

SORRY STATE OF REGULATION OF GENE TECHNOLOGIES IN FOOD & FARMING SYSTEMS IN INDIA

Alliance for
Sustainable &
Holistic Agriculture



Beginning Point

- Agricultural technologies cannot be treated the same way as other technologies
- We eat food to survive, sustain ourselves and stay healthy – if it becomes toxic....? How can this be equated with laptops, mobiles and airplanes?
- The debate really is whether GM crops are needed, whether alternatives do not exist and if Yes, then, have we assessed risks and impacts properly and are we in a position to manage them?

Beginning point...

- Transgenic technology is an imprecise, unstable, irreversible, uncontrollable, unpredictable living technology. It is NOT an extension of natural or conventional breeding – nor is it natural
Unnatural & Artificial not automatically undesirable / dangerous generally: Here, it is the consequences of the procedure along with lack of systematic assessment of potential risks
- It is scientists who first pointed out that risks result from modern biotechnology and there is a need to protect our health and environment from such risks. Additional risks are socio-economic, going beyond immediate technical implications – THEREFORE, REGULATION.
- THIS IS THE BASIS FOR AN INTERNATIONAL PROTOCOL (CARTAGENA BIOSAFETY PROTOCOL) AS WELL AS NATIONAL REGULATORY REGIME

Convention on Biological Diversity

(Asilomar Conference 1975)

- International Convention (1992) to conserve biological diversity and facilitate the sustainable use of it by the people
- India signed CBD in 1993
- In 1995 –Parties to the Convention discussed the potential risks of GMOs
- Discussions culminated in 2000-adoption of Cartagena Protocol on Biosafety

Cartagena Protocol on Biosafety

- Comprehensive regulatory system for ensuring the safe transfer, handling and use of GMOs subject to transboundary movement –to avoid the adverse effects on the conservation and sustainable use of biological diversity
- To promote biosafety, the protocol reflects a fundamental concept known as the **precautionary approach –Principle 15** of the 1992 Rio Declaration on Environment and Development
- **PRECAUTIONARY PRINCIPLE**: Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost–effective measures to prevent environmental degradation

Cartagena Protocol on Biosafety

- Biosafety protocol-It means that a government may decide on the basis of precaution not to permit a particular GMO to be imported across its borders
- The protocol applies precaution not just to biodiversity , but to potential risks to human health as well.
- Concerns like 'imported GM foods may replace traditional crops and food' are also addressed

DOMESTICALLY,

India had a regulatory system in place from 1989, and the commitments at CPB make it more binding on the country to have strong regulation

Biosafety Regulation in India

INDIA HAS NO SEPARATE STATUTE FOR REGULATION OF GMOs.

- India uses “Rules for Manufacture, Use/Import/ Export & Storage Of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989”, which are Rules under the Environment Protection Act, 1986. Other regulatory regimes flowing out of FTDR Act 1992 and FSS Act 2006 also refer to the EPA 1989 Rules as the primary regulation.
- Regulation of GM crops mainly rests with the Ministry of Environment and Forests, Govt. of India. However, a promoting ministry, Ministry of Science & Technology, through its Department of Bio-Technology (DBT) also involved in regulation. State Governments/ District Admins/ Panchayats also part of the current regulatory system.
- Rules ‘applicable to the manufacture, import and storage of micro-organisms and Gene-Technological products’ and ‘shall apply to genetically engineered organisms/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc., of which such cells, organisms or tissues hereof form part.’ Rules ‘cover the areas of research as well as large scale applications of GMOs and products made therefrom throughout India’

1989 RULES CREATED WITH A VIEW TO PROTECTING THE ENVIRONMENT, NATURE AND HEALTH, IN CONNECTION WITH THE APPLICATION OF GENE TECHNOLOGY AND MICRO-ORGANISMS

Biosafety Regulation in India

Six bodies or “competent authorities” under the 1989 Rules, for administering the rules

