International Conference on Recent Scientific Developments in Agricultural Biotechnology: Sharing Experiences and Knowledge:

September 29-30, 2006 Hotel Le Meridien, New Delhi

CONCLUSIONS & RECOMMENDATIONS

Sponsored By International Life Sciences Institute-India (ILSI – India) ILSI International Food Biotechnology Committee (ILSI-IFBiC)

> Co-sponsored By Ministry of Agriculture, GOI

Department of Biotechnology, and Department of Science and Technology Ministry of Science and Technology, GOI

Planning Commission, GOI

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Conclusions & Recommendations

1.1 The International Conference on 'Recent Scientific Developments in Agricultural Biotechnology: Sharing Experiences and Knowledge' was organized by ILSI-India and ILSI-International Biotechnology Task Force on 29th and 30th October 2006, in New Delhi. The Conference was co-sponsored by Ministry of Agriculture, Government of India (GOI), Department of Science & Technology and Department of Biotechnology of the Ministry of Science and Technology, GOI, and the Planning Commission. It was inaugurated by Shri Sharad Pawar, Union Minister of Agriculture. Conference Agenda is given in the Appendix.

The Perspective

2.1 Indian Agriculture has completed one cycle of Green Revolution which started about 35 years back. It was mainly led by dwarf hybrid varieties of wheat and rice. During these years food grains production increased 123 per cent to 208 mt (2005-06). Yield per hectare nearly doubled in respect of both rice and wheat. In spite of that presently the yield in respect of rice is about two-fifths that in US and of wheat one third that in UK.

2.2 Demand for agricultural products, however, is increasing at 2.5 per cent per year partly due to population growth and partly to improvement in incomes. It is targeted $(11^{th} Plan)$ that food grains production will cross 320 mt by 2011-12 and horticulture production will double.

2	011-12
	(in mt)
Rice	129
Wheat	125.5
Pulses	23.5
Total	320

2.3 It would be difficult to reach these targets in present conditions characterized by sub-soil water depletion, deficiency of micronutrients in soil and, with the increased use of agro-chemicals which have caused tremendous damage to environment and human health, led to widespread pest and weed resistance. Even

conventional biotechnology intended to promote use of biofertilizers and biopesticides has made limited progress. A technology deficit has emerged in agriculture and the food curve has become nearly flat.

The New Technology Tool

3.1 It is in this perspective that it is necessary to look closely at crop biotechnology, including transgenic crops, marker–assisted breeding, and structural and functional genomics, as the new tool to galvanize agriculture.

3.2 Biotechnology has implicit advantage over conventional breeding. Gene transfer is for specific traits and the gestation period to incorporate these traits is much shorter. Hence conventional breeding has to be complemented by tissue culture and molecular breeding. These new tools can not only to increase production in a sustainable manner but also enrich the quality of products and reduce costs.

3.3 It was in 1996 that the first transgenic plants were released for commercial cultivation in the US. The first generation transgenics were mainly designed for herbicide tolerance and insect/virus protection. The second generation transgenics are more comprehensive and aim at higher yield, drought resistance, fortification of foods, healthy oil content, biofuel, pharmacological applications, and so on.

3.4 The benefits of agriculture biotechnology actually realized at present are:

- Improved insect and weed control
- Higher yields
- Reduced use of agro chemicals
- Lower cost

3.5 The world over there is rapid increase in transgenic crop cultivation. Last year, the total area under transgenics was 90 m ha in 21countries cultivated by 8.5 million farmers. A little less than a half of the total area under transgenics is in the US followed by Argentina, Canada, Brazil, China and India in that order. The four major crops which have been commercialized are soybean, maize, cotton and canola.

3.6 In India, fourteen food crops have been approved for field trials by public and private sectors with insect resistance, herbicide tolerance, viral and fungal disease resistance and stress tolerance as the target traits. These crops include rice, chickpeas, potato, mustard, tomato, brinjal, cauliflower, cabbage, pigeonpeas,

groundnut, maize, okra and sorghum. Bt Cotton has already been commercialized and brinjal is awaiting approval.

3.7 Commercialization of Bt cotton has led to tremendous expansion in area under Bt cotton. From less than 29,000 acres in 2002-03, area under Bt cotton has gone up to 35,00,000 acres in 2006-07 (estimated). Currently more than 10,00,000 farmers are engaged in the cultivation of Bt cotton.

