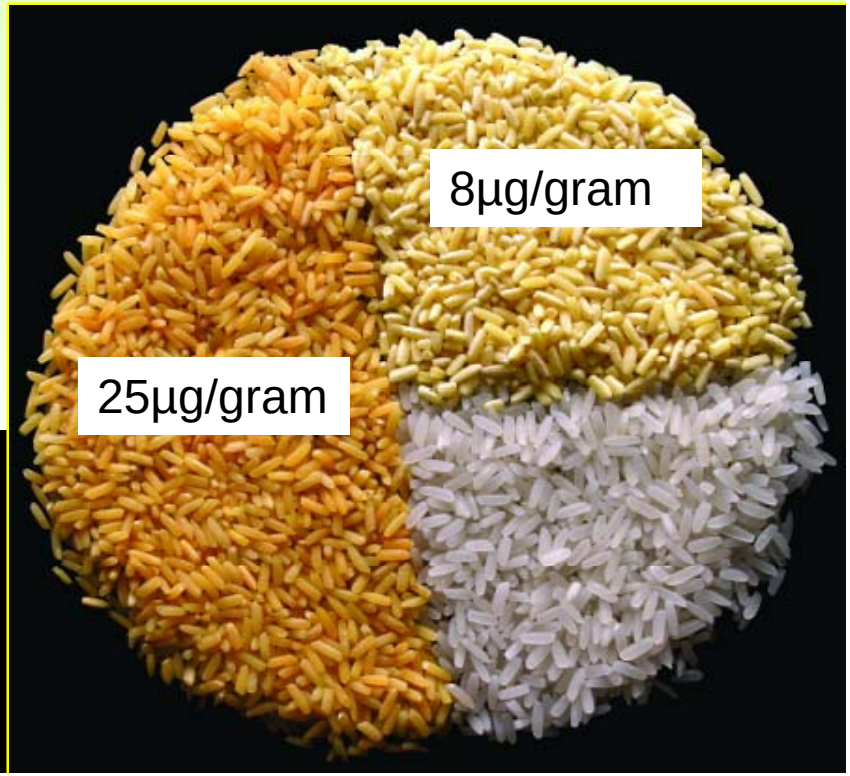
Consequences: 400 million rice eating poor suffer from vitamin A deficiency ; 6000 die per day and 500, 000 become blind every year

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

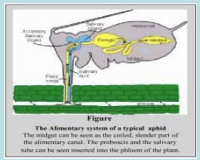
Golden rice contains genes introduced through genetic engineering required to activate the biochemical pathway leading to accumulation of pro-vitamin A

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



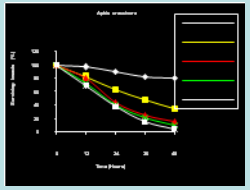
Discovery led innovation



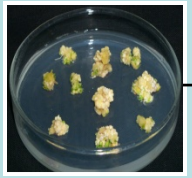
Homopteran pests suck plant phloem sap using their stylets

Allium sativum

(garlic plant)



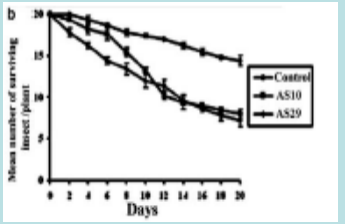
Regeneration of transgenic lines

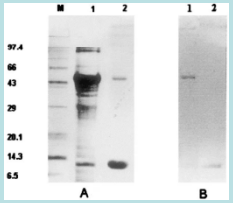


transgenic plant

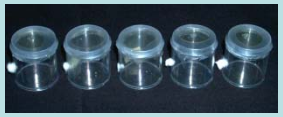
insects

In planta bioassay





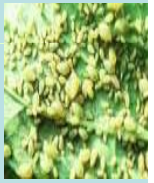
Purification of lectin

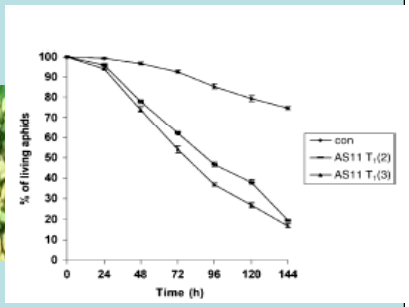


Assay on artificial diet

Agglutination assay

Rice (*Oryza sativa*)



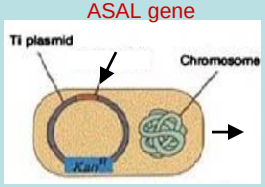


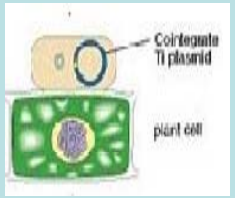
Mustard (*Brassica juncea*)

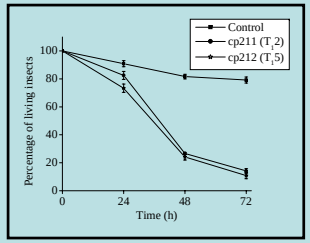
ASAL (*Allium sativum* leaf agglutinin) gene isolated from garlic

Chimeric ASAL gene construct in plant transformation vector

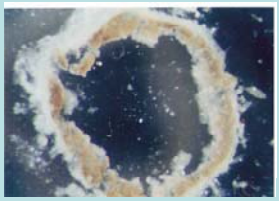
ASAL gene







Chickpea (*Cicer arietinum*)



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

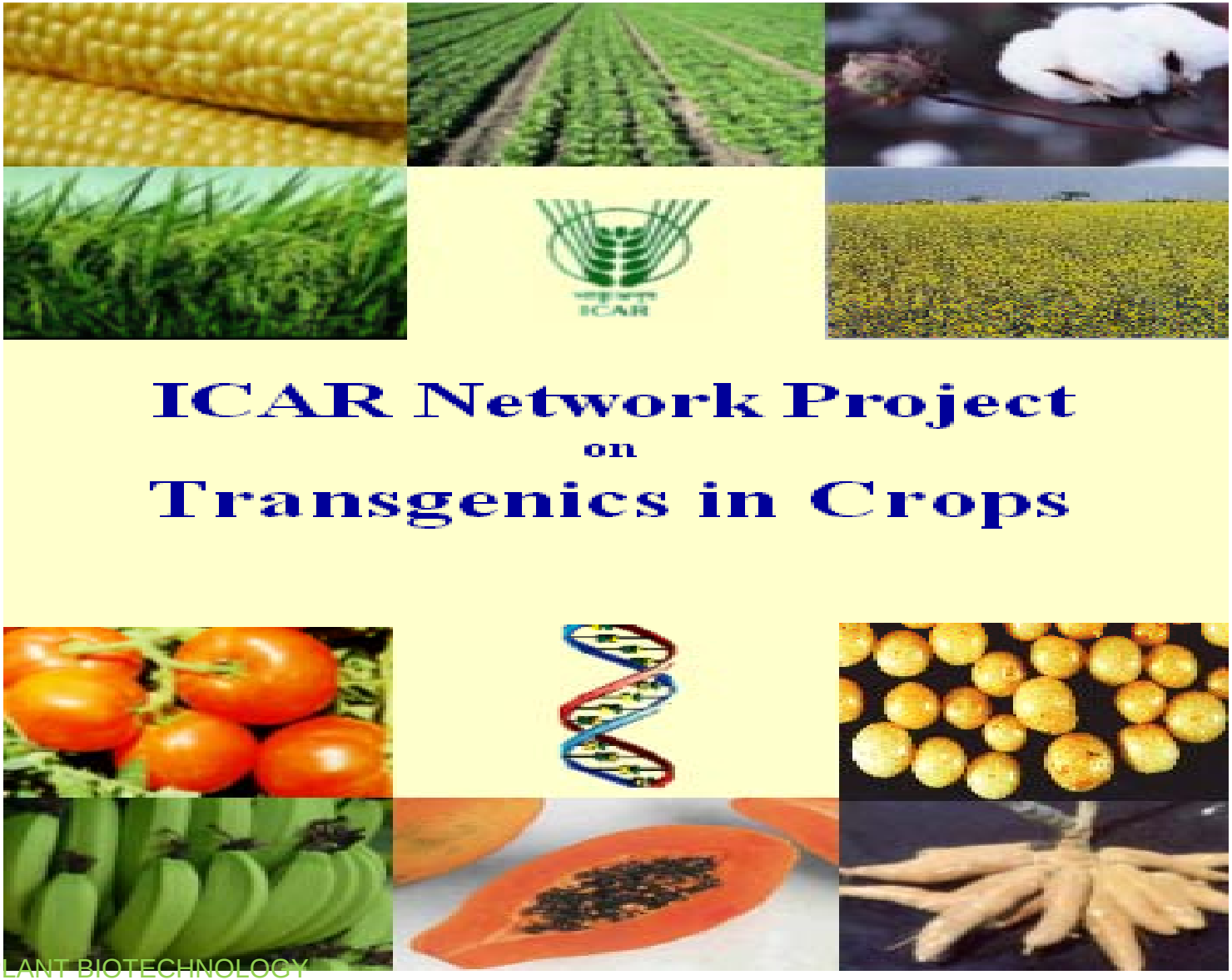
Simultaneous Transfer of Insect Resistance Chickpea Transgenic Technology from public sector to private seed company and Agriculture University for commercial and public good development

Transgenic crops developed in public sector in regulatory field trials

Crop	Organisation	Trait
Brinjal	IARI, New Delhi	Insect Resistance
Castor	Directorate of Oilseeds Research (DOR), Rajendranagar, Hyderabad	Insect resistance
Sorghum	National Research Centre for Sorghum (NRCS),Hyderbad	Insect resistance
Groundnut	ICRISAT, Hyderabad	Fungal disease resistance
Potato	Central Potato Research Institute (CPRI), Shimla	Leaf blight disease resistance
Rice	IARI, New Delhi Tamil Nadu Agricultural University Mahyco, Mumbai	Fungal diseases resistance and drought tolerance
Tomato	IARI, New Delhi	Virus disease and

ICAR Network on Transgenics in Crops

ABIOTIC STRESS TOLERANCE









World's Top Ten Seed Companies doing business in India

S.No	Seed companies	Seed sale (US $ million) 2004	Seed sale (US $ million) 1998
1	Monsanto (USA)	2,803	1,800
2	Dupont (USA)	2,600	1,835
3	Syngenta (Novartis)(SWD)	1,239	1,000
4	Groupe Limagrain(France)	1,044	733
5	KWs AG (Germany)	622	370
6	Land O' lakes (USA)	538	370
7	Sakata (Japan)	416	349
8	Bayer crop science (Germany)	387	-
9	Taikii(Japan)	366	300
10	DLF Trifolium (Denmak)	320	-







Foreign R&D Centres

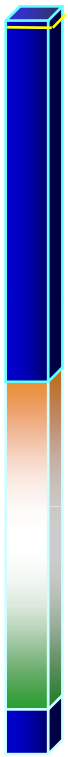
Foreign Centers in Seed Research

- **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

Knowledge Generation

Genome Initiative: India Moves Ahead !

