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BIOSAFETY PROGRAM

CONFERENCE PROCEEDINGS

Foods Derived from Genetically Modified Crops: Issues for Consumers, Regulators and Scientists

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New Delhi

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BCIL

Indian Council of Medical Research

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Foreword

The introduction of genetically modified (GM) foods has stimulated much discussion about the nature of these foods, their safety and societal acceptance as any innovation in the process of production of particularly the food crops raises concerns. The scientists, policy makers, industry and all the stakeholders have a major responsibility to address these concerns in order to instill confidence in the consumers at large.

In the light of above, Indian Council of Medical Research (ICMR) in association with AGBIOS Inc., Canada and Biotech Consortium India Limited (BCIL) organized "International Conference on Foods Derived from Genetically Modified Crops: Issues for Consumers, Regulators and Scientists" on September 26-27, 2005 in New Delhi. I am pleased to note that the conference was a big success with participation from all the major stakeholders and open wide-ranging discussions.

The proceedings of the conference are being brought out with an objective to provide a comprehensive review of discussions as well as an overview of biosafety regulations in India with respect to GM foods. The proceedings would be of immense use not only for the participants of the conference but also for the scientists, policy makers, industry, students and other stakeholders involved in issues related to GM foods in the country.

(Dr. N.K. Ganguly)

Preface

The use of genetically modified organisms (GMOs) and products derived from them has increased in different facets of human life particularly in agriculture, healthcare and nutrition. Novel foods are being produced using GM crops by introduction of new and diverse traits. Since food has a highly symbolic significance and is much more than just a source of nutrition and energy, such GM food products are being scrutinized more than any other food and the public expectation with respect to assuring the safety of these products is higher than conventional foods. Concerns about potential impacts on human health from foods derived from GM crops have led to development of regulatory regimes specifically applicable to their safety. The wide-ranging issues associated with the GM foods require consultations among various stakeholders including scientists, regulators and most importantly consumers.

In view of the increasing research and commercialization activity on GM foods in India as well as globally, Indian Council of Medical Research (ICMR) and Biotech Consortium India Limited (BCIL), organized "International Conference on Foods Derived from Genetically Modified Crops: Issues for Consumers, Regulators and Scientists" on September 26-27, 2005 in New Delhi with active involvement of Ministry of Health & Family Welfare, Ministry of Environment and Forest, Ministry of Food Processing and Department of Biotechnology, the Ministries involved in different aspects of GM food Safety regulations. The conference was organized in association with AGBIOS Inc., a Canadian agency dedicated to provide regulatory and risk assessment expertise for products of biotechnology.

Eminent national and international experts gave presentations and there was active discussion amongst the faculty and participants. It is our pleasure to present this document covering salient points of presentations and discussions so that the same could be used for awareness amongst the wider target groups and for future consultations in this extremely important subject of GM food safety.

(Dr. Vasantha Muthuswamy)
Senior Deputy Director General
Indian Council of Medical Research
New Delhi

Introduction

Indian Council of Medical Research (ICMR), AGBIOS Inc. and Biotech Consortium India Limited (BCIL) organized "International Conference on Foods Derived from Genetically Modified Crops: Issues for Consumers, Regulators and Scientists", on September 26-27, 2005 at The Metropolitan Hotel Nikko, New Delhi, India with support from South Asia Biosafety Programme (SABP) project. The objective of this conference was to provide an introduction to some of the key issues that need to be addressed for regulation of foods derived from GM crops. A note on regulation of GMOs/food is placed in Annex-I.

The themes of the conference were safety assessment of GM foods and regulations on the first day and public participation, consumer issues and challenges on the second day. Well-known International and Indian speakers made presentations in the above areas, followed by discussions amongst the participants. A copy of the prorgramme is placed in Annex-II.

It was attended by 150 participants representing a cross section of stakeholders *i.e.* government, scientists, industry, NGOs. The list of participants may be seen in Annex-III. The conference was well received and provided an excellent platform for the exchange of views among various stakeholders. This conference was very timely as several food crops are under field trial in India and regulatory reforms are in progress, particularly with the introduction of Food Safety Bill, 2005 (under consideration of Parliament). For the first time the agencies responsible for India's food control system also participated very actively along with other stakeholders and were exposed to various issues with respect to genetically modified (GM) foods. The two-day conference was a great success as for the first time a conference focused was on issues related to foods derived from GM crops.

