Round Table Discussion
on
Promoting Biotech Innovations in Agriculture and Related Issues

Proceedings & Recommendations

Organizer
Trust for Advancement of Agricultural Sciences (TAAS)
Trust for Advancement of Agricultural Sciences (TAAS)

GOAL
An accelerated movement for harnessing agricultural science for the welfare of people.

MISSION
To promote growth and advancement of agriculture through scientific interactions and partnerships with stakeholders.

OBJECTIVES
- To act as think tank on key policy issues relating to agricultural research for development (AR4D).
- Organizing seminars and special lectures on emerging issues and new developments in agriculture.
- To institute national awards for the outstanding contributions to Indian agriculture by the scientists of Indian and other origin abroad.
- Facilitating partnerships with non-resident agricultural scientists visiting India for short period.

Chairman, Dr. R.S. Paroda  Vice-Chairman, Dr. P.L. Gautam  Secretary, Dr. N.N. Singh  Treasurer, Dr. P.K. Joshi
Members, Dr. T. Mohapatra, Dr. (Mrs.) Rita Sharma, Dr. Gurbachan Singh, Dr. Ravinder Kaur, Mr. Raju Barwale, Dr. K.L. Chadha, Dr. A.K. Srivastava, Dr. Narendra Gupta
Round Table Discussion

on

Promoting Biotech Innovations in Agriculture and Related Issues

NAAS Committee Room, NASC Campus, New Delhi
August 4, 2016

Proceedings & Recommendations

Organizer

Trust for Advancement of Agricultural Sciences (TAAS)
**Citation**  

**Disclaimer**  
The technical and scientific views expressed herein are those of the individual participants, and the draft proceedings were circulated to them before finalization. The recommendations are broadly the collective views brought forward by TAAS mainly for solution finding and suggesting the most optimal way forward.

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Acknowledgements

These proceedings and recommendations are the outcome of the one day intensive round table meeting organized by the Trust for Advancement of Agricultural Sciences (TAAS) on the issue of handling agri-biotech, particularly GM crops in India and related concerns. TAAS is thankful to all stakeholders in Agriculture Research and Innovation for Development (ARI4D), including those engaged in policy, regulatory and executive function related to the sector, for continuously reposing trust in the TAAS platform for discussing important issues from time to time. In the instant issue of fixation of Bt cotton seed price and trait value royalty by the central government, the order was withdrawn and kept in public domain for 90 days to seek views of stakeholders and public. Nearly 50 stakeholders representing the government, regulatory agencies, seed and agri-biotech industry, confederations, academies and others participated wholeheartedly to discuss the issues threadbare, and suggest some suitable way forward. This is to express our thanks to each one of the participants for their active involvement and useful ideas. I express sincere gratitude to Padma Bhushan Dr. R.S. Paroda, Chairman, TAAS for bringing forth the idea to organize this roundtable meeting and throughout guiding meticulously before and during its organization. My sincere thanks to Dr. T. Mohapatra, Secretary DARE & DG, ICAR, Dr. R.R. Hanchinal, Chairperson, PPV&FR Authority, Dr. R.B. Singh, Ex-President, NAAS and Dr. Usha Rao, Assistant Controller of Patents for sparing their valuable time and systematically setting the stage for the deliberations. I also thank Dr. S.R. Rao, Sr. Advisor, DBT and Dr. Neeti Wilson for contributing useful panelists news. Further, active interventions by other participants including the representatives of NSAI and ABLE AG are duly acknowledged.

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New Delhi
September 2, 2016

(N.N. Singh)
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MNCs  Multi National Company
MOAFW  Ministry of Agriculture and Farmers’ Welfare
MOEF  Ministry of Environment and Forests
MOEF&CC  Ministry of Environment, Forests and Climate Change
MOM  Minutes of the Meeting
MOU  Memorandum of Understanding
MSP  Maximum Sale Price
MTA  Material Transfer Agreement
NAAS  National Academy of Agricultural Sciences
NARS  National Agricultural Research System
NASC  National Agricultural Science Complex
NBA  National Biodiversity Authority
NBPG  National Bureau of Plant Genetic Resources
NCAP  National Centre of Agricultural Economics and Policy Planning
NOC  No Objection Certificate
NRCPB  National Research Centre on Plant Biotechnology
NSAI  National Seed Association of India
PPP  Public Private Partnership
PPV&FRA  Protection of Plant Varieties and Farmers’ Rights Act/Authority
PVP&FR  Protection of Plant Varieties and Farmers’ Rights
R&D  Research and Development
RCGM  Review Committee on Genetic Manipulation
RTI  Right To Information
SDGs  Sustainable Development Goals
TAAS  Trust for Advancement of Agricultural Sciences
TEC  Technical Expert Committee
TOR  Terms of References
TRIPS  Trade Related Aspects of Intellectual Property Rights
USA  United States of America
WTO  World Trade Organization
Round Table Discussion on
Promoting Biotech Innovations in
Agriculture and Related Issues

1. BACKGROUND
The Trust for Advancement of Agricultural Sciences (TAAS) (www.taas.in) is an outcome of the 88th session of Indian Science Congress 2001 that focussed upon the theme, “Food, Nutrition and Environmental Security”. It is a partner in leading science-based crusade to eliminate hidden hunger and malnutrition through agricultural development and sustainability. TAAS provides inter-alia a discussion platform to all stakeholders for deliberating, assessing and identifying the right step(s) forward for the concerned bodies and agencies to take in various domains like agricultural policy, research, extension, IPR, ABS, etc., to help facilitate sustainable agrarian development and farmers’ welfare pursuits on priority. A recent publication by TAAS, ‘Building Trust: The journey by TAAS (2001-2015)’ summarises various pro-active initiatives taken over the years to help address some critical policy issues with focussed actions.

On May 18, 2016, The Department of Agriculture, Cooperation and Farmers’ Welfare, Ministry of Agriculture and Farmers’ Welfare, Government of India notified the licensing guidelines and formats for GM Technology (GM trait) licensing agreement; but withdrew the notification on May 24, 2016 for public consultation for 90 days to seek opinions of stakeholders and public. This was done due to vide ranging implications of the guidelines. The draft guidelines in its current form cancelled all existing contracts of Bt cotton and instructed to develop new contracts within 30 days to anyone seeking the licence making it a compulsory licence regime in agricultural biotechnology. The notification also fixed the trait value to 10 per cent of the maximum sale price (MSP) with a gradual decline after 5 years.