GEAC – Genetic Engineering Appraisal (earlier Approval) Committee, MoEFCC, Gol

RCGM – Review Committee on Genetic Manipulation, DBT, MoST

IBSC – Institutional Biosafety Committee, in all GM R&D centres and institutes

RDAC - Recombinant DNA Advisory Committee in DBT

SBCC – State Biotechnology Coordination Committee, in all states

DLC – District Level Biotechnology Committee, in all districts

(**MEC** - Monitoring and Evaluation Committee now morphed into Central Compliance Committees and some MECs)

For more info: <http://envfor.nic.in/sites/default/files/geac/rules1989.html>

Biosafety Regulation in India

GEAC

Under these 1989 Rules, Genetic Engineering Appraisal Committee (GEAC, renamed from Genetic Engineering Approval Committee after the Bt brinjal fiasco): for “**approval**” of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from the environmental angle.

This is also responsible for “**approval**” of proposals relating to release of genetically modified organisms and products into the environment including experimental field trials.

Right now, a 23-member body comprising of officials from different ministries and some scientists

GM Imports & GM Foods

Regulation in the Ministry of Commerce prohibits import of GM products without first notifying DGFT.

Food Safety and Standards Act (FSSA 2006) has a clause that makes any sale of GM foods without clearance from the Food Safety & Standards Authority illegal, but they are yet to frame their regulation. CURRENTLY, GM FOOD REGULATION IS IN A “DE-REGULATED” STATE, WITH NEITHER GEAC NOR FSSAI TAKING FIRM RESPONSIBILITY.

Biological Diversity Act has a clause on modern biotechnology – however, the Act does not come into routine regulation right now.

5 June 2012 ,Extraordinary Gazette publication, by the Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Civil Supplies – amendment to Legal Metrology Act to introduce labeling of GM foods: “*Every package containing genetically modified food shall bear at the top of its principal display panel the words ‘GM’*”, came into effect from 1 January 2013. However, no implementation capabilities and interest.

State Governments in the Regulatory Regime

■ *State Governments*

- Under 1989 Rules, State Biotechnology Coordination Committee (SBCCs) are to be formed to inspect, investigate and take punitive action in case of violations-**many states do not have functional SBCCs though they might have been formed**
- District Level Biotechnology Committee (DLCs)-District Collector as Chair to monitor the installation of safety measures –**not formed anywhere**
- As per directive from MoEF in July 2011 NOC (No Objection Certificate) from state govt was made mandatory for conducting GM crop field trials. Earlier Gram Panchayats and concerned depts in the local administration to be informed about trials. Panchayat to give consent.

Importantly, [Agriculture](#), including agricultural education and research; protection against pests and prevention of plant diseases come under State List of Seventh Schedule of Constitution of India (Art.246)

Other regulation related to GM seeds

- Seeds Control Order 1983 of Essential Commodities Act 1955 - State Govts have the authority to license the marketing of any kind of seeds, including GM seeds even if cleared for their biosafety by the GEAC. Price fixing is also being done under this. Some state governments have enacted state specific laws.
- Under Patents Act (Amendments) 2005, genetic sequences have been patented in India – however, this is now under examination in courts of law

“No outright ban, but only a case-by-case assessment” is India’s official stand on GMOs: Broad Risks that need assessment

- Health related
- Environment related
- Socio-economic (trade, livelihood security (including employment opportunities), riskiness in agriculture, farm economics, IPRs-Monopolies-who controls etc. etc. (Socio-economic considerations are part of Cartagena Protocol)
- NEEDS ASSESSMENT
- ALTERNATIVES ASSESSMENT

WHAT ABOUT REGULATION BASED ON PRECAUTION?

Failure to Regulate....

