- **'Introductory presentations made at the brain storming meeting held on June 1,2010 on GM crops'**

- **Prof. G. Padmanaban**

Beyond Bt Brinjal

INSA

June 1, 2010

All the brinjal growing states have expressed reservation on the introduction of Bt brinjal.

This is true. A couple of states had based the decision on the lack of evidence in terms of commercial benefits to the farmer. However, the EC-II report clearly mentions the significant decrease in pesticide spray, increased marketable yield and the projected economic gain to the farmer, in quantitative terms based on the trials conducted by the Indian Institute of Vegetable Research (IIVR), Varanasi. This, of course, needs to be replicated in private farmers' fields. The inputs available to at least some of the state governments were not scientifically broad- based .

.

The wide public consultations in the country brought several concerns to the fore.

The concerns are, of course, the standard ones: biodiversity issues, health safety, MNC strong hold, loopholes in the regulatory regime. The meetings were by and large dominated by crowds emotively orchestrated by activists and demonstrations in street corners. A more effective interaction in each centre could have been through having an intense discussion with a limited group, representing all stake holders.

- **The fact remains that a vast majority, including scientists, have not studied the issues involved, but have offered comments without any hesitation. It does become necessary to take decisions in the best interest of the nation, guided by genuine scientific inputs, rather than attempting a consensus. I am not sure, a consensus can be ever reached in any part of the world on this issue. Did India enter into the nuclear deal based on a national consensus?**

The biodiversity issue is crucial, since brinjal is 'Indian'. The gene flow studies carried out are not adequate. The trials should have been carried out in different environmental conditions. Bt brinjal may affect the rich biodiversity of this vegetable. The example given is Bt cotton, which is dominating over non-Bt cotton in the country.

- **I wonder as to why Bt brinjal needs to be developed with all its advantages, if it does not become a popular choice. The approach would be to introduce Bt in every popular variety of brinjal cultivated in different states, as has been the case with Bt cotton. Even in the case of non-transgenic crops, is it not a fact that farmers prefer only certain varieties and hybrids? What happens to biodiversity in these cases. This is the price the society has to pay ever since man started practicing agriculture, targeting specific varieties and hybrids.**

BIODIVERSITY I

. Philosophically I have never understood the issue of biodiversity with respect to transgenic crops carrying a couple of transgenes. This is in the context of horizontal and vertical transmission of genes taking place in nature all the time in evolutionary scale. How did the 2000 varieties of brinjal evolve? Can any one define a pure, unadulterated line of rice in terms of the genome? How is the biodiversity affected even if a couple of transgenes were to reach an unintended target, unless the transgene is a killer. The last two decades of experience clearly shows that Bt genes are safe from that perspective. Bt brinjal is not a killer weed. Although, I respect the regulatory protocols on gene flow demanded in transgenic crop trials, deep inside I believe that the biodiversity card is overplayed. The government can create biodiversity parks all over the country to preserve rare varieties of selected plant species .

How many genes from Toesinte to Corn to Bt Corn?!

MesoAmericans converted Toesinte to edible corn by hybridization.

The domesticated South American Tomato has evolved into 7500 varieties.

How did the 2000 varieties of Brinjal evolve?

Radiation mutagenesis is a standard practice in hybrid development.

Why the opposition to a particular method of gene transfer?

Biodiversity II

The environment has to be constantly monitored for evolution of minor pests as major. Apart from gene stacking, crop rotation needs to be scientifically planned. Bt crop is ideal to be part of IPM.

. **Bt brinjal as a food crop cannot be equated with Bt cotton**. The chronic toxicity tests carried out in experimental animals are not adequate. There are suggestions that chronic toxicity tests should be carried out during the entire life cycle of the animal. Solanacea is a unique species and the transgenes may bring the hidden toxins to the surface. Brinjal is used in native medicine without cooking and abundant caution needs to be exercised in assessing the health safety of Bt brinjal.

- As per EC-II report, the developers have indeed, carried out a variety of mandatory toxicity tests in a wide variety of experimental and domesticated animals. A 90 day chronic toxicity test has been carried out. These tests have been considered as adequate by GEAC. One should also keep in mind that there is so much published information already available on the safety of Bt toxins to humans and animals. More than this, Bt corn is being consumed across the globe for over a decade. Apart from being cattle feed, the breakfast cereal in North America, perhaps, contains Bt corn. We cannot just discard the American experience and state that it is not relevant for our discussion. In my perception, the greatest proof of safety of Bt gene is the long term consumption of Bt corn in many countries without any confirmed and authenticated ill effects to the public.

CHRONIC TOXICITY

Scientifically it is well known that Bt proteins get degraded in the acidic stomach of the mammal, whereas it gets activated under the alkaline conditions of the gut in the pests. It gets degraded during cooking. Its penetrance in the soil and microflora is not of real concern. In spite of all these arguments, the chronic toxicity tests in rodents can be carried out for 6 months or even a year, if that would satisfy the requirement. I personally do not see the logic in extended studies.

Bt brinjal has been developed by Mahyco in which Monsanto has a stake of 26%. The gene belongs to Monsanto. Priority needs to be given to the commercialization of indigenously developed transgenic products. China has developed Bt rice indigenously and has approved trials that would lead to commercialization.

First, the support for indigenous development is definitely welcome. There are atleast a few events, both in the private and public sectors, that are ready for trials towards commercialization. But, one needs to talk to the scientists concerned to understand the trials and tribulations they undergo to take their transgenics forward.

On the one hand they have to face the tough requirements of RCGM and GEAC, constant interference by activists directly or indirectly, Supreme court ruling that actually allowed on going trials (Mahyco), but clamped an embargo on newer trials that were ready (indigenous) and on the other, face an uncertain future in terms of publications and career advancement (public sector) and survival (private company). Is this the right environment for indigenous development of commercial capabilities?

CHINA POLICY

As regards China, it has followed a dual policy. It has approved specific GM products developed by MNCs (eg.GM corn and Soya), while developing its own Bt rice. As per a news item (November 4, 2009/PR news shire- First call), Monsanto was opening its first research center in Zhongguancum, Beijing. Monsanto has made a commitment to collaborate with Chinese scientists on advanced biotech and breeding technology. China is pragmatic. It wants to get the best of both worlds. We are driven by emotional activism. It is not as if that there is no opposition to GM technology in China. But, it is able to take decisions and move ahead. It is able to keep the big picture in perspective, namely food security to an over billion population and an intense ambition to become the world leader. I will not be surprised if we will be importing Bt rice from China at some point of time!

Examples of indigenous commercial efforts

Gly genes from ICGEB to industry

Bt cry 1AC from NRCPB to give Bikaneri Nerma

Bt Brinjal cry 1Fa1 from NRCPB to industry

Synthetic Bt genes developed and transferred by NBRI, Metahelix

Barstar-Barnase in mustard from South campus (in the process)

Resistance development is a serious concern in monophagous pests.

By far this is the most serious issue, which scientists should address as the primary challenge. Two different hypothesis are available to explain the mode of action of Cry toxins. One is based on generating pores (punching holes) in the insect gut cell and the other is based on killing mediated by signal transduction. In both the models, the first steps envisaged are similar. The ingested toxin is cleaved by midgut protease and the activated toxin binds to cadherin receptor located in the microvilli of midgut cells. The toxin oligomer then binds to secondary receptors anchored to the membrane such as aminopeptidase N or alkaline phosphatase. The toxin oligomer then inserts into lipid raft membranes forming pores and causing the cells to burst. In the second model, the binding of toxin to cadherin receptor is visualized to trigger a signal transduction cascade, eventually leading to oncotic cell death.

MECHANISMS OF RESISTANCE

Mechanisms of resistance development have been studied in different pests induced to become resistant in the laboratory. In general, the most frequently observed mechanism is due to defects in receptor binding followed by resistance due to defects in protease production, elevated immune response, enhanced esterase production etc. Strategies to overcome resistance include development of Bt plants with novel Cry toxins (eg.VIP3 – plants), Cry gene stacking (eg. Cry 1Ac with Cry 2Ab), modified Cry toxins that bypass primary receptor interaction (eg.Cry 1A Mod toxins), use of Cyt proteins from Bt i strain along with Cry toxins and use of cadherin fragments to counter resistance (Bravo, A and Soberon, M (2008). How to cope with insect resistance to Bt toxins? Trends in Biotechnology Vol.26, 473-579).

GENE STACKING

In addition, on the field use of refuge cropping has been shown to be effective. It is clear that in developed countries there is already a switch to the use of Bt crops with stacked genes. Indigenous efforts should only be towards developing Bt plants with stacked genes. Monsanto has already indicated of possible resistance development in Gujarat to pink boll worm in Bt cotton and has recommended the use of second generation Bollguard with two stacked genes. I wish there is an Indian authority which gives this advice based on a constant monitoring of the GM crops in the field.

. **India needs an independent authority to evaluate and approve the trials as well as to monitor the performance of GM crops in the field after commercialization.**

A unified National Biotechnology Regulatory Authority (NBRA) is under consideration. The bill pending since 2005 is likely to be taken up in the parliament for debate. I feel that the regulatory authority to evaluate and monitor transgenic crops in experimental fields and the one that performs a regulatory function after commercialization should be different. GEAC can continue to perform the former function and give approval for commercialization. GEAC has evolved over several years of experience and, perhaps, it is not a good idea to disband the same. It may need some more fine tuning. Thus, these two authorities can be two arms of NBRA in the Agriculture sector. The biggest challenge is to create independent and dedicated experimental facilities to monitor and evaluate GM crops. Till such a facility comes into existense, the existing laboratories in different institutions have to be net-worked to provide independent experimental capabilities for NBRA.

Steps in the development of Bt brinjal

1. **Nature and effect of genetic modification**
   - **cry 1AC against Fruit & Shoot Borer**
   - **npt11 gene, aad gene – Kanamycin & Streptomycin/Spectinomycin selected markers**
   - **Expression and Stability.**
2. **Environmental Safety Assessment**
   a. **Potential gene transfer to wild relatives**
   b. **Extent of outcrossing, pollen flow**
   c. **Gene transfer from brinjal to other plants**
   d. **Gene transfer from brinjal to other organisms**
   e. **Potential for relative weediness of Bt Brinjal event EEI.**
   f. **Impact on non-target organisms, including soil impact.**
3. **Food and Safety assessment**
   a. **Toxicity and allergenicity (Skin, mucous membrane tests) .**
   b. **Digestive fate (cry1AC, npt11).**
   c. **Compositional analysis.**
   d. **Feed to rabbits, fish, chicken, goat, cow.**

(Expert Committee II Report, 2009.)

Regulatory System

RDAC

IBSC

RCGM (30+ members)----- MNG

GEAC(30+ members)—MNG

SBMC

DBMC

AGENDA

Gene Stacking

Crop Rotation

Bt as part of IPM

Agricultural practices to integrate GM crops

Si RNA approach

Minor Pests

Marker-Free

Stage-Specific Promoter

Improved Nutrition &

Abiotic Stress

Finally, none of these agenda should delay the release of Bt brinjal
Bt Corn was introduced with a single Bt gene and antibiotic mrkers.
We are loosing precious time.
Nearly, 25 countries, including Europe have gone for this technology
Bt cotton has convinced many farmers to go for this technology
Success of Bt brinjal would convince public of the benefits of this technology
Bt Rice with improved nutrition and ability to grow in low rainfall and saline soil would revolutionalize Indian Agriculture
Scientists involved (private and public) are bewildered and shattered.

GM crops (Indigenous development)

Brinjal, Cabbage, Cauliflower, Cotton, Groundnut, Maize, Chickpea, Mustard, Okra, Pigeon Pea, Potato, Rice, Sorghum, Tomato

Institutions involved

Mahyco, TNAU, UAS (Dhrawad), Nunhems India, Rasi, Nuziweedu, Ankur, JK Seed, ICRISAT, Monsanto Mumbai, CPRI, NIPGR, NRCS, IARI, Metahelix, Bejo Sheetal , UDSC, ICGEB etc

Genes: *cry 1Ac, cry1cA, cry 1Ab, ama 1, Rb, cry !b, cry 2Ab, cry 1B-cry 1Aa fusion, chi 11, synthetic cry genes, Barnase-barstar, gly 1, gly 2, helicase etc*

WORLD IS MOVING AHEAD

European Union has accepted GM.
(Amflora -GM Potato)
France, Germany on selective basis
GS (Genuity SmartStax) Corn with 8 transgenes developed
(aerial pests, subsoil pests, herbicide tolerance)
China has approved commercial Bt rice trials

How green biotech turned white and blue

Lucas Laursen

Journal name: Nature Biotechnology Volume: 28, Pages: 393–395 Year published: (2010) DOI: doi:10.1038/nbt0510-393

Argentina has blazed a trail as one of the leading genetically modified (GM) crop producers. Can other developing countries import the seeds of its success? With growing markets in China, India and elsewhere, Argentina and its neighbors will continue trying to capitalize on their competitive advantages growing soy, cotton and maize. But the cost of distribution will depend heavily on international agreements, such as the pending EU approval schedules. Those challenges, which Argentina has navigated thus far, might be enough to make other countries think twice about how to implement their own biotech crop plans, but at least in Argentina, Yankelevich says, “there's no going back.”

Agriculture is not just about technology, since it embodies a culture and there are political and sociological over tones. It needs to be realized that GM is only an innovative approach to provide a technological solution, but it should not be made a scape goat if there is failure else where.

Let us not throw the baby with bath water

1. Limited release of Bt Brinjal seeds to be tested and evluated in specific farmers' fields from different states.To be strictly monitored by an independent committee
2. Accelerate the indigenous efforts to commercialise pest-resistant, abiotic-stress resistant hybrids/ varieties with improved nutrition content.
3. NBRA (Agri) should have two components. GEAC and GMMC (GM Crop Monitoring Committee). An effective technical advisory system for the farmer.
4. Decision on GM crops needs to be taken in Parliament based on scientific data and the benefit that would accrue to the country. A public consensus is neither feasible nor possible.
5. Decision on case to case basis
6. An expert committee to decide on GM priorities.

