MANAGEMENT AND MONITORING OF FIELD TRIALS OF GENETICALLY MODIFIED CROPS

In India, Bt cotton containing the Cry1Ac gene from Bacillus thuringiensis is the only crop approved for commercial cultivation and the area under cultivation in 2006 was 380,000 hectares. Several crops, including brinjal, cotton, cabbage, chickpea, cauliflower, groundnut, maize, mustard, okra, potato, rice, tomato, etc., are at various stages of research and in limited field trials by public and private sector institutions. As more and more transgenic crops are being released for field-testing and commercialization, concerns have been expressed about the potential risks associated with their impact on human health, the environment and biological diversity. Keeping in view the same, there is a regulatory system in place in the country under Rules 1989 to monitor various steps.

Field trials are an important component of this process representing the first controlled introduction of a genetically modified (GM) crop into the environment. They take place between experiments in contained facilities and commercial release to farmers. Under the present regulatory set up in India, the Monitoring cum Evaluation Committee (MEC) constituted under Review Committee on Genetic Modification (RCGM) by the Department of Biotechnology (DBT) monitors multi location research field trials and large scale field trials. MEC has been monitoring field trials during the crop season by constituting monitoring teams for each state and also for specific crops by drawing members from GEAC, RCGM, MEC, state agricultural universities (SAUs), state agricultural officers, etc. As the number of transgenic crops/hybrids under field trials has increased, it has become an extremely complicated task to constitute the monitoring teams to visit the field trials during the short period of crop growth.

In view of this, the SAUs along with state agriculture departments have been entrusted with the task of both pre-release monitoring of field trials and post-release monitoring of performance of GM crops as suggested by “Sub Committee on Bt cotton and related issues” constituted by GEAC. As per the recommendations, each SAU constitutes a monitoring team consisting of representatives from its concerned departments such as agri biotechnology, plant breeding, entomology, agronomy etc., and state agriculture departments.

To strengthen the management and monitoring of field trials, DBT has developed guidelines for conducting confined field trials of regulated, genetically engineered plants in India. These guidelines have been prepared to supplement DBT guidelines for Research in Transgenic Plants, 1998, which gave broad guidance about the conduct of the field trials. The draft Standard Operating Procedures (SOPs) for field trials of regulated genetically engineered plants have also been prepared. Formats for recording the information during the conduct of field trials have also been drafted. Prior to adoption of the guidelines, all the documents were placed on the website for public comments. MoEF and DBT also conducted a series of consultations, as indicated below, with SAUs and state departments of agriculture to discuss the guidelines.

### Consultation Location | States Covered | Date
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Nagpur | Maharashtra, Madhya Pradesh, Rajasthan, Chhattisgarh, Gujarat | March 28, 2008
Hyderabad | Andhra Pradesh, Orissa, Bihar, West Bengal, Karnataka, Tamil Nadu, Kerala | March 29, 2008

Extensive discussions took place during the meetings and useful comments were provided by participants. Once the documents are approved by regulatory authorities, training workshops will be conducted in various SAUs to ensure systematic and satisfactorily reporting of field trials, which are extremely important in the safety assessment of transgenic crops.

SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with the local governments to facilitate implementation of transparent, efficient and responsive regulatory frameworks that ensure the safety of new foods and feeds, and protect the environment.

SABP is working with its in-country partners to:
- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

**NEWSLETTER**

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www.agbios.com/sabp
Dr. Razzaque highlighted the opportunities and bottlenecks of utilizing agricultural biotechnology in Bangladesh, noting its development and role in the commercial production of tissue culture derived plants from different crops and the global status of transgenic crop cultivation. He pressed that the different regulatory bodies who will be responsible for approving field trials of Bt-brinjal and other crops be made operational. These will comprise the National Committee on Biosafety (NCB), the Biosafety Core Committee (BCC) and the, yet unformed, Field level Biosafety Committee (FBC) and ensure that, once approved, the field trials will be conducted in a safe way.

The conference incorporated six scientific sessions including production and conservation of medicinal, horticultural, ornamental, timber and other cash crops through in vitro techniques; biotechnology in pharmaceutical industries; plant transformation: status and prospect of transgenic crops in developing countries; biosafety and public acceptance of genetically modified plants; progress and prospect of commercialization of in vitro derived plants and value added products; and tools for crop improvement: marker assisted breeding, bioinformatics; and three plenary lectures, “Molecular Targeting and Drug Discovery in the post-Genomics Era” by Dr. Zaheed Husain; “Plant Breeding Systems for Increasing Agricultural Productivity” by Dr. Abed Choudhury; and “Mutation Breeding and Food Security: Achievements and Prospects” by Dr. M.C. Kharkwal and a poster session were also featured.

The conference concluded with a conference report by Prof. Dr. M. Imdadul Hoque and the adoption of recommendations that will be submitted to the government agencies.

**SHOW GM FOOD DATA, SAYS COURT**

The Telegraph (Calcutta) - April 9, 2008

New Delhi -- The Supreme Court today ordered the government to make public all data on genetically-modified (GM) crops that is relevant to environment and safety, responding to activists seeking independent scientific scrutiny of claimed results.

In a ruling on petitions filed by non-government organisations, the court said all the relevant data on toxicity and

(continued on page 4 - see Food Data)
The Department of Agriculture and Cooperation (DAC) is responsible for the formulation and implementation of national policies and programmes aimed at achieving rapid agricultural growth through optimum utilization of the country’s land, water, soil and plant resources.