The conference was divided into five sessions: the opening/inaugural session and four technical sessions:

- Technical Session-I: The Regulation of GM Foods
- Technical Session II: Key Elements in the Safety Assessment of GM Foods
- Technical Session III: Public Participation and the Consumer
- Technical Session IV: Challenges and Opportunities

Opening Session

Address: Dr. V. Muthuswamy, Senior DDG, Indian Council of Medical Research

The opening session began with a welcome address by Dr. Vasantha Muthuswamy. She informed that Prof. N.K Ganguly, Director General, ICMR could not join today because of some sudden commitments but has been extensively supportive of the conference. She remarked that the importance and concerns of GM food safety in the country are reflected by large number of participants including the presence of senior functionaries from all concerned departments and ministries in this conference particularly Shri Desh Deepak Verma,

Joint Secretary, Ministry of Environment & Forests (MoEF), Shri A.N.P. Sinha, Joint Secretary, Ministry of Food Processing Industries (MFPI), Ms. Rita Teaotia, Joint Secretary, Ministry of Health and Family Welfare (MOHFW) and Dr. K.K. Tripathi, Advisor, Department of Biotechnology (DBT).

She informed the participants about role of various ministries responsible for GM food regulation in the country. MOHFW was nodal Ministry body for ensuring food quality and safety under the Prevention of Food Adulteration Act (1954) and ICMR served as its technical advisory body. The ICMR and MOHFW propose to set up a GM Food Cell at National Institute of Nutrition (NIN), Hyderabad. The MoEF, under the government of India is the nodal ministry for environment and biosafety of GM organisms. The recently introduced Integrated Food Safety Bill was being looked after by the Ministry of Food Processing Industries.

She welcomed all the speakers and chairpersons of various sessions particularly international speakers who had traveled from far off places to share their experiences. She welcomed Dr. Morven A. McLean, President, AGBIOS Inc., working on the South Asia Biosafety Programme (SABP) in India and complemented her on initiating this conference on GM food safety. She welcomed Dr. S.R. Nair, Managing Director, Biotech Consortium India Limited (BCIL). She thanked BCIL's efforts in organizing the conference and mobilizing the large response from different stakeholders including scientists, regulators and industry. She particularly mentioned that she was extensively impressed by science based professional approach of both AGBIOS and BCIL. She appreciated Dr. Vibha Ahuja, Deputy General Manager, BCIL and Dr Geeta Jotwani, Senior Research Officer, ICMR for their efforts to organize the whole programme. She thanked the government departments, industries, research organizations, universities and social organizations for sending their delegates to the conference.

Address: Dr. Morven A. McLean, President, AGBIOS Inc., Canada

Dr. McLean introduced the USAID funded SABP programme for India and Bangladesh to the participants. She thanked ICMR and BCIL for their tremendous efforts for organizing the workshop and appreciated Dr. V. Muthuswamy for her encouragement and cooperation to make this conference a success. She introduced the programme of the workshop to be held on the two days having both national and international speakers and the conference document which was circulated.

Address: Dr. S. R. Nair, MD, BCIL

Dr. Nair highlighted the various activities of BCIL in the field of biotechnology viz. technology transfer, consultancy, manpower training and placement and information dissemination. He emphasized the importance of biosafety and stated that safety was important not only with agriculture and food but also with international relationships. It was the topic of debate since the first GM crop *i.e.* Bt cotton was released in the country and there had been considerable debate on "fear of unknown". He mentioned that BCIL has organized several workshops in the area of biosafety and rDNA technology and hoped that the participants would be beneficial from the present conference and requested for a feed back for organizing similar events in future.

Address: Shri A.N.P. Sinha, Joint Secretary, Ministry of Food Processing Industries

Shri Sinha informed that an Integrated Food Safety Bill drafted on the basis of "one law one regulator" has been framed by Ministry of Food Processing Industries and is under consideration of the Parliament. As per the bill, it is proposed to set up a Food Safety Authority in the Bill that would regulate and coordinate various aspects related to all types of food including GM food. He felt that in addition to impact on human health

and environment, livelihood, and trade issues are also equally important and may be discussed appropriately during the course of the conference.

He appreciated the content, structure and organization of the conference and hoped that all the stakeholders viz. scientists, regulators, industry would be benefited by it. He emphasized the need for building up scientific database, infrastructure and manpower capabilities in this area.