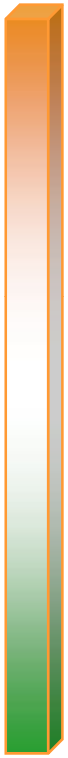
Rice



Chromosome 11

Completed

Tomato



Chromosome 5

Sugarcane

Chickpea

Wheat

Coffee

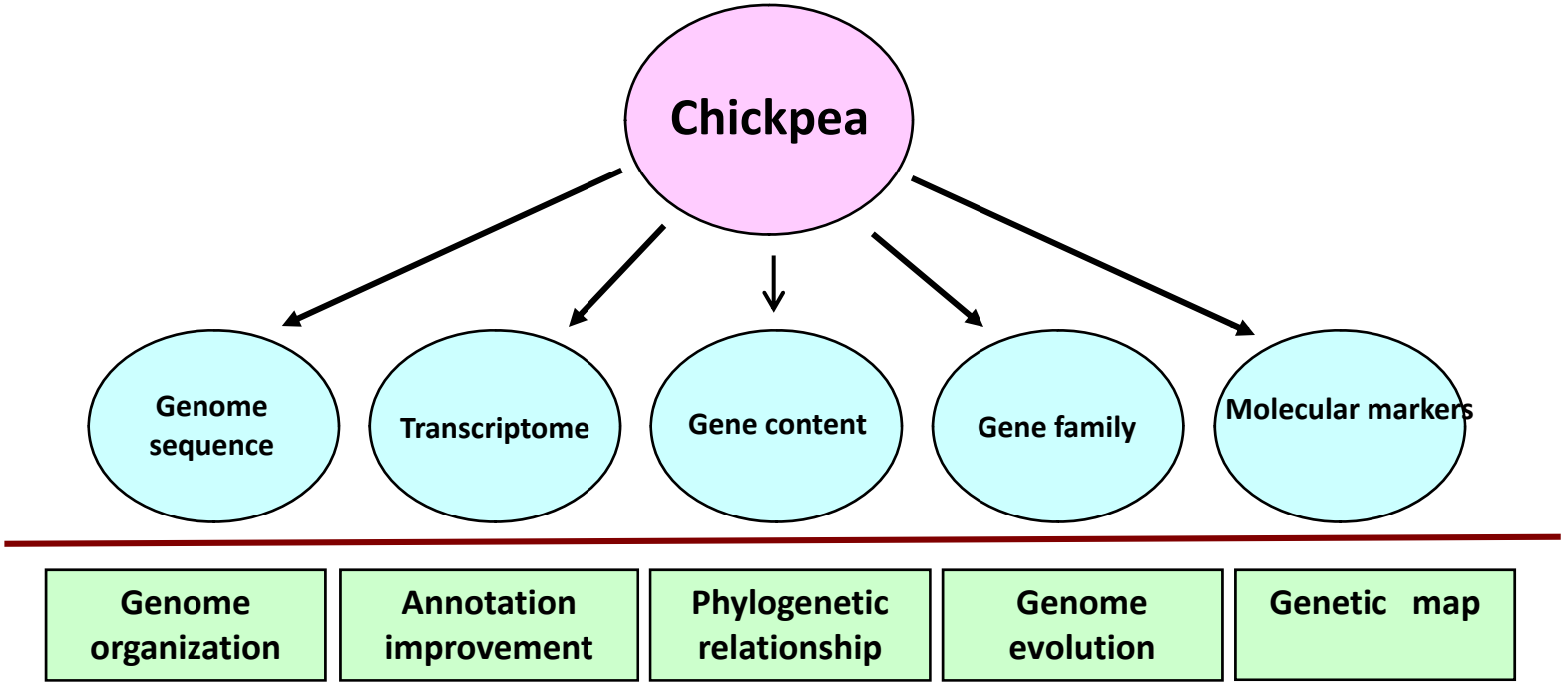
Complete Bacterial Genome

Silk worm

Cancer

Next Generation Challenge Programme on Chickpea Genomics

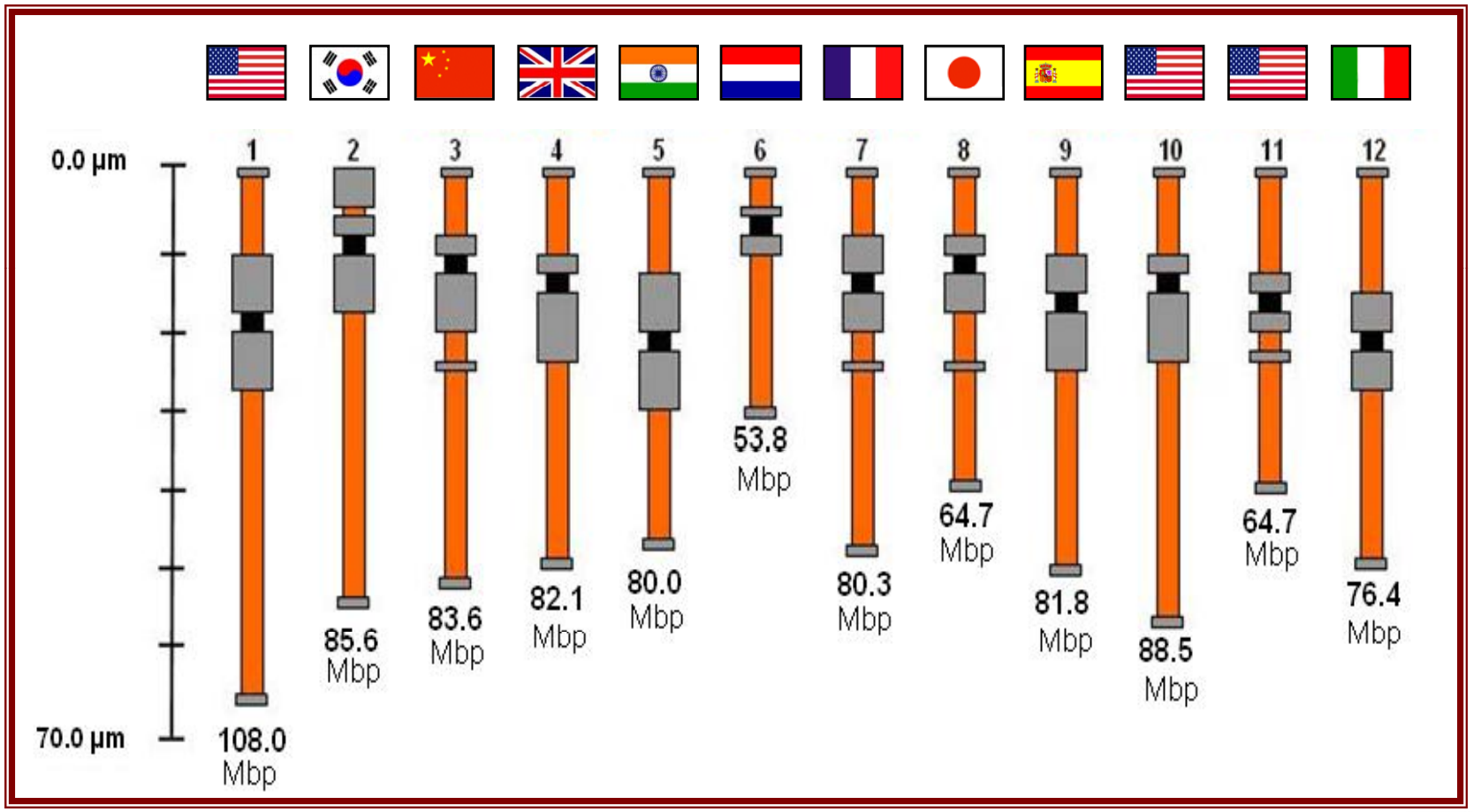
National Institute of Plant Genome Research