- No policy directives that govern regulation – all applications processed, and open air releases parallel to other tests, without any preliminary questions or biosafety assessments
- Many violations in biosafety conditions laid down for field trials documented – no action taken (Eg.: recent GM mustard case in Bathinda) - <http://indiagminfo.org/field-trials-violations/>
- Conflict of interest in the regulatory bodies – Eg.: Swapan Datta & wife; Pental's colleague – “conflict of interest” narrowly defined
- No scientific protocols used – in fact, copy and paste job found on field trials for GM rubber!
- Testing is not independent or comprehensive – no long term testing – Bt brinjal, for example
- GEAC meetings secretive and decisions taken sometimes even without a quorum!
- Studies ordered initially are dropped on some pretext or the other....

CONTRAST THIS WITH THE GENE TECHNOLOGY ACT OF NORWAY!

Main lacunae in our regulation

- No statutory Framework for Biosafety Protection
- No Policy directives used by regulators
- No Needs Assessment or Alternatives Assessment woven into regulation
- Conflict of Interest (only stepping out when certain applications are being discussed??)
- Dossiers are kept alive for years – Bt brinjal, for example
- No independent testing or analyses: TEC re-examining Bt cotton & Bt brinjal biosafety dossiers; 'problems had gone unnoticed and unaddressed in the course of the regulatory process leading to approval': TEC recommends re-examination of safety data of approved applications
- Opaqueness and secrecy : meaningful public participation or scientific scrutiny not allowed
- Illegal GM crop cultivation becoming a major menace – imports seem to be the main route, after field trial leakages
- No regulation of genome editing technologies at present!

Main Lacunae....

- **No liability regime** (violations are not acted upon: only one instance so far of mild response): who is responsible for contamination of non-GM and organic crops? Who is responsible for illegal GM crop cultivation?
- No enforcement of labeling or imports-related regulation (no segregation possible)
- No post-release monitoring systems (Bt cotton)
- FSSAI & NBA not active – de-regulated state when it comes to GM foods
- Approvals of trials even when state governments are saying NO or expressing reservations
- NO MONITORING CAPABILITIES AND INTEREST: Third party monitoring apparently being proposed! No contamination testing ever so far...

WHAT DID CREDIBLE HIGH LEVEL
COMMITTEES SAY SO FAR?

TASK FORCE ON APPLICATION OF AGRI BIOTECH (2004)

The bottom line of our national agri-cultural 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 and the security of our national and international trade in farm commodities.'

- *The transgenic approach should be considered when other options to achieve the objectives are either not available or not feasible.*
- *No transgenics should be developed in crops/commodities where our international trade may be affected.*
- *Such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. Breeding for herbicide tolerance, for example, may have low priority on this account in several parts of India where there are large numbers of landless labour families.*
- *There are regions in India which represent either primary or secondary centres of genetic diversity in major crops like rice. These areas should be conserved for posterity as Agro-biodiversity Sanctuaries.*

Task Force on Biodiversity & GMOs: 11th FYP, Planning Commission (2006)

The current adhoc programs on GMOs in agriculture must be stopped until a policy framework has been finalized.

A policy must be developed for transgenic varieties for which India is a center of origin and diversity, particularly rice. India has a special responsibility to protect the native germplasm of rice from incursion of alien genes.

Alternatives to the GM approach must be carefully evaluated in each case before deciding on the GM route

http://planningcommission.nic.in/aboutus/committee/wrkgrp11/tf11_biodiv.pdf

Parl. Standing Committee on Agriculture (2012 AND 2014)

- (ICAR) Animal feeding study report with Bt cotton: needs to be re-looked by an expert committee
- Several shortcomings in composition, powers, mandate etc., of GEAC & RCGM: sister Committee in Parliament to take up in-depth and comprehensive examination
- Grossly inadequate and antiquated regulatory mechanism, serious conflict of interest, total lack of post commercialisation monitoring: country needs an all encompassing umbrella legislation on BioSafety – Govt to immediately evolve (and not a biotechnology regulatory legislation)
- (Re) Examination of research reports on Bt brinjal by an agency other than GEAC (by some public sector agency such as CSIR)

