

Brainstorming Session

on

**ENABLING REGULATORY MECHANISMS FOR
RELEASE OF TRANSGENIC CROPS**

October 18, 2003

HIGHLIGHTS



TRUST FOR ADVANCEMENT OF AGRICULTURAL SCIENCES
Indian Agricultural Research Institute
New Delhi-110 012, India

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Enabling Regulatory Mechanisms for Release of Transgenic Crops

INTRODUCTION

Biotechnology offers innovative ways to improve both productivity and quality of the agricultural produce while ensuring better income for the resource-poor farmers by reducing the costs on the inputs. The varieties produced through the techniques of genetic engineering are popularly known as genetically modified (GM) crops or transgenic crops. In the recent past, GM crops have attracted attention of scientists as well as the society. As is expected with any new technology, apprehensions and some concerns have been raised about the safety of products derived through biotechnology, particularly transgenics, in relation to human health and environment. In order to keep much needed pace with the rapid developments taking place worldwide, it is essential that precise mechanisms are evolved to assess the biosafety and performance of the new GM products before recommending them for large-scale cultivation. This process has to be both efficient and fast. India, like several other countries, has developed procedures and guidelines for the release of transgenic crops. Yet there are concerns that need to be looked into, in order to further improve the system. To address these questions dispassionately, a neutral platform comprising all stakeholders such as scientists, policy makers, representatives of private sector, farmers and NGOs is required.

*Dr. R.S. Paroda, Chairman, TAAS, addressing the audience at the Inaugural Session.
Seated on dais are Dr. S. Nagarajan, Director, IARI, New Delhi and Member Trustee of TAAS,
Dr. Manju Sharma, Secretary, DBT, Government of India, Prof. Anupam Varma, Vice-Chairman, TAAS
and Dr. N.N. Singh, Secretary, TAAS*





Dr. Manju Sharma delivering the First Foundation Day Lecture

The Trust for Advancement of Agricultural Sciences (TAAS), founded on October 17, 2002 with Headquarters at the Indian Agricultural Research Institute (IARI), New Delhi organized a Brainstorming Session on “**Enabling Regulatory Mechanisms for Release of Transgenic Crops**” on October 18, 2003 to discuss relevant issues on the subject. The Agenda of the meeting is provided as Annexure. About 100 participants from various Research Institutes, Government Organizations, International Centres, Private Sector and NGOs deliberated intensively on various relevant issues.

The highlights and the salient recommendations of the one day brainstorming session are presented here.

HIGHLIGHTS OF THE BRAINSTORMING SESSION

At the outset, Dr. R.S. Paroda, President, TAAS, former Secretary, Department of Agricultural Research and Education (DARE), Government of India and the Director General, Indian Council of Agricultural Research (ICAR), expressed global and national concern on biosafety, biosecurity and biodiversity related issues. He emphasized the need for discussion on the enabling regulatory mechanisms that could help faster adoption of agricultural biotechnology in the national context, especially in view of the new opportunities that biotech products offer to both resource-poor farmers and the consumers, while ensuring the concerns of biosafety and usefulness of such products to the society.

The Brainstorming was organized in four main sessions:

- Present status of biotechnological developments in India
- Product development: Public-private sector partnership
- Enabling regulatory measures framework
- Plenary session: Adoption of recommendations

SESSION I: PRESENT STATUS OF BIOTECHNOLOGICAL DEVELOPMENTS IN INDIA



The session was chaired by Dr. H.K. Jain, former Director, Indian Agricultural Research Institute, New Delhi. Four presentations were made in this session. Dr. R.P. Sharma, former Project Director, National Research Centre on Plant Biotechnology, was the lead speaker and Dr. Akhilesh Tyagi,

Dr. H.K. Jain, Former Director, IARI, Chairing the Session and Dr. K.R. Koundal, Project Director, National Research Centre on Plant Biotechnology, IARI, recording the proceedings.