Gene/allele discovery

Genetic enhancement for stress tolerance, yield and nutrition

International Tomato Genome Sequencing Project



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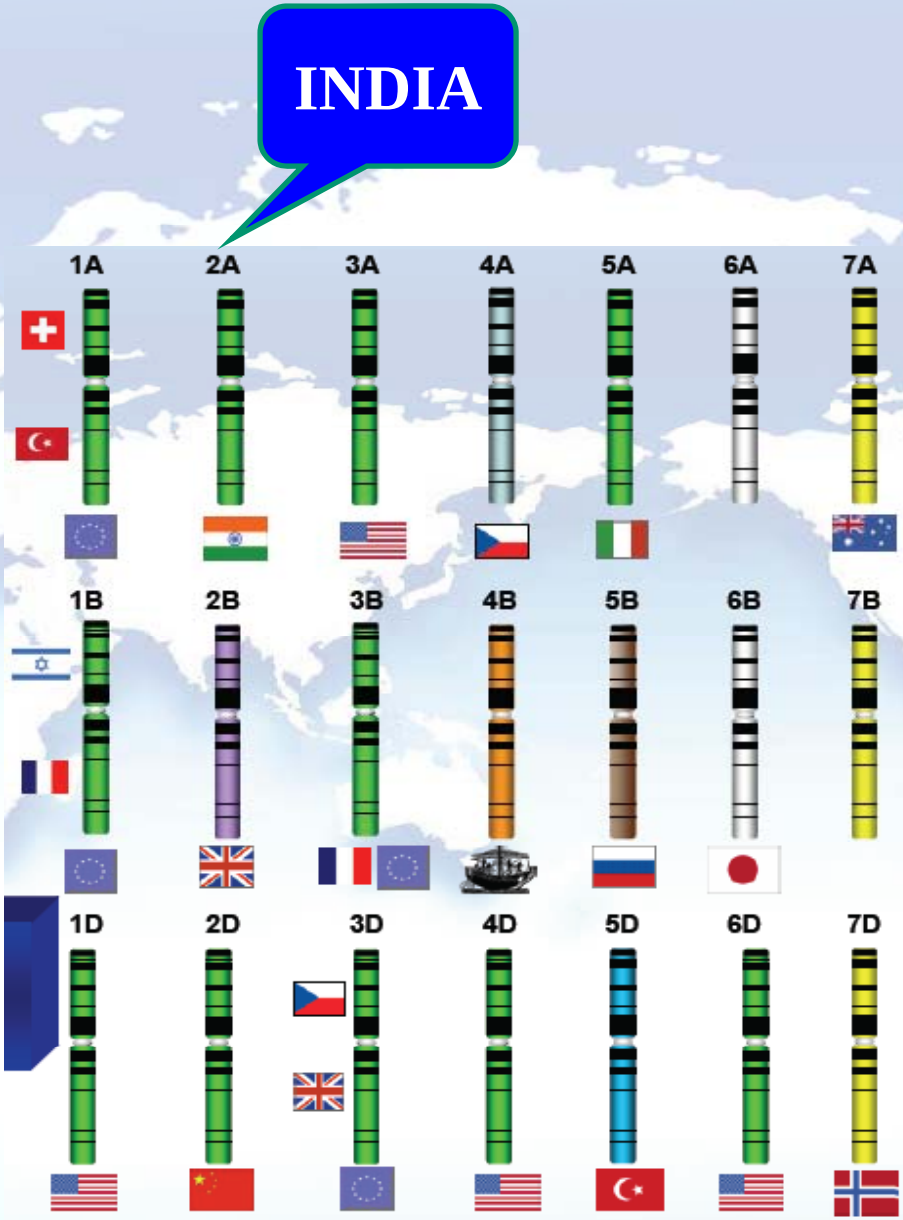
The International Wheat Genome Sequencing Consortium (IWGSC)



An internationally coordinated sequencing bread wheat genome for accelerating wheat improvement

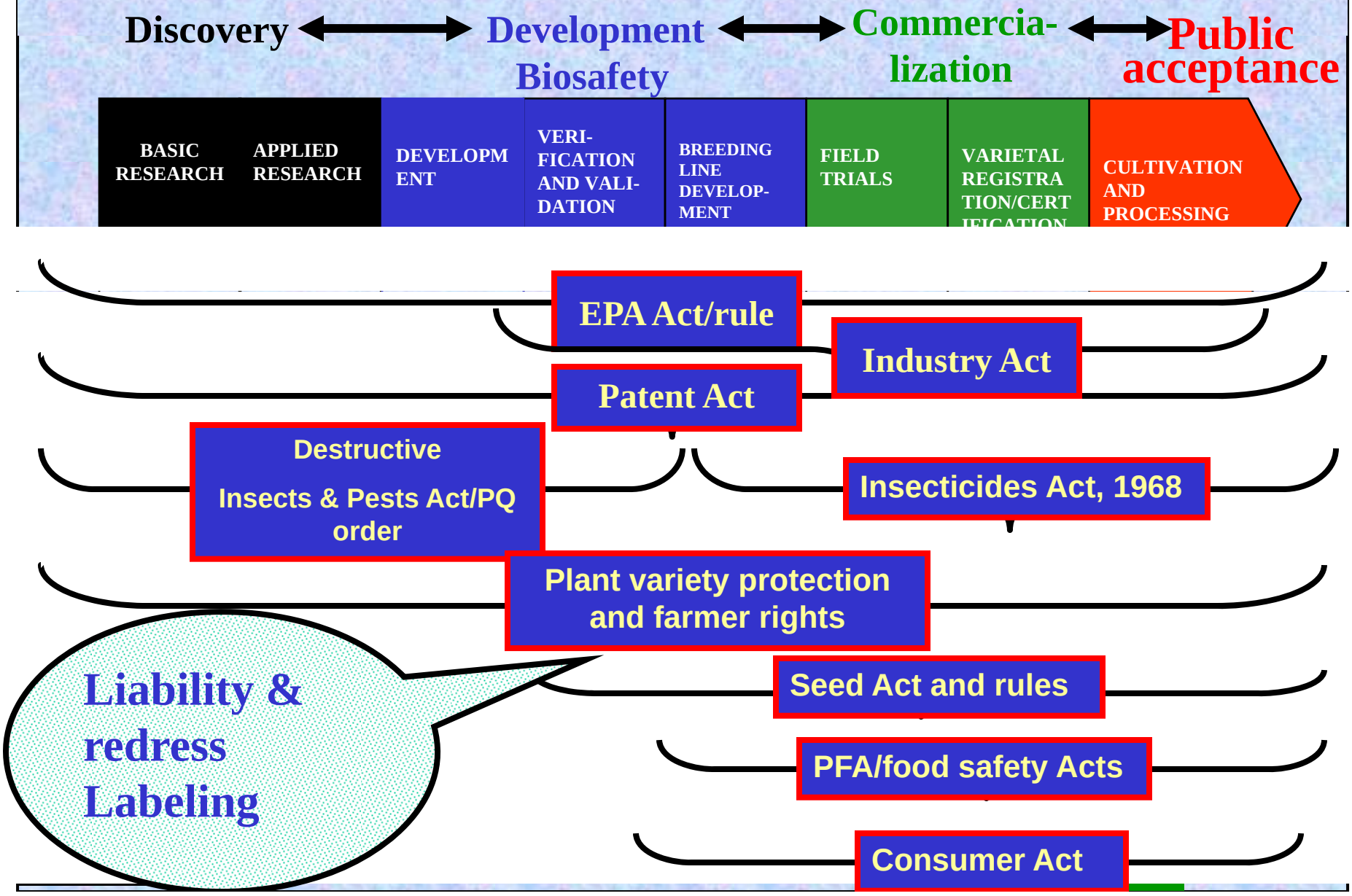
Indian Partners

DBT, NIPGR, UDSC and IARI (ICAR)

Wealth of Genes and DNA markers from Genome Research

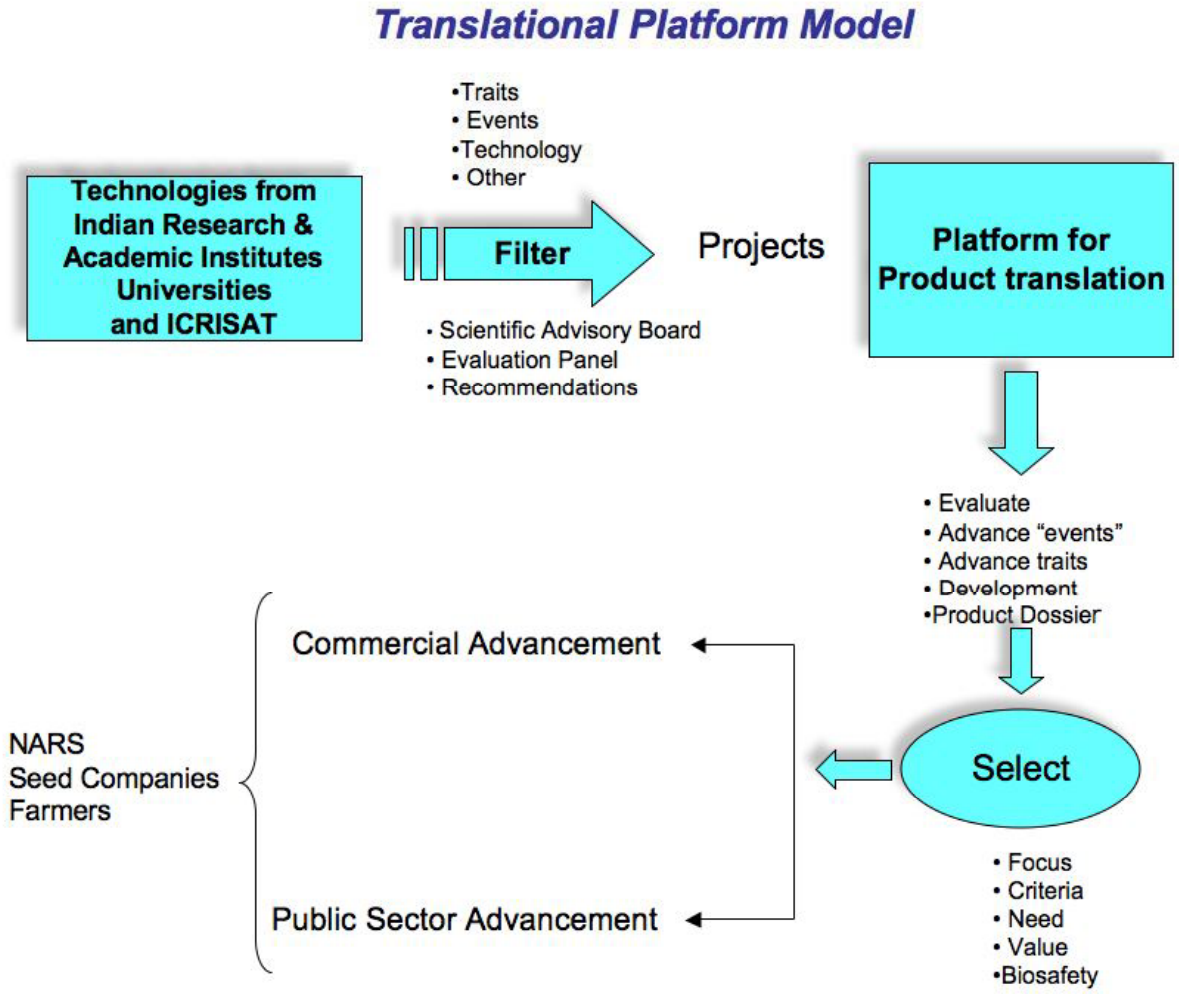
- ✓15 genes in 12 reproduction and vegetative stages of rice
- ✓500 stress response genes in rice
- ✓1000 EST sequences from Jatropha
- ✓150 SSR markers in 200 stress pacific EST database in coffee
- ✓400 EST in mulberry
- ✓4000 buffalo EST markers
- ✓100 SNP markers for buffalo
- ✓4 genes for alkaloid 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



Shared Infrastructure, Facilities And Services For Translational Research And Product Development.....