2. ROUND TABLE DISCUSSION
Given the importance of the subject, and impact these guidelines could have on the future of agricultural biotechnology in India, TAAS organized a brainstorming session with researchers, industry, regulatory agencies and other stakeholders, on August 4, 2016 in New Delhi. In addition, several related topics such as scale
up of existing technologies, public private partnership and developing clarity on the existing laws such as PVP&FR and Patents Acts were also discussed. The concept note for the Round Table, program and list of participants are appended (Appendix 1, 2 & 3). About 50 participants representing various stakeholders attended the roundtable discussion. The participants included eminent scientists, government officials, industry representatives and legal experts. The deliberations were comprehensive and meaningful which focused on the promotion of biotech innovations in agriculture and related policy and regulatory issues, including the instant issue of price and trait value fixation of Bt cotton seed.

The active deliberations resulted in general consensus for promoting biotech innovations in agriculture for overall development and sustainability. For this, the institutional arrangements for facilitating and regulating biosafety, respect for innovation and fair opportunity for competitiveness among market players altogether need to be strengthened. The Brainstorming did not support instant government intervention with regard to the specific issue of Bt cotton seed price and royalty fixation and also recommended quick corrective measures to avoid repetition of such action without wide consultations. Capacity building of the secretariats of regulatory agencies was also considered a critical need.

3. PROCEEDINGS

The stage was set by the opening remarks from the chair, Dr. R.S. Paroda and special invitees/dignitaries; Dr. T. Mohapatra, Secretary (DARE) & Director General (ICAR); Dr. R.R. Hanchinal, Chairperson PPV&FR Authority; Dr. R.B. Singh, Chancellor Central Agricultural University on behalf of NAAS, and Dr. Usha Rao, Assistant Controller of Patents on behalf of IP India. It was reiterated that GM technology is highly relevant for Indian agriculture for accomplishing the vision of doubling the farmers’ income by 2022, and also bringing in the second green revolution as soon as possible. Farmers need technologies that can save cost on their inputs and are also environmentally safe while ensuring faster production growth to meet ever increasing demand for food and nutrition, especially through customized genetic modification, including the designer crops and biofortification. The GM food crops may have a key role for nutritional security to help mitigate the malnourishment among children and anaemia in pregnant women which is very high in India as compared to other countries in the world.

Views of panelists on specific issues and thematic areas were critical and analytic. Their perception and analysis along with quick views and focused comments of many of the participants outside the panel have brought out worthy recommendations, which are elaborated below, for the immediate course correction for the Bt cotton seed price issue, and also the road ahead for promoting agri-biotech broadly. The detailed minutes of the meeting are given in annexure.
4. RECOMMENDATIONS

The round table discussion had resulted in specific recommendations needed to promote further agricultural innovations, especially in the field of agricultural biotechnology, for accelerated growth and development in the national interest. These are summarised below for consideration:

4.1. Licence Agreement and Trait Value Guidelines

4.1.1. The first step taken by the Ministry of Agriculture and Farmers’ Welfare to withdraw the Gazette Notification issued concerning cotton seed price and trait value royalty fixation guidelines on May 18, 2016 and put it on hold for 90 days, inviting stakeholders’ and public comments on May 24, 2016 is a step in right direction. It was a considered view of participants that the notification was not well thought of action as its implementation would certainly discourage innovation culture in agri-biotech research in the country. Therefore, it must be permanently withdrawn in the first place.

4.1.2. Our national system must respect intellectual property (IP) to facilitate introduction of new innovations related to agriculture in India. Also the IP laws must be seen in compliance to the International Treaties to which we are signatory to.

4.1.3. Before some decision is taken on any further corrective step, it is highly necessary to officially review, analyse and rationalize the entire techno-legal and socio-economic scenario as well as the seed industry perspective which had led to this unprecedented situation. For this, a High Powered Committee (HPC) comprising eminent scientists, senior officials, legal experts, and the representatives of all stakeholder groups (seed sector, farmers etc.) be appointed by the Government with a well defined TOR and timeline. Also the technical backstopping of all concerned government agencies and regulatory bodies like DBT, MOEF, DIPP, ICAR, PPV&FRA, Patent Office, etc. must be sought in this regard.

4.1.4. The proposed HPC may recommend to the government about the gaps, if any, in the provision for compulsory licensing made under the PPV&FRA, and the Patents Acts, and how to harmonise various provisions under the two Acts with that of the new National IPR Policy 2016. HPC may also consider if any required understanding/guidelines need to be issued or any amendment(s) in the Act are required to resolve the discrepancies or implementation difficulties in the best interest of innovators, industry and the farmers. The recommendations of HPC must consider initiatives that can promote further innovations needed for the growth and development
of seed sector in India. Due attention should be given to farmers' welfare while making recommendations for market regulations of both protected and generic inventions/plant varieties. Exceptional conditions under which the provision of compulsory licensing has to be enforced must be clearly defined to avoid any ambiguity with international agreements or the national IPR policy.

4.1.5. A wider consultation with farmers on this subject is necessary to understand whether there is really some problem in accessing seeds and technology, and their quality and to come out with short, medium and long term strategies for implementation in future.

4.1.6. Capacity building, including management development of government departments/agencies engaged in regulatory tasks concerning agri-biotech R&D, biosafety, NOC, IP, marketing and trade, bioresources/ABS, other benefit sharing, etc., must be accelerated in some organized and transparent manner. Training of staff in the areas of market competition, confidentiality, and information/RTI and other related matters may, therefore, be ascertained from time to time.

4.2. **Promoting Agri-biotech Innovations**

4.2.1. A National Policy on Agricultural Biotechnology embracing GM crops must be brought out to promote, respect and protect innovation in agri-biotech and to ensure its benefits to all stakeholders and end users. Such a policy is needed on lines of already available policies, for example: the national agricultural policy, new seed policy, new IPR Policy etc. It may be considered jointly by the Department of Biotechnology, Ministry of Agriculture and Farmers' Welfare, ICAR, Ministry of Environment, Forests and Climate Change, Ministry of Commerce and Industry, and the Ministry of Law. To ensure this, a Task Force of eminent experts, agri-biotech Industry representatives, progressive farmers, eminent biotechnologists etc. with well-defined Terms of Reference (TOR) and secretariat be constituted by DBT to come out with a well articulated policy document at the soonest possible.

