Expert Consultation On Regulatory Science For Risk Assessment in Agriculture Biotech

REPORT ON PROCEEDINGS & RECOMMENDATIONS

Department of Biotechnology
Govt. of India

Sponsored by

International Life Sciences Institute-India

&

Department of Biotechnology

Ministry of Science and Technology, GOI

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Jointly Organized

By

International Life Sciences Institute-India

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Department Of Biotechnology,

Ministry Of Science And Technology,

Government Of India

सत्यमेव जयते

Department of Biotechnology
Govt. of India

Contents

Introduction

ILSI-India and Department of Biotechnology, Ministry of Science and Technology, GOI, organized an "Expert Consultation on Regulatory Science for Risk Assessment in Agriculture Biotech" on July 23, 2014 in Claridges Hotel, New Delhi.

The Consultation was attended by 70 participants representing regulatory bodies (RCGM, GEAC, FSSAI) academic institutions and industry.

The meeting discussed the advances in data requirements for safety assessment, challenges in data generation for risk assessment, global scenario on stacking, international regulation for stacks and draft India guidelines on stacking.

The meeting was addressed by elevennational and international experts from Government, Academia and Industry.The Meeting provided an overview of the current guidelines on risk assessment in India for both Environmental Safety and Food/Feed Safety. It also discussed the following:

- Advances in data requirements for safety assessment both national and international:
  - Rationale for tiered approach for risk assessment and its implementation in Indian context.
  - Is there a global risk assessment strategy- opportunity for broader harmonized approach to data requirements.
- Challenges in data generation for risk assessment: Environmental safety assessment, food/feed safety assessment and challenges in conducting field trials.
- Global scenario on stacking-stack products in global market.
- International regulation for stacks and draft Indian guidelines on stacking.

A brief Report of the proceedings is given along with Conclusion and Recommendations and it is hoped that necessary steps will be taken by the stakeholders to implement the recommendations and enable adoption of scientific approach towards this modern tool for agriculture biotechnology.

Power Point Presentations are available at ILSI-India Website : *http://www.ilsi-india.org*

Summary Recommendations

The society has many concerns on the safety of GM crops, which are predominantly political and emotional. These concerns may not be answered by scientific reasoning. However, safety assessment of GM crops has to be strictly science-based. In the last few decades with the advent of GM crops, an exclusive discipline called Regulatory Science has evolved that assess the safety of GM crops to animal health and environment in a systematically.

Published guidelines (2008 ICMR Guidelines) are available for safety assessment of food and feed derived from GM crops. SOPs for conducting field trials have been posted on IGMORIS website to enable applicants to proper conduct of trials. These protocols are based on international guidelines like FAO/ WHO, Codex and OECD. During the process of field trials and food safety assessment, applicants are required to generate enormous data on GM crops. Some of these requirements have to be revisited against the background of experience.Applicants face challenges while generating some of the data due to lack of clarity. Clarity is required on stack policy, compositional study and pollen flow study. Regulators are equally concerned about these challenges.

Following Recommendations have been drawn on the basis of presentations and the suggestions made during Panel Discussion:

1. There is a need for a document that can give a comprehensive list of data to be generated for approval of GM crops. There draft version of "The Guidance for information/ data generation and documentation for safety assessment of regulated, GE plants" can be used as a starting point. DBT and MoEFshould revise the document after receiving inputs from different stakeholders at the earliest possible.

2. Experience suggests that animal feeding studies do not add new data to the safety conclusions already established from studies such as molecular characterization, protein safety, agronomy, phenotype, and crop composition of a GE crop. Hence, livestock feeding studies have to be recommended when compositional equivalence of GM crop could not be established.

3. Regulators may consider the option of data transportability of feeding study data wherever possible.

4. Isolation distances around GM field trials are increasingly becoming a challenge to adopt since it requires large area. This has the potential to restrict the options to conduct more trials in a given area and increasing the trial costs manifold. On case-to-case basis, alternate options like temporal isolation and removing floral parts can be recommended in addition to spatial isolation.

5. Observations on non-target organisms (NTO) such as predators and parasites in field trials do not add new information to the risk assessment of GM crops when laboratory studies do not indicate any concerns. Hence, a tiered system could be followed where field studies have to be conducted when early tier, laboratory studies indicate any safety concerns.

6. The requirement for 0.01% level of detection (LOD) protocol for an event before applying for confined open field trial is a very stringent requirement and is not justified at the stage of field trials.