RECOMMENDATIONS

THANK YOU

- **Dr. H.S. Gupta**

Bt Brinjal, Transgenic Crops & BRAI

H. S. Gupta

National Academy of Agriculture Sciences

NASC Complex, Pusa Campus

New Delhi – 110 012

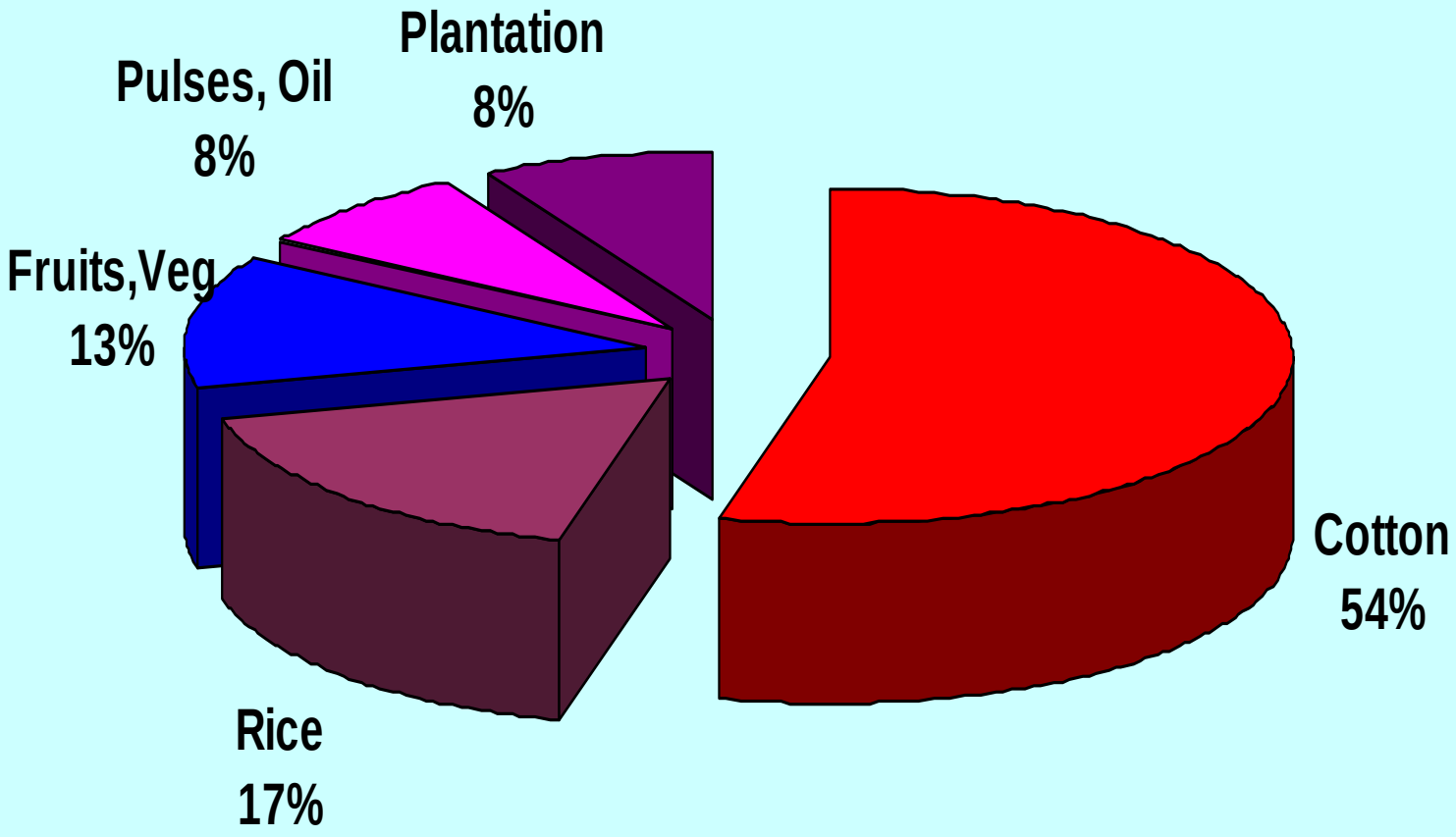
What is Bt brinjal?

Genetically engineered crop expressing a gene encoding an insecticidal protein of a soil bacterium

***Bacillus thuringiensis* (Bt)**

DO WE NEED Bt-BRINJAL?

Brinjal Shoot and Fruit Borer
(*Leucinodes orbonalis*)



ANNUAL PESTICIDE CONSUMPTION

50,000 Metric Tons; Rs 3,500 crores

PUNJAB'S TRAGEDY IS NATION'S TRAGEDY

CANCER EXPRESS

RED HARVEST Punjabi farmer, the poster boy of Green Revolution, is dying. Pesticides overuse is the likely cause

Praveen Donthi

Passenger Express 339 enters Bathinda railway station around 9 p.m., as if blindfolded by the dark winter night. The sight of it brings a glint to the lifeless eyes of Balwinder Singh (42) waiting on platform number two. He is too weak and turns to his brother who will be his crutches.

There are many like him, battling cancer, frail and fragile, waiting to board. But all the commotion and noise is on the other platforms. Here, silence hangs in the air heavily.

BALWINDER
42, Bhagawa
Bathinda

Balwinder Singh used
and wheat in his two ac
his family happy. He
learn that his son Jas
now is mentally retard
ies have concluded t
affected mental grow
Bigger shock awaite
March, 2009. His sev
stomach was diagnose
the oesophagus. Now h
farm on lease.

After crying out the

Insect Pest Management: Imperatives

- **Drastic reduction in pesticide use**
- **Eco-friendly and sustainable strategies**
- **Bio-pesticides- Bt formulation used for long**
- **GM crops – A tangible and long term strategy**

Bt-BRINJAL VARIETIES

(Fruit Borer Protection by *cry 1Ac*)

Trials at IIVR, UAS-D, TNAU

PUBLIC-PRIVATE PATNERSHIP WITH M/S MAHYCO

ABSP II

AICVIP FIELD TRIALS WITH BT BRINJAL HYBRIDS

Field Trials	Reduction in insecticide use		Increase in fruit yield (%) over	
	For FSB	All pests	Non-Bt	
2004-05	80.0	40.4	154.2	
2005-06	74.5	43.2	113.0	
Average	77.2	41.8	133.6	

AICVIP, ICAR, 2007

Is Bt-brinjal Biosafe?

Bt-Brinjal Event EE 1– Biosafety Tests

- Pollen flow studies - 2 Locations (Mahyco).
- Germination and weediness studies (Mahyco).
- Aggressiveness studies (Mahyco).
- Molecular characterization and event ID (Mahyco).
- Acute oral toxicity studies in rats (Intox, Pune).
- Mucous membrane irritation test in female rabbit (Intox, Pune).
- Primary skin irritation test in rabbit (Intox, Pune).
- Effects on non-target and beneficial insects (Mahyco).
- Sub chronic oral toxicity study in Sprague Dawley rats (Intox, Pune).
- Assessment of allergenicity of protein extract using Brown Norway Rats (Rallis, Bangalore).
- Responses, as a dietary feed ingredient to common carp growth performances (Central Institute of Fisheries Education, Mumbai).
- Chemical fingerprinting of Bt and non-Bt brinjal (including alkaloids) (IICT, Hyderabad).
- Sub-chronic (90 days) feeding-New Zealand rabbit (Advinus, Bangalore).
- Effect on performance and health of broiler chickens (CARI, Izatnagar).
- Sub-chronic (90 days) feeding studies in goats (Advinus, Bangalore).
- Feeding studies in lactating crossbred dairy cows (GBPUAT, Pantnagar).

SOCIO-ECONOMIC ASSESSMENT OF Bt BRINJAL

- **Will reduce use of insecticides and increase the marketable yield**
- **Aggregate economic gains around US$108 million per year**
- **Benefits for farmers' health from reduced insecticide applications are worth an additional $34 million per year**
- **Availability of OPVs would make the technology more accessible especially to resource-poor farmers**

Krishna & Qaim, 2008

Bt - CROPS

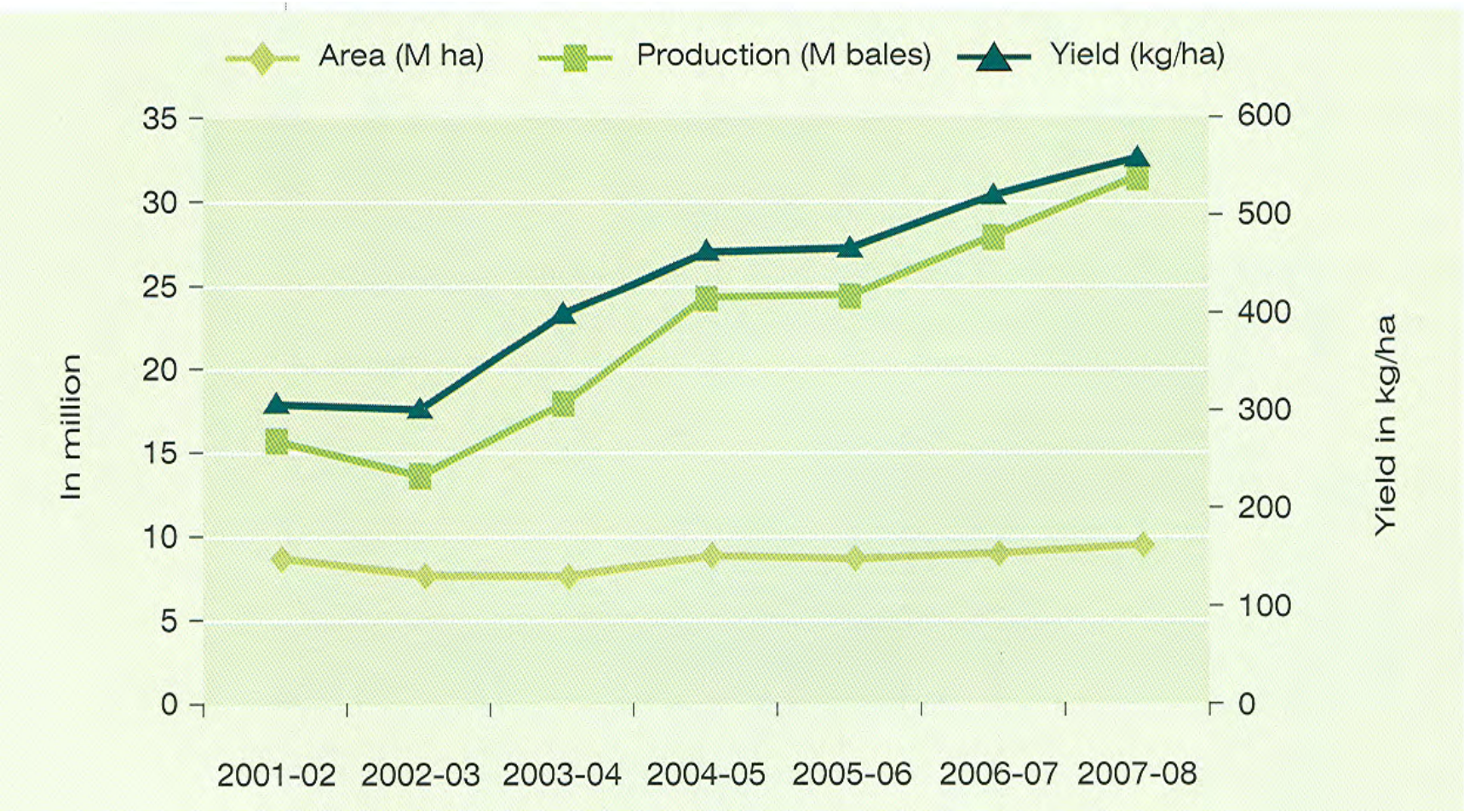
COTTON, MAIZE, RICE and POTATO

USA, Australia, China, Argentina, South Africa, Spain, Germany, France, Bulgaria, Indonesia, Canada, Romania and India