Address: Mr. Desh Deepak Verma, Joint Secretary, MoEF

Mr. Verma complemented ICMR, AGBIOS and BCIL for their initiative in organizing a conference on GM foods. He termed the initiative as very timely as country had gathered valuable experience in commercialization of transgenic crops and recombinant drugs but have yet to move forward and gain experience in GM food. Briefing about the recent initiative for strengthening the regulatory framework, he mentioned about two committees that had been set up in the country namely the M.S. Swaminathan Committee for Processes, Rules and Regulations of GM crops and Mashelkar Committee for Regulation of Recombinant DNA Drugs. Their reports had been submitted to the Government of India and were under consideration.

He also highlighted issues related to the transboundary movement of GM crops/food and stressed on a case-by-case study review for decision making. Regarding labeling issues, attitude of the consumer is a foremost consideration to be kept in mind. For example labeling of vegetarian and non-vegetarian food in India would be important, whereas for other countries it may not have the importance. Mr. Verma explained the significance of animal health in India and said that animal feed may not be an issue in developed countries as crop residue was not used for feed. But in India, crop residue is a major part of animal feed and hence this issue could not be ignored when using GM crops/food.

He stressed that there was a need of conscious investigation, discussion and public awareness in the area of GM food.

Address: Dr. S.R. Gupta, Deputy Director General (PFA), MoHFW

On behalf of Ms. Rita Teaotia, Joint Secretary, MoHFW, Dr. S.R. Gupta delivered the address. He mentioned the importance of the PFA Act in India, which takes care of food including GM food. He informed that MoHFW has constituted an expert body under DG, ICMR for GM Food and the committee has given recommendations. One of the important recommendations was on GM food labeling wherein labeling of GM food in India would become mandatory by 2006.

Dr. Gupta informed regarding the testing facilities for GM food in India. There were about 80 testing laboratories for GM food, out of which 72 were with state governments and four with Central government. Among them, the Central Food Technological Research Institute (CFTRI) and National Institute of Nutrition (NIN) were the important centers for testing which are also were being funded by the government (DBT) to upgrade the GM testing facilities in the country.

Dr. G.S. Toteja, Deputy Director General, ICMR proposed a vote of thanks.

Technical Session I: The Regulation of GM Foods

1.1. Regulating GM Foods: A Global Snapshot:

Dr. Morven A. McLean, President, AGBIOS, Canada

Dr. McLean introduced the audience to the South Asia Biosafety Program (SABP) and its various activities in India and Bangladesh. SABP is funded by the United States Agency for International Development (USAID) and Dr. McLean thanked USAID for their support of this project which is jointly implemented by the AGBIOS and the International Food Policy Research Institute. She introduced the SABP Country Coordinators: Ms. Purvi Mehta Bhatt in India and Dr. Imdadul Hoque in Bangladesh. Activities to date in India include communication training of state-level extension personnel, an economic analysis of domestic and international biosafety and marketing regulations for agricultural biotechnology in India and Bangladesh, and technical training for regulators and scientists in the area of GM food safety assessment. The activities under the programme for Bangladesh include communication activities through the Bangladesh Biotechnology Information Centre, technical training and awareness raising, and support for the development and implementation of a system for the regulation of confined field trials.

Dr. McLean then provided a brief overview of the regulation of GM foods. She described four crosscutting considerations in the development of regulations to address GM foods: clarity; transparency; workability and enforceability; and adaptability. She emphasized that regulatory systems should be clear and unambiguous. The risk assessment process and the means by which decisions are reached should be transparent and regulations should be practical, effective and efficient. There should also be flexibility to accommodate case-by-case variations.

Dr. McLean indicated that there is no single best model to regulate GM foods that can be applied in all countries as approaches to regulation necessarily reflect national priorities and issues such as transparency, public participation and the inclusion of social and/or economic considerations which vary between countries. However, international consensus with regard to approaches to the safety assessment of GM foods has been achieved.

1.2 Regulating GM Foods in India (Part I)

Dr. T.V. Ramanaiah, Director, Department of Biotechnology, Government of India

Dr. Ramanaiah the participants that all activities involving GMOs and products thereof were controlled activities under the Rules - 1989 of Environment (Protection) Act (EPA-1986). The objective of the Rules-1989 was to provide safe products to the society on the existing scientific knowledge. He briefly explained the role of six competent authorities in India viz. Recombinant DNA Advisory Committee (RDAC); Review Committee on Genetic Manipulation (RCGM); Institutional Biosafety Committee (IBSC); Genetic Engineering Approval Committee (GEAC); State Biotechnology Co-ordination Committee (SBCC); District Level Committee (DLC). The approval and prohibitions, etc. under Rules, 1989 were detailed. He explained the different biosafety parameters used in India assessing environmental safety of transgenic crops in India. He stated that DBT had prepared a set of biosafety guidelines as per 1989 rules to generate required biosafety data on the GMOs and products thereof before their release in to environment. A list of transgenic crops approved for conducting

contained limited field trials including multi-location field trials during 2004 in different institutes of India, was also presented.