7. Time taken for getting regulatory approvals for commercialisation of GM crops is very long. Regulators should try to reduce this time. A pre-consultative approach should be followed where applicant can discuss the requirements with a few regulators and then submit relevant information. This would be helpful in minimizing basic questions at later stages of review.

8. The quality of data generated has to be improved so that regulators can take appropriate decisions while reviewing the dossiers.

9. The regulatory guidelines for stack products have to be clarified to applicants, and hence the draft guidelines should be posted on the website for comments.

10. A Regulatory Science Working Group can be formed to advise the regulatory agencies on Critical areas including protocol design, methodologies, data requirements, regulatory developments and trends. Industry may be invited to share their experiences as well.

11. There has to be hypothesis-driven approach for all data requirements during risk assessment.

Inaugural Session

Welcome Address
By Mr. D H Pai Panandiker, Chairman, ILSI-India

In his welcome address Mr. D H Pai Panandiker Chairman, ILSI-India, listed data requirements for safety assessment and regulation for stacks in the context of international experiences.He emphasized that the safety of GM crops can be assessed only on the basis of requisite data. There is a need to review the current DBT guidelines in the light of recent international developments in regulatory science to make the risk assessment more scientific and credible. The data required should be a good combination of necessary and right quality for efficient risk- assessment facilitating introduction of GM crops and their acceptability by all stakeholders.

Regulatory Science In Agriculture Biotechnology : An Overview
By Dr. S. R. Rao, Advisor, DBT

Dr S. R. Rao, Advisor, DBT, gave an overview of regulatory science in agriculture biotechnology. Dr Rao informed that the purpose of the consultation is to focus on the science behind risk assessment. Some key messages from his presentation are

- Policies followed by countries on Ag biotechnology have been largely promotional, precautionary or prohibitory.
- Many of current guidelines have outlived their purpose, and there is a need to recalibrate them based on international learning.
- Introduction of Bt Cotton in India had significant positive impact on cotton farmers as well as cotton trade and industry. General accusation is that long term environmental impact has been neglected. Yield increase has overshadowed these concerns.
- “Regulatory science” and “regular science”should be kept separate.
- The draft guidelines available now for risk assessment will be reviewed and finalized in a couple of months. The guidelines have tried to accommodate or follow OECD consensus document, and there may be scope to improve on this aspect.
- In Compositional Analysis, it is very important to examine the biological relevance Vs. statistical significance.It is time to introspect and see how confined the approach is.Composition Analysis needs to be restricted to only key nutrient and anti-nutrients.
- As far as the protein toxicity is concerned, establishing “History Of Safe Use (HOSU)” is the key and other tests are supplementary in nature.
- As regards gene transfer, crossability is not a key issue, as simple spill or mixtures can lead to issues of gene transfer.
- There is a need for co-existence and policies around MAD(Mutual Acceptance of Data).
- For Soil microbe analysis (NTO study), metagenomic studies are redundant, and may not provide any insights as far as risk assessment is concerned.

Session One

Data Requirement For Safety Assessment

Moderator: Dr S R Rao, Advisor, Department of Biotechnology, GOI

This session had 5 presentations followed by a panel discussion. Highlights are given below.

Data Requirement For Safety Assessment In India

By Dr. B Sesikeran, Chairman, Review Committee on Genetic Manipulation (RCGM)

- The data required to be generated and submitted to regulatory authority in India for environmental release of Genetically Engineered crops/ Genetically Modified Crops (GE/GM) are provided in the guidelines under "Protocols for food and feed safety assessment of GE Crops" published by the DBT (Department of Biotechnology) under the Ministry of Science and Technology Government of India in 2008. and the protocols are based on WHO/ Codex guidelines.
- The safety of a GM product is tested by toxicity and allergenicity studies.
- There is no documented proof that any approved, commercially grown GM crop has caused allergic reactions owing to a transgenically introduced protein,or that generation of a GM crop has caused a biologically significant increase in endogenous allergenicity of a crop (Goodman 2008).
- The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance.
- Feeding studies are not required once the compositional equivalence is established. Moreover, feedingstudies are not toxicological studies.