4.2.2. Steps be taken to strengthen and further streamline the existing regulatory system for testing and release of GM crops while making it simple, effective and efficient so as to facilitate and promote agri-biotech research and innovation both in public and private sector. For this, DBT, ICAR, MOAFW, MOEF&CC and DIPP/IP India must take a joint initiative for wider consultation to identify focused areas for reforms and initiating determined steps for better coordination and convergence. The purpose is
to visualize a simple, efficient and transparent regulatory system, and its processes which overcome ambiguity and duplication of efforts. Further, till the time BRAI Act is passed by the Parliament, it was a considered view of all that the needed reforms should be stepped up by strengthening the secretariats of RCGM and GEAC as independent entities, for enabling competition in seed industry by timely GM approvals. Also facilitation role of ICAR for testing/validation of technologies and involvement of MOAFW for commercial release under the existing provisions of Seed Act be ensured simultaneously.

4.2.3. Committee of Secretaries involving Agriculture, Environment, Biotechnology, Science and Technology, Industrial Policy and Promotion vis-a-vis IPR may consider specific complexities arising and ensure harmonization of existing laws, and regulatory processes particularly the related executive actions/steps; provide due encouragement to innovativeness, protection of innovation, and respect innovators’ interests while ensuring that farmers benefit from the technology. Such directions may include steps for creating better public awareness, catalysing public sector research in agri-biotech, public confidence building, and strengthening of public-private partnership.

4.2.4. For translating the potential of agri-biotech into products, and their up-/out-scaling, Public Private Partnership (PPP) must be promoted, being the most effective mechanism that would help increase farm productivity and improve the economic conditions of farming community. Such partnerships should be based on common goals, and driven by complementary strengths and resources; aimed at achieving the objectives of mutual (industry-industry; industry-farmer, etc.) as well as national interests. The partnership should start from the beginning (research stage) rather than at a later stage in the R&D chain to merely share the finished products for multiplication, commerce and trade. There is a need for building capacity, transparency and mutual trust for ensuring much needed PPP, and any such guidelines must focus on Good Operating Procedures.
Minutes of the Meeting (MOM)

SETTING THE STAGE

Dr. R.S. Paroda, Chairman TAAS, while moderating the round table discussion welcomed all participants including the leadership of ICAR and PPV&FRA, representative of DBT, Patent Office, NAAS, seed industry, legal profession, confederation of industries, research managers, scientists and other stakeholders. To set the stage Dr. Paroda briefly reiterated the agrarian scenario, sustainable development goals and national needs, besides introducing the subject of brainstorming.

AGRARIAN SCENARIO AND INNOVATION NEEDS

The Indian agriculture sector engages nearly 55 per cent population but contributes only around 14 per cent to GDP. Dr. Paroda emphasized the need to accelerate sector’s growth at around 4 per cent and produce 70 per cent more foodgrains to meet the SDGs concerning food and nutritional security, poverty reduction (by 20%), health, and climate change by 2030. Recent government initiatives like Farmer First, Doubling Farmers’ Income by 2022, Electronic National Agricultural Market (e-NAM), Make in India, new IPR Policy, and commitment to skill development and improving efficiency in public delivery are welcome steps which also echo the pragmatism shown by Hon’ble Prime Minister of India. Dr. Paroda emphasized that to achieve all this farmers also need “Innovations” in terms of new technologies, cost-effective agri-inputs, more economic good agricultural practices, and efficient value chains that would ensure the farmers an assured delivery of their produce in competitive market at more remunerative price for which all concerned stakeholders must contribute.

BENEFITS OF AGRI-BIOTECHNOLOGY AND ISSUES

Dr. Paroda said that various previous discussions have highlighted the benefits of biotechnology, so this Round Table will straight away discuss the new options and opportunities that can help farmers with reduced cost of inputs and increased farm income with higher yield. He summarized that the experiences by countries in GM crops the world over for more than two decades now, including the successful Indian experience in growing commercial Bt cotton cultivation for nearly 15 years,
suggest that Biotech Innovations have much to offer in food and agriculture sector in days to come. He highlighted that government is giving high priority to farmers' welfare, which resonates the Prime Minister’s vision of doubling the farmers' income by 2022 as well as emphasis on ‘Make in India’. Dr. Paroda said this can be achieved if innovation succeeds in India as it is directly linked to the GDP. Countries like China having a high rate of innovation have succeeded in increasing their GDP significantly, while India needs to catch up.

In India, Bt cotton has already shown its benefits and its impact on GDP; and now the need for second green revolutions being widely emphasized. However, Dr. Paroda observed that for realizing this, innovations need more enabling environment and regulatory system. The legal framework also needs to promote rather than hinder the process of innovation. Thus biotech innovations need to be adopted, commercialized and promoted through (i) appropriate regulatory framework for testing and release, (ii) legal framework for IPR, ABS, licensing and para-legal instruments (like arbitration, mediation, reconciliation), and (iii) agricultural research and innovation for development (ARI4D) support in both public and private sectors in which Public-Private-Partnership (PPP) in technology generation, validation, scaling up and/or scaling out has to be “A Must”. He reminded the importance of regulatory predictability in agricultural biotechnology and the issues of NOC for conducting field trials. Dr. Paroda said that the Government of India has established the system for capacity development, and various laws and regulations like Essential Commodities Act (ECA, 1955), Patents Act, 1970, Seeds Act, 1966, Cotton Seeds Price (Control) Order, 2016, PVP&FRA, 2001 and Biological Diversity Act, 2002 need to understood better, the gaps identified and harmonized to avoid any ambiguity.

Dr. Paroda laid emphasis on a better understanding of the policy framework and its implementation. He said that the biotech innovations in coming days will deal with many “traits” and their ‘value’ for agriculture vis-a-vis seed industry is likely to be either challenged or exaggerated at various points of time for which immediate solutions will have to be found in larger interest. For this, at least a national policy on agricultural biotechnology must be brought out; a national regulatory system for meeting the biosafety requirements be established as per the framework already widely discussed for BRAI; the regulatory systems need to be better understood with regard to grey areas and harmonized by having an Expert Committee; public awareness must be created far and wide; public system must be supported and adequately financed to deliver, and PPP must be developed and efficiently harnessed as a pragmatic way ahead.

