Brainstorming Session

on

ENABLING REGULATORY MECHANISMS FOR RELEASE OF TRANSGENIC CROPS

October 18, 2003

HIGHLIGHTS

taas
Progress Through Science

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 inter-disciplinary 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. S. Nagarajan, delivering Lead Lecture

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

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

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 Falck-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

Dr. Suman Sahai, Director, Gene Campaign, New Delhi, delivering Lead Presentation

During the discussions, Dr. H.K. Jain recalled the significant role of agricultural scientists in enhancing and stabilizing the crop productivity and in making the country self-sufficient in food grain production. He added that the policy issues need to be handled at a different level. He emphasized the role of plant biotechnology for further enhancing agricultural production and productivity, and also the need to be cautious about biosafety related issues.

Subsequently, the Chairmen of different technical sessions presented the recommendations for general adoption. These were as follows:

RECOMMENDATIONS

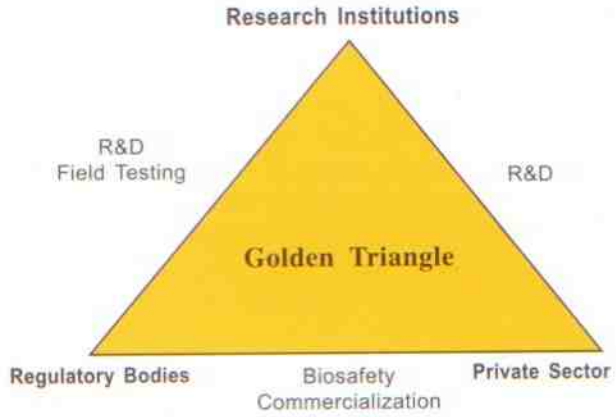
Present Status of Biotechnological Developments in India

- India's approach for the development of transgenic crops has largely depended on individual initiatives without the formulation of a composite product-oriented, integrated approach. While this has helped the nation in the generation of competent human resources, time has come to evolve a national policy, which would promote required collaboration and coordination at different inter-institutional levels, including the ICAR institutes, State Agricultural Universities (SAUs), academic institutions and the private sector so as to ensure delivery of the products to end users. Large-scale development and commercial release of transgenic crop varieties would not be possible in the absence of a collaborative approach of this kind, and hence immediate efforts to build required partnerships is rather critical at this juncture.
- Development and commercial release of transgenic varieties should be attempted in two phases: (i) In the first phase, molecular biologists and biotechnologists should have the primary responsibility and play an important role. It would, however, be unrealistic to believe that they can also take the responsibility for the field-testing and evaluation of newly developed transgenic varieties for biosafety and other regulatory requirements. (ii) In the second phase there should be much closer collaboration with scientists from various relevant disciplines, including plant breeders, and also with the private sector in order to ensure timely production and commercialization of transgenic varieties.
- While India has made significant progress in the field of molecular biology and biotechnology, critical gaps in R&D efforts still remain. Increased investments and intensified efforts are, therefore, necessary at this stage to create additional research capacity in areas such as gene and promoter isolation, vector construction, and cloning and transformation protocols relevant to important Indian crops. India must embark upon a major research programme in the area of functional genomics, especially in crops of considerable economic value.
- A national facility need to be created to assist the biotechnologists through facilitated access to the agronomically and economically important genes and the promoters.
- India needs to generate a critical mass of highly trained molecular biologists and biotechnologists to develop cutting edge technologies, which are becoming increasingly important. There is an urgent need to organize elaborate training programmes in a large number of

institutions having well equipped laboratories and highly trained scientists. The training programme should be of longer duration (at least 6 months), in order to develop required competence in the younger generation of scientists.

Product Development: Public-Private Sector Partnership

- Mechanisms need to be developed to build a strong string of public-private sector partnership. The golden triangle of partnership between various Research Institutes and Universities; ICAR and the SAUs; and the private sector can help in bringing the transgenics from the laboratory to the field at a much faster pace.
- Steps will have to be taken so that there is a swing from 'mistrust' to 'trust' between the public and private sectors, especially in terms of IPR related issues and benefit sharing.
- Possibility of developing a consortium at the national level, of both public and private sector institutions in order to promote agricultural biotechnology needs to be explored.
- Steps should be taken to create awareness and appreciation for transgenics among the stakeholders as well as general public.
- Economic concerns of the farmers/ consumers in relation to transgenic varieties need to be effectively addressed.



Enabling Regulatory Measures Framework

- There is considerable overlap in the functions of the Monitoring-cum-Evaluation Committee under the DBT and the agronomic evaluation of the transgenics undertaken by the ICAR. Harmonization of these functions could considerably reduce the time required for the evaluation and release of transgenic materials and also save resources.
- There is a distinct need for 'referral laboratories/institutes' for evaluating specific aspects of biosafety of transgenics, related to the human, animal, plant health and also the environment.
- Prevention of commercialization of spurious seeds in the name of transgenics; establishing minimum standards and criteria for the release of transgenics, revision of the Seed Act and Rules, procedures for litigation and dispute settlement, and speedy process of evaluation of the transgenics, are some of the major concerns in relation to the regulatory framework in India, which need to be addressed on priority for effectively reaping the benefits of biotechnology.
- The significance of the patents and related aspects in relation to the development and commercialization of transgenics have to be clearly understood by the researchers/institutions involved in this field. There are a number of intellectual property rights/patent issues related to plant regeneration, plant transformation, gene sequences, promoters, vectors and screening techniques which need to be kept in mind while commercializing the transgenics. There is a need to develop appropriate mechanisms and approaches to overcome the intellectual property

barriers for the successful commercialization of the transgenics developed so that farmers are able to reap the benefits of biotechnology.