Advances In Data Requirement For Safety Assessment: A Global Perspective

By Dr. Alan McHughen, D.Phil., University of California, USA

- Farmers have adopted and supported GE technologies and opposition to this technology comes from different quarters.
- When the farmers realise the benefits of potential technologies, they are very eager to use and reap the benefits. It should be noted that at times many transgenic cropshave been introduced not necessarily following legal routes. For example: Canada non GM wheat- 1984, India Bt cotton- 2002, RR Soybean in Brazil - 2003, various GE crops in Eastern Europe.
- Theory of risk assessment is science based and proven by analysis.
- Product driven assessment should be judiciously decided. Not everything has to be regulated e.g. O2

coming from GE sugarbeet crop - who regulates it?Mere presence of transgene does not imply threat; hence, the risk assessment should be based on sound and rational methods. Interventions to detect vanishingly smaller limits are irrelevant.

- The global adoption and use of GM crops in the last 15+ years have shown that they are safe and beneficial for the environment.
- Testimonies on the safety of GM crops have been issued by many global scientific academies and associations. ***European Union*** carried out two different studies, one for the period of 1985-2000, the other for 2000-2010, and examined 131 Government funded projects on GM safety, worth 270 Million Euros, and concluded that GM crops are as safe as their conventional counter parts. There is no safety concern that has been reported as yet and hence there is no requirement for additional safety data.

Challenges In Data Generation For Risk Assessment: Indian Perspective

By Dr. K. K. Narayanan, Managing Director, Metahelix Life Sciences Ltd. TATA Enterprises

- There is a critical need for changes in the regulatory system.
- The current criteria imposed by the regulatory agencies of 0.01% LOD (Limit of Detection), do not really follow any principle of risk assessment and is not driven by scientific principles.
- Though the guidelines make reference to temporal and reproductive isolations, the regulators demand spatial isolation, and fix the isolation distance.
- The protein studies are primarily designed and needed when the protein expressed in the transgene is toxic in nature to selected target pests. The rationale for seeking the protein studies for other kind of proteins is not clear. These studies are expensive, and require stronger infrastructure and capacity building, and this kind of investment when these studies are not really needed is not welcome.
- High cost and long-time involved for regulatory approvals are detrimental to undertake research and place a product in the market.
- There is a need to create a common platform for the applicant and regulators to discuss the application, identify the uniqueness of the application so that the specific requirements for assessment are well laid out using the broader risk assessment frameworks.

Challenges In Data Generation For Risk Assessment: Public Sector Research Institute Perspective

By Dr. Deepak Pental, Head, Dept. of Genetics, Delhi University

- Two major Biotech Indian mustard projects are being executed at University of Delhi.
- **The first one is the development of a transgenic mustard hybrid DMH-11.**In this case the induction of male sterility and restoration of fertility are facilitated by genetic engineering technologies using bar, barnase and barstar gene system. All the

necessary environmental and safety studies have been completed and reports submitted.Application for BRL-II trials has been submitted to Genetic Engineering Approval Committee (GEAC). **Another project is on development of zero erucic acid mustard**. In this case events have been developed using cre-lox system and hence are marker free.

- The experiences so far with these two projects indicate that while broader guidelines are fine, the risk assessment has to be undertaken on case-by case approach.
- If the safety studies of a given transenics are available elsewhere, approvals should be given with minimal studies.
- In order to help and encourage the public research institutes to develop transgenic products, people should be trained in biosafety evaluations/ data generation and regulatory dossier preparation.
- Tough liability laws should be enforced if false data is submitted by any applicant.
- The current regulatory logjam and the time taken for deregulation are big hurdles for public research institutes and discourage young people working in the area of GM crops.

Challenges In Data Generation For Risk Assessment: Industry Perspective

By Dr. B. Gajendra Babu, Scientific Affairs Lead, Biotech Affairs & Regulatory, DuPont Pioneer Industry

- There are certain guidelines in place – ICMR guidelines (2008) and SOPs for conducting Confined open field trials (2008). However, the guidance document for data generation in GM plants developed in 2009, is still a draft and there is an immediate need to finalize this document.
- It needs to be examined whether animal feeding studies are really needed, when protein familiarity/ safety is illustrated and compositional equivalence is demonstrated.
- Data transportability should be encouraged for studies such as subchronicrodent studies and livestock feeding studies.

Data Quality InSafety Assessment Of GE Crops:Issues And Challenges

By Dr Vibha Ahuja, Chief General Manager, Biotech Consortium of India Ltd.