1.3 Regulating GM Foods in India (Part II)

Dr. S. R. Gupta, Deputy Director General (PFA), Ministry of Health and Family Welfare

Dr. S. R. Gupta said that genetic engineering had opened new vistas for crops in the area of food for humans and animals, as well as other uses like pharmaceuticals *etc*. He pointed out that the use of genetically modified crops and products, have posed a range of issues, in the context of policy and implementation before the regulatory bodies in different countries, which include the ethical, social, economic, scientific, environmental and health aspects. The challenge had been further compounded by variation in the capacity of regulatory bodies to enforce guidelines regulating their uses, or even to formulate policies in this regard. He advised that in the backdrop of complex technical issues, that there was a need for more investment, time and resources to develop capacity.

Dr. Gupta remarked that in the wake of complexities, an international perspective on these issues had not evolved till date, even in the Codex Alimentarius, which could effectively promote international trade on GM foods. He stated that in the absence of an accepted international perspective, nations have developed their own regulatory systems to tackle GM foods. The Ministry of Health and Family Welfare was responsible for making regulations for sale of safe foods including GM Foods under PFA Rules 1955. Dr Gupta pointed out that presently in India an appropriate regulatory mechanism for monitoring sale of imported or locally produced GM foods was lacking in the country and there was an urgent need to incorporate appropriate regulatory provisions.

He presented the recommendations given by the sub-committee on biosafety of GM foods set up by ICMR and MOHFW. One of the important recommendations was to have mandatory labeling on GM products imported and domestically produced. He stated that for enforcing of labeling requirements, laboratories capable of testing presence of GM foods are necessary. Dr. Gupta concluded his presentation by saying that an appropriate coordination mechanism should be developed in the country for an effective implementation and execution of various guidelines regarding biosafety of GM foods.

Technical Session I: Questions and Answers

Q: Was it necessary to adopt the recommendation of Sub-committee on GM Food to change the term modern biotech to biotechnology?
A: The recommendations given by the sub-committee are for consideration of the MoHFW, which after international discussions, propose to prepare a draft policy. This draft would be circulated to all stakeholders and based on the feedback received the Ministry would take steps to finalize the policy on GM food.

Q: Is there a need to repeat the test of a GM product in India; if it has already been tested for safety in another country?
A: In case of drugs, only Phase III trials are done if the drug is approved for use in the country of origin and Phase I & II trials are not repeated. Similar approach could be considered for other GM products although at present there is no clear cut policy.

Q: What is India's stand for mandatory labeling and is there any standard for it?
A: It has been proposed that labeling should be mandatory and the standards are under development.

Q: What are the mechanisms to implement the issues related to harmonization in various regulatory committees?
A: Representatives of all concerned ministries are members of various regulatory committees, but in case somebody is left, they are invited/inputs sought before the draft policy is finalized.

ICMR supported this statement by giving example of five committees in the area of GM food by MoHFW *i.e.*, biotechnology, biosafety, public awareness, ethics and trade committees where the representatives of all concerned ministries are there. It was stressed that stepwise involvement and monitoring was required in case of GM foods, since it was an evolving area.

It was further added that views of all the concerned ministries are considered before the draft of any policy is formalized even at the level of MPs and ministers.

Q: Are there any rules for regulating GM foods at state and experimental level, field trial?
A: The 1989 rules are the centralized rules and are applicable for all GMOs and products thereof across the board. The states have no role to play in monitoring of drugs/policy making since health was a centre subject. However, agriculture, being a state subject, framing the guidelines the state government and state agricultural universities (SAUs) are involved but not for policy making which is done by the central government. The responsibilities of state government and SAUs include monitoring of transgenic crops in order to help RCGM and GEAC take decisions related to their approvals for commercial use.

Q: What are the monitoring mechanisms for GM crops and how they are applied?
A: At present, the capacity of the country (central, state and district level regulatory agencies and relevant stakeholders) to monitor GM crops is limited and needs to be built up. However, at the contained and field trial levels which comes under the preview of the RCGM, the monitoring mechanism was well established and was working very effectively.