46 mha out of 134 mha of transgenic crops - 2009

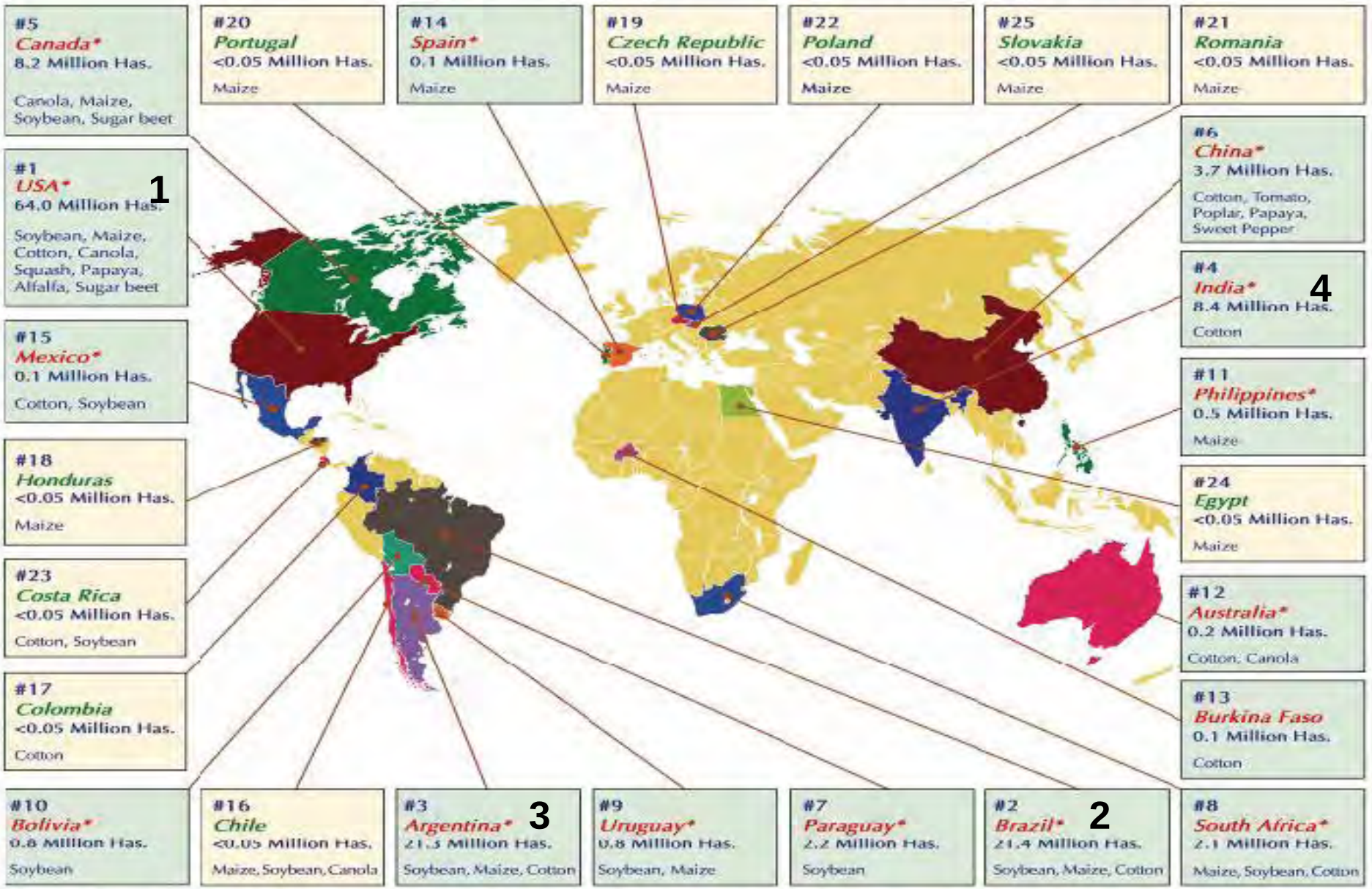
Bt- Cotton – a Success Story in India

Area, Production and Productivity of Cotton



Exported 8 million bales during 2009-10

Biotech Crop Countries and Mega-Countries*, 2009



* 15 biotech mega-countries growing 50,000 hectares, or more, of biotech crops.

Source: Clive James, 2009.

Future Demand for food grains

	Study	Demand for 2020 (million tonnes)
1.	Planning Commission	247
2.	Other studies	253 to 280

- **Yield of the food crops plateuing**
- **Biotic & abiotic stresses increasing**
- **Natural resources are degrading**
- **Climate change has further compounded the problem**

Global cereal demand in 2020 to increase by 40%

We have to maintain self-sufficiency in food grains

Crop improvement programs to be pursued vigorously making biotechnology & GM crop as a major partner

Questions We Need to Address

1. GM crops are reality- should we use this powerful technology or wait & watch
2. GM crop is not a panacea but can we feed ever growing population without deploying this technology?
3. Similar outcry was raised when hybrids were released, and in early 1970s about research on rDNA – creation of deadly viruses – wiping out human race etc..
4. Vaccines based on rDNA technology are accepted. Why not in Agriculture
5. Should irrational obstacles without scientific basis & speculative fear hold us back?
6. We missed industrial revolution in the past. Do we want to miss this revolution in biotechnology?
7. Dispassionate assessment of the technology and come out with clear policy

Progress in Agriculture

Nature has been transferring genes at its own pace. Thus, it has indeed been doing 'Genetic Engineering' but slowly.

What we are doing today is at accelerated pace.

Science-led Agriculture

Domestication

↓

Selection

↓

Breeding HYV

↓

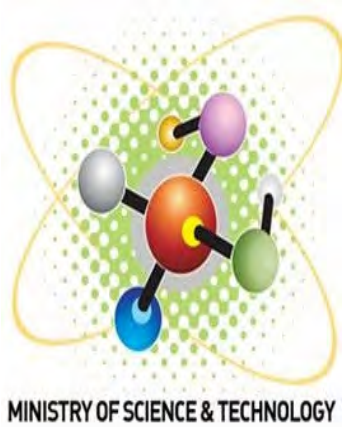
Hybrids

↓

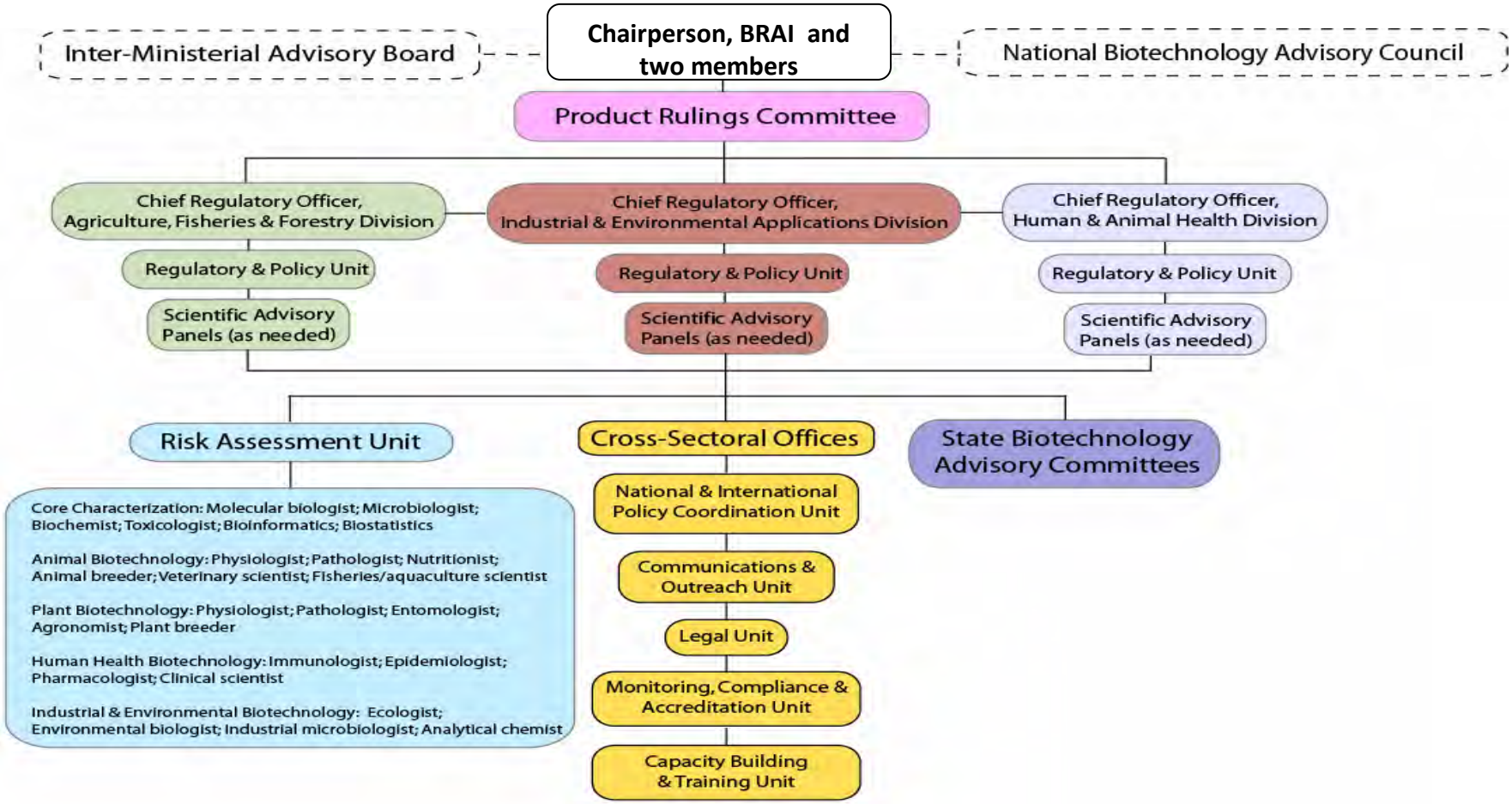
Transgenics (GM)

BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA

Department of Biotechnology
Government of India



ORGANOGRAM OF BRAI



The Biotechnology Regulatory Authority of India Bill, 2009

Suggestions proposed by NAAS

- BRAI should strictly act as a single window clearance system

- BRAI should confine to biosafety clearance with regard to food, feed or environment.

- Once declared safe by the BRAI, the GM crop/genotype should enter into :

a) the AICRP of the ICAR, which evaluates and monitors the improvement in productivity or quality of the newly developed crop varieties/hybrids (whether bred through conventional or biotechnological methods)

b) the multi location performance trial (VCU) as proposed under the New Seed Bill, 2004 for the purpose of Registration of plant varieties in commercial use.

- Once a GM crop is declared safe by BRAI it should be governed by the prevailing Seed Act with respect to improvement in productivity or quality.

- Import of GM crops/seed material should continue to be routed through NBPGR, as is the case currently under the Plant Quarantine Order, 2003.

- BRAI should have synergy with Food Safety and Standards Authority, and Biological Diversity Authority of India.

- The inter-ministerial advisory board may also include among others a representative of DARE

The Biotechnology Advisory Council should include the following:

- Plant Breeders (two in number) instead of Plant Scientists
- Agricultural Extension Expert (One)
- Social Scientist (one)
- Medical doctor of eminence (one)

The Technical Members of the Appellate Tribunal have been referred as Part time members in the Bill. Since ‘they shall not hold any other office during their tenure as such’, they should also be given the status of full time members.

PROPOSED MANAGEMENT STRUCTURE: GOVERNANCE

- The Authority shall consist of a Chairperson and two whole-time members.
- The Chairperson shall be a person of outstanding scientific calibre with a Ph.D., M.D. or equivalent in a field relevant to the mandate of the Authority
- To hold the rank of Secretary to the Government of India.
- The Chairperson and Members of the Authority, to be appointed by the Central Government through selection committee chaired by Cabinet secretary including scientific experts and others
- To be supported by two advisory bodies: an Inter-ministerial Advisory Board (IMAB) and a National Biotechnology Advisory Council (NBAC) in the governance of the BRAI

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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

ADVISORY BODIES

- The **Inter-ministerial Advisory Board (IMAB):** To promote and ensure inter-ministerial coordination with regards the implementation of the regulatory system. The Board will include high level representations from key line ministries.
- The **National Biotechnology Advisory Council (NBAC):** To address overarching policy-related issues that may affect the regulation of biotechnology in India. The Council members will include representatives from the scientific community, farmers , consumers, public and private sector and civil society.

Reports of studies accepted by the regulatory authorities in various countries.

- **Assessment of the *in vitro* digestive fate of *B.t.k.* HD73 *cry1Ac* protein *B.t.k* HD-73 protein**
- **A Dietary Toxicity Study with parasitic hymenoptera (*Nasonia Vitripennis*)**
- **Evaluation of the dietary effect(s) of purified *B.t.k.* endotoxin proteins on honey bee larvae**
- **Evaluation of the dietary effect(s) of purified *B.t.k.* endotoxin proteins on honey bee adults**
- ***B.t.k.* HD-73 protein: A dietary toxicity study with ladybird beetles**
- ***B.t.k.* HD-73 protein: A dietary toxicity study with green lacewing larvae**
- **Effect of *Bacillus thuringiensis* insecticidal protein *cry1Ab*, *cry2A*, cry3A on *Folsomia* and *Xenylla grisea* (Insecta: Collembola)**
- **Acute oral toxicity of Bt var. kurstaki *cry1Ac* HD-73 protein-albino mice.**
- **Assessment of degradation of neomycin phosphotransferase II (nptII) protein in *in vitro* mammalian digestion models**
- **Acute oral toxicity study of nptII protein in albino mice**

Bt-Brinjal – Expert Committee I - 2006

Expert Committee recommended additional studies

- **Field trials under IIVR, Varanasi**
- **Crossability studies with wild relatives - IIVR**
- **Soil impact assessment (Microflora) - IIVR**
- **Socio-economic study – NCAP**

Complied – 2007-2008

Bt-Brinjal – Timeline

January 2009
Expert Committee (II) headed by Dr A.R. Reddy assessed all the biosafety studies,
additional studies as per EC-I and also the concerns raised by various scientists, NGOs and other stakeholders.