Professor, Delhi University, South Campus, New Delhi, Prof. Sudhir Sopory, Programme Leader, International Centre for Genetic Engineering and Biotechnology (ICGEB) and Dr. Vibha Dhawan, Dean, The Energy and Resources Institute (TERI), acted as panelists/discussants. The four speakers provided a broad perspective of various achievements in agricultural biotechnology, presented the major concerns and highlighted the issues involved. Dr. Sharma dwelt in detail on the present status of biotechnology in India. He urged that the projects on development and commercial release of transgenic varieties should be taken up in two phases. In the first phase, involving the development of transgenic plants, molecular biologists have to play a pivotal role. In the second phase, involving biosafety and agronomic evaluation, there is a distinct need for closer collaboration with scientists from different fields, especially plant breeders and agronomists. He also emphasized that for commercialization of transgenic varieties, collaboration with the private sector is critical so that the benefits are available to the end users, especially the resource-poor farmers. Dr. Sharma also expressed that in public institutions, different partners need to be identified right at the time of conceptualization of a project. The project should be critically peer reviewed and fully funded to ensure proper development and commercialization of transgenic crops. Such an approach would require effective coordination and monitoring.



*Dr. R.P. Sharma,
Former Director, National
Research Centre on Plant
Biotechnology, IARI,
delivering Lead Lecture*

Dr. Akhilesh Tyagi traced the development of biotechnological research in the country. While recalling that almost 50 genes have been isolated and cloned in various laboratories, he was concerned that so far very little work had been initiated in the area of functional genomics. He emphasized that India has to develop a large pool of highly trained molecular biologists and biotechnologists to quickly evolve and apply cutting edge technologies. This could be achieved by organizing training programmes in the institutes of repute involving eminent scientists and experts.

Prof. Sudhir Sopory pointed out that four countries (the United States, Canada, Argentina and China) accounted for 99% of transgenic crop releases. He felt that while the required technologies were available in India, there is a distinct need for networking of all the concerned institutions involved in the development and release of transgenic crops. Lack of a designated agency for biosafety testing and non-existence of a proper feedback mechanism from the farmers are some of the important constraints in the successful development and commercialization of transgenic varieties in India.

Dr. Vibha Dhawan referred to some of the neglected applications of biotechnology, like *in vitro* plant propagation and biopesticides. She opined that increasing shelf-life, improving nutritional quality and developing crop varieties that would withstand changes in global climate would indeed be the priority areas of biotechnology research in India. She emphasized that the regulatory mechanisms need to be streamlined. She felt that to be fully effective, training programmes in biotechnology will have to be extensive in nature and of longer duration, at least for six months, and should be a part of specially designed post-graduate courses and diploma programmes.

During the discussions that followed the above presentations, a number of important issues were deliberated, which were summed up by Dr. H.K. Jain as follows:

- Development of technologies through a networking approach, and coordination of interdisciplinary projects on biotechnology in the same way as that of Indian Council of Agricultural Research (ICAR) Coordinated Projects;
- ICAR and the Department of Biotechnology (DBT) jointly to deliberate critically on the existing mechanisms of testing and evaluation of transgenics in order to bring in the needed improvements and efficiency and to overcome overlaps, if any;
- Review of the existing regulatory mechanisms for evaluation and release of transgenics and the precise role of ICAR as a key player for evaluation of transgenics be clearly defined and assigned;
- Notification and seed certification of transgenics has to be made an essential pre-requisite;
- Networking of all research institutes addressing various biosafety issues should be ensured by DBT;
- Human resource development in biosafety be given priority through long-term programmes (6 months) at some selected centres having the requisite facilities.