- Product Developers are generating data during product development and this plays a crucial role in assessment and review by the regulators.
- The food and feed safety assessment tests done in private testing labs, contract research organisations and national institutions are accepted by regulatory agencies. The private testing labs and CROs are either accredited by National Accreditation Board for Laboratories or GLP Compliance Committee under DST.
- At times the confined field trials and environmental safety studies are conducted by product developers, in association with SAUs or agriculture research institutions. Safety protocols are dependent on the trait/crop and use and hence require multidisciplinary expertise and calls for constant interaction between product developers, the labs conducting the study and regulators. There is a need for capacity building,

special training and guidelines for handling GM crops and products.

- As far as data analysis is concerned impact analysis is more important than empirical data, for example, it is important to consider the consequence pollen flow rather than only highlighting the frequency of gene flow.
- While considering the quality of data, focus should be on appropriateness, accuracy, integrity and transparency.
- "Hallmarks of data quality" have been notified by WHO in 2008 and the same could be applied to safety assessment of GE plants.
- Data quality facilitates assessment by regulators, as it helps in peer-review and reproducibility. Better quality of data also promotes transportability of data across boundaries. The focus should be on "need to know" rather than "nice to know" elements of risk assessment.

Panel Discussion on: Data Requirement For Safety Assessment

Moderator: Dr. S R Rao,Advisor, Department Of Biotechnology, GOI,

Panellists: Dr. B Sesikeran, Dr Alan McHughen, Dr. K. K. Narayanan, Dr. Deepak Pental, Dr. B. Gajendra Babu, Dr Vibha Ahuja and Dr. B. Mazumdar

Some of the questions addressed during the Panel Discussion and responses are given below:

Query: When will the draft guidelines be finalized?

Response by Dr S R Rao: The draft guidelines on data requirements for GM crops will be revised after consulting the relevant stakeholders and will be finalized subsequently before the end of the year.

Query: What is the rationale behind regulation against marker genes?

Response by Dr Deepak Pental: There was no scientific reason to remove the marker gene except that it was easier to remove it by molecular tools instead of running it though the regulatory system. (the observations were based on experience with mustard project).

Query: Why southern blots are no longer essential?

Response by a Panellist: The information to be provided is to be purpose specific. A scientific reasoning can be provided and the course of action can be decided on a case to case basis.

Session Two

Stacking Regulations

Chair: Dr. S R Rao,Advisor, Department of Biotechnology, GOI

Regulation of Stacked Trait Products

By Dr. Simon Barber, Asia Pacific Head, Regulatory Affairs & Stewardship (Seeds), Syngenta

- There is some divergence and lack of uniformity in the regulatory process for breeding stacks across different regions. In Aus/ NZ and USA, there is no requirement for separate approvals, and stack approvals are based on safety conclusions onsingle events. EU requires extensive additional data for stacked events, as also separate approvals for each stack.
- Conventional breeding has been predictably providing safe food and feed products. Combining biotech-derived traits through conventional breeding poses no greater risk to food or feed safety than combining non-biotech traits. Thus, there is no need for separate safety assessment for breeding stacks. A more efficient regulatory process is required to cover rapidly increasing market demand for breeding combinations of more events

Safety Regulations For Stacks And New Technologies

By Dr. Alan McHughen, D.Phil., University of California, USA

- Gene expression differs more between two soybean varieties than between a transgenic and its closest conventional cultivar.
- Combining biotech traits by conventional breeding will not be any different from combining non-biotech traits and hence there is no requirement for additional data for stacked approvals.

Strategy For RA With Stacked Events

By Dr. K V Prabhu, Joint Director, Indian Agriculture Research Institute

- The key question asked by RCGM for RA of stacked event is:"Is the stack (comprising approved orunapproved events) likely to create any new or additional risk to biosafety?"
- When all concerned events are individually approved, the data needs for stack RA as per RCGM are:
  a. *Molecular characterization (Southern blot) for stability and integrity of the stacked events.*
  b. *Phenotypic, agronomic and compositional characterization (additional feeding or environmental studies may be required in few cases).*
  c. *Food/Feed toxicity and allergenicity tests* :
     - Tests required only when the expression of one or both traits exceed the parental line expression.
     - An overall allergenicity potential to be assessed due to possible interaction between the events/genes.

   d. *Compositional analysis for the stack to identify any adverse effects due to change in composition by two or more event introgression.*

- When one or more events are not individually approvedthen the data for stack RA as per RCGM are:
   a. *The stack would be considered a 'new' event and therefore a complete RA is required of the stack.*
   b. *If the biosafety RA is carried out only on stacked line, the parental event line (unapproved event donor) will not be considered as approved. If the latter is to be used for commercial seed production, a separate approval application needs to be filed. This will apply to a stack where none of the events is approved.*