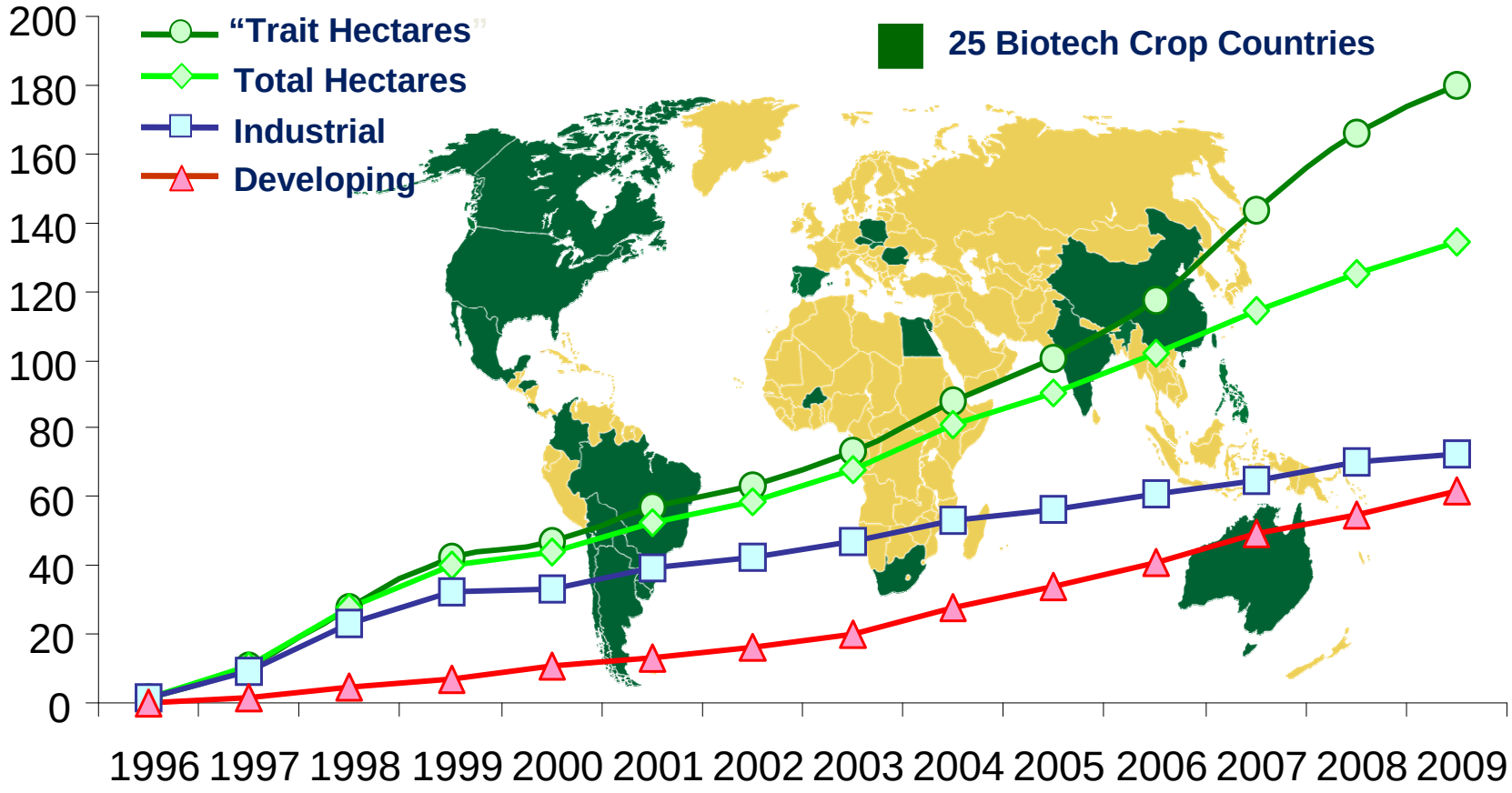
October 14, 2009: GEAC approved Bt brinjal hybrids and varieties with respect to environmental Safety.

January 13th to February 6th, 2010: Union Environment Minister Mr Jairam Ramesh held Public consultations with scientists, farmer's outfits, consumer groups and non-governmental organizations.

February 9, 2010
Union Environment Minister announced that a moratorium on the release of Bt brinjal is imposed.

Prime Minister's Statement (February 24 , 2010):
GEAC to address all concerns for resolving all scientific issues relating to Bt brinjal including safety aspects

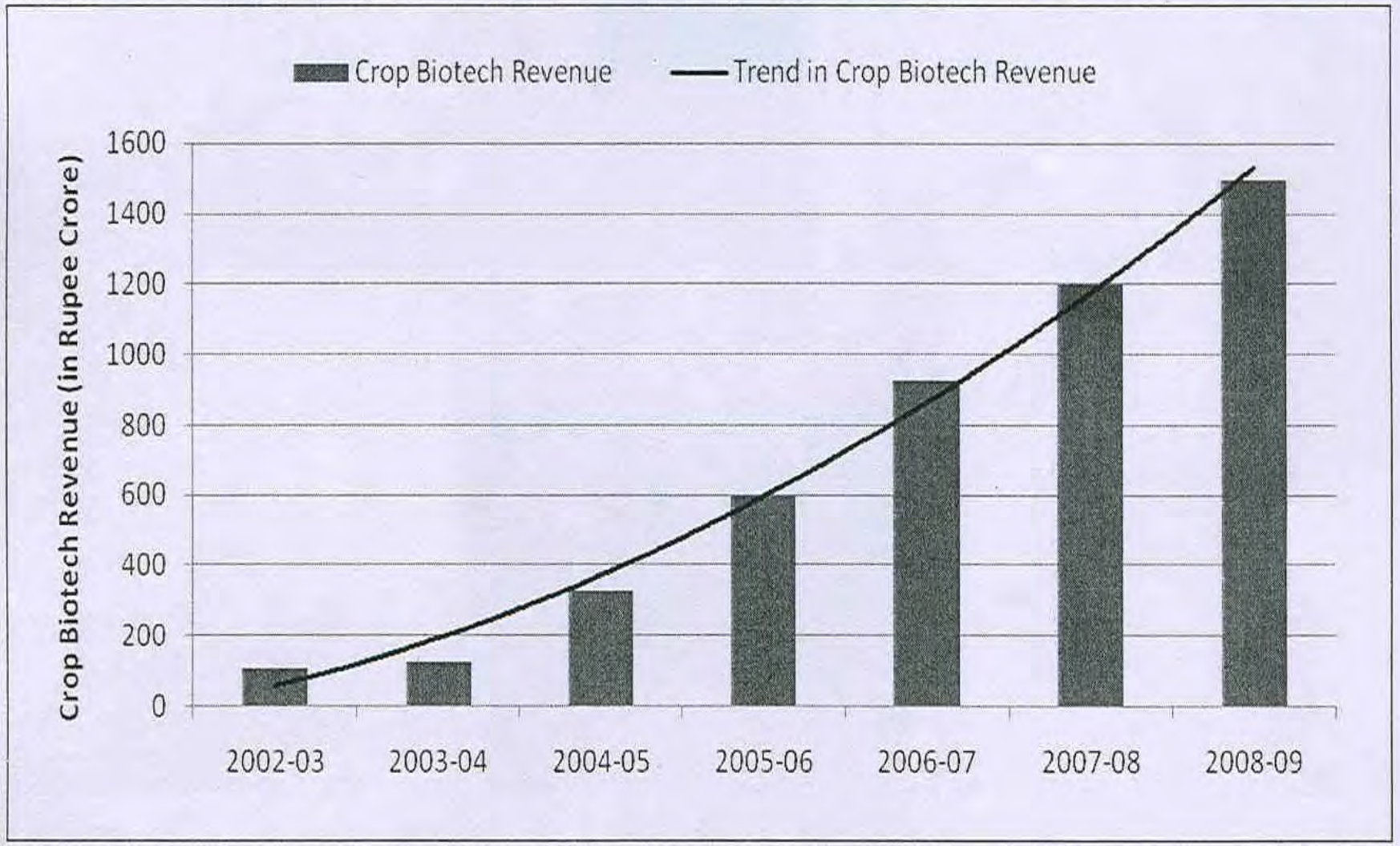
GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996 to 2009)



A record 14 million farmers, in 25 countries, planted 134 million hectares (330) million acres in 2009, a sustained increase of 7% or 9 million hectares (22 million acres) over 2008.

Source: Clive James, 2010.

Figure 23. Crop Biotechnology Industry Market in India (in Rupee Crore), 2002 to 2008



(1 Crore = 10 Million Rupees)
Source: BioSpectrum India, 2009.

THANK YOU

Dr. P.C.Kesavan

Brainstorming Session on Transgenic Crops (INSA, New Delhi)

Need for Holistic Approach in evaluating Transgenic Crops

P.C. Kesavan

Distinguished Fellow
M.S. Swaminathan Research Foundation, Chennai.
and
Honorary Professor
Centre for Sustainable Development, IGNOU, New Delhi.

Modern Biotechnology as of now

- Inadequate Scientific Premise; strong commercial push

- Random, unpredictable insertion of transgene – position effect? L-tryptophan from transgenic bacteria, Beltsville pig etc.

- Inadequate understanding of the implications of breaking the **naturally** – **evolved sexual barriers to gene exchange from widely different taxa.**

- Questionable premise – "**Bt is specific to Lepidopteran pests**"

- "Substantial equivalence" – **Scientifically untenable, but commercially favourable philosophy.**

- **Students of 'Genetics and Evolution'** know:

  • Copying nature **Seldom** yields desired results, but going against it spells doom.

  ↔ e.g. induced polyploidy – nature vs induced

  ↔ Induced mutations – eg. Dwarfing genes of **desired type** could **not** be induced.

  Nature provided these in the form of "Norin" in wheat; "Dee-gee-woo-gen" in rice.

Pest Ecology

Prevalence of pests and their natural enemies in the IPM* and Non-IPM** cotton fields

Insect Pests	Population status	
	IPM adopters*	Non-IPM adopters**
Helicoverpa armigera	2-3% damaged fruiting bodies; 1 larva per 10 plants; 1 damaged boll/ plant from 20 randomly selected plants	30% damaged fruiting bodies; 1 larva per plant; 3 damaged bolls/plant from 20 randomly selected plants
Pectinophora gossypiella	5% infested flowers/bolls	10% infested flowers/bolls
Amrasca biguttula biguttula	1 jassid/nymph per five leaves; third grade jassid injury	2 jassids/nymph per five leaves; second grade jassid injury (yellowing in the margin of leaves)
Bemesia tabaci	Less than 5 nymphs per leaf	5-10 nymphs per leaf

Contd…

Beneficial Insects parasitoids

Egg parasitoid	*Trichogramma* spp.	**Absent**
Larval parasitoid	*Campoletis chlorideae; Bracon hebetor*, *B. greeni*, *Apanteles* sp., 1-2 cocoons/parasitized larvae per 5 plants	**Absent**
Predators	*Cheilomenes sexmaculatus, Coccinella septempunctata; Cryptolaemus montrouzieri; Anagyrus sp.* 10 – 20 per 5 plants	**Absent**
Dragon flies / Damsel flies	*Pantala flavescens; Agriochemis femina femina* - **Abundant**	**1 or 2** per plant
Green lace wings	*Chrysoperla carnea* – **5-10** adults per plant	**1 or 2** per plant
Spiders	*Oxyopes* sp., and *Tetragnatha* sp. - Numerous	**Rare**
House sparrow; Black drongo; Common mynah others	*Passer domesticus; Dicrurus macrocercus; Acridotheres tristis* - **Abundant**	**Absent**
Beneficial Organisms Earthworms	**Abundant**	**Rare**

***IPM includes use of biopesticide as sprays, *Trichogramma* cards, pheromones, mechanical elimination with a very few chemical pesticides sprays**
**** Use of mostly chemical pesticides as sprays**

Tilting the Ecological balance in favour of Lepidopteran Borers (FSB and Bollworm)

1. Balance in nature - containing borers + their natural enemies

   The FSB and Bollworm menace seldom exceeds acceptable "*economic injury level*"

2. Chemical pesticides kill more readily the non-borer pests + beneficial species (i.e. enemies of FSB and Bollworm) since FSB + boll worm remain inside of plant tissue

Chemical Pesticides tilt the balance in favour of borers.

Contd…

3. Bt- transgenic crops:

Justification on the basis that borers have become the most serious menace.

4. Mutations and Natural Selection:

Bollworm feeding on Bt-transgenics already developed resistance to Bt. (**Science,** March 19, 2010)

Possible consequences:

(i) More suicides of farmers?

(ii) Threat to Food security

The last laugh of the bollworm:

Science 327, p. 1439, March 2010

"Bollworm feeding on Bt-cotton has become resistant"- large number of pink bollworms from Bollgard cotton, a first-generation GM hybrid expressing a single Bt-toxic protein, were collected during 2009 from cotton fields in Gujarat. They were also found to resist normally lethal concentrations of Bt-toxin fed to them in the laboratory.

Lesson: Respect laws of nature, Darwinian Evolution.

"Many a slip between cup and the lip"

Developing Scenario

- **Failure of Bt transgenics – Not unexpected on scientific basis**

↓

Millions of resource-poor marginal and small farmers face economic distress, social problems and prospects of committing suicide

↓

Threat to Food Security of millions of rural-poor.

Bt transgenics should be in accordance with the principle that "**Good Ecology is Good Business**"

Contention on Bt-Cry toxins being specific to Lepidopteran pests

Should we ignore the following findings?

- Cry 1Ab is quite toxic to beneficial predator, *Chrysoperla carnea* (Neuroptera); Hillbeck et al., Environ. Entomol 27, 1255-1263, 1998.
- Bt-transgenic plant root exudates adversely affect beneficial earthworms.

  Zwahlen *et al.,* 2003, Mol. Ecol., 12, 1077-1086.

  Saxena *et al.,* 1999, Nature, 402, 480.

  Saxena *et al.,* 2002, Soil Biol. Biochem, 34, 133-137.

  Wold *et al.,* 2001, J. Entomol. Sci, 36, 177-187.
- "Bt Cry 5B protein is highly efficacious as a Single-dose Therapy (SdT) against an intestinal roundworm infection in mice" (Hu *et al.,* 2010, Plos. Negl. Trop. Dis, 4, e614).

Lesson from reliance on Substantial Equivalence- ignored!

- 1980s, US Company SHOWA DENKO.
- Production of food supplement, aminoacid, L-tryptophan, using rDNA technology using bacteria to accelerate production; Normal route of production is fermentative process.
- US Government cleared L-tryptophan produced by genetically-engineered bacteria without biosafety testing.
- **No** testing because– Method/Process of production **does not** matter! Also, trust in **"Substantial Equivalence"!**
- 37 people died; over 1500 paralyzed.
- Analyses revealed that a "toxin" – a **dimerized product of tryptophan (EBT)** causes the disorder/disease called **Eosinophilia Myalgia Syndrome (EMS)**.