SESSION II: PRODUCT DEVELOPMENT: PUBLIC-PRIVATE SECTOR PARTNERSHIP

This session was chaired by Dr. Sudhir Sopory. Three presentations were made by representatives of the ICAR institutes and the private sector. Dr. S. Nagarajan, Director, Indian Agricultural Research Institute (IARI), New Delhi presented the lead paper and Dr. M.K. Sharma, Maharashtra Hybrid Seed Company (MAHYCO), Dr. Harbeer Singh, Senior Scientist, National Centre for Agricultural Economics and Policy Research (NCAP), New Delhi participated as panelists. They were of the unanimous view that there is need to have greater collaboration between the public and private sector R&D institutions. Dr. Nagarajan emphasized the need for reorganization of facilitation network at the institutional level. He felt that sharing of the facilities and technologies is an important pre-requisite, which somehow is lacking at present due to mistrust and absence of well-placed institutional framework. He also pointed towards lack of an acceptable system for possible negotiations to initiate joint ventures with the private sector in the field of transgenic development and their subsequent launch in the market. He urged for a greater institutional autonomy in this context. It was imperative to develop

transparent standardized guidelines for much needed negotiations and transactions for collaborative research and benefit sharing with the private sector. Dr. Nagarajan felt that for the success of transgenic development and dissemination from the laboratory to the field, the major challenging task is to ensure effective



Dr. Sudhir Sopory, Professor & Head, Plant Molecular Biology Division, International Centre for Genetic Engineering and Biotechnology, Chairing the Session and Dr. R.K Jain, Principal Scientist, IARI, recording the proceedings

coordination and partnership among concerned research institutions, universities, ICAR and the private sector.

Dr. M.K. Sharma pointed out that the indigenous private sector has relatively limited infrastructure for transgenic development compared to public institutions. Therefore, effective cooperation between the public and private sector is needed for promoting transgenic research and development, and for evolving a policy for promotion of biotechnology in the country. He also felt that such cooperation could be through proper understanding on sharing of the resources as well as royalties. He strongly urged to have in place, clear policies regarding testing of transgenics, regulatory system and the Intellectual Property Rights (IPR). He stated that *Bt* cotton, which was released in 2002, was being marketed by different companies under sub-licensing system with MAHYCO. Hence, partnership models are possible. With widespread use of transgenics, Dr. Sharma felt that there is an urgent need for appropriate public awareness by the Government, especially with regard to specific benefits and possible risks of using transgenics.

Dr. Harbeer Singh presented the socio-economic view point on transgenic crops. He informed that globally there was a reduction in production cost by about 15-20 per cent, by using *Bt* cotton. Economic concerns of farmers/consumers in relation to transgenic varieties, therefore, need to be adequately addressed by all the stakeholders. He also stressed upon the need for greater public awareness, public-private collaboration and sustained follow up with regard to various international developments in this field.

During the discussion on the subject, the following important issues were highlighted:

- Public and private sector partnership is critical to have full benefits of transgenic varieties reaching the farmers.
- An efficient and transparent regulatory framework for testing and evaluation of transgenics has to be put in place by overcoming existing gaps and shortcomings.
- There is an obvious need to establish a consortium at the national level, so as to ensure convergence of public and private interests in such core issues and to develop and sustain long-term partnerships in the national interest.

SESSION III: ENABLING REGULATORY MEASURES FRAMEWORK

Prof. Anupam Varma, National Professor and Vice-Chairman, TAAS, chaired the session while Dr. C.D. Mayee, Agriculture Commissioner, Government of India was the lead speaker and

Prof. Anupam Varma, National Professor, ICAR, Chairing the Session and Dr. B.M. Prasanna, Senior Scientist, IARI, recording the proceedings



Dr. S. Nagarajan, delivering Lead Lecture





*Dr. C.D. Mayee,
Agriculture Commissioner
delivering Lead Lecture*

Dr. (Mrs.) Malthi Lakshmikumaran, Fellow, TERI, Prof R.B. Singh, former Chairman, Agricultural Scientist Recruitment Board and Mr. Anil Mishra, an Advocate having expertise in IPR, were the panelists. The presentations highlighted the existing regulatory mechanisms and offered possible new options.