DBT-ICRISAT Platform for translational Research on transgenic Crops



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Translational SMEs Biotech Programme With new Governance

National Clinical Development Services Agency with multiple functions, and Phase I – IV capacity

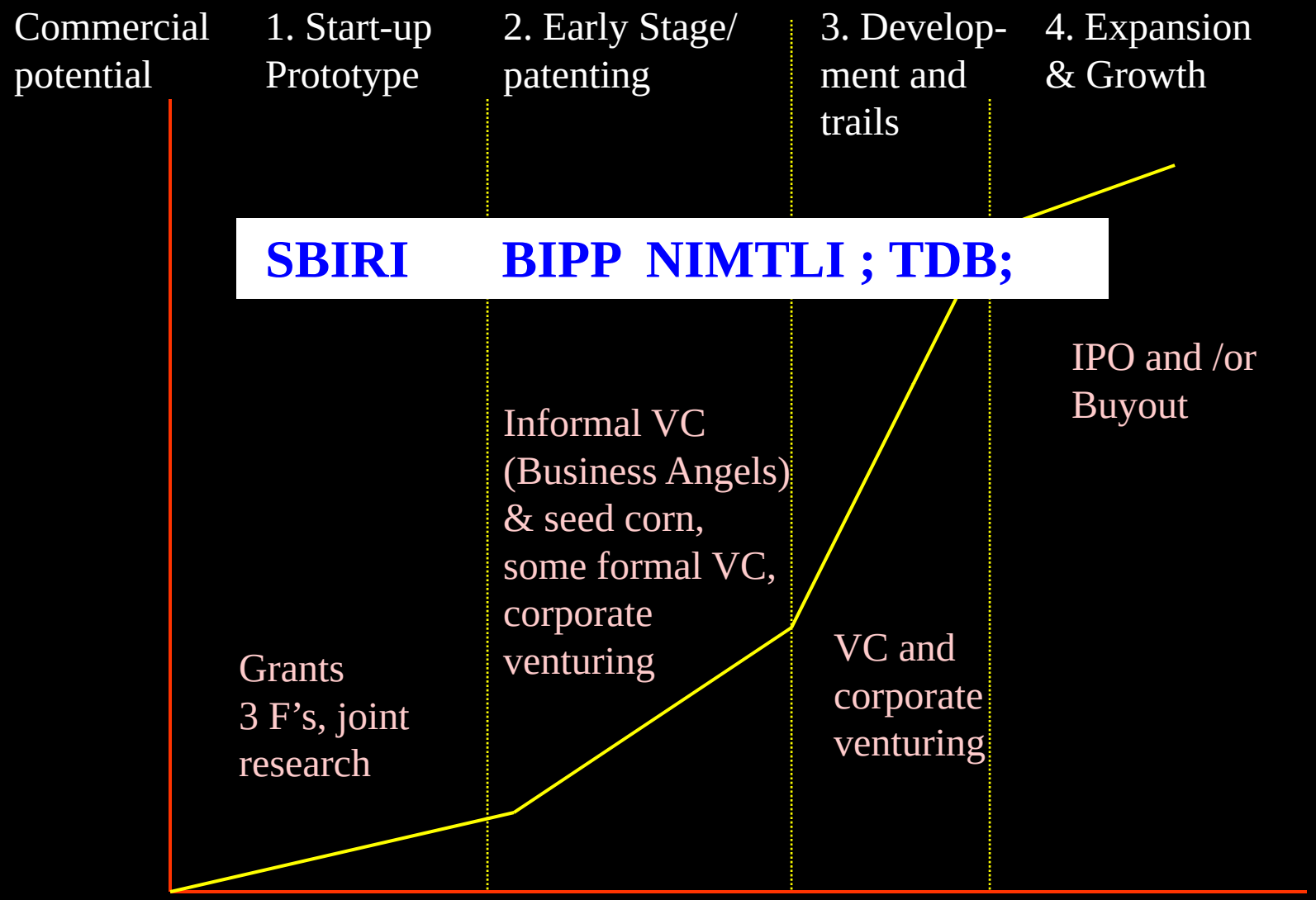
To be set up in NCR Biotech Cluster

- **CRO for agri-biotech translation and field trials**

  Established in partnership with ICRISAT, Hyderabad

ICRISAT Facilty

Encouraged proactive funding to promote SME R&D



A biotechnology finance life cycle

Public-Private partnerships

Small Business Innovation Research Initiative (SBIRI)

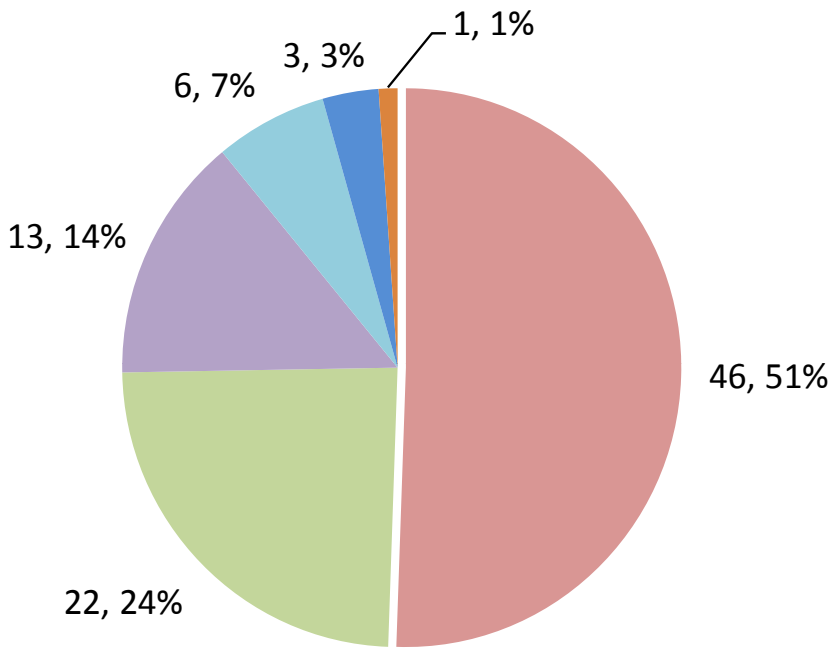
Eighty nine **projects supported** **Seventy six** **companies have been benefitted**

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



FOLIGRAF : Recombinant human follicle stimulating hormone (commercialized)

Rapidec: An auto-dispenser

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

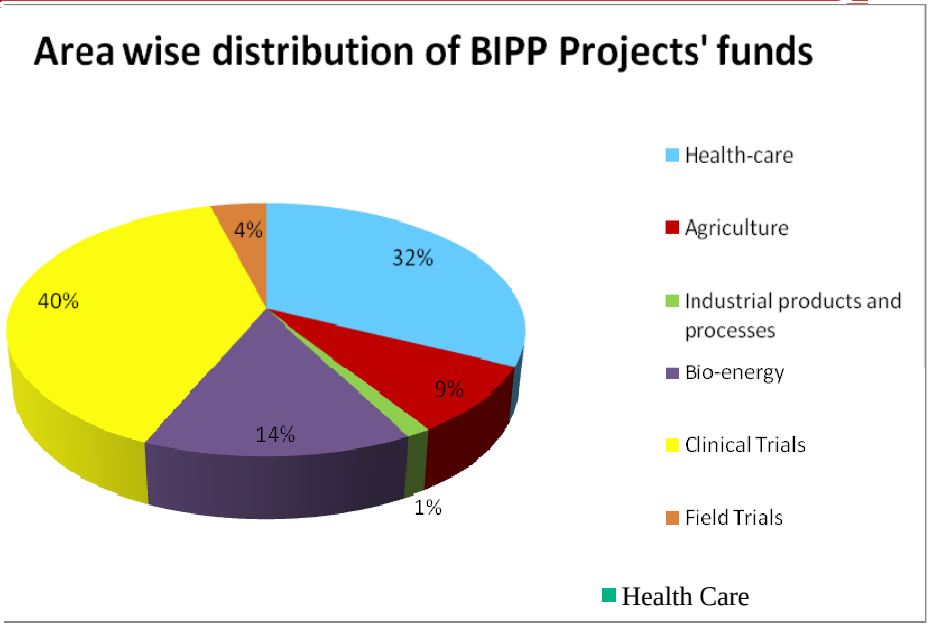
Total Proposals Received: 450

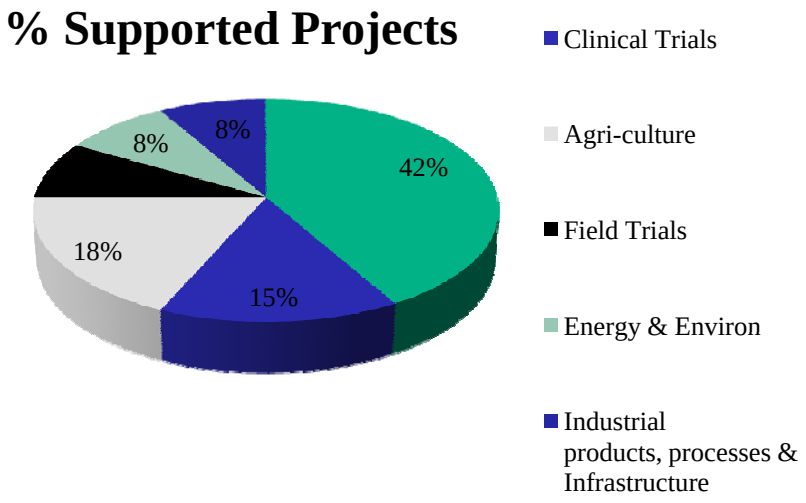
Process automated 6th Batch onwards (Feb 2010)