Overall India has done well and Bt cotton has given good experience to everyone broadly, which will enable other crops and traits to be introduced in
the country. Dr. Paroda urged the participants to freely provide their considered views and comments on the recent GM trait draft licensing guidelines so that a suitable note with the collective response input is submitted to the government. He further hoped that an active participation by all in the discussion may lead to a better understanding of the issues and concerns, and the possible way out so that the innovator is willing to invest without any concerns of the disincentives.

**CONSOLIDATING THE ISSUES**

Dr. Hanchinal opened his remarks by stating that the seed industry has achieved annual growth of 14-16 per cent in the recent past and it is more than Rs. 16,000 crore business now out of which Bt cotton alone is around 9,000 crore. This growth has come because of creativity, innovation and favourable policy of the government. Public sector too has contributed in this development. Dr. Hanchinal reiterated India’s commitment to the WTO and TRIPS agreement and opined that the new IPR policy will boost innovations in agriculture. He felt that our laws should not be contradictory to the international treaties and expressed hope that the TAAS platform will be suitable to critically review the grey areas in existing laws to help remove any ambiguity.

Dr. Hanchinal said that the farmers’ interests also should not be ignored, and the patent system should be seen as facilitator that shares the benefits with both users and developers. He informed that the current PVP&FR Act is a balanced one for both breeders and farmers and transparent too. He highlighted various sections that protect breeder’s rights as well as give rights to farmers for compensation. He explained about the overriding provision of the Act under section 92, and said that there is no ambiguity with the Patents Act and both can co-exist. He informed that the progress in implementation of the Act is satisfactory. He told that the EDV applications are reviewed by a working committee of eminent scientists, and also the progress and interface made with the NBA. Dr. Hanchinal said that the Act provides for compulsory licensing on specified grounds after 3 years of grant of protection and it also provides benefit sharing and community rights provisions. He pointed out to the issue of NOC for Bt cotton from tech provider to users and urged this to be resolved amicably.

Dr. R.B. Singh on behalf of NAAS thanked Dr. Paroda for organizing this brainstorming. He said biotechnology is important; India needs agri-biotechnology more that others and beyond Bt cotton. He emphasized that now discoveries like CRISPR Cas can bring in new innovations in agriculture but it is unfortunate that these technologies are not yet adopted in India. He was, however, optimistic with the readiness in GM/biotech products in about 20 crops. He expressed concern
that the number of post graduate students in agri-biotech is reducing in India. He appreciated the work of scientists like Dr. Pental for developing GM mustard in India, which needs to be encouraged, and should be approved at the earliest.

Dr. Singh felt that for encouraging new innovations, enabling regimes like PPV&FRA and NBA have to be aligned. The enabling regimes should encourage cutting edge technologies to be developed in India, and a better regulatory process can enable their commercialization faster. Continuing with the regulatory process, Dr. Singh said that the NOCs from states should be obtained at a faster rate. He mentioned that NAAS has submitted its response to Hon’ble Prime Minister in favour of allowing research field trials of GM crops, and is also a party in legal case with Hon’ble Supreme Court.

Dr. Paroda elaborated that earlier 50 eminent scientists, who included 10 Padma Awardees and 4 Food Laureates, with Dr. M.S. Swaminathan as first signatory, had submitted a memorandum to Hon’ble Prime Minister, Shri Narendra Modi relating to GM crops.

Dr. Usha Rao, representing the Patent Office, said that agriculture plays a pivotal role but it is immensely sensitive sector as >55 per cent population depends on it. She recalled the vision of doubling farmers’ income by 2022 and the new IPR policy as being new initiatives capable of addressing the sensitive issues. Patent system is paramount but she expressed concern over the very low number of applications for biotech patents filed by resident Indians. She said that of the patents applications filed about 30 per cent are from Indian organizations and individuals while remaining 70 per cent are from foreign applicants. She highlighted that in China 7,000,000 patents were filed in 2013 and 90 per cent of these were from Chinese organizations and individuals. To address this low filing, she informed that the Indian Patent Office is creating awareness and trying to identify if there is any lacuna in the filing process.

Dr. Rao stressed the need to protect innovation and to reward the innovator appropriately; the launch of National IPR policy being a great step in this direction. She highlighted the exceptions to patentable inventions in agriculture under sections 3(h) and 3(j), and said that these innovations (plant varieties) are protected under the PPV&FR Act rather than the Patents Act. However, she emphasized that this still does not dilute the scope of patents in agriculture. She reaffirmed the commitment of Patent Office to look at the harmonization needs and remove lacunae in any of the policies.

Dr. Paroda echoed the concern of low number of patent filing by agricultural scientists in India and hoped that new IPR policy will protect innovations, thereby help in increasing the number of patent applications filed in future.
Dr. T. Mohapatra, Secretary (DARE) & Director General (ICAR), informed that the issue of technological innovations has been discussed in depth by ICAR, DBT and NAAS and that Hon’ble Prime Minister himself has given a solid push to technology in agriculture. He appreciated Dr. Deepak Pental’s persistent push in GM mustard to see that the research reaches a stage of a product. He expressed that at present the public sector, however, may not have much to push after GM mustard. Both awareness and public perception on the benefits and safety of GM technologies will be important for NARS to move ahead in this regard. He urged TAAS and NAAS to play important role in this direction.

Dr. Mohapatra said that Indian organizations are not making enough efforts or investing much on the research on biosafety, and suggested to create an innovation fund in collaboration between DBT and ICAR. He stated that technology licensing to private partners is taking place now but we need to see that the public-private partnerships in agri-biotech should grow in a right spirit. Dr. Mohapatra expressed that once an event of biotech crop is approved there should be no further need for seed R&D agencies to approach GEAC for approval of new hybrids. He shared that there is enough progress in joint initiatives being taken or to be taken by DBT and ICAR in promoting biotech research and told that around 40 different locations will be identified to field test GM crops to overcome the challenges of NOCs.

Dr. Paroda thanked Dr. Mohapatra for sharing information on current status and said that monopolies and pricing will disappear if the public system can also deliver. For this, PPP is critical and a mission approach is required. He concluded the stage setting session by stressing the need to promote the innovation and simultaneously protect the innovator; to help in bringing the needed growth in Indian agriculture, agro-industries, and at the same time take care of farmers’ welfare.

**COFFEE BREAK**

A group photograph of participants was also taken during the Coffee Break.