Dr. C.D. Mayee explained the regulatory mechanism for testing and evaluation of transgenics in India. He remarked that the evaluation trials being conducted under the supervision of Monitoring-cum-Evaluation Committee (MEC) on the direction of Review Committee on Genetic Manipulation (RCGM) under the DBT were mere duplications of work being done under the ICAR Coordinated Trials. He, therefore, suggested that these two should be harmonized in order to save time and resources. He felt that the major concerns related to commercialization of transgenics were spurious seeds, lack of standardized protocols for testing of transgenics, need for revision of Seed Act to provide guidelines for the release of transgenics, litigation and dispute settlement mechanism and quickening the process of evaluation. He felt that the country urgently needed to have referral laboratories established for the certification of transgenics.

Dr. Lakshmikumaran explained the importance of the patents and other intellectual property protection mechanisms involved in the development and commercialization of transgenics in the emerging scenario. She emphasized that before development and commercialization of transgenics, all issues concerning IPR need to be taken care of.

Dr. R.B. Singh put forth the idea of having a 'National Authority for Biosecurity' in order to ensure effective harmonization among biotechnology, biodiversity and biosafety so that required policy framework at the national level is properly converged and coordinated. It was emphasized that the programmes and policies should be science-led with proper institutional support for required impact and also for information empowerment.

Mr. Anil Mishra highlighted several complex legal issues related to the existing regulatory framework for the transgenics, and stressed that these need to be widely discussed and resolved. He felt that the existing legal mechanism and the Government set up provided under the Environmental Protection Act (EPA) had not been adequately designed to handle the biosafety issues. Hence, there is an urgent need to have a separate legislation for handling the transgenics and for addressing biosafety issues that are based upon a self-regulatory mechanism model. A broad-based and formal system of Tribunals and Adjudicatory Bodies, with legal and technical experts would be essential to facilitate quicker settlement of disputes. It was also emphasized that there is a distinct need to have more transparency in the existing regulatory framework.



*Dr. R.B. Singh,
Former Assistant
Director General and
Regional Representative
for Asia and Pacific,
FAO Regional Office,
Bangkok, delivering
Lead Lecture*

During the discussion, several issues related to the regulatory mechanisms were raised and discussed, which were as follows:

- Based upon indigenous and global experiences and keeping in view the broader national interests, it is time now to put in place a separate yet comprehensive national regulatory mechanism on transgenics.
- Collaboration with the Asia-Pacific Consortium for Agricultural Biotechnology (APCoAB), a regional Forum being set up by the Asia-Pacific Association of Agricultural Research Institutions (APAARI) and the National Agricultural Research System (NARS) of the region would be highly desirable at this juncture.
- Need for a separate autonomous body is fully justified for managing biosecurity and biosafety related issues, for strengthening of on-going networks and for establishing collaboration among the stakeholders.
- Building consumer's confidence in transgenic crops and food products is indeed critical for the success of agricultural biotechnology.

SESSION IV: PLENARY SESSION

In the Plenary session, chaired by Dr. R.S. Paroda, three presentations were made. Two of these were made by representatives of the NGOs, who highlighted the social concerns with respect to the transgenic crops, and the third was by a scientist from International Service for National Agricultural Research (ISNAR), focusing on biosafety related aspects.

Dr. Suman Sahai of Gene Campaign, emphasized the need to improve the regulatory mechanisms for release of transgenic crops. She stressed upon the need for transparency, accountability and public debate on issues related to development and release of transgenic crops in India *vis-a-vis* the role of DBT, Ministry of Environment and other associated organizations in various Ministries.

Dr. Devinder Sharma, a Journalist with focus on agriculture, urged upon the scientists to take a realistic view of the agricultural needs of the country and develop technologies and products suited to our specific needs and in tune with existing resources. Policy decisions on food grain distribution, subsidies and diversification of agriculture should be based on the local/national priorities and not in the context of international obligations and directions. He also expressed his reservations for the use of GM crops, especially when India has large food reserves.

Dr. Jose Falek-Zepeda from ISNAR made a presentation focusing on the mission and scope of ISNAR programme on biosafety. The discussions emanating from these presentations stressed for a pragmatic approach and need to have a national level resolve on various policy related matters on GM crops.

Dr. R.S. Paroda, Chairing the Plenary Session and Dr. B.S. Dhillon recording the proceedings