Approved Projects: 60

Agreements Executed: 60

Beneficiary Companies: 51





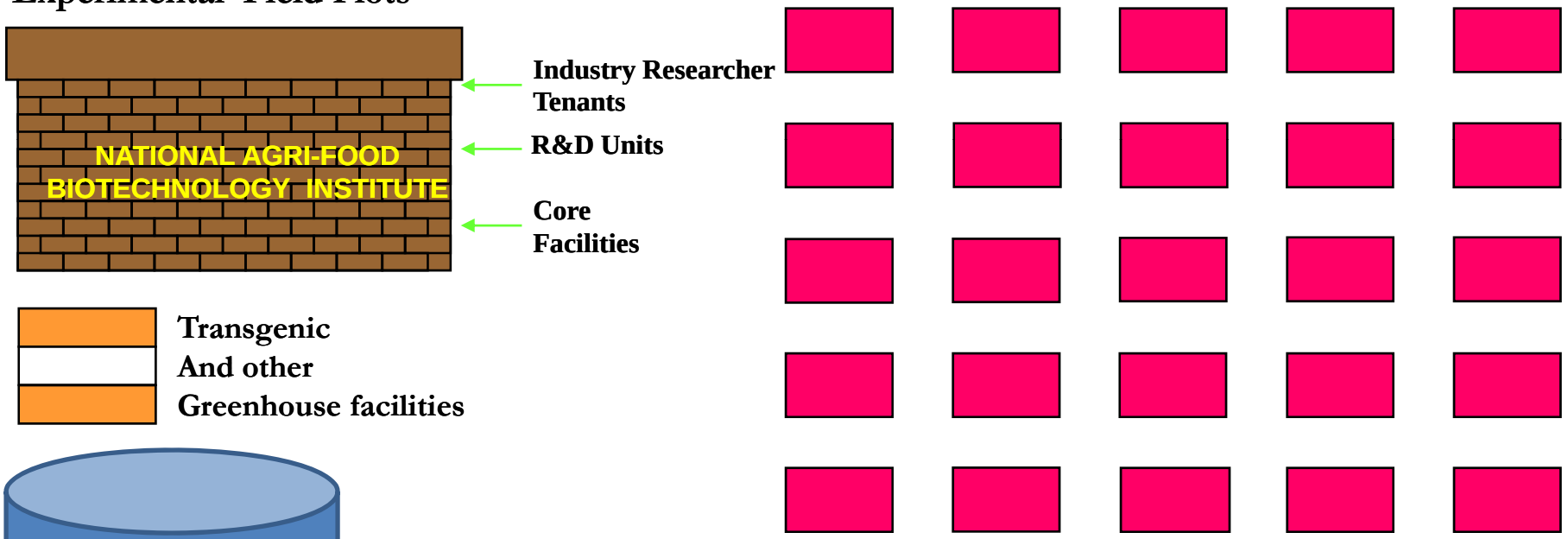
HUMAN ACTIVITY TAKES PLACE IN CLUSTERS

Nanotechnology Institute

Indian Institute of Science Education & Research

PUNJAB AGRI-FOOD CLUSTER

Experimental Field Plots



Consult : http://igmoris.nic.in

Indian GMO Research Information

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.

MINISTRY OF SCIENCE & TECHNOLOGY

Today Topics

- Policy and Government
- Research and technology Development
- **Regulations**
- Are we ready for the future

MINISTRY OF SCIENCE & TECHNOLOGY

Current Indian Regulatory System

IBSC

EPA Act 1986

Rules 1989

RCGM

GEAC

State Biotechnology Committee

District Level Committee

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

STUDIES TO BE COMPLETED	Food & Feed Safety Assessment			Environmental Risk Assessment		
	Before first field trial	Field studies	Non-field studies*	Before first field trial	Field studies	Non-field studies*
Description of the genetically engineered plant						
Biology of the non-transgenic host plant						
Donor organism information						
Bioinformatic analysis: potential toxicity and allergenicity						

run concurrently with field trials

Contd/-

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

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

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 (c*ry1Ab –cry1Ac*),

JK-1 (c*ry1Ac)*

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 (11.12.1997-31.3.2006

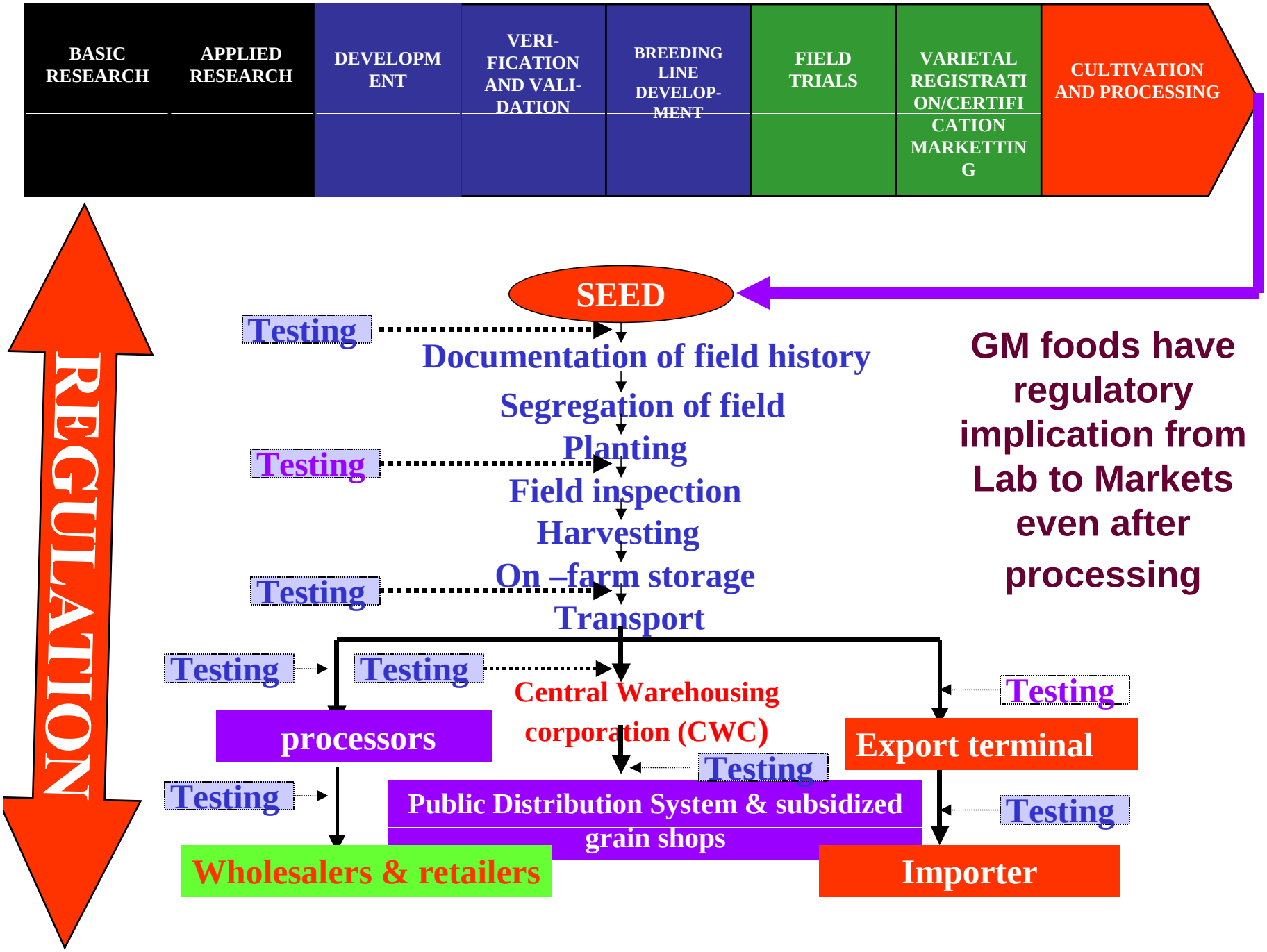
Crops	No of samples	Source
Brassica	199	Australia, Belgium
Chickpea	34	Australian, Scotland
Cotton	46	China, USA
Maize	50	USA, South Africa
Paddy	6898	Belgium, Germany, Philippines, Singapore, Switzerland, UK, USA, Vietnam
Potato	10	USA
Soybean	359	USA
Tobacco	3	Canada
Wheat	43	Germany

50:50 Public: Private

GE CROPS UNDER CONFINED FIELD TRIALS IN INDIA IN 2007-08

S.No.	Crop	Gene/event	Event selection	Biosafety Research Level-I	Biosafety Research Level-II
1	Brinjal	*cry1Ac*			
		cry1Aa & cry1Aabc			
2	Cabbage	cry1Ac			
		cry1Ba & cry1Ca3			
3	Cauliflower	*cry1Ac*			
		cry1Ba & cry1Ca3			
4	Corn	*cry1Ac + cp4epsp4*			
5	Groundnut	Chitinase gene			
6	Okra	cry1Ac			
7	Potato	RB gene			
8	Rice	*cry 1 Ab, cry 1C & bar*			
		cry1Ac			
9	Tomato	unedited NAD9			

MINISTRY OF SCIENCE & TECHNOLOGY


BASIC RESEARCH
APPLIED RESEARCH
DEVELOPMENT
VERI-FICATION AND VALI-DATION
BREEDING LINE DEVELOP-MENT
FIELD TRIALS
VARIETAL REGISTRATION/CERTIFICATION MARKETTING
CULTIVATION AND PROCESSING
REGULATION
SEED
Testing
Documentation of field history
Segregation of field
Planting
Testing
Field inspection
Harvesting
Testing
On –farm storage
Transport
Testing
Testing
Central Warehousing corporation (CWC)
Testing
processors
Testing
Export terminal
Testing
Testing
Public Distribution System & subsidized grain shops
Testing
Wholesalers & retailers
Importer
GM foods have regulatory implication from Lab to Markets even after processing

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

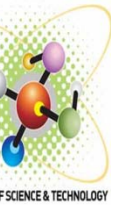
September, 2008- Courts do not give judgment on science it should be left to scientists

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

Trade

Traceability

Terminator Gene

Burning *Bt*-rice tria
28 October 2006Hara

under the Chairmanship of M. S. Swaminathan

Burning *Bt*-cotton trial
28 November Karnatak
2 December 1998 Wara
district, Andhra Prad

elines for research in
ts and Guidelines for Toxicity
y Evaluation of Transgenic
d Plant Parts, 1998 0

Recombi

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)