Contd…

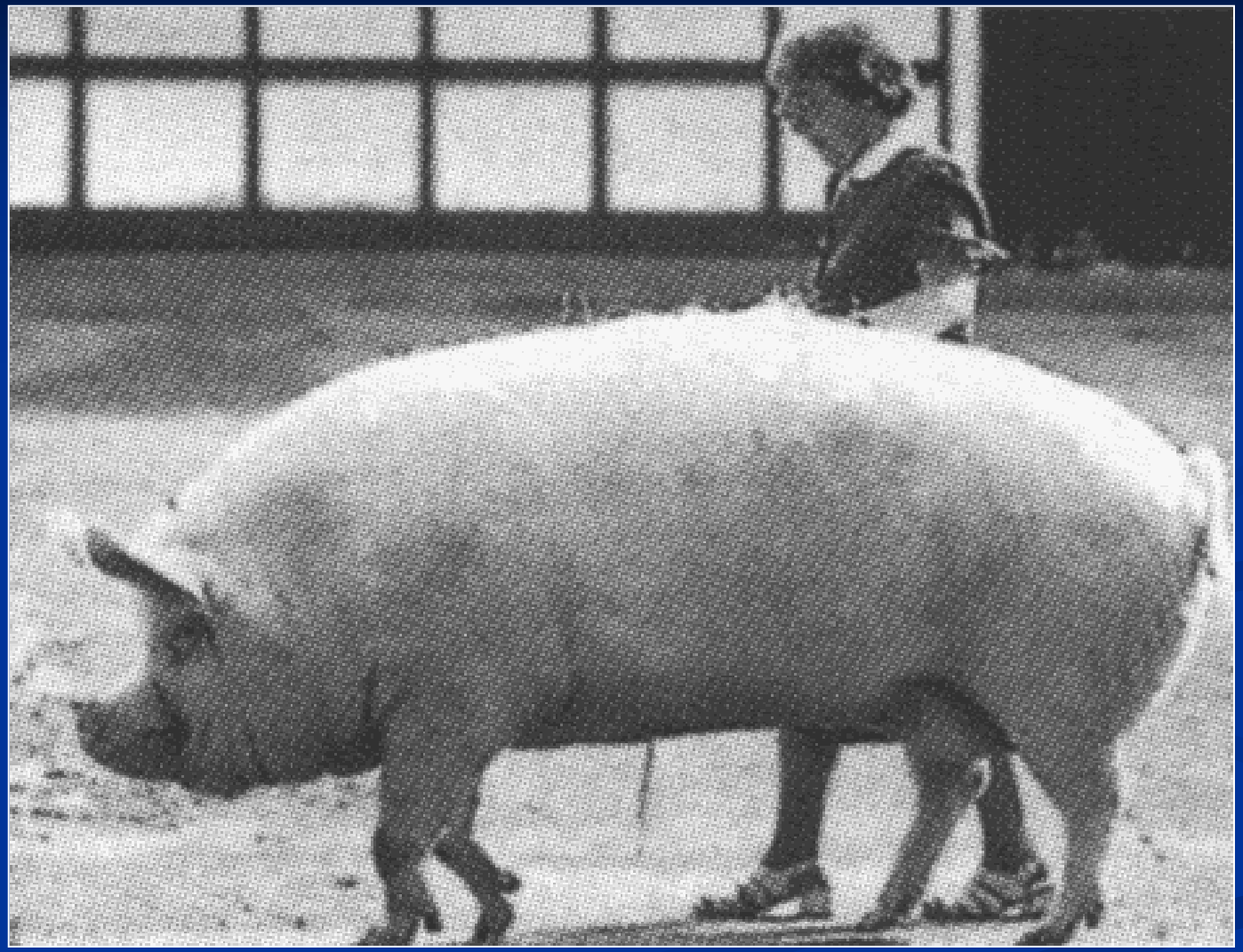
Lesson from reliance on Substantial Equivalence- ignored!

- Took a lot of time to withdraw the genetically engineered toxic tryptophan from market since the philosophy was genetically engineered products are “exactly similar” to naturally-produced products and so **No** labelling had been done.

- EBT has NEVER been found in the original (non-genetically engineered) bacteria: no further research to settle this issue.

- “**Commercial Push**” – does **not** recognize **inconvenient truth** - needs an **“ethical pull**”.

“Beltsville” pig



Courtesy: www.science.anth.org.uk

Scientifically Imprecise statements that:

1. transgenic crops/animals are **not** different from those resulting from conventional Mendelian breeding.

2. involves the same processes as go on in nature.

Double-standards for food materials derived from Public- and Private-funded R & D

- Radiation preservation/sterilization of perishable food material was demonstrated in the labs during 1950s and 1960s. BARC, Mumbai sought clearance of the Ministry of Health and Welfare, Govt. of India in late 1960s.
- Repeated studies in India and **abroad** were called for during the next two decades. Hundreds of papers on genetic toxicology of irradiated foods. Dozens of labs worldwide confirmed their safety for human consumption.
- Clearance was finally accorded in June 1994.
- On the other hand, the US FDA readily cleared many transgenics within short periods on the principle of "substantial equivalance".

Social Contract of Science and Technology- Failed

1. DDT- Dichloro diphenyl trichloroethane	Paul Muller. Nobel Laureate in 1948	Rachel Carson, 1962 "Silent Spring"-havoc to non-target organisms. National Geographic. June 2009 p. 38-59- chemical pesticide induced cancers among members of farming families in Punjab
2. Thalidomide	1960s-administered as tranquilizers and pain killer	Thousands of deformed babies. Work at Safdarjang Hospital-Orthopaedic Unit New Delhi in 1960s
3. Mad Cow Disease, Bovine Spongiform Encephalopathy (BSE)	1980s to 1990s	Tragic case of basing public policy on limited scientific knowledge. Top UK Scientists had to eat a humble pie and retract their earlier assurances to the public that beef from affected cows was "*safe*" to eat and that mad cow disease would not affect humans. It turned out that mad cow disease is a variant form of the human Creutzfeldt Jacob Disease (v CJD)!

4. Transgenic “Beltsville” pig	Inserting human growth hormone gene to create pigs which will produce “lean” pork. Animals suffered bone deformation, severe arthritis, blindness, respiratory and cardiac problems.
5. Abnormal transgenic animals in New Zealand 2009-2010	Failure to publish the details of abnormal animals resulting from transgenic research is contested in the courts.
6. CFC	“Ozone hole”

LESSONS

Half-knowledge of science and technology causes more harm than good, especially when defying nature.

“Drowning in Information while starving for wisdom

(E.O. Wilson, Harvard Biologist)

Analysis of the Socio-economic impact of Bt-transgenic crops vis-a-vis Biopesticides, *Trichogramma chilonis* and possibly *Trathala flavoorbitalis*

Mode	Impact on ecology and millions of resource-poor small and marginal farmers			
	Pro-nature	**Pro-poor**	**Pro-women**	**Pro-income generation**
Bt transgenic	No i) Refuge ii) a few chemical pesticides required iii) Borers become resistant	No i) Seeds are expensive ii) Bt hybrid cotton follows the destructive path of green revolution on soil, water and biodiversity	No	No
Biopesticide, *T. chilonis* produced in the huts by landless women (MSSRF)	Yes	Yes Landless poor women generate income through culturing **Trichogramma** in their huts	Yes	Yes

Pest Ecology of Brinjal

Pests and natural enemies of eggplant in a few areas of Tamil Nadu

Arthropod Fauna	Scientific name	Family
Pests		
Hemiptera		
Aphids	*Aphis gossypii*	Aphididae
Leaf hoppers	*Amrasca devastans*	Cicadellidae
Mealy bugs	*Centrococcus insolitus*	Pseudococcidae
White flies	*Bemisia tabaci*	Aleyrodidae
Lacewing bugs	*Urentius hystricellus*	Tingidae
Stink bugs	*Nezara viridula*	Pentatomidae
Cow bugs	*Oxyrhachis tarandus*	Membracidae

Contd…

Lepidoptera		
Fruit and Shoot borer	***Leucinodes orbonalis***	**Pyraustidae**
Leaf miner	*Pthorimaea operculella*	Gelechiidae
Coleoptera		
Spotted leaf beetles	*Henosepilachna vigintioctopunctata*	
Ash weevils	*Myllocerus spp*	
Acarina		
Red spider mites	*Tetranychus cinnabarinus*	Tetranychidae

Contd…

Natural Enemies Parasitoids		
Egg-larval parasitoid	*Phanerotoma* sp	Braconidae
Larval parasitoids	*Campyloneurus mutator; Iphiaulax* sp.	
Larval-pupal parasitoid	***Trathala flavoorbitalis***	Ichneumonidae
Larval parasitoids	*Peristomerous testaceus; Diadegma apostata; Eriborus argentiopilosus; E. sinicus*	
Predators	*Cheilomenes sexmaculatus,* *Coccinella septempunctata,* *Brumoides suturalis* *Scymnus coccivora*	Coccinellidae
Syrphid flies	*Ischiodon scutellaris* *Paragus serratus*	Syrphidae
Green lace wings	*Chrysoperla carnea*	Chrysopidae
Spider	*Oxyopes* sp., and *Tetragnatha* sp	Oxyopidae; Tetragnathidae

Policy Proposed and Field Reality

- Professor M.S. Swaminathan: *"The bottom line of a National Agricultural Biotechnology Policy should be the economic well-being of farm families, food security of the nation, health security of the consumer, protection of the environment, biosafety of the country, and security of our national and international trade".*
- None of these is **unequivocally** established so far with respect to Bt-transgenic crops.

About Future of Modern Biotechnology

First: Basic research to remove uncertainties

Assess biosafety in long term chronic toxicological studies

Second: Assess Ecological Impact

Third: Analyse Social, cultural, environmental, economic impact on millions of resource-poor small and marginal farmers; their food security

Fourth: Assess Impact on India's International Trade

THANK YOU

- **Dr. Manju Sharma**

TRANSGENIC CROPS

INSA, New Delhi

1st June, 2010

INITIATIVES OF DBT

Major Programmes supported during 9th&10th Plan

CROP BIOTECHNOLOGY

- **A modest yet systematic beginning made in 1990- setting up of 6 CPMB's.**
- **Purpose was to have pooled inftrastructure, sharing of expertise/germplasm, training of manpower.**
- **One of the centre at JNU was converted to autonomous institution- NIPGR.**
- **On R&D front only selected crops were choosen, however list later on enlarged.**
- **A beginning was made to support multi-institutional projects.**

CROP BIOTECHNOLOGY

Major Programmes supported during 10th&11th Plan

- Rice Genome Sequencing
- Rice Functional Genomics
- Dev. & field Trials of Mustard hybrid with Barnase/Barstar Genes
- Dev. of Rice Tolerant to Drought & Salinity
- Rice Resistant to Tungro Virus
- Cotton Resistant to BollWorm
- Brinjal Resistant to Fruit & Shoot Borer
- Development of Markers for Wheat Quality Improvement
- Gene Pyramiding for Leaf & Stripe Rust Resistance in Wheat
- Improvement of Millet Crops
- Crop Biofortification
- Indo-US Collaboration

GM Crops under Field Trials

Sr. No.	Crops	Organization	Traits/Gene
1.	Brinjal	IARI, New Delhi, Sungro Seeds Ltd., New Delhi, MAHYCO, Mumbai TNAU Coimbatore	Insect resistance/ *cry*1Aa and *cry*1Aabc *cry*1Ac *cry*1Ac
2.	Cabbage	Nunhems India Pvt. Ltd.	Insect resistance/ *cry* 1Ba and *cry*1CA
3.	Cauliflower	Sungro Seeds Ltd., New Delhi Nunhems India Pvt. Ltd.	Insect resistance/ *cry1Ac, cry1Ba and cry1Ca*
4.	Cotton	Mahyco,Monsanto, Rasi, Nuziveedu, Ankur,JK Seed, CICR,UAS-D	Insect Resistance, herbicide tolerance cry 1Ac gene
5.	Groundnut	ICRISAT, Hyderabad	Virus resistance/ Chitinase gene
6.	Maize	Monsanto, Mumbai	Shoot borer / cry1Ab gene
7.	Chickpea	ICRISAT	Insect Resistance/ Pod borer, Cry 1Ac

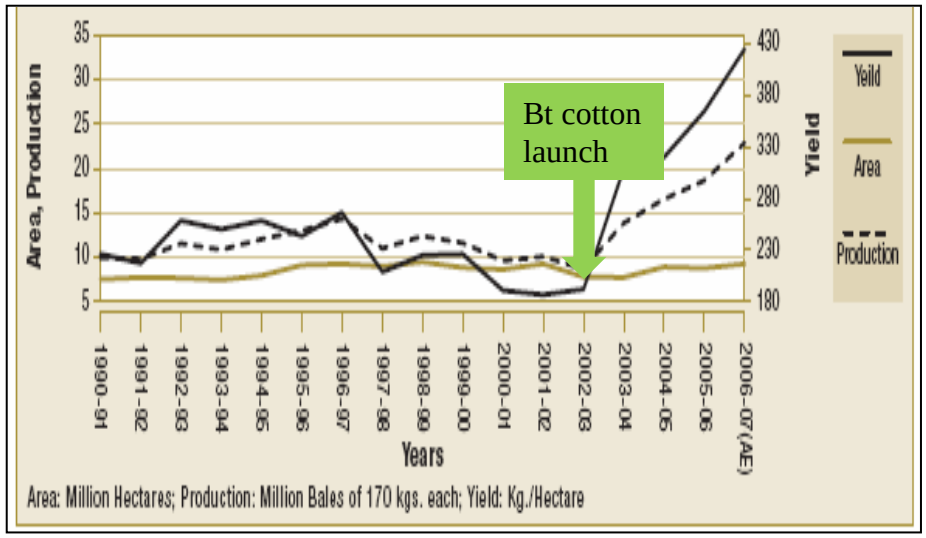
Sr. No.	Crops		Traits/Gene
8.	Mustard	UDSC, New Delhi	Hybrid seed, barnase/ barstar gene
9.	Okra	MAHYCO, Mumbai, Beejo Sheetal, Jalna	Borer *cry 1Ac* , *cry2Ab*
10.	Pigeonpea	ICRISAT, MAHYCO	Pod borer and Fungal pathogene, Cry 1Ac and chitinase
11.	Potato	CPRI, Shimla, NIPGR, New Delhi	*Ama1* and *Rb gene derived from Solanum bulbocastanum*
12.	Rice	MAHYCO, Mumbai TNAU, Coimbatore	*cry1B-cry1Aa fusion gene* *cry1Ac, cry2Ab* *Rice chitinase (chi11) or tabacco osmotin gene*
13.	Sorghum	NRCS, Hyderabad	Insect Resistance, Shoot borer
14.	Tomato	IARI, New Delhi MAHYCO, Mumbai NIPGR, New Delhi	*Antisense replicase gene of tomoto leaf curl virus* cry1Ac