Panel Discussion On: Stacked Regulation

Moderator: Dr S.R. Rao, Advisor, Department Of Biotechnology

Panellists: Dr Alan McHughen, Dr. Simon Barber and Dr K.V. Prabhu

The participants expressed their appreciation for RCGM to have presented current thinking on regulation of stacked products. Many questions and comments were made in the context of Seed production scenario and the results of segregating populations. Dr S.R. Rao, and others in the Panel, felt that this needs more review and consultation, and hence it was decided that the draft stack guidelines willbe uploaded to the IGMORIS website for seeking public comments. Following broader stakeholder consultation, the guidelines will be finalised.

ANNEXURE I

Expert Consultation On Regulatory Science For Risk Assessment In Agriculture Biotech

Jointly Organized By
ILSI-India & DBT, GOI

Wednesday, July 23, 2014

Venue- Claridges Hotel, New Delhi

AGENDA

09.00 AM-09.25 AM	**Registration**
	Opening Session
09.30 AM	**Welcome Address** ***Mr. D H Pai Panandiker,*** Chairman, ILSI-India
09.45 AM	**Regulatory Science In Agriculture Biotechnology – An Overview** ***Dr. S R Rao,*** Advisor, Department of Biotechnology, Ministry of Science & Technology, GOI
10.15 AM	**Session One: Data Requirement For Safety Assessment**
	Moderator: *Dr S R Rao*
10.20 AM	**Data Requirement For Safety Assessment In India** ***Dr. B Sesikeran,*** Chairman, Review Committee on Genetic Manipulation (RCGM)
10.40 AM	**Advances In Data Requirement For Safety Assessment: A Global Perspective** **Dr. Alan McHughen,** D.Phil., University of California, USA
11.10 AM	**Challenges In Data Generation For Risk Assessment:** ***Dr. K. K. Narayanan*****,** Managing Director, Metahelix Life Sciences Ltd. TATA Enterprises
11.25 AM	***TEA BREAK***

11.40 AM	**Challenges In Data Generation For Risk Assessment: Presentations Continue…..**
11.40 AM	***Dr. Deepak Pental,*** Head, Dept. of Genetics, Delhi University
11.55 AM12.10 PM	**Dr. B. Gajendra Babu,** Scientific Affairs Lead, Biotech Affairs & Regulatory, DuPont Pioneer Industry
	Challenges in Data Generation –Quality ***Dr Vibha Ahuja,*** Chief General Manager, Biotech Consortium of India Ltd. (BCIL)
12.20 PM01.10 PM	**PANEL DISCUSSION** **Panel of Experts:** ***Dr. B Sesikeran,Dr Alan McHughen, Dr. K. K. Narayanan, Dr. Deepak Pental, Dr. B. Gajendra Babu,Dr. B. Mazumdar, Dr Vibha Ahuja***
01.10 PM	**Sum Up By the Moderator**
01.15 PM	***LUNCH BREAK***
02.15 PM	**Session Two: Stacking**
	Moderator: *Dr. S R Rao*
02.20 PM	**Global Scenario in Stacking** ***Dr. Simon Barber*****,** Asia Pacific Head, Regulatory Affairs & Stewardship (Seeds), Syngenta
02.35 PM	**International Regulations for Stacks (40 minutes)** ***Dr Alan McHughen,*** University of California, USA
03.15 PM	**Draft Indian Guidelines on Stacking** ***Dr. K V Prabhu,*** Joint Director, Indian Agriculture Research Institute
03.35 PM	**PANEL DISCUSSION** **Moderator: *Dr. S R Rao***
	Panel of Experts: ***Dr. Simon Barber, Dr Alan McHughen, Dr. K V Prabhu***
04.45 PM	**Sum Up By the Moderator**
04.55 PM	**Observations By Chairman, ILSI-India**
05.00 PM	***TEA BREAK***

