Field Trials of GMOs in India: A story of violations of, & blatant disregard towards Biosafety

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Threat from field trials….

- Technology: uncontrollable & irreversible, living
- Field trials are of new & untested organisms right now - this requires more scrutiny for decision-making than when decisions are taken for commercial release (theoretically, since commercial cultivation decision-making is after a whole set of information is generated on the new organism)….
- Contamination instances from field trials have indeed led to serious repercussions in the past elsewhere - while most instances are trade-related, they could also force regulatory approvals.

Instances of risks arising out of trials….

- GM wheat (2013, USA - still being investigated)
- GE Linseed/Flax (2009, Canada)
- Liberty Link Rice (2006-07; Trials stopped in 2002 itself. Total cost to rice industry-more than 1 bn$ worldwide; Bayer pays settlement for claims of abt 11000 US farmers, worth $750 mn)
- GE maize (of Syngenta Bt10, containing ARM for ampicillin, from experiments mistakenly used in breeding of Bt11 - USDA fine on Syngenta: US$375,000; EU blocked US grain imports unless guaranteed to be free of Bt10)
- GM Papaya (2004, Thailand)
- GE maize pharma crop (Prodigene, 2002, that grew with soybean - $3mn fine)
- India’s public sector Bt cotton that needed to be withdrawn

Let’s start at the beginning…

- No policy directives that govern R & D applications, especially ones that can declare their commercialisation intent.
- All applications for R&D and field trials are permitted without any discretion - a clearing house function to the regulator : NO ASSESSMENT OF SOCIO-ECONOMIC IMPLICATIONS. NO NEED ASSESSMENT OR ASSESSMENT OF ALTERNATIVES PRECEDES APPLICATIONS BEING ENTERTAINED (Norway’s Gene Tech Act)
- Institutional factors too: GEAC & RCGM have no farmer or consumer representation; GEAC has some stakeholder-ministries sending their reps; RCGM has no experts to evaluate an application against broad policy directives

Report of Task Force on Agri-Biotechnoloy Chapter II. Application of Biotechnology in Agriculture - Point 1.6:

- *Biotech applications, which do **not** involve transgenics such as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas*
- *Transgenic approach should be considered as complimentary and **resorted to when other options to achieve the desired objectives are either not available or not feasible***
- *Transgenic research should **not** be undertaken 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**. (4. Choice of Research Problems)*
- *Report also cautions against transgenics in crops for which we are the Centre of Origin and asks for preservation for mega-biodiversity centers and hotspots of agro-biodiversity viz., Western and Eastern Ghats and NE Region*

Main issues with field trials

- No policy directives used - no need assessment taken up
- Biosafety / containment norms inadequate (isolation distances, for instance…..) - even these are not always practised
- Monitoring, including of any contamination, is not done: monitoring sorely inadequate both for biosafety norms and for results declared - often this is determined by the crop developer
- No rationale to where and when field trials are allowed to happen - approvals being given for several seasons in one go!
- Faulty assessment frameworks for field trials?
- No sequence adopted for such open air field trials

Other issues with field trials…

- Accepted/Documented contamination in India: no improvements apparent
- Conflict of interest allowed in decision-making
- Absence of a liability regime - even EPA liability clauses are not applied/invoked
- Violations galore - showcasing incapabilities, apathy, lack of independence, lack of scientificity, illegalities

Violations/Bad Practices: Some Egs

6 instances for illustration

1. GM maize trial in UAS-Dharwad, of unauthorized HT Maize planting as recorded by a monitoring team of the GEAC (2011-12)
2. Gujarat field trials without SBCC, as found in RTI responses (2011-12)
3. Annual crop test protocols being prescribed for GM rubber tree trials (2011)
4. Bt rice contamination and volunteer plants in Jharkhand (2008)
5. Biosafety violations in Bijapur GM maize production plot (2011-12)
6. Violations of field trials (captured in video documentation too) in GM okra trial in Guntur and Gulbarga by Centre for Sustainable Agriculture (2006)
7. Conflict of Interest in Bt rice and Bikaneri Bt narma cases

Case 1. GM MAIZE TRIAL OF MONSANTO

- A GEAC Monitoring Team discovers NK603 planted without authorisation… (as revealed by RTI applications which sought monitoring team reports)
- GEAC covers this up by saying that they authorised, and that the monitoring team was not aware of such an authorisation!
- This response clearly not in line with various other evidences we present….

Case 2: Field trials without SBCCs

- RTI responses show confusion between Dept of Agriculture and Dept of Environment & Forests, indicating that no SBCC exists in Gujarat, while field trials continue
- When confronted with evidence, GEAC only says that “views of the state government will be obtained before taking a view on the matter”
- SBCCs/DLCs are referred to as the “implementation arms” of GEAC by regulators themselves in their presentation

Case 3: Annual crop test protocols for GM rubber trials

- 21/12/2010: RCGM approves field trials of GM rubber, to be taken up by Rubber Research Institute of India
- Copy and paste job from annual field crops for protocol for the trial!
- GEAC receives complaint and acknowledges that no protocols for tree species have been developed
- Explanatory response from GEAC only mentions how trials have not been initiated so far, rather than cancel the trial permission immediately! Another case of permission given first, and protocols worked out later….