Global Area of Biotech Crops in 2009: by Country (Mh):Total 134.0 Mh

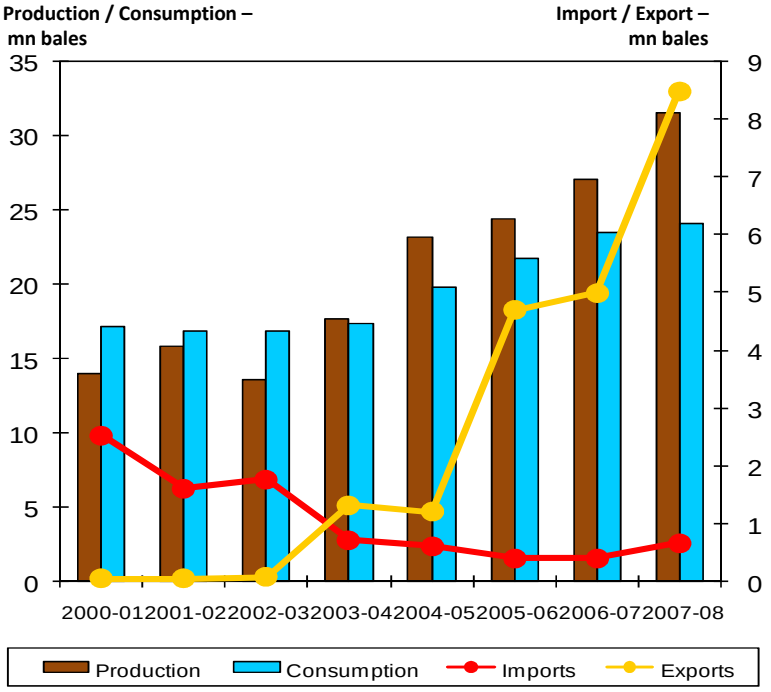
Rank	Country	Area (million hectares)
1*	USA*	64.0
2*	Argentina*	21.3
3*	Brazil*	21.4
4*	India*	8.4
5*	Canada*	8.2
6*	China*	3.7

Bt cotton, India's first commercial biotechnology crop, has helped to double India's cotton production

All-India Area, Production and Yield of Cotton



Source: Economic Survey 2007-08



Source: Cotton Corporation of India

- **The significant increase in productivity has ensured supply and kept pace with increasing consumption**
- **From being a net importer of cotton, India exported 8.5 million bales in 2007-08**
- **With India emerging as a major cotton supplier globally, farmers have benefited from high cotton prices**

Malnutrition

- Micronutrient deficiency is serious public health concern. In India, iron deficiency, vitamin A deficiency, and iodine deficiency disorder greatest public health significance.

- Countrywide surveys conducted by the National Nutrition Monitoring show Indian diets are qualitatively adequate in proteins but deficient in some micronutrients. If protein requirements too are fulfilled the requirement of several micronutrients remain unmet. While dietary deficiencies of vitamin A and riboflavin are seen in all age, sex and physiological groups, those of other micronutrients, such as iron, calcium, thiamine (vitamin B1), niacin and vitamin C are seen in children and pregnant and lactating women.

- Malnutrition and infections often coexist in underprivileged communities, the presence of one predisposing and aggravating the other.

- Crop biofortification is a food-based strategy for reducing micronutrient deficiencies in a sustainable way among the poor. The goal is to increase the nutritional content of important staple crops in India.

CROP BIOFORTIFICATION

1. Wheat

Biofortification of wheat for micronutrients through conventional and molecular breeding approaches

- Wild species & cultivated wheat germplasm be characterized for phytic acid content and, the genetic stocks with low phytic acid content will become available when variability is present in the wild species germplasm for this trait.
- The lines biofortified for enhancemed iron and zinc content with varying levels of linkage drag and with or without low phytic acid will be available for testing and further use
- The molecular markers linked to various introgressed QTLs will be made available for use in marker assisted breeding and pyramiding

CROP BIOFORTIFICATION

2. Maize:

Development of Micronutrient enriched maize through molecular breeding

- To combine genes (lpa-1 & mal/sall-1) in agronomically superior normal and QPM lines developed by CIMMYT, VPKAS, DMR and other ICAR centres through integrated strategy of phenotypic and marker aided selection.

- Analysis of bioavailability in newly developed lines.

CROP BIOFORTIFICATION

3. Rice

Biofortification with enhanced iron and zinc in high yielding non-basmati cultivars through marker assisted breeding and transgenic approaches

- Screening of selected traditional germplasm, Wild rices, and improved varieties for identification of iron and zinc rich genotypes
- Varietal improvement for enhanced micronutrients in rice
- Study of inheritance of high iron and zinc density in grain and formulation of breeding strategy
- Study of genotypic-by-environmental inter-actions, Gene tagging and development of molecular marker-assisted selection techniques for both high iron and high zinc in the grain
- Developing transgenic rice cultivars in elite varieties and evaluation
- Introgression of the transgenic to other promising varieties

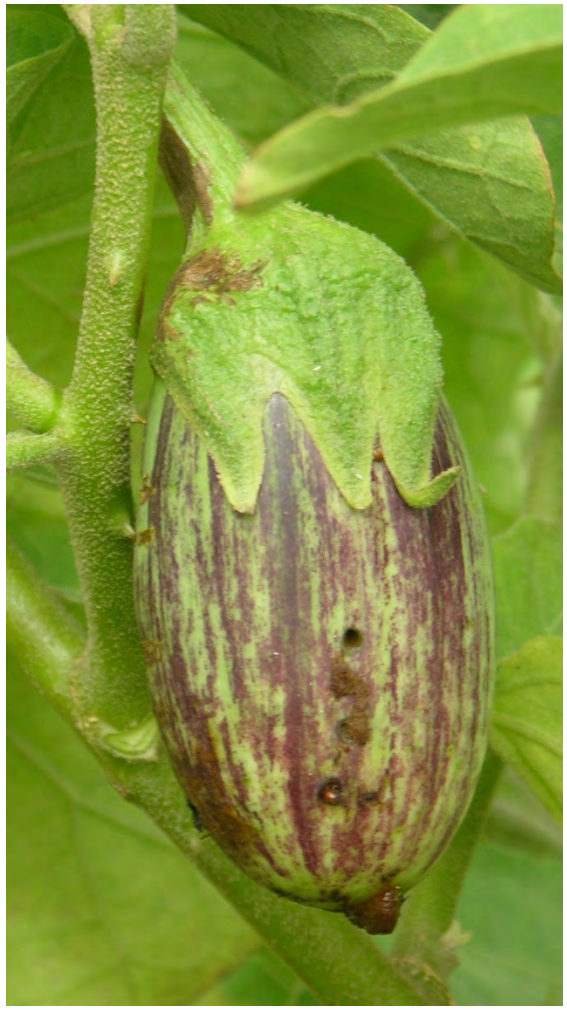
Use of molecular Approaches in Wheat Quality Breeding

1. To analyze parental and RILs at multi-locations
2. To identify markers for each QTL, of all trats under study
3. Fine map markers linked to traits, validate in same varietal bachground
4. To develop & characterize NILs or HMW alleles
5. To use the markers developed for breeding improved quality wheat

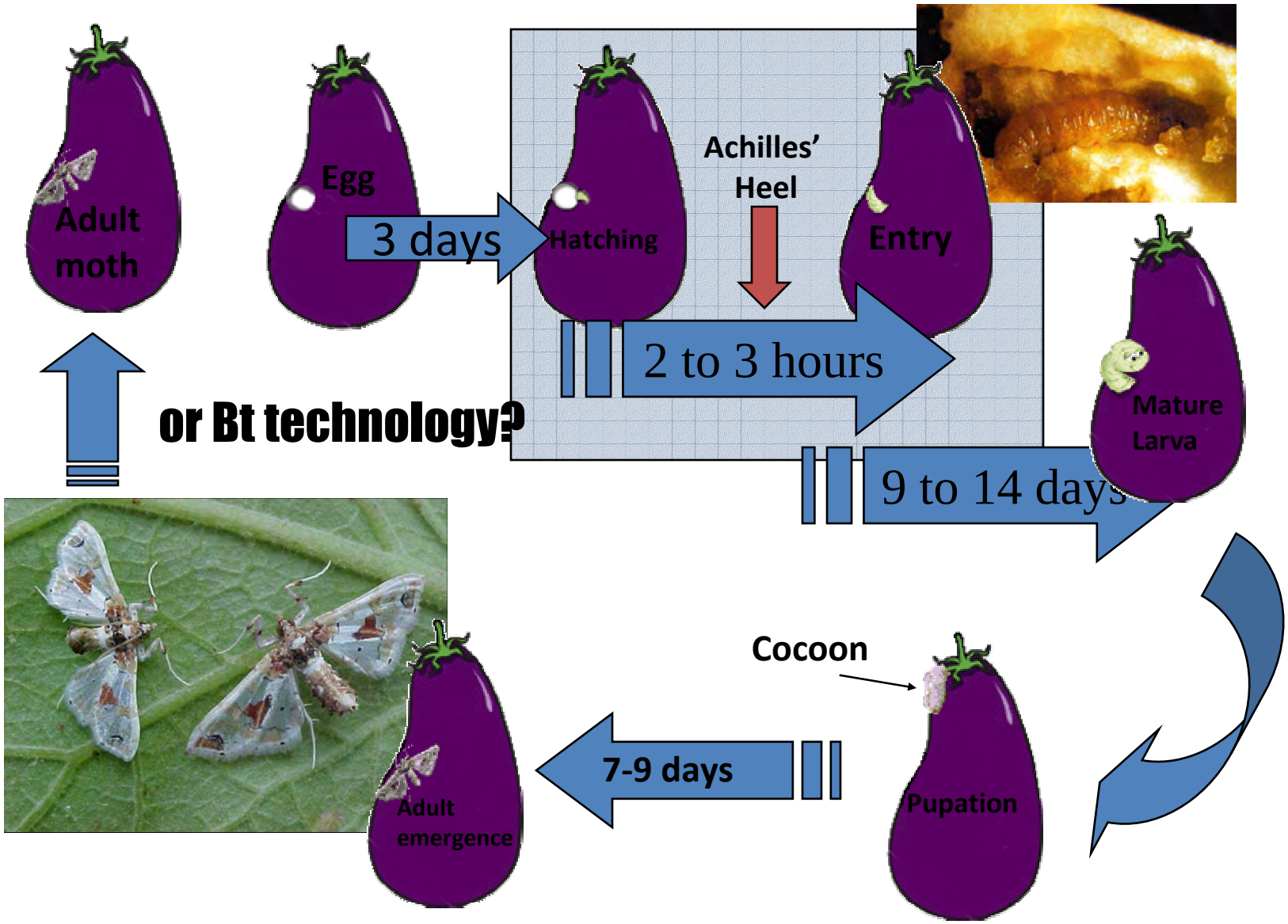
Development & Application of Biotechnological tools for Millet improvement

1. DNA –Marker assisted improvement of rabi Sorghum
2. QTL mapping and marker assisted selection to improve drought tolerance, downy mildew resistance in pearl Millet.
3. Saturating linkage maps of Millets & comparative mapping- identify useful genes or markers for selection
4. Transgenics of Millets to improve resistance to abiotic and biotic stresses, and forage quality

Nature of shoot and Fruit Infestation



Why Bt technology in brinjal?



or Bt technology?

Farmer's Dilemma: Repeated pesticide sprays?

REGULATORY MECHANISMS

3 Tier System

- IBSC
- RCGM - MEC (Monitoring-cum-Evaluation)
- GEAC

Advantages of transgenics under Indian conditions

- Enormity of biodiversity and vast gene pool
- Diverse infrastructure and network of institutions
- Basic biosafety guidelines and regulatory framework available
- Urgency to enhance the productivity and improve the nutritional contents of the crops
- Ensure bioavailabilty and sustainability of food

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 considered 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.**

(Source: DBT)

MANDATE OF THE NBRA

An independent, autonomous, statutory agency to safeguard the health and safety of the people of India

To protect the environment by identifying risks posed by, or as a result of, modern biotechnology, and

Managing those risks through regulating the safe development and deployment of biotechnology products and processes.

Current status of NBRA now named as BRAI

A draft Biotechnology Regulatory Authority of India Bill has been prepared through a consultative process involving interdisciplinary and inter-ministerial experts, State Governments and Stakeholders representing farmers and consumer's organizations, industry, legal experts, media and academia /scientists from research institutions/universities. The proposed Bill also envisages setting up of a National Biotechnology Advisory Council of various stakeholders to advice the authority on policy related issues that may affect the regulation and use of biotechnology products. The council members would include representatives from the scientific community, farmers, consumers, public and private sector and civil society. It will be placed before Parliament in coming monsoon session.

Some Reports

- Transgenic Plants and World Agriculture
  7 Academies – *July, 2000*
- Report of National Research Council, USA
- National dialogue on genetically modified crops - *October, 2007*
- Bill Gates backing GM Crops – *May 15th , 2010 Indian Express*
- Many others

THANK YOU

- **Dr. Mahtab S. Bamji**

Bt Brinjal- risk and benefits

Issues:

- **Economic advantages,**
- **Safety health**
- **safety environment**
- **Sustainability.**

Economic advantages

Brinjal production in India is the third largest, after onions and potatoes. It is indeed a widely consumed vegetable. Considering its susceptibility to certain types of pests, its protection would mean reduced use of pesticides and economic advantage to the growers.

Q. Can IPM achieve the same?.

Protection built in to seed would reduce labour and cost associated with IPM.

