I welcome you to this *Expert Consultation on Regulatory Science for Risk Assessment in Agricultural Biotech* organized jointly by International Life Sciences Institute-India, and Department of Biotechnology, Ministry of Science & Technology, Government of India.

A word about ILSI. It is an international research foundation with focus on nutrition, health and well-being, food and water safety, bio-technology, toxicology and risk science, sustainable agriculture and nutrition security. ILSI has 16 regional branches the world over apart from the Health & Environmental Sciences Institute. ILSI Research Foundation along with Centre for Environmental Risk Assessment (CERA) and Centre for Integrated Modelling of Sustainable Agriculture and Nutrition Security (CIMSANS) undertakes and supports research with the final objective of promoting human health and well-being.

ILSI Research Foundations center of excellence called: The Center for Safety Assessment of Food and Feed (CSAFF) promotes science-based approaches to the safety assessment of foods and feeds, with a strong emphasis on improved knowledge dissemination and capacity building. The ILSI Center for Risk Science Innovation and Application (RSIA) contributes to enhanced human health and well-being by developing new and improving existing methods and evaluations used in risk management.

ILSI has consultative status with Food and Agriculture Organization and NGO status World Health Organization. ILSI-India, which represents South Asian Region, has similar objectives and works closely with governments, academia and industry. This tripartite approach has made science an efficient tool to conceive, shape and implement steps to improve and enhance public health.
ILSI-India has deep interest in agricultural biotechnology. We are convinced that it is presently the most potent technology to achieve food and nutrition security. Since the late nineties ILSI-India has been organizing discussions, workshops and conferences on agricultural bio-technology. The regulatory system at that time was in a formative stage, the risks implicit in genetically modified foods were not well understood and safety tools were not precisely identified or evolved. ILSI-India’s first seminar on GM Plants and foods was held in 1999 with collaboration and support of DBT. The deliberations helped develop the basic approach to biosafety, evolve a framework that was necessary to assess and manage risk and provide requisite inputs for formulation of relevant laws and regulations.

In 2003 with DBT, CDFD, ITRC and ILSI IFBiC we organized two workshops and training programs in Hyderabad and Lucknow on detection methods of GM-foods and plants. This workshop helped us to create a pool of resource persons for biotech applications. It was followed by a conference to review “Recent Scientific Developments in Agriculture Bio-Technology for sharing knowledge and experience”. This conference gave us an opportunity to look at the global progress in transgenics, the rapidly increasing area under genetically engineered crops, the different products that were genetically modified, the countries which opted for GM foods and the regulatory systems that were put in place internationally. Building on this experience, we reviewed safety issues more intensively in subsequent conferences and seminars. We also organized a second training programme on sampling and detection methods applied to transgenic crops in 2011 at NIN, Hyderabad along with DBT, FSSAI and NIN.

With the research undertaken over the years, it has also been possible to broadly identify and assess the risks involved in genetically modified foods and plants. The main risks that have been addressed are allergenicity, toxicity and antibiotic resistance.

Today we will look at two issues. First, data requirements for safety assessment and second, regulation for stacks in the context of international experiences. Safety can be assessed only on the basis of requisite data. Surely, there are guidelines laid down in 2008 by DBT. A review of the guidelines in the light of
recent international developments in regulatory science will help to make the assessment more scientific and credible. Stacking has raised further issues about data and risk assessment methodologies. The data called for should be minimum necessary and of the right quality for efficient analysis which will facilitate introduction of transgenics and their acceptability by all stakeholders.

I have pleasure in welcoming members of RCGM and GEAC and the speakers on different subjects. I welcome Dr. Sesikeran, Chairman, RCGM, Dr Alan McHughen, University of California USA, Dr. K K Narayanan, Chairman Metahelix Life Sciences LTD, Dr Deepak Pental, University of Delhi, Dr. B Gajendra Babu DuPont, Dr. Simon Barber Syngenta, and Dr. K V Prabhu, IARI, Dr Majumdar, and Dr Vibha Ahuja, BCIL.

To Dr. S R Rao I must express my sincere gratitude for guiding us all the way and for agreeing to chair the two panel discussions which will provide opportunity for comprehensive exchange of views.