**PANELISTS’ VIEWS ON THEMATIC ISSUES**

Dr. S.R. Rao Advisor, DBT defined the challenges in biotechnology as being “two sides of the coin”. First, the determination of biosafety in the development process, and second, the protection of the ownership of the inventive step(s). He informed that regarding the biosafety reforms, 9 out of 10 Supreme Court TEC Report reforms are implemented. Stage has been set to establish an “Office of Biosafety” that will elaborate and administer the processes envisaged to be
addressed under BRAI. He said that GEAC will determine the biosafety aspects. Everything that comes to GEAC will be also examined for vetted legal acquisition of the technology. Dr. Rao explained that asking NOCs or the MTA for Bt cotton hybrid approvals ensures the fulfilment of underlying requirement that protection under relevant Act is duly sought by the applicant, if any, and confirms that the innovator has no objection for the transfer of technology or for transferring the material for research or commercialization purpose.

Sometimes innovators themselves are in doubt on ownership, Dr. Rao said, and NOC process paves way for win-win situation. He informed that many points submitted by Dr. Paroda’s team to Supreme Court have been considered in the reforms process and others will also be looked into. The licensing guidelines will have far reaching implications for access and benefit sharing, he opined. Reforms will also include public sector innovations; nitty-gritty of access to technology, and respect for innovation on the whole. Dr. Rao assured that the reforms framework is coming up fast and an ICAR/DBT working group will be institutionalized to address all concerns in the reforms process by December 2016.

The other side of the coin i.e. the “ownership issue’ also broadly includes benefit sharing aspect. It encompasses access to biodiversity, patents, plant variety protection, essential commodities, competition, markets and socio-policies. There have been vested and legal challenges, and RTI concerns have also made things much slower. He said that it is a critical time to respect innovation in biotechnology; there is no ambiguity between PPV&FR and Patents Acts and there is no question of one Act overriding another one in terms of scope of ownership granted.

Mr. Rao stressed that the current licensing guidelines on hold are highly restrictive and have wide ranging implications. He said that there is need to facilitate win-win situation for everyone through such guidelines, if properly developed. Dr. Rao was of the view that even foreign universities may not give any material or technology to Indian counterparts because of these guidelines. He said that the Bt cotton has brought a discipline in industry by way of licensing and urged everyone to opt for reconciliatory negotiation rather than pull down each other after huge initial boost in cotton production with the existing licensing arrangement. He concluded by saying that access to technology and respect to innovation would ultimately benefit the farmers.

Dr. Suresh Pal, Member, CACP said that the onus of strategic planning to promote agri-biotech is on central government. Dr. Pal felt that the uncertainties in the adoption of agri-biotechnology, and the licensing and trait value guidelines issued and kept on hold by central government indicate that this was the right
time to thoroughly deliberate upon the entire issue. Investment in agri-biotech sector is the foremost issue and the question is whether we are spending enough to promote innovation for development. Further, regulations are the key to harmonized development and growth of biotech R&D but the question is whether these are legally well understood. Dr. Pal spelled out four areas needing focussed attention on priority; (i) harmonization among various provisions of ownership grant and their enforcement under the patents and PPV&FR Acts, (ii) better understanding to incentivize the innovation, (iii) reforms in regulatory processes, (iv) cost of regulatory approvals to innovators, which is very high in India. Dr. Pal concluded his comments by adding that the agri-biotech industry can move faster if the government action is simple and more facilitating.

Mr. Prabhakar Rao, President NSAI made a presentation summarizing the association’s views on the current situation of Bt cotton seed pricing and approval of new Bt cotton hybrids. He said that the government policy appears to be to prevent monopoly in seeds within the boundaries of the TRIPS Agreement. The IPR for seeds and plant varieties is granted under the *sui generis* PPV&FR Act, and the transgenic varieties can also be protected in the same manner as the non-transgenic varieties under this legislation after their release for commercial cultivation. He explained various sections of PPV&FR and patents Acts, emphasizing that Section 26 of the Act provides for determination of benefit sharing, and procedure specified is explained in PPV&FR Rules 40-45. He opined that as breeders are given the right to access any variety under section 30, there is no requirement of a license from the trait developer to incorporate a GM trait into a new variety after the approvals are granted by GEAC to the trait. He said that a variety developed by a breeder by using his rights under Section 30 can be registered as per the provisions of Section 24 if it meets the criteria specified under Section 15 and on such registered variety, the breeder enjoys exclusive rights to commercialize as provided under Section 28. In case of EDVs where the Bt trait is transferred, the breeder can register under Section 23 subject to having rights on the original non Bt variety.

Mr. Rao further said that the issue NOC requirement by GEAC has caused suppression of statutory rights that were available to the breeders under section 30 and farmers under section 39, and this practice need to be disbanded. Mr. Prabhakar Rao on behalf of NSAI clarified that the seed industry believes in innovation, invests heavily for breeding new varieties and understands the importance of new traits for breeding superior varieties. However, the PPVFRA provides for appropriate returns to all the trait developers including the developers of GM traits under benefit sharing provisions. Within the IPR policy of India, the Dept. of Agriculture, Cooperation & Farmers Welfare can play a pivotal role in
bringing about guidelines under PPV&FR Act for harmonious functioning of GEAC and ICAR to remove the monopolies as well as apprehensions.

Dr. Paroda asked Dr. Hanchinal for some clarification about the exemption to the farmers and other views stated by Mr. Rao. Dr. Paroda also urged the members of NSAI to reconcile on this sensitive issue among themselves in larger interest, before the closing date after 90 days, as the association was unified with great efforts in the past. In response, Dr. Rao affirmed with a positive nod. He also informed that NSAI is holding a series of consultations to review the developments, on 8th August in Gandhinagar, and later in Delhi. He said that NSAI is willing to find solution in existing IP laws, and also willing to have modified guidelines to find a solution.

Dr. Paroda also urged NSAI to unify the industry in the larger interest.