Safety- Health

- **Bt foods being consumed since many years in many countries**
- **Q. Processed Vs. unprocessed foods**
- **Safety concerns for malnourished populations**
- **Bt gene product inactivated/broken down in acid medium of human gut, but not alkaline medium of insect gut.**
- **No evidence of allerginicity in standard tests**
- **Issue of informed choice through labeling?.**

Environmental issues

- **Lesser pesticide load good for environment**
- **Increase in minor pests due to lesser spraying is of concern. Needs S&T solution**

Sustainability

- **Need for refuge zone. Small and marginal farmers may not have the land for it.**
- **Dependence on an outside agency for seed. –Issue same as for all other conventional hybreed crops.**
- **Gene migration and biodiversity: Migration of a single gene/protein is unlikely to alter biodiversity. If advantageous for the plant migration may help biodiversity.**

Conclusions

- **Scientific evidence suggests minimal risk to health or environment, but economic and environment benefits.**

- **Nutritionally, brinjal is not high on the agenda of nutrition security, like food grains or vegetables with high micro-nutrient density, like beans, GLV, carrot etc.**

Suggestions

Introduce Bt brinjal slowly, in larger farms where refuge plantation is possible. Expand based on experience. Be vigilant

BUT

Don't throw away the baby with the bath water

THANK YOU

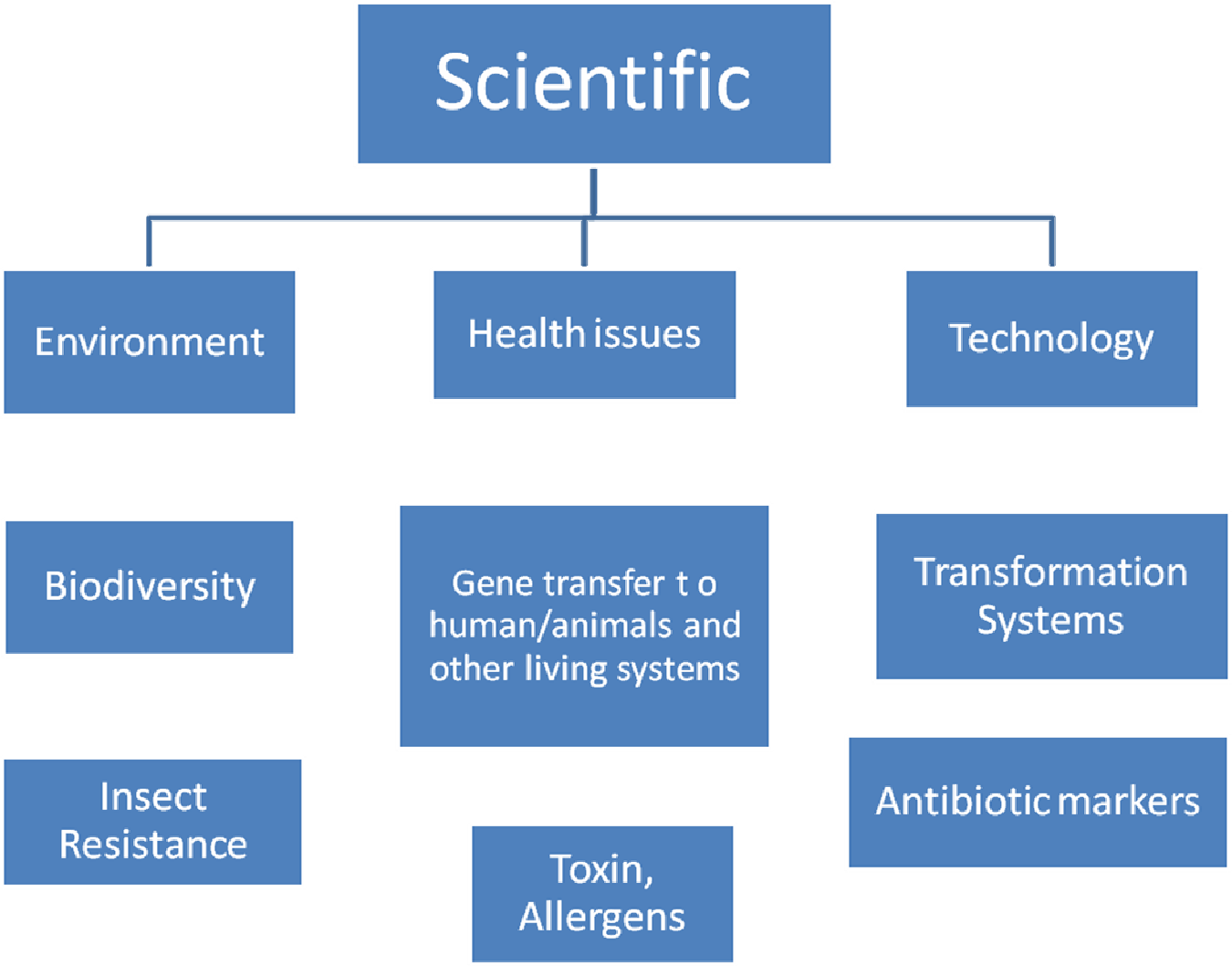
Dr. V.S. Chauhan

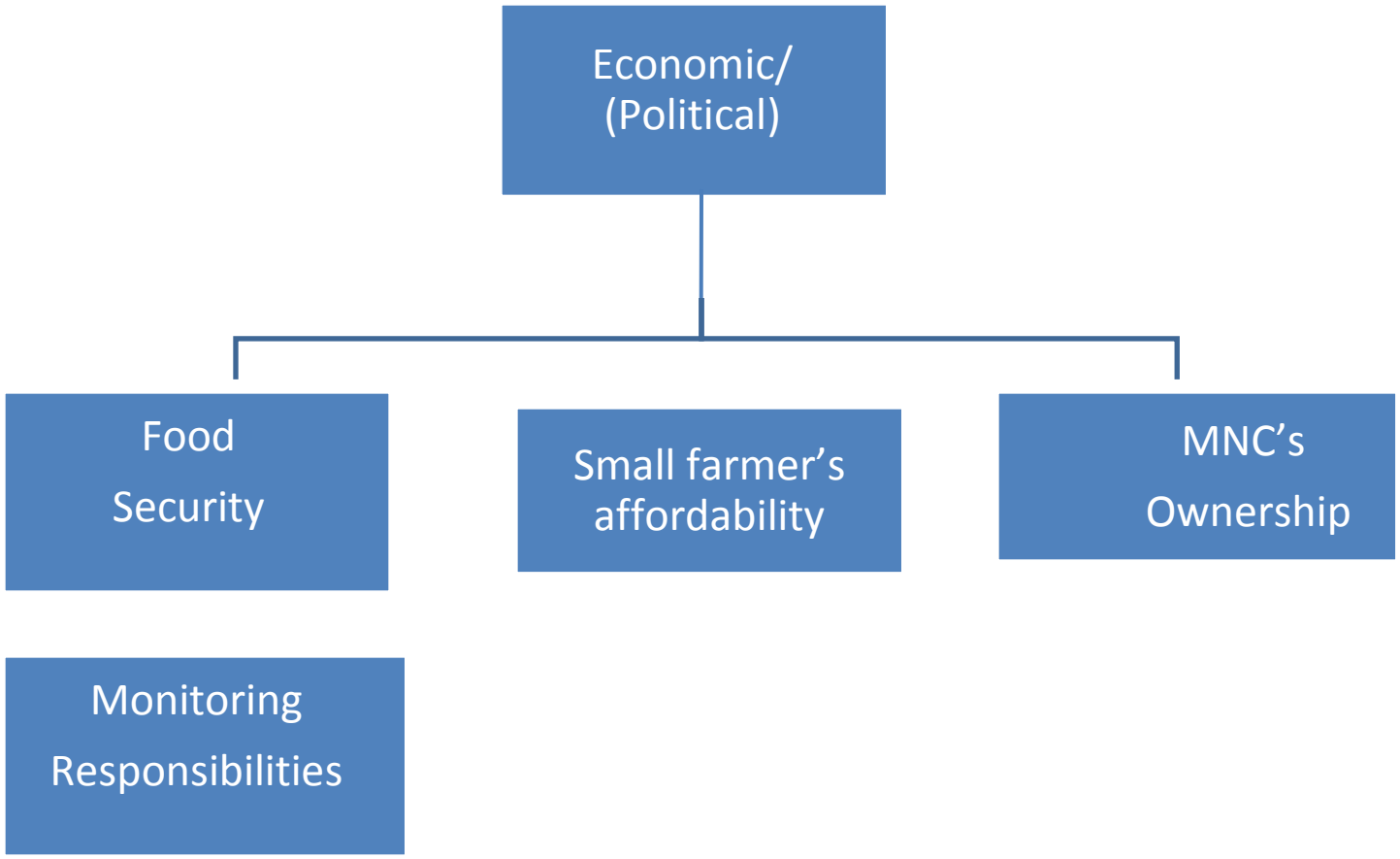
GMO's

- GMO's can (and will) be used in variety of different ways,. Crops, plants, animals, bacteria, viruses etc. etc. (we already use them for our benefit)
- Do we need GMO's?
- Can we produce enough food by organic/ traditional methods?
- Technology exists and is continuously being developed. Should we or should we not adopt them?
- Who will decide?

Concerns

- Are GMO's safe? How do you prove them to be so?
- Damage to environment and biodiversity.
- Food security, MNC's, Economics and politics.
- What role may scientist have in these issues?


Scientific
Environment
Health issues
Technology
Biodiversity
Gene transfer t o human/animals and other living systems
Transformation Systems
Insect Resistance
Toxin, Allergens
Antibiotic markers


Economic/
(Political)
Food
Security
Small farmer's
affordability
MNC's
Ownership
Monitoring
Responsibilities

Health and Safety Issues

- Toxicity and other detrimental effects on living beings exposed to GMO. How to measure these; we need a consensus.

- Animal trials
  - Is Expert's advice sufficient? Can there be standard protocols?
  - How long is long enough?
  - What should be the safety markers – reasonable vs unreasonable
  - Who should do these tests? Who pays?
  - Human trials – Need, Ethics. Is this an option?

- Quality data available from other locations that are better placed to produce data.

New areas (Non-Bt)

- Most concerns have been on or around Bt (Cotton, Brinjal….).

- What about other genetic engineering based products (crops, plants, seeds etc.)
  - salt and drought resistant crops (rice).
  - Better self-life; enhanced food values (tomato, potato, rice, maize).
  - RNAi based technology (gene silencing methods).
  - anti viral strategies. Already in use.
  - Bio energy/bio metabolic engineering.
  - Novel bacteria for multiple uses including environment fix; vaccines, drug etc. etc.

Possible Role of Science Societies

- Focus on scientific matters only.

- If possible, have a coherent one voice (hopefully after "debating" the issue(s) a consensus can emerge!).

- Communication with public/civil society. Explaining the unexplained in easy to understand language/medium. Remove, not add to the confusion

- Scientists are also part of the civil society and share the concerns. This message needs to go out.

THANK YOU

- **Dr. V.P. Kamboj**

GM Foods & India's regulatory regime

V. P. Kamboj
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Biosafety Guidelines for GM Foods

- **Substantial equivalence agreed before GM foods came to market – 1993**
- **Adopted by FAO/WHO -- 1996**
- **Codex Alimentarius Commission -2003**
- **Codex Plant Guidelines -- 2003**
- **Annexure to CAC & CPG -- 2008**

Regulation of GM Foods in India

- **Under Environment Protection Act (1986), MoEf rules formulated in 1989 which created six competent authorities namely RDAC, RCGM, GEAC, IBSC, SBCC, DLC; MEC for field trials under RCGM and GEAC**
- **Recombinant DNA Safety Guidelines 1990, modified 1994**
- **DBT Revised Guidelines for research on Transgenic Plants – 1998, also includes guidelines for Toxicity & Allergenecity evaluation of transgenic seeds, plants & plant parts**
- **Safety assessment of GM Food Crops –2007, modified 2009**
- **Guidelines for the safety assessment of foods derived from GE plants -2008**
- **Guidelines & SOPs for Confined Field Trials of Regulated Genetically Engineered Plants –2008**

Comparison of Regulatory requirements for Environmental, Feed & Food Safety assessment of GM Plants (AGBIOS, 2006)

Information/Data Requirement **Potential Toxicity/Allergenicity**	Canada	Australia	China	India	Japan	Korea	US
Known toxin/allergen production in host or donor organisms, and any changes to these	X	X	X	X	X	X	X
For each novel protein, amino acid sequence comparison with known protein toxins	X	X	X	X	X	X	X
For each novel protein, amino acid sequence comparison with known proteins allergens	X	X	X	X	X	X	X
Data demonstrating digestibility of novel proteins (e.g. , SGF+pepsin or SIF-pancreatin)	X	X	X	X	X	X	X
Data on heat stability of novel proteins	X		X	X	X	X	X
Acute mouse oral toxicity study (15-day) with a single dosage of purified novel protein (or equivalent surrogate protein)	O[1]	X	X	X	X	X	X
Sub-chronic toxicity testing (e.g., 90-day rat, multiple dosage, study)	O[1]		X	X	X	O[1]	
Additional testing if any potential toxicity or allergenicity suggested2	X	X		X	X		X

Comparison of Regulatory requirements for Environmental, Feed & Food Safety assessment of GM Plants (AGBIOS, 2006)

Information/Data Requirement **Nutritional Data**	Canada	Australia	China	India[4]	Japan	Korea	US
Proximates (e.g., total fat, ash, moisture, carbohydrates, crude protein)	X	X[2]	X[3]	X	X[5]	X	X
Acid detergent fibre, neutral detergent fibre	X			X	I		
Minerals	X[1]	X	X	X	I	X	X
Amino Acids	X[1]	X	X	X	I	X	X
Fatty Acids	X[1]	X	O	X	I	X	X
Vitamins	X[1]	X	O	X	I	X	X
Other secondary metabolites and antinutrients crop specific	X	X	O	X	I	X	X
Other Bioactive molecules crop specific	X	X	X	X	I	X	X
Data from broiler chicken feeding trial	O		X	X			
Data from swine feeding trial	O		X	X			
Data from other livestock (fish) feeding trials	O			X	O		

Comparison of Regulatory requirements for Environmental, Feed & Food Safety assessment of GM Plants (AGBIOS, 2006)

Information/Data Requirement **Dietary Exposure**	Canada	Australia	China	India	Japan	Korea	US
Significance of the product in the diet and expected exposure to the newly expressed or modified protein[1]	X	X	X	X	X	X	X
Effects of animal age and species with respect to intended use of the genetically modified feed	O			X			
Expected changes in exposure on introduction of modified food product	X	X		X			X
Identify other novel substances (metabolites etc.) which may be altered in the product	X	X		X	X	X	X
Levels of newly expressed protein in processed food products			X	X			

Indian Regulatory System

- Aims to ensure that GM crops pose no risk to food safety, environmental safety and agriculture productivity
- To demonstrate potential benefits over the conventional variety/hybrid in terms of economic benefit to the farmer and /or the environment
- To generate quantitative biological, ecological and agronomic supportive data
- Rules and guidelines formulated to achieve above objectives

Comparative approach for Safety assessment of GM Foods

- **Safety assessment of GM foods based on the principle that these products can be compared with traditional foods that have established history of safe use**
- **To determine any new or altered hazard**
- **Whether it can be used alternatively without affecting health or nutritional status of users**

Comparative approach for Safety assessment of GM Foods
(Contd.)