FEAR

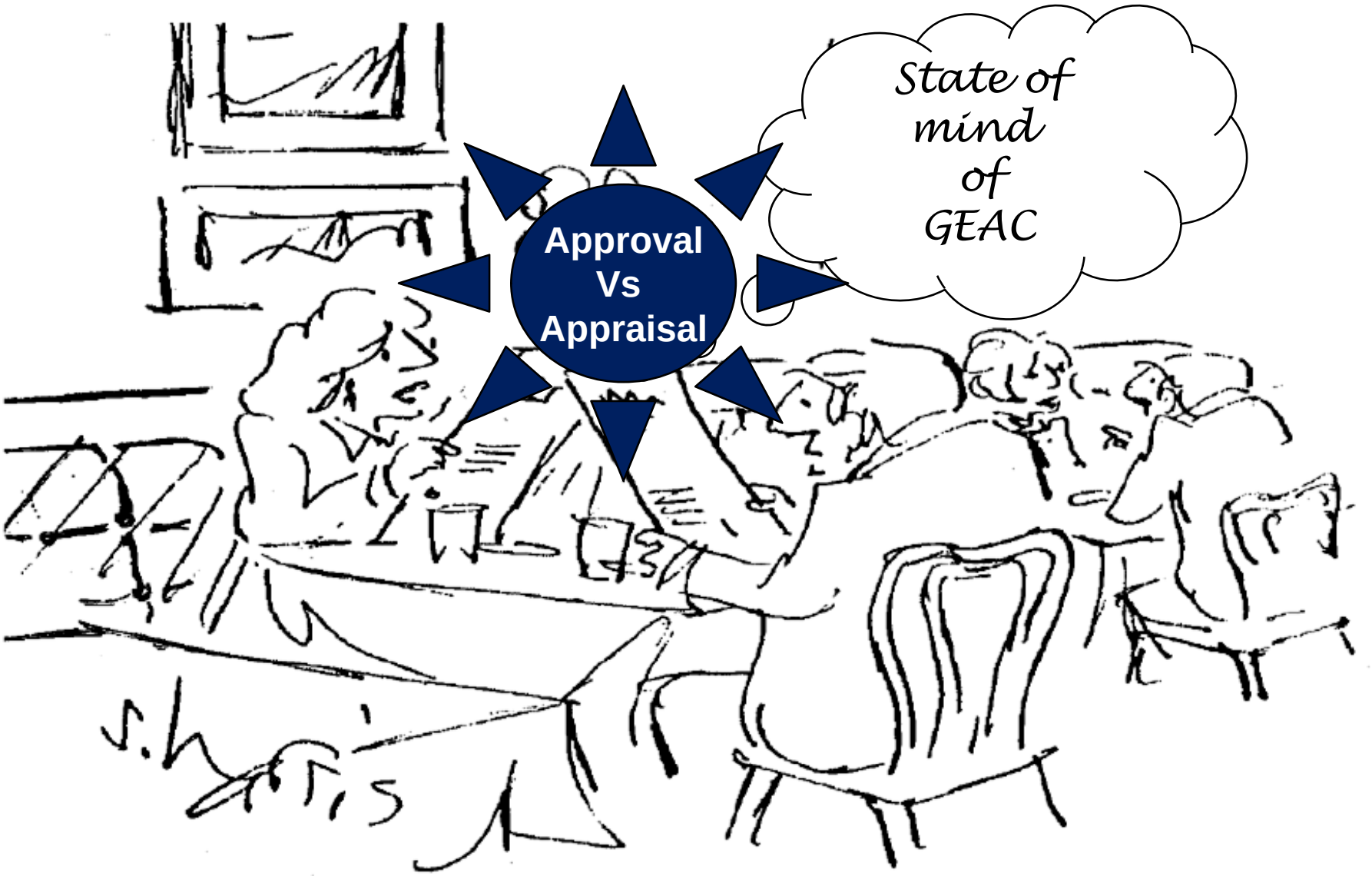
1986 1989 1992 1994 1998 2001 2004 2007

Some concerns in public consultations for Commercial release of Bt Brinjal

The Final diagnosis

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 welath existing in brinjal

Jairam Ramesh
MOS(I/C)E&F; February 9th , 2010


State of mind of GEAC
Approval Vs Appraisal
"WHAT'LL IT BE — ONE LARGE RISK OR SEVERAL SMALL ONES ?"

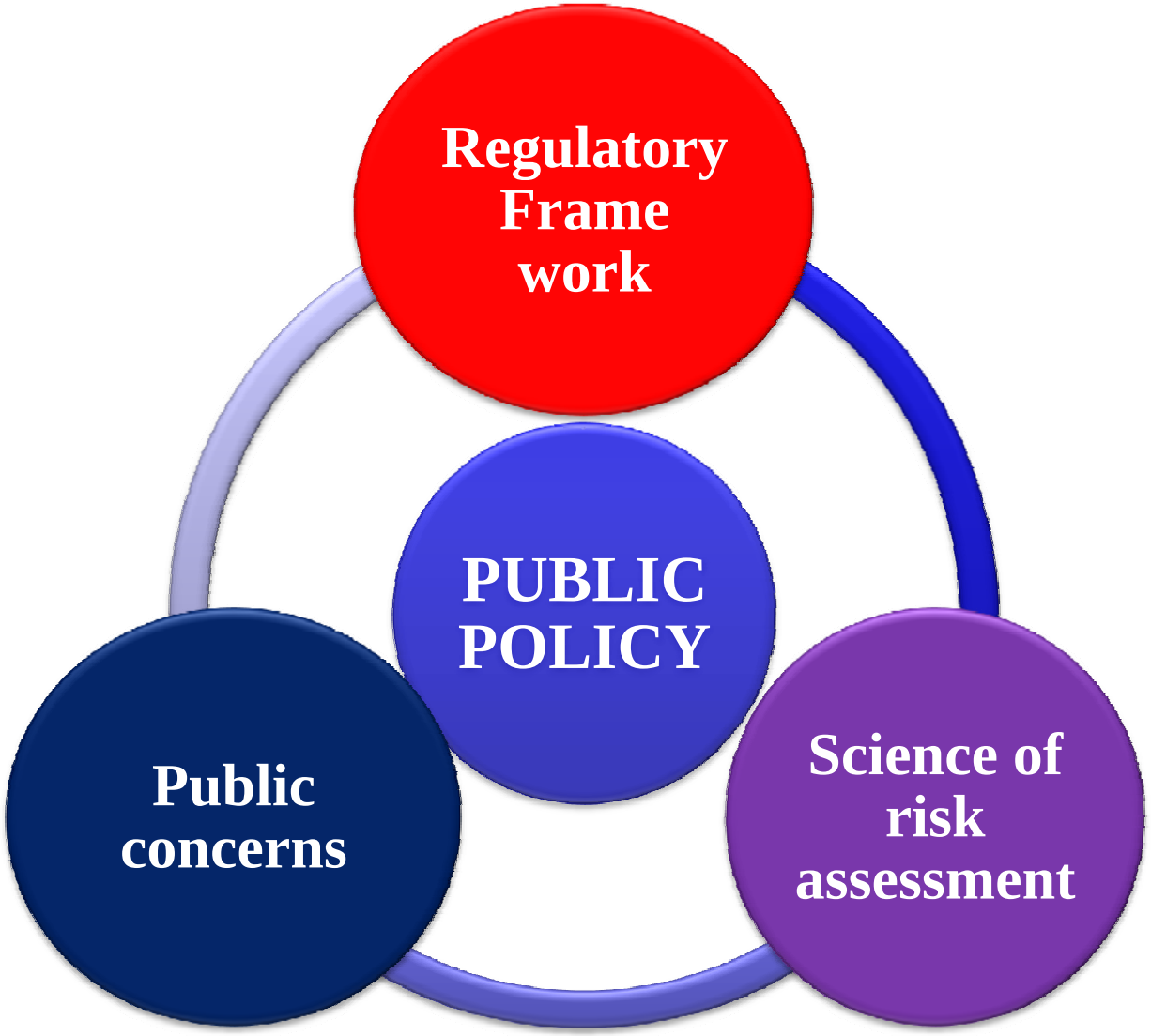
Today Topics

- Policy and Government
- Research and technology Development
- Regulations

- **Are we ready for the future !**

MINISTRY OF SCIENCE & TECHNOLOGY

Lessons learnt…..



Several lessons around 12 topics in 10 years

- REGULATORY EXPERIENCE AND EVALUTION 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 COMUNICATION
- INTER-MINISTERIAL COORDINATION
- CENTER- STATE RELATIONS
- INTELLECTUAL PROPERTY, BIODIVERSITY AND LEGAL ISSUES.
- PILS – SCIENCE VERSUS PROCESS
- HUMAN RESOURCE DEVELOPMENT

Way forward

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

Policy intervention……..Address by the President of India to the Parliament

New Delhi; February 16, 2006

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

Characteristic of Regulatory Framework	Argentina	Australia	Canada	Philippine	Japan	S. Africa	EU	USA
	Presence of an "X" indicates conformity with the first alternative in each dichotomous comparison							
New laws were passed to specifically address gene technology		X			X	X	X	
Statutory instruments are employed	X	X	X	X	X	X	X	X

POLICY INTERVENTION– GOVERNMENT OF INDIA

Setting up NBRA will require the promulgation of new legislation, namely the: Biotechnology Regulatory Authority of India Act , 2011" or the BRAI Act.