Parl. Standing Committee

- Criticism of failure of DAC in policy-making with regard to transgenics in agriculture – look at commercial release of Bt cotton (incl. how Bt cotton became priority when avowed goal was to ensure and maintain food security)
- Tonnes of Bt cotton seed oil getting into food chain unnoticed – explanation sought from Dept of Consumer Affairs
- Negative impact of transgenics on country's agricultural exports needs to be factored into regulatory decision-making
- Suitably equipping NBA and FSSAI for effective discharge of their mandated roles
- R&D on transgenics should be done in strict containment and field trials under any garb should be discontinued forthwith

Parliamentary Standing Committee

- “We are the Centre of Origin for several crops, as also one of the richest centres of biodiversity in the world....need an umbrella legislation on biosafety which is focused on ensuring biosafety, biodiversity, human and livestock health, environmental protection and which specifically describes the extent to which (modern) biotechnology fits in the scheme of things without compromising with the safety of any of the elements mentioned above”.
- National Biodiversity Authority’s submission and presentation to the Committee....esp. on lack of comprehensive and long term assessment related to impact on biodiversity right now, needing Centres of Excellence for the same, and assessment of alternatives. NBA said that NO ONE SEEMS TO HAVE THE MANDATE TO LOOK INTO THIS AS OF NOW despite the existence of Sec.36(4) of BDA!

PSC 59th Report February 2014

- The Committee are not satisfied with the replies furnished by the Government in respect of the above-mentioned recommendations. They therefore, reiterate their earlier recommendations and desire that further research and development on transgenics in agricultural crops should be done only in strict containment and field trials should not be undertaken till the Government puts in place all regulatory, monitoring, oversight, surveillance and other structures.

SC TEC majority independent report, 2013

- No Bt food crops for India
- No transgenics in crops for which India is the Centre of Origin or Centre of Diversity
- No herbicide tolerant GM crops in India – technical as well as socio-economic reasons

No field trials until the regulatory system is overhauled completely;

SEC to be part of risk assessment, that too at an early stage; need to broaden our expertise in this context

The SC case & TEC report

Deliberate open air releases happening right now parallel to biosafety testing whereas the SC TEC recommended:

the sequence of testing should be carried out in order of increasing environmental exposure required to perform the test. Tests should be done under the minimum conditions of exposure required for the test. Testing therefore proceeds in a progressive manner that increases confidence regarding safety with increasing exposure

SC TEC Independent Majority Report (2013)

- The release of a GM crop into its area of origin or diversity has far greater ramifications and potential for negative impact than for other species. To justify this, there needs to be extraordinarily compelling reasons and only when other choices are not available. GM crops that offer incremental advantages or solutions to specific and limited problems are not sufficient reasons to justify such release.....**The TEC therefore recommends that release of GM crops for which India is a centre of origin or diversity should not be allowed.**

Standing Committee on S&T/Envir. & Forests, 2017

- The committee strongly believes that unless the biosafety and socio—economic desirability, taking into consideration long run effects, is evaluated by a participatory, independent and transparent process and a retrieval and accountability regime is put in place, no GM crop should be introduced in the country
- The Committee, therefore, recommends that the Central Government should, in consultation with the State Governments and Administrations of Union Territories ensure that the whole process of field trials should be done in closed environment keeping bio-safety and health safety in mind and in collaboration with the agricultural universities so as to minimise the scope of fudging the primary data.
- The Committee recommends that the Ministry of Environment, Forest and Climate Change should review the functioning of GEAC along with the organisational set up of GEAC and take necessary corrective measures to make the whole process of assessment and approval more transparent so as to ensure environmental safety, bio-diversity safety, bio-safety, health safety, food and feed safety of our country.
- The non acceptance of the most advanced agricultural technology, GM technology, by the most developed countries raises doubts about the efficacy of the technology. The Committee, therefore, feels that the Government of India should conduct a comparative study to examine the reasons for not accepting this technology by these developed countries viz-a-viz the reasons led to its acceptance.
- The Committee, therefore, feels that the Government agencies have made attempts to portray a rosy picture with regard to the success of Bt Cotton in the country which actually is not the case.