Q: How many states in India have State Biotechnology Co-ordination Committees (SBCCs) and how they are functioning?
A: There are 13 states which have SBCCs and the MoEF is taking necessary steps in coordination with the concerned departments and agencies at the state level to improve their functioning.

Q: Very little attention is made on purpose of GM and very little information is given about benefits, cost to public and there is no discussion on it. In India, are you looking at economic benefits for approval of GM crops?
A: The socio economic advantages of a GM crop are taken into consideration before giving approval for its commercialization by the Government of India.

Q: China repeats all field trials even after the testing is done already. What is the Indian position.
A: In India, ICAR is primarily involved in the field trials of GM crops including hybrids containing the same event, under different agro-climatic conditions. Independent studies on the performance of the GM crop under

field conditions are done by ICAR, the farmers and the applicant, which is supervised by committee members of the Monitoring and Evaluation Committee (MEC).

In case of toxicity and allergenicity studies, if these have already been done in public funded/recognized institutes abroad then it is not necessary to repeat these studies in India. The regulatory authorities in India accept applications containing toxicity and allergenicity studies done abroad.

In the cases of South Africa and Argentina, the safety assessment is done independently of an economic assessment. Economic benefits of the GM crop can therefore be taken into account in the decision making process but how much weight economic benefits are given versus safety was not known. Regarding repeating field trials of GM crops, GM potato was tested in different agro-ecosystems in USA. Data from a sub-set of these trials was accepted in Canada as the applicant could demonstrate that the agro-ecosystems in these U.S. trials were comparable to agro-ecosystems in Canada where potato is grown.

Q: A post market surveillance is required, is there any feasible and cost effective way for it? Does MoH have made any rules for it?
A: The sub-committee of GM foods has recommended that there should be 2 years post market surveillance and MoHFW was in the process of setting up pharma vigilance committee.

Q: Implementation of labeling is extremely difficult in countries like India and Bangladesh, please comment on how India proposes to implement?
A: India has the capacity for testing food in the country and the facilities are being strengthened. MoHFW has taken a loan of Rs.350 crores to build capacity in the area of food using 2/3 of the budget and drugs using 1/3 of the budget.

Techncial Session II: Key Elements in the Safety Assessment of GM Foods

2.1 The Work of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology

Mr. Patrick Deboyser, Minister-Counsellor (Health and Food Safety), European Commission

Mr. Patrick Deboyser informed Codex means 'Food Code'. Codex Alimentarius which was part of the joint Food Standard Programme of FAO and WHO. He described the objective, guidelines and principles of the Codex Alimentarius. The ruling organ of Codex is the Codex Alimentarius Commission (CAC) and there were three types of subsidiary bodies, namely Codex Committees, Coordinating Committees and Ad hoc Intergovernmental Task Forces. One of the Ad hoc Intergovernmental Task Force was on Food Derived from Biotechnology which is hosted by the Government of Japan. Its mandate was to elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology; to coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and, to take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora. The Task Force developed three texts which were adopted by CAC

in 2003. These are Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, Guidelines for the Conduct of Food Safety Assessment of Foods Derived from recombinant DNA Plant and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from recombinant DNA microorganisms.

He said that the scope of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology covers the safety and nutritional aspects of foods derived from modern biotechnology and does not address environmental, ethical, moral and socio-economical aspects of the research, development, production and marketing of these foods. With regard to risk assessment he emphasized that a pre-market safety assessment should be undertaken on a case-by-case basis, including a comparison between the biotech food and its conventional counterpart. He said that risk management should be based on the outcome of risk assessment and may include food labelling, conditions for marketing approval and post-market monitoring. Specific tools may be needed to facilitate implementation and enforcement of risk management resources. He also emphasized that risk communication is essential at all phases of risk assessment and risk management, and implies to transparency of processes, access to information and documents through effective consultation mechanisms.

He concluded by saying that efforts should be undertaken to improve the capabilities of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from biotechnology.