- Aimed to establish relative safety but not absolute safety under anticipated conditions of processing and consumption
- E.g. 1. Cassava root is quite toxic but processing converts it to nutritious food,

  2. Widely used Soyabeans and Lime beans contain antinutrients and require proper processing

Substantial Equivalence

- Comparative approach embodies concept of substantial equivalence
- Provides flexibility for food safety assessment
- Helps identify any differences intended or unintended for further study
- Can be applied along food chain – unprocessed food, individual processed fractions, final food or ingredients

Substantial Equivalence
(contd.)

- Helps identify similarities and differences between new food and conventional food
- Can be applied if sufficient analytical data available in literature or is generated through analysis
- Assessment simple because so far one or two gene traits introduced

Standard categories of Human Health testing

A. Health effects assessment

- **Mammalian testing**
- **Digestibility testing**
- **Allergenecity testing**
- **Homology with known food allergens and toxins**

B. Human Safety assessment

- **Compositional analysis**
- **Nutritional assessment (conc. & effect on bioavailability)**
- **Unexpected or unanticipated effects**
- **Dietary exposure assessment**
- **Determination of substantial equivalence**
- **Animal feed consideration**

2008 GE Food Guidelines

- Acute oral toxicity limit study in rats and mice
- Sub-chronic (90 days) feeding study in rodents
- Protein thermal stability
- Pepsin digestibility assay
- Live stock feeding study
- Bioinformatics analysis (being finalized)
- Specific serum screening (being finalized)

Protocols for Toxicity evaluation

- Acute oral toxicity in rats
- Sub-chronic (90 days) oral toxicity in rats
- Primary skin irritation test in rabbit
- Irritation to mucus membrane test in female rabbit
- Skin sensitization test in guinea pig
- Sub-chronic (90 days) oral toxicity in goats
- Sub-chronic (90 days) oral toxicity in male rabbit

Protocols for Allergenecity testing

- ***In vitro* assays :**
  Radioallergosorbent (RAST) inhibition test; Enzyme Linked Immunosorbent Assay (ELISA)
- ***In vivo* assay :**

  Passive cutaneous anaphylaxis; Prausnitz – Kustner test

Environmental Safety Studies

- Pollen flow studies to prevent effect on conventional species
- To study effect on non-target organisms including non-target insects, birds, fish, soil microorganisms and non-target animals- mammals and wildlife
- Impact on endangered species
- Response plans to control environmental unfavourable effects

Food Safety evaluation of GM cotton seed in India

- Composition of cotton seed/oil comparable to four non-Bt hybrids and other conventional varieties
- Allergenecity in Brown Norway rats- Not observed
- Allergenecity potential in guinea pig model- Not seen
- 90 Days feeding in goat for toxicity- NAD
- Evaluation in chicken and Indian cat fish for nutrition effects- Similar in Bt and non-Bt groups
- Bt cotton seed effect on food intake, milk production and composition in lactating water buffaloes for a period of 28 days- No difference between BT & non-Bt
- Bt cotton seed effect on food intake, milk production and composition in lactating water buffaloes for a period of 28 days- No difference between BT & non-Bt
- Cry 1Ac protein present in crude oil but below detection limits in purified oil

Food Safety evaluation of GM Brinjal in India

- **Bt brinjal contains Cry 1Ac gene**
- **Bt brinjal effective against fruit and shoot borer (*Leucinodes orbonalis* & *Helicoverpa armigera*)**
- **Chemical composition in fruit, leaf, stem and root tissues of brinjal plant substantially equivalent to non-Bt control**
- **Bt Brinjal is non-allergenic and contains no new allergenic compd.**

Food Safety evaluation of GM Brinjal in India – Toxicology studies

- **Acute oral toxicity study in Sprague Dawley rats – No toxicity observed**
- **Sub-chronic (90 days) toxicity study in Sprague Dawley rats – Non-toxic in the animal by oral route**
- **Sub-chronic (90 days) oral toxicity in goats fed in diet for 90 days – No toxicity observed**
- **Sub-chronic (90 days) oral toxicity in rabbit – No difference between Bt and non-Bt brinjal fruit fed groups**

Food Safety evaluation of GM Brinjal in India – Allergenecity studies

- **Active cutaneous anaphylaxis in brown Norway rats – No biological difference between allergenecity response amongst Bt and non-Bt hybrids**
- **Primary skin irritation test in rabbit – Non-irritant and no skin reaction seen in rabbit**
- **Irritation to mucus membrane test in female rabbit – Non-irritant to mucous membrane in rabbit**

Food Safety evaluation of GM Brinjal in India – Alkaloid study

- **Alkaloid content – Alkaloid profile from samples of Bt and non-Bt brinjal same with not much of appreciable variation in their relative abundances**

Food Safety evaluation of GM Brinjal in India – Nutritional studies

- **Fish (common carp) feeding study for 45 days – No difference between Bt and non-Bt groups**
- **Chicken feeding study – Growth performance and nutrient utilization similar**
- **Cow feeding study – Nutritional value of both Bt and non-Bt brinjal fruits similar in terms of feed intake, milk production and milk constituents without any adverse effect on health of cross breed cows**
- **Food cooking studies – Bt protein was undetectable in the cooked fruits at the first sampling time-point irrespective of the cooking method used**

Environmental Impact studies of Bt Brinjal

- **Growth & Development– No difference in agronomic or morphological traits as compared to no-Bt brinjal**
- **Pollen Flow– Maximum of 15-20 meters; outcrossing %age 1.46-2.7% indicating no possibility of gene flow**
- **Agressiveness or weediness– No agressiveness or weediness noticed during monitoring 3 months post-harvest**

Environmental Impact studies of Bt Brinjal (contd.)

- **Soil analysis– No difference in soil bacterial and fungi counts and soil invertebrates between Bt brinjal and non-Bt brinjal groups**
- **Effect on non-target organisms– No effect on non-target pests and beneficial insects**

Pertinent Information

- **> 25 countries (USA, Canada, China, European countries, Brazil, Australia, Egypt, India, etc.) trying GM technology**
- **GM crops grown in 125 mha in 2008**
- **Bt crops constitute ~30-40% of total GM crops**
- **No reports of adverse consequences in environmental, health & nutrition parameters**
- **Economic benefits to farmer by increase in yield and reduced pesticide use**

Pertinent Information (contd.)

- Bt gene incorporated into 40 varieties of cotton
- Compositional equivalence studies with transgenic crops- corn, cotton, soybean, wheat, rice, potato, revealed that transgenic crops were equivalent to their non-transgenic counterparts
- Bt protein in all Bt plants & sprays registered so far:

  -- Food consumption breaks down rapidly in simulated digestive systems

  -- Do not resemble any food allergen or protein toxin

  -- No oral toxicity even at high doses

  -- No toxicity of Bt protein to birds, fish & invertebrates including earthworm

  -- No toxicity of Bt protein to non-target organisms and beneficial insects

Pertinent Information (contd.)

- Do we know what is a pure line of a crop?
- Do we know how many genes (horizontal & vertical) they have acquired during evolution?
- Do we know how 2,000 varieties of Brinjal evolved?

Biosafety Tests for BT Crops

- **Can be stated with confidence that no other food technology has gone through such rigorous safety testing procedures as biotech derived crops.**

Pt. Jawaharlal Nehru

- **“It is science and science alone that can solve the problem of hunger and poverty, of insanitation and illiteracy, of superstition and deadening custom and tradition, of vast resources running waste, of a rich country inhabited by starving people.”**
- **So give science a chance**

THANK YOU

- **Prof. P.N. Tandon**

"Talk Delivered at the Inter-Academy Discussion Meet at INSA on GM Food" (June 1, 2010)

Presidents of the Science, Medical, Agriculture and Engineering Academies and distinguished Fellows:

It is a red letter day in the history of the Academies to have been requested to deliberate on a subject of great societal significance. This unique opportunity we should utilize with sincerity, objectivity in the overall interest of the country, not just as a one-time exercise but as our continuing responsibility to the society. I find myself somewhat ill equipped to contribute to the debate on this complex subject specially in the presence of such distinguished experts, who have already expressed their opinion. My only justification to participate in this discussion is firstly the order of the President to do so. For this purpose, I familiarized myself with the issues under consideration. Nearly a decade ago I was asked by the then President to Chair the national committee which represented INSA in the preparation of the "Seven Academy" document* already referred to by earlier speakers. Ever since I have tried to keep abreast with the global debate on the subject related to GM Food and health issues. I have also gone through the sizeable literature provided by the Academy few days ago.

Before I talk about the specific issues, let me quote from the Seven Academies report a few general comments:

"Scientific advances require an open system of informative exchange in which arguments are based on verifiable evidence"

Much of the discussion that recently took place on Bt. Brinjal, even by some scientists, does not fulfill this basic tenet. We should therefore be careful not to fall in the same trap.

***Transgenic Plants and World Agriculture**: Report prepared under the auspices of the Royal Society, London, the US National Academy of Sciences, the Indian National Science Academy, The Brazilian Academy of Sciences, The Chinese Academy of Sciences, the Mexican Academy of Sciences, and the Third World Academy of Sciences.

I quote further:

"The many crucial decisions to be made in the areas of biotechnology in the next century (i.e. the present one) by private corporations, governments and individuals will affect the future of humanity and the planet's natural resources. These decisions must be based on the best scientific information in order to allow effective choices for policy options".

Many of the opinions expressed by several Fellows of the academies sent to me and several others in recent past as gleamed through the media, were obviously not based on the latest available scientific data.

Notwithstanding the introduction of GM technology nearly 4 decades ago "concrete information about their actual effects on environment and on biological diversity is still very sparse. As a consequence there is no consensus as to the seriousness or even the existence, or any potential environmental harm from GM technology".

I believe that during the decade that has elapsed since this statement was made by the seven academies, there has been no substantial information accumulated to contradict this.

The report highlighted that, “A large proportion of developing world agriculture is in the hands of small-scale farmers whose interests must be taken into account”.

Any decision we take, irrespective of its scientific merit, must address these societal concerns, if we are to reap the potential benefits of this new technology.

Let me now come to the specific issue of Health and GM Foods.

- In spite of tomato, corn, soybeans already in market since 2000 – there are hardly any scientifically valid report establishing any toxicity or allergy in humans following consumption of these foods. According to Deborah Whitman (CSA Discovery Guides 2000) "American diet virtually ensures that all US consumers have been exposed to GM Good products (Cereals, Veg. Oil if not whole fruit) (60% of corn + 50% Hawaiian Papaya, 75% rapeseed) consumed in US are genetically modified.

- 60% of US grocery food contains GM ingredients (as per new estimates this figure is 75% of all processed food).

- A 2004 report by US NAS stated, "To date, no adverse health effects attributed to genetic engineering have been documented in human population". However, no large scale epidemiological studies have been done to detect any harmful effect.

- A 2008 review published by the Royal Society of Medicine noted that GM foods have been eaten by million of people worldwide for over 15 years, with no report of ill effects.

One of the oft quoted report in this regard was the Pusztai's Lancet report (1999) claiming potatoes modified with sundrop lectins produced unusual changes in rats intestine. However, a critical appraisal of this study found faults with the study design and its interpretation.

A 2009 paper in Intl. J. Biol. Sc.: Statistical review of three feeding trials on three Monsanto potential crops – found damage in liver, kidney, heart of mammals. Another expert review of same data contradicted these findings.

In this connection the recommendation of the seven academies is as relevant today as when it was stated.

I quote:

“we recommend (i) public health regulatory system need to be put in place in every country to identify and monitor any potential adverse human health effects of transgenic plants, as for any other variety. Such systems must remain fully adaptable to rapid advances in scientific knowledge. The possibility of long-term adverse effects should be kept in view when setting up such systems. This will require co-ordinated efforts between nations, the sharing of experience, and the standardization of some types of risk assessments specification should be made available to the public concerning how their food supply is regulated and its safety ensured”.

Let me acknowledge that we as members of the various academies have not followed these cardinal recommendations.

In conclusion, let me state my personal views based on the review of the available data, so far there is no hard core scientific data to indicate any adverse health consequences of consumption of currently available GM Foods, a large quantity of which is being consumed by virtually millions of people around the world. I therefore don't presume that Bt. Brinjal would be any different.

However, since so much public discontent has been aroused it behoves us as members of the science academies to once more critically evaluate the objections raised in the light of the most recent information available. If necessary these fears need to be alleviated by carrying out fresh investigations using latest technologies. This would require a small group of scientists with unimpeachable credentials and expertise in the field to undertake this task so as to regain public confidence.

P.N. Tandon
Former President, INSA

THANK YOU