Progress With Caution

4.1 Progress in respect of gene technology has been slow because of apprehension about the safety of GM foods and concerns about environment.

4.2 GM foods, it is feared, can be anti-nutritional, toxic and allergic. FAO/WHO, OECD, INFOSAN, and a variety of expert groups have made intensive studies about the health and environmental aspects of GMOs. All products have passed risk assessments and it is found that they are not likely to present risks for human health. Commercialization of alfalfa, canola, carnation, chicory, cotton, flax, linseed, green pepper, maize, melon, papaya, potato, rice, soybean, squash, sugar beet, sunflower, tobacco, tomato and wheat, is now allowed in a number of countries.

4.3 Risk assessment is based on substantial equivalence model for which a number of compositional parameters are tested (e.g. proximates, fibre, minerals, vitamins, fatty acids, amino acids, secondary metabolites and crop specific anti-nutrients). Substantial equivalence model is followed in most countries though there are national differences in biotech policies. Tolerance limits for the presence of GMOs vary from 1 per cent in Australia and EU to 5 per cent in Japan. China has zero tolerance.

4.4 To caution the consumer about the presence of GMOs some countries have encouraged labeling of these products. The Ministry of Health, GOI, has issued draft provisions for labeling of GM foods.

4.5 There are no globally recognized standard methods for testing for GMOs and the number of reference materials for products of modern biotechnology are limited. Each laboratory may have its own validation criteria and protocols for determining GM content.

4.6 Ecological hazards are only implied and yet there is hardly any information about actual damage to environment. More than 50,000 tests in the field have been

carried out around the world and these have given no indication of real danger or consequences which had not been predicted.

4.7 There are extensive regulations, in India, for r-DNA/GMO and products under the Rules of EPA (1986) and adequate infrastructure is also in place to prevent any damage to human health and environment. It needs to be recognized that the implied risks in the application of biotechnology to agriculture are minimal and the benefits enormous.

Access to Technology

5.1 Research in agricultural biotechnology applications in India began more than two decades back. Since 1984 the DBT, DST, CSIR, ICAR, and UGC have been assisting research and monitoring progress of crop biotechnology, apart from the initiatives taken by the private sector. Intensive research is undertaken at different plant molecular biology centers and other universities and institutions. In the private sector a number of companies have transgenic lines in advanced stage of development for field trials for a variety of crops.

5.2 The pace of progress in biotech applications in agriculture is governed by knowledge production and knowledge transfer. Both are facilitated when GMOs become acceptable. In that situation, private sector will be an equally dependable source of biotechnology innovations.

5.3 Although research is undertaken by different institutions and organizations in public and private sectors there are hardly any linkages inter-se. It would be useful to forge relationships through public-public and public-private partnerships to share experiences and knowledge. This is particularly important at this juncture when a number of products are at advanced stage and have to be commercialized

5.4 Since indigenous research is limited, cross border transfer of technology is critical to keep up with world developments. There are internationally accepted regulations which govern technology transfer generally, like for instance, TRIPS, CBD etc. Subject to these international regulations technology transfer can take a variety of forms since research is at public and private sector levels, and the objectives can be both commercial as also altruistic.

5.5 There are multiple owners of technology involving considerable transaction costs and possible holdups leading to a situation that has been described as 'crisis of the anti-common' Consequently there is serious underutilization of a valuable resource. Management of IPRs has therefore become a critical issue.

5.6 There are a variety of ways in which institutions and firms can obtain biotechnology genes and tools:

- For free if the transfer is done on humanitarian basis as, for instance, in the case of golden rice.
- The technology can be purchased outright, acquired on license with conditions for commercialization, or secured through joint ventures, and so on.
- Technology transfer may be institutionalized as for instance, PIPRA, (Public Sector Intellectual Property Resource for Agriculture) or AATF (African Agricultural Technology Foundation) set up by Rockefeller to assist countries which have limited access to IPRs.

5.7 The success of biotech applications must be judged by the number of products that can make it to the market. For that it is important to discover the right genes to develop the best product. Apart from technology it necessitates good project management and an efficient regulatory system.