Dr. Paresh Verma, Head, ABLE AG management committee informed that seed companies, including Indian companies, which have credible research programs are investing 5-15% of their turn over in R&D. IPR is not a MNCs vs Indian companies issue. Dr. Verma said that the seed and agri-biotech industry considers that three key policy related questions are critical; (i) how to promote innovation, (ii) how to protect the interest of innovator, and (iii) how to make available innovations to end users. He felt that biosafety, ownership and regulatory processes are equally important for agri-biotech to flourish. The question of a compulsory licence should not arise when the seed availability to farmers was not a constraint. He expressed that the regulatory process should be predictable, transparent and merit based, and policy environment should be such that the IPRs can be protected, enforced and commercialized based on ‘value-to-customers’ and ‘free-market-competition’. He emphasized the need to protect the inventors’ fundamental right to make business decisions related to management of their IPRs, in cases of agri-biotech inventions under Patent Act and for new plant varieties/hybrids/EDVs under PPV&FR Act. He reminded India’s commitment to WTO-TRIPS obligations, and also highlighted the need for safeguards to manage stewardship that could lead to long duration of a technology. He said that existing anomalies arising due to the new licensing guidelines kept on hold must be revisited in a win-win policy and regulatory environment. He also said that Patent and PPV&FR Acts can co-exist and these are not infringing on each other; the IP in agri-biotech can be protected by a combination of both patent and PVP, as already provided under Article 27.3(b) of the TRIPS Agreement.

Dr. C.D. Mayee, former Chairman ASRB said that the public perception of GM technologies in India is only Bt. With the adoption of Bt cotton India has become one of the top 3 cotton producers in the world. He, however, expressed concern
over the longevity of the technology because of its misuse due to various reasons.
He told that seed industry has benefited tremendously from the adoption of
Bt cotton by Indian farmers. The ratio of benefits to Tech Provider: Seed Companies:
Farmers is 1:4:40. He explained that the cotton seed price control order has not
resulted in much benefit to the farmers but to the seed companies. He opined
the draft licensing guidelines are legally untenable and beyond the jurisdiction
of Essential Commodities Act. It takes away the fundamental rights of negotiating
a mutually acceptable bilateral contract between private parties, and puts the
laws enacted by Parliament at conflict and subservient to each other (PPV&FRA
vs the Patents Act).

Dr. Paroda thanked Dr. Mayee for his presentation supported by substantial data.
He then enquired if the farmer is asking for a lower price. If not, then innovator
interest will be lost with the issuance of such guidelines. Consequently, the seed
availability may become a constraint although currently it is available in plenty.
He said that the monopolies can be avoided by healthy competition but need of
technology must be met by encouraging innovation.

Dr. J.S. Chauhan, ADG (Seeds) ICAR, summarized rules, and laws related to
seeds. He said that currently ICAR receives huge indents of breeder seed of NARS-
bred varieties requested by NSAI and urged Indian seed R&D companies to develop
an innovation culture of their own. He said that the price value determination
should involve stakeholders’ views and should not be unilateral, which could harm
the industry.

Dr. Neeti Wilson, Partner Anand and Anand spoke about the IPR laws in India
but awareness of these laws is quite limited. Due to this, the innovators do not
take full advantage of their existence, which is clear from patent statistics in
agri-biotech. The legal view is that the patent filing step starts the IPR protection
and this could trigger initiation for exclusive business in the invention by the
inventor. This requires both awareness and skill. However, in India the number
of patent applications filed in agri-biotech by Indians is meagre. She cited that
out of 45,000 patent applications filed in Indian Patent Office in 2015, only less
than 5,000 applications were from biotech sector. Further, out of these, a major
portion was from the pharmaceutical sector; patent applications in agri-biotech
were very few. She also supplemented that low awareness of these laws by the
public further aggravates concerns, which retards the socio-economic benefits of
IPR culture to the society.

Dr. Wilson said that the issues and concerns arising from the access and
licensing guidelines on hold also reflect inadequate awareness and skill, and this
should be judiciously handled in larger interest to meet the purposes of IPR laws
and international agreements. Regarding the issue of NOC, Dr. Wilson suggested that a declaratory approach may be more helpful. Let there be a ‘green book’ in which all agri-biotech innovations including the events approved, the patent applications filed, the patents granted, and the licensing contracts executed/MOUs signed, etc. are published. She emphasized that MOUs signed for material transfer for research only must have this clause ‘for research only’ because once the commercial product is developed from such outcome, if any, a separate agreement for commercialization will have to be reached. However, instead of the need to obtain NOC for any new clearance based on an existing innovation, a declaration by the applicant along with its reference citation in the green book should be accepted by the approving authority for processing of application if this is ‘for research only’ request. Adding a step further to Dr. Rao’s views that IP must be recognized and respected, Dr. Wilson said that for effective enforcement, IP must be protected. Dr. Neeti said biotech patents are more techno-legal than just legal in nature and urged that the views of technical experts be valued alongside the legal views for a better interpretation.

COMMENTS FROM PARTICIPANTS OUTSIDE THE PANEL

Dr. Paroda invited views and focused comments from all other participants. The following supplementary comments/views were presented:

Dr. Mauria stated that as a general practice Government would not go for public consultation on issues of sub-ordinate legislation. In this case, considering the sensitivity involved, Government withdrew the notification and opened it for public comments, for three months. He opined that the notification had not come in haste but it is a follow-up of price fixation independently by different State Govts., which was leading to difficulties. Yet, Government withdrew the notification to receive comments from all concerned.

Regarding the granted patent for Bt cotton (number 232681), Dr. Mauria desired a review of the claims, particularly claim number 12.

Dr. Rajvir Rathi expressed his concern that if public sector has failed, then there is need to retrospect as to in which areas this has happened and what course correction could be made. He was of the opinion that control mechanism of any kind will damage innovation. He said that in the instant case the government action has damaged everyone and other interests may also be acting in the current dispute. The differences must be narrowed down.

Dr. Arvind Kapur questioned the need to put cotton under essential commodities act. Otherwise, the issue of government control for price fixation would not have arisen. He also questioned as to how uniform single price of different cotton
Round Table Discussion on Promoting Biotech Innovations in Agriculture and Related Issues

hybrids with different performance and adoptability could be fixed throughout the country. He said that clause 133 of the Patents Act 1970 states about the convention countries and the other patent treaties that India has to respect. He also said that section 18(h) of PPV&FR Act clearly states that all genetic material for breeding should be lawfully acquired.

Dr. Raju Kapoor forcefully said that cotton price control order is retrograde which will lead to destruction of seed industry. Stakeholders were not consulted in drafting licensing guidelines. The draft licensing guidelines will put India in violation of international treaties and innovator will not recover their investment. There can't be uniform pricing, hybrid performances need to be valued. Not allowing competition in agriculture creates artificial monopoly. But the seed companies have to be competitive in terms of R&D to bring more agri-biotech innovations. He said that the interests of some in the seed industry need not to be confused with the farmer interests.