The Department undertakes all possible measures to ensure timely and adequate supply of inputs and services such as fertilizers, seeds, pesticides, agricultural implements and also to provide agricultural credit, crop insurance and ensure remunerative returns to the farmer for his agricultural produce.

The Department is entrusted with the responsibility for collection and maintenance of a wide range of statistical and economic data relating to agriculture, required for development planning, organizing agricultural census, assisting and advising the cooperative organizations, cooperative training and education. The Department also participates in activities of international organizations that foster bilateral cooperation in agricultural and allied sectors and for promotion of export in agricultural commodities.

The website includes, among other things:

- Department circulars and notifications;
- Acts and rules;
- Farm produce prices;
- Agricultural statistics;
- Weather watch;
- Parliamentary questions and answers;
- National and international agricultural news.

Information on:
- Department programmes;
- Active, expired and government tenders;
- E-governance projects (DACNET and AGMARKET);
- Rabi Campaign;
- Cooperatives;
- Directorates;
- Conferences and seminars;
- World Trade Organization;
- Drought management;
- Land use statistics; and
- Frequently asked questions.

- Search functions for:
  - State agriculture departments;
  - Offices under DAC.
Food Data - continued from page 2

Allergenicity studies conducted on laboratory animals should be made public by the Genetic Engineering Advisory Committee (GEAC).

The GEAC is a government agency that approves GM crops for field trials and commercial cultivation after evaluating the results of such studies. But it has never made public details, such as design and analysis of the studies on the animals.

Petitioners said they are still unsure what data will be released.

“We need fine details for independent scrutiny,” said Suman Sahai, director of Gene Campaign, a research and advocacy organisation that had filed a petition seeking transparency and strengthened regulatory mechanisms to govern GM crops in India.

“We need data that will tell us how the animals responded, what were the doses given, what measurements were done on the immune system, the statistical analysis used,” she said. “We still don’t know whether they’re going to make this public.”

In response to an earlier request, Sahai said, the GEAC had merely provided information about what animals were used in tests, where the studies were conducted and the conclusions.

“It was a pretence of giving information without giving anything useful at all,” Sahai said. “We’re going to be on our guard that they don’t do the same thing again.”

In the past, GM crop companies and the Department of Biotechnology have argued that research data is "proprietary and confidential" and its public release was likely to "harm the competitive advantage" of the companies.

“We have in place independent regulatory systems for evaluation of such data,” biotechnology secretary M.K. Bhan said. “Whatever data is available will be made public,” he had said yesterday, when asked whether the department would support the release of the data.

The clamour for independent examination of safety data has grown in the past two years after data submitted to European regulators by an international company was found by independent scientists to have adopted inappropriate statistical methods to draw favourable conclusions about GM crops.

“All we’re asking for is a transparent system where any qualified scientist can have a look at how the animals responded,” said Jai Shankar, an activist with Greenpeace India, which has also been trying to access safety data from the government.

Greenpeace activists have pointed out that several countries have adopted a cautious approach on genetically engineered crops.

The following papers were published recently and may be of interest to readers of the SABP newsletter.

**BT corn in Spain— the performance of the EU’s first GM crop**

Nature Biotechnology - Volume 26 Issue 4 Page 384-386, April 2008 - Correspondence

Your March issue indicates that last year 114 million hectares of farmland across the world were planted with genetically modified (GM) crops. And yet in Europe, the cultivation of these crops remains both limited and controversial. Indeed, scientific and policy debates in the European Union (EU) have rarely focused on the agronomic aspects of GM crops and economic impacts for EU farmers. Currently, the only GM crop authorized for commercial cultivation in the EU is a GM corn resistant to corn borer by virtue of the transgenic expression of a gene encoding *Bacillus thuringiensis* (Bt) toxin. Spain now has over nine years of experience in commercial cultivation of this type of GM corn (and is the European member state with the highest adoption rate for this GM variety). It is thus an opportune time to analyze ex post the agronomic and economic performance of Bt corn in Spain. We present the results of this analysis below—the first for a GM crop cultivated in the EU.

For more information go to: http://www.nature.com/nbt/journal/v26/n4/full/nbt0408-384.html

**Beyond risk - A more realistic risk-benefit analysis of agricultural biotechnologies**

EMBO Reports - Volume 9 Issue 4 Page 302-306, April 2008 - Viewpoint

Here, we argue that limiting the ethical discussion about agricultural biotechnologies to questions of risk assessments is problematic for at least two reasons. First, doing so incorrectly assumes that the potential risks and benefits of agricultural biotechnologies, as normally understood in current risk assessments, are the sole significant normative concern. Although risk assessments are certainly important, there are many other ethical and social concerns that must also be addressed with respect to agricultural biotechnologies. Second, framing the debate as one that involves only technical problems effectively limits who can legitimately participate in the discussion. Presumably, only scientific experts are trained sufficiently to determine the risks or benefits of GMOs, and non-scientists are therefore disqualified from participating in the dialogue. But this erroneously presupposes that the evaluation of risks and benefits requires only scientific and technical analysis. Nonetheless, risk assessments not only involve scientific values, but also ethical and social ones. Thus, we make the case that these normative issues must not be left to scientific experts in a democratic society, but should be subjected to proper public deliberations—not ones steered by the media or pressure groups.

For more information go to: http://www.nature.com/embor/journal/v9/n4/full/embor200839.html

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