Steps to Gene Revolution

6.1 It is important to devise a systematic coordinated approach to application of biotechnology to agriculture to get the best returns. The success of Eleventh Plan will depend to a large extent on achieving a 4 per cent annual growth in agriculture. Hence emphasis in the immediate future will have to be placed on technologies that enhance yields while developing a system that will secure food security. It is in this perspective that the following steps must be vigorously pursued.

- i. National biotech regulations need to be harmonized with Codex. This will facilitate introduction of biotechnology and also minimize disruption to external trade.
- ii. There is need to exercise prioritization with eye on outcome. Hence crops in respect of which research is already undertaken and field trials are under way have to have the first priority.
- iii. While indigenous discovery of new genes should be encouraged, wherever there is need for a product to achieve food or nutritional security, external sourcing of important genes through licensing arrangements should be immediately explored.

- iv. It would be useful to evolve a scientific and globally acceptable system of deregulation of bio-safe events.
- v. It is necessary to encourage public-private partnerships to facilitate commercialization of research and post release monitoring.
- vi. The proposed autonomous National Biotechnology Regulatory Authority should be set up as soon as possible to approve biotechnology products.
- vii. Greater attention should be given to capacity building and providing adequate facilities for researchers and a mechanism should be developed to share information about researches done by different organizations.
- viii. An interdisciplinary collegium should be set up to explore possibilities of comprehensive interdisciplinary scientific applications.
- ix. Institutions like PIPRA and AATF are good vehicles for transfer of technology. A similar institution at the international level should be set up to facilitate technology transfer. This institution should develop guidelines for licensing and retaining rights if the technology transfer is for public benefit and also provide funding for such transfer.
- x. It is extremely important to educate the consumer who is currently exposed to considerable misinformation and disinformation about the safety of genetically modified foods and the farmer about efficient use the new farm technology and thus create conducive conditions for acceptance of GMOs in the country.

Annexure

CONFERENCE AGENDA

International Conference on Recent Scientific Developments in Agricultural Biotechnology: Sharing Experiences and Knowledge

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AGENDA

Friday, September 29

1000-1100 Hrs	Inaugural Session
1010 – 1030 hrs.	Welcome Address By Mr D H Pai Panandiker, Chairman, ILSI-India
1030 – 1055 hrs.	Inaugural Address by the Chief Guest, Hon'ble Union Minister of Agriculture, Mr. Sharad Pawar
1055 – 1100 hrs.	Vote of Thanks By Dr. P. K. Seth, Member, Board of Trustees, ILSI-India and CEO, Biotech Park
1130-1330 Hrs	Session One: Beyond Green Revolution
	Chair: Mr. D. H. Pai Panandiker, Chairman, ILSI-India
	Dr. Anne Bridges, American Association of Cereal Chemists
1130 – 1135 hrs.	Observations by Chair
1135 – 1155 hrs.	Mustard Breeding through Conventional and Molecular Method Prof. Deepak Pental, Vice Chancellor, Delhi University
1155 – 1215 hrs.	Biotechnology and Agriculture Development in India: Strategies and Challenges Dr C D Mayee, Chairman, Agriculture Scientist Recruitment Board
1215 – 1240 hrs.	International Developments in Agricultural Biotechnology Dr Roy L. Fuchs, Lead, NALN, Regulatory Affairs, Monsanto
1240 – 1325 hrs.	DICUSSIONS
1325 – 1330 hrs.	Sum Up by Chair

	Chair: Dr. S R Rao,	Advisor, Department of Biotechnology, GOI
	Dr Roy L. Fu	chs, Lead NALN, Regulatory Affairs, Monsanto
1430 – 1445 hrs.	Sharing Knowledge	verview on Institutional Arrangements for and Experience , Department of Biotechnology, GOI
1445 – 1455 hrs.	Observations by Dr. Monsanto	Roy L. Fuchs, Lead NALN, Regulatory Affairs,
1455 – 1510 hrs.	Reference to Agricul	hip Initiatives in New Millennium with Specific Iture Biotechnology Head, TNBD, Council of Scientific and Industrial
1510 – 1625 hrs.	Case Studies	
1510 – 1525 hrs.	Bt Brinjal:	Dr. P. Balasubramanian, Director, Centre for Plant Molecular Biology, Tamil Nadu Agriculture University
1525 – 1540 hrs.	Bt Cotton:	Dr. P. S. Dravid, President, J K Agri Genetics Ltd.
1540 – 1555 hrs.	Golden Rice:	Dr S R Rao, Advisor, Department of Biotechnoogy
1555 – 1610 hrs.	Rice :	Prof. J P Khurana, Department of Plant Molecular Biology, South Delhi Campus, Delhi University
1610 – 1625 hrs.	Tomato:	Dr K C Bansal, Professor, NRC on Plant Biotechnology, Indian Agricultural Research Institute
1625 – 1640 hrs.	Agriculture (PIPRA)	lic Intellectual Property Resources for) PIPRA, Director Biotechnology Resources,
1640 – 1725 hrs.	DICUSSIONS	
1725 – 1730 hrs.	Sum Up by Chair	