2.2 The Work of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology: the Indian Perspective

Dr. D. Chattopadhya Assistant Director General (PFA), DGHS, MoH

Dr. D. Chattopadhya started his presentation by providing the background information about the 26th Session of the Codex Alimentarius Commission and the 53rd Session of the Executive Committee. He stated that the 26th Session of the Codex Alimentarius Commission agreed to consider the proposal to establish a new Task Force on Foods Derived from Biotechnology and requested Japan to submit a proposal on the new Task Force. The 53rd Session of the Executive Committee agreed that Japan would prepare a project document in the form of Draft Terms of Reference for a new Ad Hoc Task Force with a list of potential areas of work and summarized the agreements made by the task force from 2000-2004 at Japan. He also informed about the proposals submitted in fifth session of the task force held on 19-23 September 2005 in Japan. It included comparative food composition analysis of staple food, evaluation of nutritional and safety components, of nutritionally enhanced GM food produced from plants: study on safety limits of herbicides in GM food and comprehensive labeling of GM foods.

He concluded that the draft guideline with regard to general labeling requirements of GM food was still in an early state of discussion. The 37th session of The Committee on Food Labeling held in May 2005 agreed to reconstruct the draft guidelines for the consideration at its next session. The most controversial point is whether or not mandatory labeling provisions should be established for the case where the difference between original products and genetically modified products was solely the production method (in this case gene modification).

2.3 Assessing the Potential Allergenicity of Foods Derived from GM Crops (Part I)

Dr. Richard E. Goodman, University of Nebraska, Lincoln

Dr. Goodman started his presentation by describing food allergy. He said that foods contain hundreds of different proteins and most people become tolerant to food proteins by an active immune response, but a few people become allergic to one or a few proteins due to genetics, dietary factors and environmental factors. He mentioned that most allergic reactions are caused by specific IgE antibodies to food proteins and specific IgE is useful against parasites, but may cause allergic reactions if specific to dietary proteins. He presented the food allergy prevalence and studies on diagnosis of food allergies in US. Dr. Goodman explained the methods for assessing the potential allergenicity of GM crops. He said that if source of the allergen is known, the allergenicity can be assessed by performing specific serum screening. The other methods to test allergenicity included sequence matching of the introduced protein with known allergens at > 35% identity over 80 amino acids and performing specific serum screening if such a match is found (matches of > 50% are more predictive), pepsin stability – if stable; other factors such as heat stability and abundance of the protein should be considered as potential risk factors regarding the likelihood that the protein would become an allergen.

He concluded by saying that Codex recommends continuing research on animal models, targeted serum screening and cell culture assays, but indicated clearly that these methods must be scientifically justified before use.

2.4 Assessing the Potential Allergenicity of Foods Derived from GM Crops (Part II)

Dr. Naveen Arora, Institute of Genomics and Integrative Biology

Dr. Arora made a presentation on allergenicity assessment of GM food. He described food allergy as an adverse reaction to a food or food component involving the body's immune system. The allergy reaction involves two primary components namely contact with food allergens and Immunoglobulin E (IgE), most cells and basophils IgE reacts with the most cells and together with the mast cells (tissue cells) and basophils (blood cells), release histamine and other mediators causing allergic symptoms. He described the types of food allergies and the symptoms of an allergic reaction. The common world-wide food allergens include legumes (peanuts and soybeans), milk, eggs, fish (cod, salmon, haddock, *etc.*), crustacea (shrimp, crawfish, lobster, *etc.*), wheat, tree nuts (almonds, walnuts, Brazil nuts, *etc.*), mollusks (snails, mussels, oysters, scallops, clams, squid) and selected food additives. The top ten allergic foods in India as found in a survey of 2000 patients under an ICMR project included rice, blackgram, lentil, citrus fruits, pea, maize, banana, lima bean, peanut and fish.

Dr. Arora mentioned the various guidelines available for allergenicity assessment such as WHO/FAO decision tree for allergenicity assessment, which gave its first report for allergenicity assessment in 1997 and included animal model studies for allergenicity in 2001. Then there are OECD guidelines (2001/2003) for safety assessment by substantial equivalence between GM and native crop. He also detailed the methods of allergenicity assessment of GM crops, which are based on source of gene, sequence homology studies, comparative proteomics analysis, digestibility and heat stability studies, animal model studies and specific and target serum screening. He concluded by stating that the GM crops could help counter global food problem/nutrition, but proper assessment was needed.