Case 4: Bt rice violations in Jharkhand

- March 29th 2008: a Bt Rice plot sown in Jharkhand by Mahyco; Harvested on 11/8/08, final burning on 15/8/08 and Mahyco writes to RCGM/GEAC on 28/8/08 that all norms have been complied with
- 10th Sept 2008: Gene Campaign produces photographic evidence belying Mahyco's claims (unusual planting time with no pest incidence, farmers uninformed, state govt not informed, no isolation or physical containment and volunteer plants and stumps throwing up tillers shown etc.)
- 20th Jan 2009: Gene Campaign lab analysis (Eurofins Gene Scan Laboratory, Germany) confirms that seeds and leaves picked up by the NGO for testing contain cry1AC.
- No investigation by GEAC - only one reference in Dec 2009 meeting, questioning Gene Campaign's sending of rice sample without approval of NBA/GEAC!!!

Case 5: Monsanto's GM maize seed production in Bijapur

- 24/12/2010: GEAC's 104th meet approves 25 acres of seed production of Monsanto's GM maize (no rationale for why so much seed production for a GMO whose biosafety is not cleared)
- 4/7/2011: GP and Samaya TV show on camera cobs lying around in a Bijapur plot, and test positive on camera for being GM corn - complain to GEAC about viable corn cobs lying around after harvest and completion of seed production
- Secretary, GoK's letter reveals that Monsanto did not disclose location within stipulated 15 days

Bijapur case contd…

- No conditions and protocols laid down for such seed production (ref: permission letter dated 24/12/2010)
- 6/7/2011: first Show Cause notice by JDA to Monsanto
- No record to show that Monsanto provided records to the effect of plant residue being destroyed after harvest by burning to the state dept of agriculture and district authorities as laid down in the permission letter conditions.
- JDA's investigation report (17/9/11) shows that 3-year lease agreements were not found with concerned farmers and company
- Meanwhile, on 21/9/2011, in its 112th meeting, GEAC approves seed production on another 25 acres!!

Bijapur case contd….

- 1/11/2011: GEAC constitutes a 2-member team for investigating the alleged irregularities as there is ‘no reply from GoK to a Jul 19th GEAC ltr (unaware that GoK had initiated its own action promptly)
- 24/2/2012: GEAC reconstitutes the committee - 8 months after the complaint by GP
- March 2012: Field visit by committee - the investigation did not include any interaction with the complainants!!
- 10/4/2012: Committee report finalised: it concluded that the GM crop residue was burnt at the site and no residue left - based on cross-examination of farmers! Reports also that while permission for rabi and kharif, January-May 2011 were used for seed production
- 11/4/2012: GEAC meeting notes ‘the need for specific guidelines for seed production trial as well as monitoring of the seed production site’; further, ‘it was acknowledged that the outcome could have been better if the inspection has been done earlier when the alleged violation came to light’.

Case 6: Conflict of interest

- Transgenic rice trial in Chinsurah Research Station, WB - Dr Swapan Datta comes into the picture, even though he himself was associated with the research and his wife is the PI, to influence the decision-making (Nov. 2010, Jan. 2011 GEAC meeting minutes). Only in July 2011 does GEAC extend the conflict of interest clause, for the first time, to a “member or his/her spouse or children” being involved!!!
- Bikaneri Bt cotton case: BM Khadi and K R Kranthi two key people involved in development of BN Bt were part of the regulatory body and during decision-making!

All these illustrations showcase….

- regulatory apathy/inaction, incapability and lacunae which pose a serious question on the credibility, rigour, independence and trustworthiness of GM regulation in India
- Also pose a serious question on ability to uphold biosafety

Current debate…..

- What can be termed as “environmental release”? (Other regulatory regimes have ‘deliberate release’ which is anything other than ‘contained use’)
- Can one set of biosafety tests be first done before the GMOs are brought out for field trials?
- Is there a case for some GMOs not being brought out into the environment at all?
- Given the nature of the technology and given the regulatory experience, what should be done specifically in India?

Environmental Release….

It is only a Euphemism in India that Field Trials of upto 2.5 acres per location are called “Confined” and commercial cultivation is called “Environmental Release” - terminology misleading - everything has been open air release, with many documented instances of GMOs from field trials entering food chain, for example…

5-member SC TEC recommended that unless all the lacunae are addressed first and foremost, all field trials should be stopped.

My conclusion….

Given the challenge posed by an irreversible, uncontrollable living technology with every environmental release, given the pathetic state of affairs with regard to capabilities, commitment, interest and independence in terms of monitoring, given the state of distrust of state governments and the public towards the regulators, given that no firm policy directives are adopted, given that no scientificity governs when, where and why field trials are taken up, including with what protocols, given that biosafety containment and confinement procedures are inadequate and given that no liability regime is in place…..**ALL OPEN AIR FIELD TRIALS SHOULD BE STOPPED**