Participant List

ANNEXURE II

S.No.	Participants
1.	Mr. Sunil Adsule,Tresurer, ILSI-India & Director - Scientific and Regulatory Affairs , Coca-Cola India Pvt. Ltd., Gurgaon
2.	Dr. Vibha Ahuja , Chief General Manager , Biotech Consortium India Limited, New Delhi
3.	Dr. B. Gajendra Babu,Scientific Affairs Lead - India , Biotechnology Affairs & RegulatoryE.I.Dupont India Pvt Ltd.,Hyderabad
4.	Dr. S.N. Sudhakar Babu, Principal Scientist (Agronomy), Directorate of Oilseeds Research,Hyderabad
5.	Dr. Simon Barber, Asia Pacific Head, Regulatory Affairs & Stewardship (Seeds), Syngenta
6.	Dr. S. R. Bhat, National Research Centre on Plant Biotechnology, Indian Agricultural Research Institute, New Delhi
7.	Dr. Vinay Bhardwaj , Senior Scientist, Central Potato Research Institute, Shimla
8.	Dr. Kailash C Bansal, Director, National Bureau of Plant & Genetic Resources, New Delhi
9.	Dr. S. S. Banga, Plant Breeder , Punjab Agriculture University , Ludhiana
10.	Mr. Purushotam M Chandra, ABLE-AG, New Delhi
11.	Dr. S. Dayananda, Professor, Dept. of Animal Sciences, University of Hyderabad, Hyderabad
12.	Mr. Manish Deshpande, Regulatory Affairs Manager, E.I.Dupont India Pvt. Ltd.,Hyderabad
13.	Dr. Rajneesh K Gaur, Scientist-C, Department of Biotechnology, New Delhi
14.	Dr. N Gopalakrishnan, ADG (CC), Indian Council Of Agricultural Research, New Delhi
15.	Prof. O.P. Govila, Former Prof. of Genetics, Indian Agricultural Research Institute, Delhi
16.	Ms. Ashima Jain , BayerBioScience Pvt. Ltd., Gurgaon
17.	Dr. Nitin K. Jain , Scientist- D , Programme Officer, DBT, New Delhi
18.	Mr. Nitin Joshi, Ph.D., Regulatory Specialist, Dow AgroSciences India Private Limited, Noida
10.	Mr. Sanjeev Kalia, Regulatory Affairs Manager, Monsanto India Ltd., New Delhi
20.	Dr. Arvind Kapur, CEO, Rasi Seeds Pvt. Ltd., Coimbatore
21.	Dr. Rekha Kansal, PS
22.	Dr. P. Karnan, Ph.D, Lead - Regulatory Affairs, Rasi Seeds (P) Ltd, Coimbatore
23.	Dr. J K Kaushik , Principal Scientist, Animal Biotechnology Centre, National Dairy Research Institute (NDRI), Karnal
24.	Dr. Krishna Kumar, Technical Officer, FSSAI
25.	Dr. Rajesh Kumar, Scientist IV(1), FSSAI
26.	Dr. Pradyumn Kumar , Principal Scientist, Directorate of Maize Research, ICAR, New Delhi
27.	Dr. Vinod Kumar, Syngenta, Manager, Regulatory & Govt. Affairs, M/s. Syngenta Biosciences Pvt. Ltd. , Pune
28.	Mr. Yogesh Kumar , BayerBioScience Pvt. Ltd., Gurgaon
20.	Dr. B. Mazumdar, M/s. BejoSheetal Seeds Pvt. Ltd, Maharashtra
30.	Dr. Alan McHughen, D.Phil., University of California, USA
31.	Mr. Ritesh Mishra, Lead Regulatory , MAHYCO, Maharashtra
32.	Dr. Sreela Mondal, Biotech Consortium India Limited , New Delhi
33.	Ms. Rajalakshmi Muralidharan, Scientist-E, Department of Biotechnology, New Delhi