Saturday, September 30

1000-1300 Hrs	Session Three: Safety Assessment
	Chair: Dr. P K Seth, Former Director, ITRC & Chief Executive Officer, Biotech Park
	Dr. Morven Maclean, President, AGBIOS
1000 – 1005 hrs.	Observations by Dr. P. K. Seth, Former Director, ITRC & Chief Executive Officer, Biotech Park
1005 – 1010 hrs.	Observations by Dr. Morven Maclean, President, AGBIOS
1010 – 1030 hrs.	GM Crop Composition Database Dr Roy L. Fuchs, Lead, NALN – Regulatory Affairs, Monsanto
1030 – 1050 hrs.	Case Studies on Nutrition and Safety Assessment of Biotech Foods Dr. Donald Mackenzie, AGBIOS
1050 – 1110 hrs.	Food Safety Assessment of GMOs : Current Scenario-India Dr. Venkata Ramanaiah Terala, Director, Department of Biotechnology, GOI
1130 – 1150 hrs.	Protein Safety Review Dr. Susan MacIntosh, President, MacIntosh & Associates
1150 – 1210 hrs.	Harmonization of Detection Methods for GM Foods / Crops Dr Anne Bridges, American Association of Cereal Chemists
1210 – 1230 hrs.	Post Release Monitoring System: Agronomic and Environmental Considerations Dr K V Prabhu, Head, Genetics Division, Indian Agricultural Research Institute
1230 – 1300 hrs.	DICUSSIONS
1400-1730 Hrs	Session Four: Round Table Discussion on Future Steps for Development of Agricultural Biotechnology
	Chair: Prof. V L Chopra, Member, Planning Commission, GOI
	Mr. D. H. Pai Panandiker, Chairman, ILSI-India
1400 – 1410 hrs.	Observations by Chair
Precursor Talk:	Dr. A. Bandopadhyay, National Coordinator, National Agricultural Innovation Project (NAIP), ICAR
Discussants:	Mr Pallav Bagla, Journalist Dr D Chattopadhyay, ADG (PFA), Directorate General of Health Services, GOI

	Dr S L Mehta, Vice Chancellor, Maharana Pratap University of Agriculture & Technology Dr T P Rajendran, Assistant Director General – Plant Protection, Indian Council of Agricultural Research Dr A K Singh, Senior Scientist, Genetic Division, IARI Dr. C. D. Mayee, Chairman, Agriculture Scientist Recruitment Board Dr. Roy L. Fuchs, Lead, NALF, Regulatory Affairs, Monsanto Dr. S. R. Rao, Adviser, Department of Biotechnology, GOI Dr. Yogeshwar Rao, Head, TNBD, Council of Scientific and Industrial Research Dr. P. Balasubramanian, Director, Centre for Plant Molecular Biology, Tamil Nadu Agriculture University Dr. K. C. Bansal, Professor, NRC on Plant Biotechnology, Indian Agricultural Research Institute Dr. Cecilia Chi-Ham, PIPRA, Director Biotechnology Resources Dr. P. K. Seth, Former Director, ITRC & CEO, Biotech Park Dr. Morven Maclean, President, AGBIOS Dr. Donald Mackenzie, AGBIOS
1645 – 1700 Hrs.	Concluding Remarks by Chair
1700 Hrs.	Valedictory Address Dr. M. K. Bhan, Secretary, Department of Biotechnology, Ministry of

Science and Technology, GOI