- There are several complex legal issues related to the regulatory framework for the transgenics. It appears that the EPA framework is not properly suited to handle the biotechnology related issues in India. Hence, there is an urgent need to formulate a separate legislation that would have no overlap with other legislations. A scheme of certification and internal regulatory procedures and committees should facilitate self-regulation as far as possible. Also, a formal system of Tribunals and Adjudicatory Bodies, having legal and technical experts, would help in quick dispute settlement. The bottom line is that unless transparent regulatory framework is put in place, the growth of biotechnology would be hampered.
- The need was felt to have a brainstorming session to examine the pros and cons of setting up of a 'National Authority for Biosecurity' in order to have congruence of biotechnology, biodiversity, biosafety and biosecurity.
- For successful utilization of biotechnology in India, it is critical to devise a clear National Biotechnology Policy, which covers the important elements of *contract sociale*, science-led impact and risk analysis, information empowerment and awareness, and proper R&D support.

Dr. R.S. Paroda, in his concluding remarks, thanked all the participants, particularly the invited speakers, panelists and the chairpersons of the respective sessions. He also informed that TAAS will be publishing the First Foundation Day Lecture entitled "Regulatory Measures for Utilizing Biotechnological Developments in Different Countries" delivered by Dr. Manju Sharma, Secretary, DBT, Government of India, as well as the proceedings of the brainstorming session. These shall be distributed widely, and efforts shall also be made to communicate the important recommendations to the concerned Ministries and organizations for immediate attention and initiation of appropriate actions, so that the benefits of biotechnology are harnessed in the national interest without further loss of time. He also highlighted the need to have similar dialogue in different regions involving all stakeholders to generate proper public awareness based on scientific reasoning so that the society ultimately reaps the benefits of agricultural biotechnology.

ANNEXURE

FOUNDATION DAY LECTURE AND BRAINSTORMING SESSION ON "ENABLING REGULATORY MECHANISMS FOR RELEASE OF TRANSGENIC CROPS"

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Progress Through Science

TRUST FOR ADVANCEMENT OF AGRICULTURAL SCIENCES (TAAS)

Venue: Auditorium, Virology Centre, Division of Plant Pathology
Indian Agricultural Research Institute
New Delhi-110 012

October 17, 2003

Foundation Day Lecture on "Regulatory Measures for Utilizing Biotechnological Developments in Different Countries"

18:30 hrs	**Chairperson**	: **Dr. R.S. Paroda**
	Speaker	: Dr. (Mrs.) Manju Sharma

October 18, 2003

Brain Storming Session on "Enabling Regulatory Mechanisms for Release of Transgenic Crops"

10:00 hrs	SESSION I	
	Present Status of Biotechnological Developments in India	
	Chairman	: **Dr. H.K. Jain**
	Recorder	: Dr. K.R. Koundal
10:05 hrs	Lead Speaker	: Dr. R.P. Sharma
10:25 hrs	Discussants	: Dr. A.K. Tyagi : Dr. Sudhir Sopory : Dr. Vibha Dhawan
11:00 hrs	General Discussion and Chairman's Remarks	

11:45 hrs	SESSION II	
	Product Development: Public-Private Sector Partnership	
	Chairman	: **Dr. Sudhir Sopory**
	Recorder	: Dr. R.K. Jain
11:50 hrs	Lead Speaker	: Dr. S. Nagarajan
12:25 hrs	Discussants	: Dr. M.K. Sharma
		: Dr. Harbir Singh
12:40 hrs	General Discussion and Chairman's Remarks	
14:30 hrs	SESSION III	
	Enabling Regulatory Measures Framework	
	Chairman	: **Prof. Anupam Varma**
	Recorder	: Dr. B.M. Prasanna
14:35 hrs	Lead Speakers	: Dr. C.D. Mayee
		: Dr. (Mrs.) Malathi Lakshmikumaran
		: Dr. R.B. Singh
		: Mr. Anil Mishra
15:55 hrs	General Discussion and Chairman's Remarks	
16:45 hrs	SESSION IV	
	Plenary Session	
	Chairman	**: Dr. R.S. Paroda**
	Recorder	: Dr. B.S. Dhillon
16:50 hrs	Lead Presentation on Social Concerns	: Dr. Suman Sahai
		: Dr. Devendra Sharma
17:30 hrs	International Service for National Agricultural Research, ISNAR's initiatives relating to biosafety issues	: Dr. Jose Falck-Zepeda
17:50 hrs	**Presentation of Recommendations**	: Dr. H.K. Jain
		: Dr. Sudhir Sopory
		: Prof. Anupam Varma
18:05 hrs	Chairman's Remarks	