34. Dr. K. K. Narayanan, Managing Director, Metahelix Life Sciences Limited, Bangalore
35. Dr. K S Narayanan, M/s. Syngenta Biosciences Pvt. Ltd., Pune
36. Dr. Sunil Nayak, Department of Biotechnology, New Delhi
37. Dr. Jasdeep Padaria, PS
38. Mr. D H Pai Panandiker, Chairman, ILSI-India, New Delhi
39. Dr. Dhiraj Pant, Monsanto Holdings Pvt. Ltd., New Delhi
40. Mr. Dwarkesh S Parihar, Head Biotechnology, Bioseed Research India, Hyderabad
41. Dr. Amit P Parikh, Scientist-C, Department of Biotechnology, New Delhi
42. Dr. Debasis Pattanayak, PS
43. Dr. Deepak Prem, Monsanto
44. Dr. Deepak Pental, Head – Department of Genetics, Delhi University, New Delhi
45. Dr. K V Prabhu, Joint Director, Indian Agriculture Research Institute, New Delhi
46. Prof. Akshay Kumar Pradhan, Department of Genetics, University of Delhi, New Delhi
47. Dr. Atanu Purkayastha, Joint Secretary (Seeds), Department of Agriculture & Cooperation Ministry of Agriculture, New Delhi
48. Dr. S.J. Rahman, Principal Scientist & Head, AICRP on Biological Control of Crop, Pests and Weeds, Hyderabad
49. Dr. V V Ramamurthy, Principal Scientist, Indian Agriculture Research Institute, New Delhi
50. Dr. T. Venkata Ramanaiah, BioSafety And Regulatory Lead, Advanta Ltd., Hyderabad
51. Dr. S R Rao, Advisor , DBT, Ministry of Science and Technology, New Delhi
52. Dr. Uma Rao, Head, Principal Scientist, IARI, New Delhi
53. Mr. Rajvir S Rathi, General Manager - Market Acceptance India, Bangladesh & Pakistan Bayer BioScience Pvt. Ltd., Gurgaon
54. Dr. (Mrs.) Praveen Rishi, Professor, Panjab University, Chandigarh
55. Ms. Suchismita Roy, Communications Consultant, ABLE-AG, New Delhi
56. Dr. B. Sesikeran, Former Director, NIN& Chairman, RCGM,Hyderabad
57. Dr. N Seetharama, Executive Director, ABLE – AG, New Delhi
58. Dr. H C Sharma, Principal Scientist – Entomology , ICRISAT, Hyderabad
59. Ms. Prateeksha Sharma, Manager - Regulatory Affairs, BASF India Ltd., New Delhi
60. Dr. M. S. Sheshshayee, Associate Professor, Department of Crop Physiology, University of Agricultural Sciences , GKVK Campus, Bangalore
61. Dr. Faujdar Singh, Regulatory Consultant , Devgen Seeds and Crop Technology Pvt Ltd., Hyderabad
62. Dr. N.K. Singh, Secretary, National Academy of Agricultural Sciences, New Delhi
63. Ms. Rekha Sinha, Executive Director, ILSI-India, New Delhi
64. Dr. Rohini Sreevathsa , Senior Scientist, National Research Center on Plant Biotechnology, IARI, New Delhi
65. Dr. R D Tripathi, Chief Scientist, Division Of Plant Ecology And Environmental ScienceCSIR-National Botanical Research Institute, Lucknow
66. Dr. K Veluthambi, Co-Chairman, Professor (Retd) & Head, School Of Biotechnology, Madurai Kamraj University Madurai
67. Dr. M. Venkatachalam, Regulatory and stewardship Affairs Manager, Syngenta Biosciences Pvt. Ltd., New Delhi
67. Mr. VikramJeet Yadav, Assistant Director (Labs), FSSAI, New Delhi
69. Dr. S K Yadav, Principal Scientist, Central Research Institute for Dryland Agriculture, Hyderabad

Department of Biotechnology, Ministry of Science and Technology, Government of India (DBT)

Website: *http://dbtindia.nic.in*

The setting up of a separate Department of Biotechnology (DBT), under the Ministry of Science and Technology in 1986 gave a new impetus to the development of modern biology and biotechnology applications in India. In more than 25 years of its existence, the department has promoted and accelerated the pace of development of biotechnology in the country. Through several R&D projects, demonstrations and creation of infrastructural facilities a clear visible impact of this field has been seen. The Department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry. Necessary guidelines for transgenic plants, recombinant vaccines and drugs have also been evolved. A strong base of indigenous capabilities has been created.

International Life Sciences Institute- India (ILSI-India)

Website: *http://www.ilsi-india.org & http: www.ilsi.org*

ILSI- India is a branch of the International Life Sciences Institute (ILSI) which is a global foundation with headquarters in Washington, D C and 16 regional/country branches in North America, Europe, Japan, China, South East Asia etc. ILSI addresses scientific issues relating to food safety, nutrition, toxicology, agriculture sustainability, biotechnology and environment through its branches and Research Foundation. It has a special consultative status with Food and Agriculture Organization (FAO) of United Nations and is affiliated with World Health Organization as a non-governmental organization.

ILSI-India has been working on agriculture biotechnology issues in the country since 1999. It has organized a number of national and international workshops, conferences, and training programs activities in the country.

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