2.5 Nutritional Evaluation of Genetically Modified Plants/Foods:

Dr. B. SivaKumar, Director, National Institute of Nutrition

Dr. Sivakumar started his presentation by mentioning about the typical limitations of diets in developing countries which included low energy density food with basic components being cereal/legume mixtures which had poor protein quality (cereals limited by lysine and legumes by- sulfur amino acids) and poor micronutrients. He listed the spectrum of GM foods undergoing field trials in India to improve nutritional quality i.e. improving event of lysine content of potato and other legumes like groundnut, chickpea, improvement the ß-carotene content in rice (golden rice), improvement of the carotene content of rapeseed oil or canola or mustard oil (Brassica) or groundnut (golden oil) and bio-fortification through both natural and transgenic mechanisms, of millets and lentils with iron and carotene. While explaining the importance of nutritional issues, Dr. Sivakumar stated that the estimated cost of simple safety evaluation of a GM food was at least US$ 5-10 million. Therefore, it would be more useful that simple in vitro evaluation along with the food of interest should be done in picking up potential value added products which could then be subjected to safety testing.

He also described some recent studies done on Bt cotton seeds at NIN. He suggested the steps involved in nutritional assessment of GM foods, should include screening the foods for nutritional impact using in vitro methods on a case by case, checking the compositional profile of nutrients, evaluating the role, if any, of inhibitors, toxins *etc*., prediction of immuno-toxicity and allergencity by computer simulations, evaluating the cost-effectiveness and out-reach and conduct biosafety assessment as per respective national regulations of the Cartegena Protocol.

He concluded by stating that the technology of golden rice and canola, which involved multiple gene-recombinations and high protein potato had opened up enormous possibilities in the area of nutrition. However, in view of many technological, social and safety considerations, more focused effort was needed before the fruits of modern biotechnology could benefit the common people.

2.6 Nutritional Assessment of GM Foods

Dr. I. Munro, CANTOX Health Sciences International, Canada

Dr. Munro began his presentation by outlining the benefits and general principles of nutritional safety and quality of GM foods. He described the key elements of nutritional safety assessment, which included molecular characterization, safety of expressed proteins, compositional analysis (substantial equivalence) and animal performance studies. Using maize as an example, Dr. Munro explained the concept of substantial equivalence. He also provided an explanation on the development of a free publicly accessible crop composition database sponsored by International Life Sciences Institute (ILSI) which represents many crops, diverse geographies and multiple years. This electronic database would be accessed via the internet at http://www.cropcomposition.org. Using the poultry feeding study with Roundup Ready Maize as an example he described how animal nutrition studies were conducted.

Dr. Munro concluded his presentation by saying that there has been widespread acceptance of GM crops with considerable benefits to farmers and the potential to alleviate hunger and malnutrition. Nutritional safety assessment involves the application of the concept of substantial equivalence and any identified differences should be subjected to detailed evaluation. He stated that no adverse nutritional effects have been observed with GM crops to date.

2.7 Assessing the Potential Toxicity of Genetically Modified Foods:

Dr. W. Seinen, Institute of Risk Assessment Sciences, Utrecht University, The Netherlands

Dr. Seinen started his presentation by mentioning the international perspective of risk assessment strategies for GMOs, which included the global agencies related to biosafety of GMOs viz. OECD, FAO/WHO, Codex, EU scientific committees and ENTRANSFOOD. He stated that given the known history of accepted use of food crops and their biology, and the availability of analytical, toxicological, nutritional and environmental assessment tools, the GMO Panel was of the opinion that an assessment process could be put in place for GM plants and derived food and feed, which provides an internationally accepted level of safety for the consumer, animals and the environment. The assessment of unintended effects of GMOs should be done by comparative studies with the conventional counterparts. Thus comparisons between the GM lines and commercial non-GM varieties (or quality-assessed literature data) may allow identification of differences that are of biological significance. In the area of toxicology he described the safety evaluation processes for GM food and feed which included molecular characterization of the modification, compositional equivalence between GM product and its conventional counterpart on case by case approach. Safety evaluation involves new proteins which are formed as a result of the intended modification, detection of unintended new proteins or other constituents as a result from the modification, presence of natural constituents beyond their level of normal variation and analysis of whole food/feed, in case of any indication for unintended effects. Details of each aspects were presented. He said that additional toxicological studies may be required depending on nature and extent of deviation from traditional counterpart and any remarkable findings in the feeding studies.