Dr. T.R. Sharma highlighted the contribution of the public sector in agri-biotech and mentioned his own work in marker identification towards the development of GM mustard. He said IARI is facilitating GM field trials with one being conducted in Delhi itself. Regarding NOC, Dr. Sharma told that ICAR-NRCPB has recently come up with a sound policy. According to this, response for any request for NOC has to be sent within two days. Regarding Post Graduate education in agri-biotech he informed that contrary to the diminishing claims by Dr. R.B. Singh, there is great demand. For Ph.D. Agri-Biotech, he told, NRCPB has received nearly 250 applications for just 7 slots.

Dr. Niranjan Kauipara informed that Bt cotton issues are not public vs private or MNC vs Indian but this has become a socio-economic issue now. The Bt cotton disputes are historical and state governments have intervened to bring the prices down. He cited the AP Cotton Act for example. He favoured controls of this type.

Dr. Shyam Sunder Singh said to the contrary that the guidelines have come as a big surprise and there is urgent need to reverse the government action in order to encourage innovations for development.

Mr. Raju Barwale said that his company has invested more than Rs. 600 crore in agri-biotech R&D which has led to 21 intermediary products and 6 complete products but their fate hangs in balance for their release in India. It could be an ideal ‘Make in India’ situation in agriculture sector but the agri-biotech products have to be put on hold for their commercial release, and several hard working persons have lost jobs because of the delays and uncertainty. The Rs. 50 crore per year budget of the company is on risk and will come down if the licensing guidelines are implemented.
Dr. Sudhir Kochhar said that it is basically industry vs industry issue for which it is obligatory for India to provide a level playing field, which was agreed at the WTO-TRIPS. He said that the industry should constructively engage in licensing/cross-licensing/sub-licensing modes of business to be adept to ‘competitive’ business modes and eventually come out of the present logjam.

Dr. Kochhar further said that the extant varieties protected under the PPV&FR Act must be licensed by the public system to all interested seed companies (even if on a notional license fee of INR 1 per protected extant variety, as a good gesture, so as to legitimize the access. The companies can use these varieties in their R&D or avail any win-win business opportunity with these varieties in other countries to earn and plough back foreign exchange. Once adept with market forces beyond the Indian market companies may themselves not favour any control over pricing or trait value determination or licensing format in their seed business. He cautioned that patent revocation will cause unhealthy precedence but also warned that the ‘claim 12’ vis-a-vis sec. 3(j) type of situation in the granted patent, which was indicated in Dr. Mauria’s remarks, is indeed a challenge before the Patent Attorneys, which must be diligently addressed.

Dr. Deepak Pental, who had chosen to speak last, opined on behalf of public sector that we are reactive not pro-active. He said that it is important to understand IPR properly and apply where applicable but felt that open source was the key to the development of agri-biotech. He cited the example of Agrobacterium mediated transformation process, which is the foundation for achieving many key milestones in agri-biotech field. He emphasized the urgent need for public sector to rise to the present challenge. He said there is no system of depositing copies of approved events with NBPGR. Similarly, there is no system of incentives to innovators, or determination of trait value at any stage. Dr. Pental said companies have also done some pioneering work and have also taken the work done by public sector to commercial levels. Indian public sector needs to step up now like China but currently India is facing a terrible problem of human resource in agri-biotech. In NARS, we have multiplied institutions/universities but not research, which should be looked into. Dr. Pental suggested to provide genes to both public and private sector, and that MNCs should be allowed to compete in India.

**CHAIRMAN’S CONCLUDING REMARKS**

Dr. Paroda thanked the participants and concluded by saying that the PPV&FR Act was enacted in a record time in India with great enthusiasm of the Joint Parliamentary Committee and with due consultations with states, and participation by all stakeholders in the enactment process. The implementation success is also
satisfactory as summarized by the Chairperson, PPV&FRA in the round table. But the problems of interpretation are being seen. Therefore, at this stage it appears the Act may require further revision in certain sections. Also, it has to be seen how the provisions under the Patents Act and PPV&FR Act can be used in combination to protect and promote agri-biotech innovations.

He emphasized that although the views emerged from the round table touched both sides of the coin but it has clearly emerged that the current dispute is counter-productive to innovativeness, innovation and the innovators. He wondered as to who decides to bring out petty things out, which could have been easily reconciled and settled without much effort at the initial stage itself, and who inflates them to the level of a dispute where central government has to intervene and bring out a gazette order, which has several unanswered questions, and then withdraw it or keep it on a hold for seeking public opinion. For example, Dr. Paroda felt that it is curious as to who decided what is in national interest? Who decided that seeds are not available? Who decided cotton is an essential commodity? Who decided farmers are unhappy with the seed price? Who ascertained that all farmers know that the seed price has two components; seed value and trait value? Who caused a stressful government action at a time when the country was seriously engaged in improving its image on the implementation of WTO-TRIPS compatible IPR system, including the launch of new IPR policy which stresses on compatibility and harmonization among different IPRs, including patents and plant varieties? Dr. Paroda felt that the collective opinion emerging from the round table suggests that we must remind the government that any action taken with regard to the instant guidelines and licensing format, should be such that it does not hamper progress in science that could potentially contribute to second green revolution. He said that preferably central government should permanently withdraw the Gazette notification, and constitute a High Powered Committee to recommend corrective action to the government.
Appendix 1

Concept Note

BACKGROUND

New agricultural technologies, including the genetic modification and other biotechnologies need to be developed, produced, up scaled and/or out scaled on a continuous basis for sustained growth. The new vision of doubling the farmers income by 2022 can be better realized by promoting indigenous production of diverse agri-input technologies, including the seed and tissue cultures of crop varieties and hybrids, in harmony with the central government’s ‘Make in India’ initiative. Sufficiency, quality and affordability of various agri-input products by farmers can potentially enhance their remunerative incomes. This requires constant ARI4D (agricultural research and innovations for development) efforts ably supported by the regulatory mechanisms implemented under relevant Acts, Policies and Administrative procedures.

Agri-business domain could be broadly divided in three distinct areas; (i) technology generation and identification; by public agencies or private sector, including by imports; (ii) intellectual property rights; assignments and/or licensing for sustained availability of proprietary products to farmers/other end users during the term of protection; and (iii) market regulatory provisions, mainly covered under administrative procedures of concerned nodal departments.