METHODOL0GY 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**

Step 2

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 3

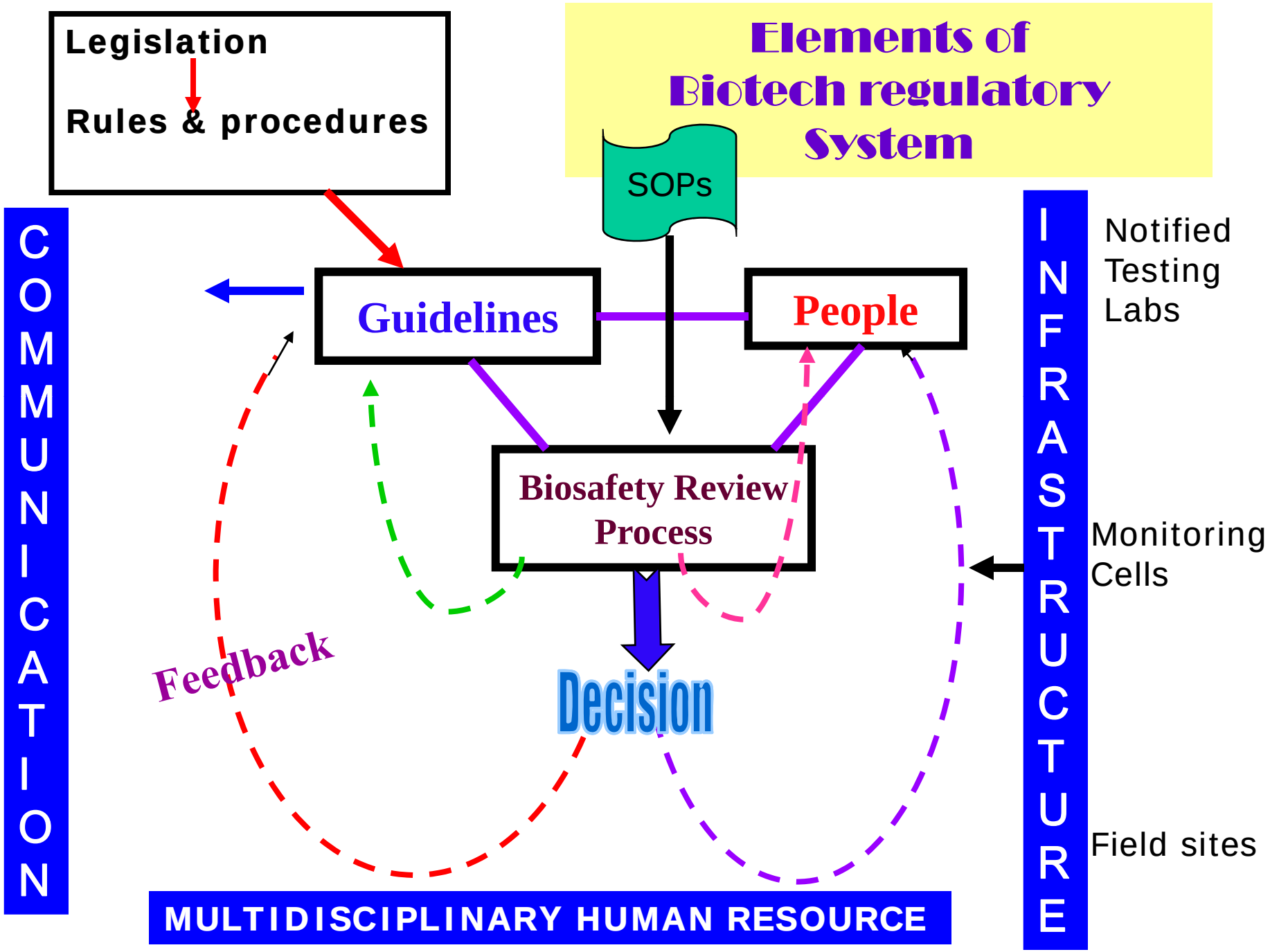
Preparation of a preliminary establishment plan for the BRAI.
Stakeholder interviews to obtain feedback on the preliminary plan.
Preparation of a revised, draft plan incorporating stakeholder feedback.

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
Feedback
COMMUNICATION
INFRASTRUCTURE
Notified Testing Labs
Monitoring Cells
Field sites
MULTIDISCIPLINARY HUMAN RESOURCE

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 feed back
- ☒ 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**