Standing Committee on S&T/Envir. & Forests

- The Committee is at a loss to understand as to why the Government is pushing for GM crops without even having thoroughly assessed its environmental impacts, even when the desired result of increased productivity could be achieved through our own traditional methods of farming and the long term benefits of GM crops were under a doubt.
- The Committee recommends that the whole process of evaluation should be carried out by an independent agency consisting of the people of impeccable credentials in the relevant field to ensure that there is no violation of the existing regulations in this regard.
- The Committee is of the considered view that given the topography of our country and its diversity, it is imperative that the government agencies should come up with indigenous studies to substantiate their claim that there is no threat posed to our environment on account of GM crops.
- The Committee notes with surprise that the Department of Health Research has not taken any action with regard to examination of impact of GM crops on human health except narrating the studies done in other countries growing GM crops. Equally surprising to note is that there has been no in house scientific study carried out till date to study the impact of GM crops on human health.

Latest Demands from GM-Free Movement in India, with regard to threats from Illegal GM Crop Cultivation

Illegal GM crop cultivation

- Bt cotton, HT cotton, HT soybean and Bt brinjal.....all 4 GM crops entered illegally
- No Standard Operating Procedures in place when illegal GM crops are detected and complaints lodged
- State and district authorities ill-equipped to deal with such instances
- Accredited laboratories don't have primers and event-specific protocols for fixing liability on event developer
- No liability fixed so far on seed suppliers and crop developers – some action against farmers, however
- No proactive surveillance – no systematic surveys even after complaints

Systems to be put into place.....

- Liability for illegal GM crop cultivation to be placed squarely on Event Developer
- All testing labs to be provided with primers and event-specific protocols
- Standard Operating Procedures to be put into place when complaints are received
- SOPs for proactive surveillance to check on illegal cultivation
- Ban on herbicides being used on illegal GM HT crops
- Biosafety dossiers submitted for commercial cultivation approval to have a time window in which they are closed, if approval not obtained
- Ministry of Commerce & Ministry of Finance's Customs Dept should be fully vigilant about illegal GM imports into India – Plant Quarantine Authorities to be roped in for active scientific surveillance

Current biosafety assessment regime

- Serious questions around the biosafety assessment regime – which tests, in which sequence, with what protocols (including sample number of animals in experimental studies and length of study), by who/in which labs?
- No clarity on how FSSAI will regulate GM foods
- Raging scientific debates on analyses and interpretation of results especially on the toxicology front

**HOW MUCH FUND DID DBT SPEND IN ALL THESE YEARS ON
INDEPENDENT RESEARCH ON BIOSAFETY, AS COMPARED TO R&D OF
TRANSGENICS??**

Instead of addressing these,...BRAI BILL!

- A statute to set up a single window, fast track clearance system called the BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA.
- Repeated attempts to introduce & get it passed
- Regulation interpreted as ease of approvals
- No role for state governments, and regulatory body under promoting Dept – DBT!
- Attempt to criminalise those who question modern biotechnology!
- Secrecy and opaqueness built into the statute!

WRONG BILL BY THE WRONG PEOPLE FOR WRONG REASON

So, what are the compelling reasons for going ahead with business as usual transgenic regulation in India? When will we begin by asking more fundamental questions around need, alternatives first, and then, get into impact assessment? Where is the precautionary principle in practice?

**WE DEMAND A BIOSAFETY PROTECTION
LEGISLATION, INSTEAD OF BRAI BILL –
and Genome Editing Techniques have to be
regulated too...**

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