The Trust for Advancement of Agricultural Sciences (TAAS) has been providing discussion platform to all engaged in or concerned with agricultural development to discuss, assess and/or make recommendations to concerned bodies for further improvement in various domains, procedures and processes so as to ensure agricultural development and farmers’ welfare on sustainable basis.

Recent developments in Bt cotton production, including technology acquisition, licensing, production and continuous supply of seed input to farmers in different parts of the country leading to abundant production and enhanced remuneration to small holder farmers exhibit exemplary demonstration value in India and the world. Biotechnology in agriculture will increasingly play key role in future agriculture, both commercial agriculture and sustainable farming. Scientific achievements in GM food crops include their commercial success, for example, corn, soybean and canola in Argentina, Australia, Brazil, Canada, the Philippines, South Africa, and USA among other countries. In the Asia region, Bangladesh has
already commercially released GM eggplant, while Pakistan and Vietnam have recently approved GM maize whereas in India policy decisions are awaited for few GM foodgrain and oilseed crops. GM technology is highly relevant for Indian agriculture in the present as well as future contexts. GM crops are grown by 18 million farmers over 180 million hectares in 28 countries. Compared to their non-GM counterparts, GM crops have been estimated to give 21.6% higher yield, consume 36% less pesticides and earn 68.2% higher profits for GM adoption farmers. With respect to their utility for consumers and environment, GM crops are now being developed with such desirable qualities as biofortification, healthy oil composition and abiotic resistance. Farmers need technologies that can save cost on their inputs and are also environmentally safe while ensuring faster production growth to meet ever increasing demands for food and nutrition, especially through customized genetic modification, including the designer crops and biofortification. The country needs another Green Revolution, in which GM food crops may have a key role, to fortify nutritional security to mitigate malnourishment among the children and anaemia in pregnant women which is very high compared to other countries in the world.

Development and adoption of appropriate GM technologies would need a mission mode approach; strengthening of the public research system; enhancement of private sector investments on GM technologies; and enhancement and simplification of an enabling environment. Following the declaration of new national IPR policy, appropriate protocols and processes in the unified IPR regime are required to be put in place so that both public and private sector research/R&D are encouraged, and the much needed public-private partnerships and agricultural value chains are promoted.

Substantial investments have been made in the country to build capacity and human resource, and to firm up new GM technologies. Focused efforts, both in public and private sectors, have led to a number of GM products, which are either at different stages of trials or ready for commercialization. The outcomes of these efforts are beginning to become a reality with more than 20 GM crops having traits for hybrid seed production, abiotic and biotic stress resistance and improved nutritional quality are at advanced stages of development/regulatory approval. R&D and business incubation in GM crops need to be promoted to bring out commercial products remunerative/acceptable to farmers as well as consumers. In order to let this happen through a well articulated, guided process, the enabling policy and regulatory environment in the country will have to be upheld/improved/enhanced as appropriate. The need to reward innovation while ensuring its access and improvement has been well recognized and balanced in Indian IPR Laws. However, recent development with regards to technology
licensing and seed pricing are being considered by some stakeholders as hindrance for scaling new innovations in agricultural biotechnology. The implementation of recently launched IPR policy, and revisiting the domain of market regulatory controls including the pricing and [compulsory] licensing of proprietary and non-proprietary technologies becomes imperative to encourage ARI4D in agricultural biotechnology. There is also an urgent need for Public Private Partnership in this strategic R&D area.

The Trust for Advancement of Agricultural Sciences (TAAS), in the pursuit of meeting its objectives (www.taas.in) vis-à-vis address the imminent need, contemplates holding a half-day brainstorming session on 4th August, 2016 at NAAS Committee Room Number 1, NASC Campus, Dev Prakash Shastri Marg, New Delhi - 110012. The aim is to prompt a meaningful dialogue among the policy makers and other key stakeholders on promoting the biotech innovations in agriculture and related issues and emerge with relevant and worthy recommendations.
Program

10.00  OPENING REMARKS

Moderator: Dr. R.S. Paroda, Chairman, TAAS

10:15  Comments by Special Invitees:

Dr. T. Mohapatra, Secretary, DARE & DG, ICAR
Dr. R.R. Hanchinal, Chairperson, PPV&FRA
Dr. R.B. Singh, Ex-President, NAAS
Dr. Usha Rao, Assistant Controller, Controller of Patent and Designs

11:00-12:00  Views of Panelists: (5 Minutes each)

Dr. S.R. Rao, Adviser, Department of Biotechnology
Dr. Deepak Pental, Former Vice-Chancellor, Delhi University
Dr. Suresh Pal, Member, CACP
Dr. M. Prabhakar Rao, President, NSAI
Dr. Paresh Verma, Head of ABLE AG Management Committee
Dr. C.D. Mayee, Former Chairman, ASRB
Dr. J.S. Chauhan, ADG (Seeds), ICAR
Dr. Anupam Varma, Adjunct Prof. & INSA Scientist, IARI
Dr. Neeti Wilson, Partner, Anand and Anand

12:00-13:20  General Discussion (All Participants)

- Eminent Scientists and Officials
- Members from Seed/Agbiotech Industry
- Members of Business Chambers

13:20-13:30  Concluding Remarks

13:30-14:30  Lunch
Appendix 3

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Recent TAAS Publications

- TAAS Foundation Day Lecture on “Harnessing Knowledge for India's Agricultural Development” by Dr. Uma Lele, August 12, 2011.
- Implementing the International Treaty to Address Current Concerns about Managing our Plant Genetics Resources - Strategy Paper by Dr. R.S. Paroda, January 23, 2012
- The Sixth Dr. M.S. Swaminathan Award Lecture for “Challenges and Opportunities for Food Legume Research and Development” by Dr. M.C. Saxena, January 25, 2012.
- Special Lecture delivered at Indian Seed Congress 2013 on “Indian Seed Sector : The Way Forward” by Dr. R.S. Paroda, February 8, 2013.
- A Brief Report on Seventh Dr. M.S. Swaminathan Award presented to Dr. William D. Dar, DG ICRISAT, Hyderabad, June 24, 2013.
- The Indian Oilseed Scenario : Challenges and Opportunities - Strategy Paper by Dr. R.S. Paroda, August 24, 2013.
- The Eight Foundation Day Lecture on “Sustainable Agricultural Development - IFAD’s Experiences” by Dr. Kanayo F. Nwanze, President, IFAD, August 5, 2014.