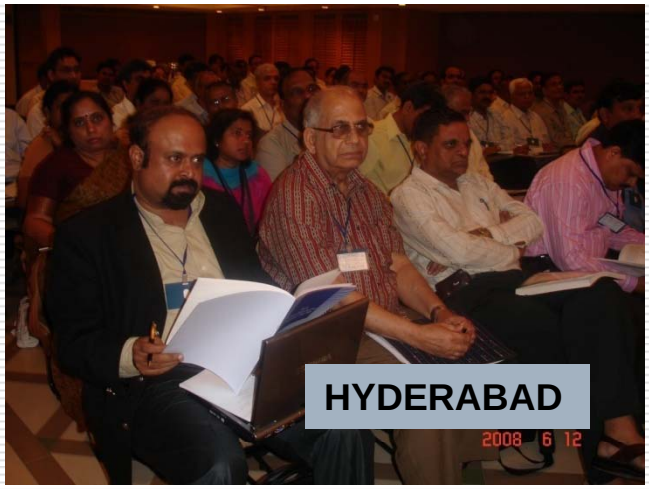
GLIMPSES OF THE REGIONAL CONSULTATIONS


at Mumbai


Chennai


Kolkatta

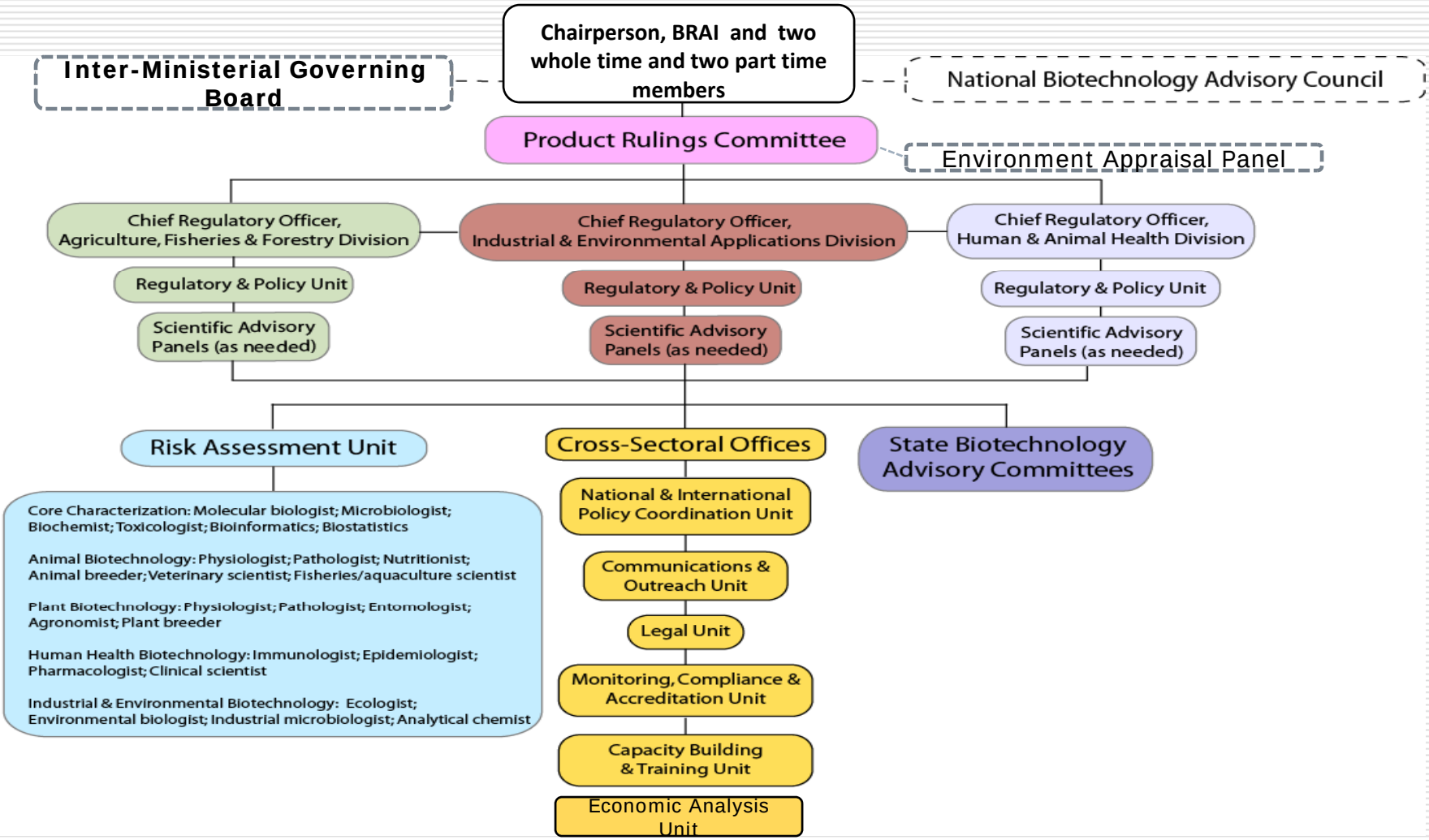

at Delhi



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



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

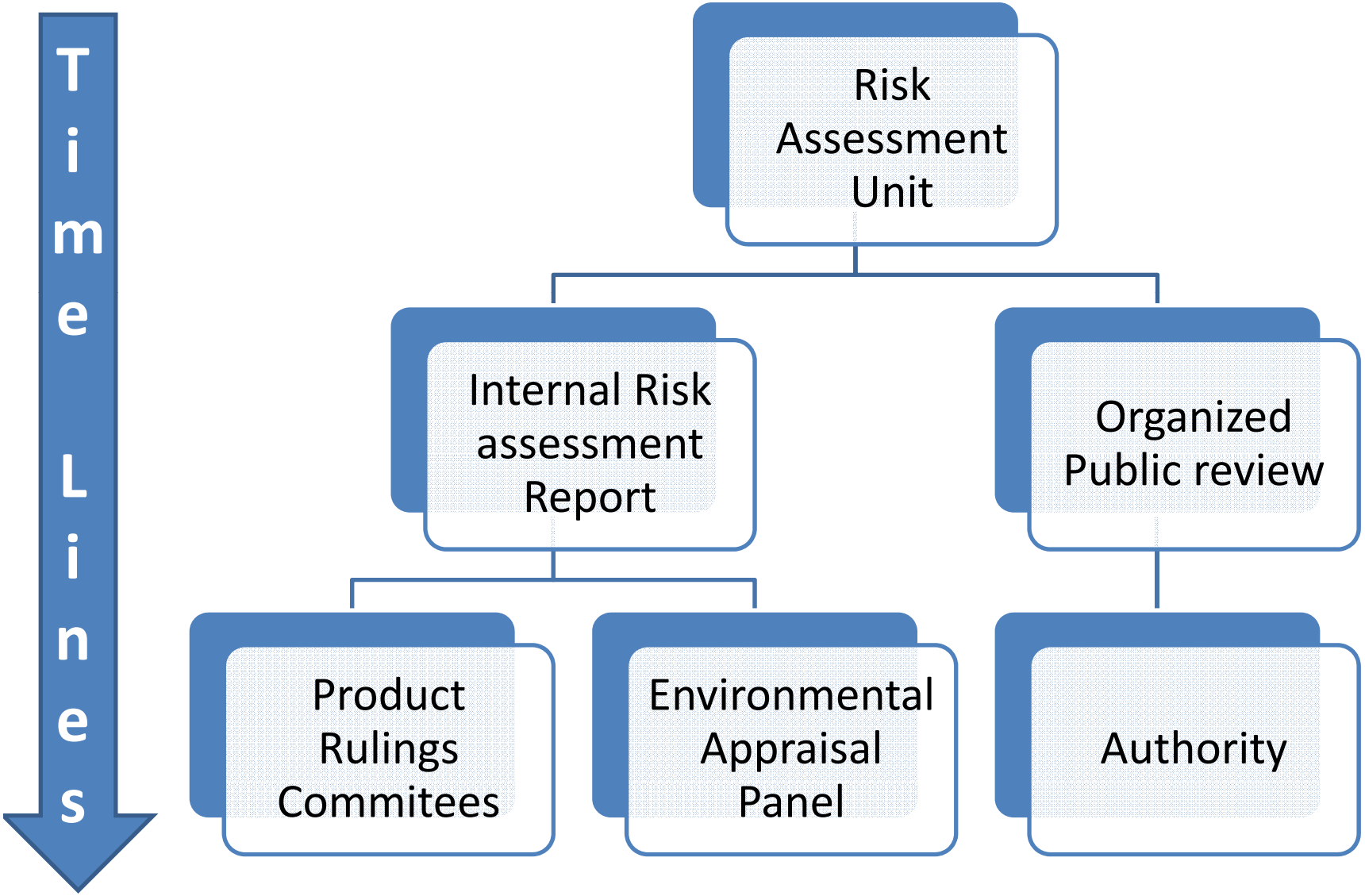
GOVERNING BOARD AND ADVISORY COUNCIL

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 PROCESSESED



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

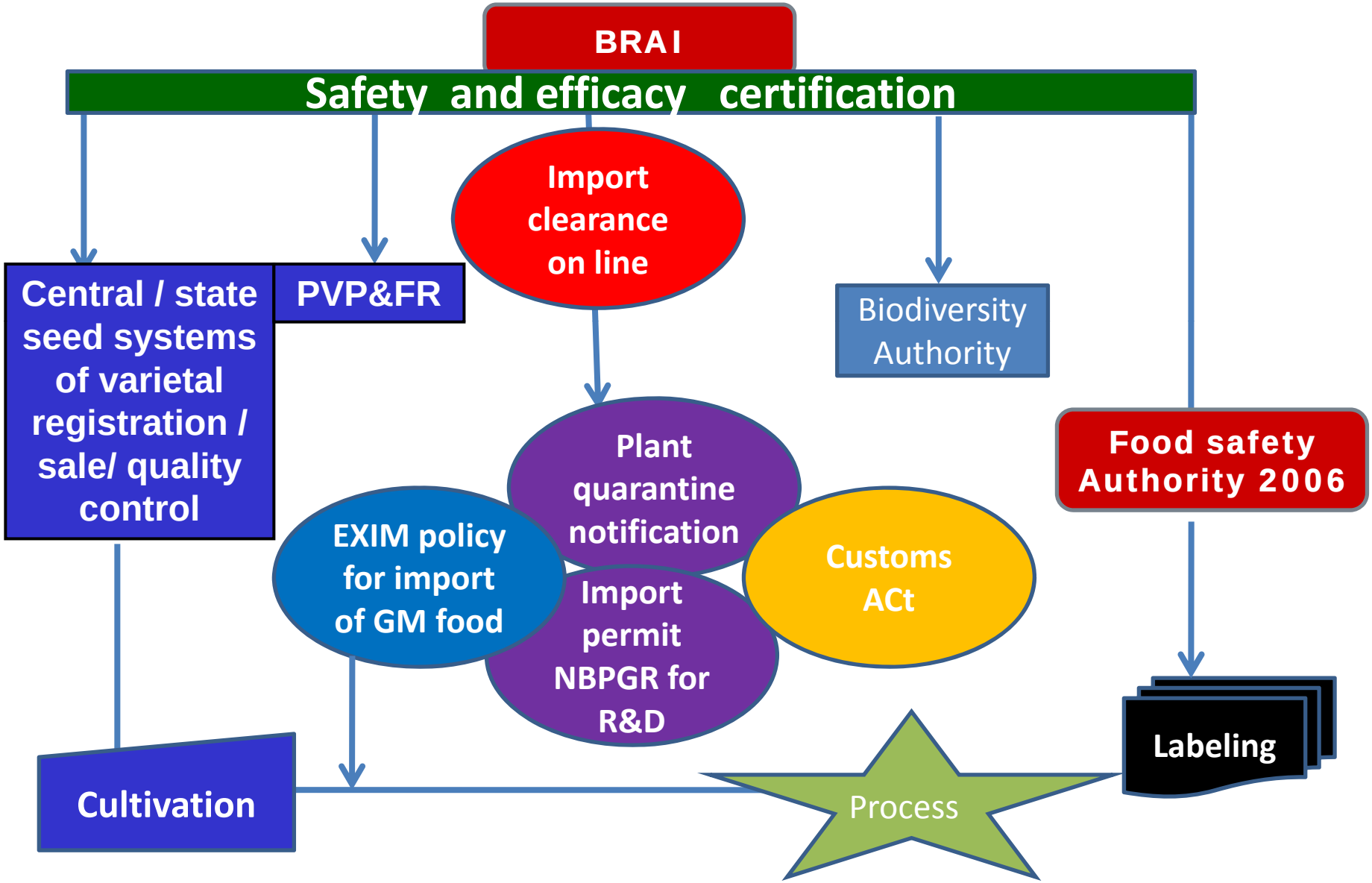
- Provides for notification by the Authority of accredited laboratories and research institutions for the purposes of proposed legislation.

- 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 atleast 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



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

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

Stage 01 Sourcing ideas Market application	**Stage 02** IP Protection	**Stage 03** Proof of Concept Product Development	**Stage 04** Licensing	**Stage 05** Formation and incubation of technology businesses	**Stage 06** Investment	**Stage 07** Exits
						

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

Groundnut
Precocious germination
-Pre-harvest

Storage
-Post harvest

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 % over all

Upto 30% in some crops like pulses

What are the major constraints?

- **Preharvest:**

  Precocious germination

  seed shattering

- **Post harvest:**

  - **Biotic:** **Mycotoxin**

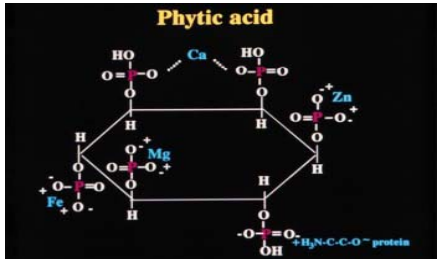
  Storage pest

  - **Abiotic**

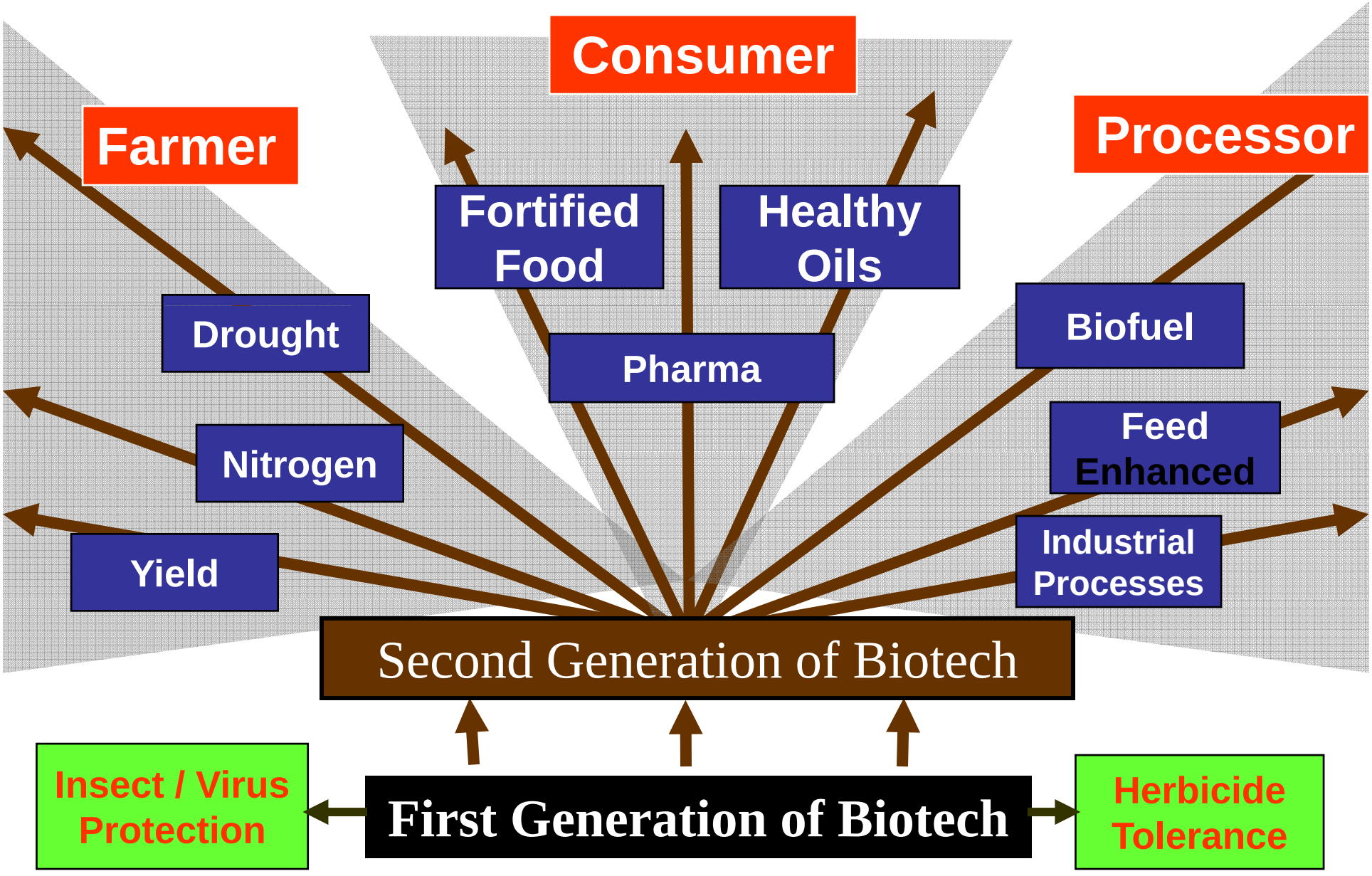
    Seed deterioration

- **Anti-nutritional factors**

  [Protein digestibility]



R&D on Second Generation of Biotech Crops



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