Dr. Seinen stated that foods are complex mixtures of nutrients, vitamins, minerals and other health-beneficial substances, and also contain anti-nutrients, and natural toxins. Therefore, safety evaluation of whole foods as performed with single chemicals or food additives is not possible. He said therefore, substantial equivalence approach is required which includes a systematic comparison of agronomic properties, morphological characteristics, compositional parameters of the GM organism and its closest traditional counterpart. Further, substantial equivalence was not a safety assessment in itself, it identifies but does not characterize the hazard, it was the starting point of the assessment rather than the endpoint and above all helps in structuring the safety assessment framework of a GM food relative to its conventional counterpart. He informed about the OECD Consensus Documents for various crops prepared by the OECD Task Force on the Safety of Novel Foods and Feed. These documents provided analysis of newly expressed proteins in food crops using parameters such as structure-function analysis, degradation behaviour, biological/immuno activity etc. He mentioned that the need for animal studies for whole food arises if database is insufficient for a full assessment is required, for foods which contribute significantly to the diet, if no history of consumption is there, if the modification affects several metabolic pathways and in case of significant changes other than those expected. For analysis of the unintended effects, in addition to the targeted approach of specific analysis, a non-targeted approach of various profiling techniques involving genomics, proteomics metabolism etc. was also gaining importance.

Dr. Seinen concluded by stating that for detection of unintended effects comparative targeted analysis of GM and non-GM crops offers a high degree of certainty with respect to detection of unexpected compositional alterations, and is the leading approach in risk assessment of GM crop derived foods. On the other hand, profiling techniques could be used as to supplement the comparative target analysis approach, as they could increase the understanding of metabolic pathways and their interconnectivities. However, these techniques required further development and validation before they could be used in a formalized risk assessment procedure.

Techncial Session II: Question and Answers

Q: Is it appropriate to incorporate genes from animals to plant irrespective of the source. Please comment.
A: Ethical and religious issues need to be considered separately. Ethically it is important to consider from which source of genes are taken.

Q: History based studies on allergenicity are not available in India. Please comment.
A: History based studies on allergenicity are carried out at Vallabhbhai Patel Chest Institute, Delhi under a project sponsored by ICMR.

Q: Is potato in India listed as allergen as mentioned in Dr. R. Goodman's presentation?
A: Patatin is an allergen from potato. It was reported from Finland that they had allergy from GM potato. Therefore, Monsanto stopped working on a potential GM product that contained the potato protein.

For a person to have allergy, he should have high specific IgE against the allergen non- allergic individuals (normal) have low levels IgE. We have not studied potato allergenicity in India.

Q: What are the real toxins or allergens available in general?
A: There is no data as such available listing toxins and allergens. However, lower bacteria have a number of toxins and various proteins have been studied for toxicity. It is not a well researched area therefore toxicology terminology has not been developed

Q: Are GM crops stable genetically from generation to generation and how many generations have been tested in India say of Bt cotton?
A: Some non-significant variations were seen in EU after 2-3 years in GM crops.

For 3, 6 & 9 generations genetic stability is checked and it has been seen that the GM crops breed true.

In Canada, regulators require that stability of expression over multiple generations must be demonstrated as part of the safety assessment.

In case of rice resistant to bacterial blight Xa21 molecular characterization was done for 6 generations at IRRI and then homozygous lines were developed and the bio-efficiency and breeding aspects were studied. It was found that they bred true without any variation following which it was commercially cleared. Same studies were carried out for golden rice.

Technical Session III: Public Participation and the Consumer

3.1 GM Foods and Consumer Acceptance in Asia:

Mr. Kelvin Keh, Asian Food Information Centre (AFIC), Singapore

Mr. Keh started his presentation with the introduction of the activities of his organization. He informed that Asian Food Information Centre (AFIC) is involved in communicating sound science-based information on

food safety, health and nutrition in Asia. He mentioned that AFIC works with media and health/scientific communities to disseminate factual information and does not engaged in any propaganda.

He informed about results of the surveys carried out by AFIC on consumers communication on food and biotechnology in the years 2002 and 2003, in Philippines, India and China. The objective of the surveys mainly focused on to explore the awareness and attitudes towards biotechnology in food, food safety and quality in general and to develop appropriate educational messages for consumers on food biotechnology. The main consumer concerns that was highlighted from the surveys were nutritional values of foods and the presence of pesticides and preservatives in the food. Majority of consumers were not much aware about GM foods. He said that the respondents who were aware of biotech foods expressed acceptance, emphasized positive benefits and the respondents with limited or no prior awareness were more likely to express concern and/or skepticism.

Mr. Keh also presented results regarding the communication channels that should be used to disseminate biotech news. The most effective method was found to be mass media (*e.g.* TV, newspapers, magazines and advertisements to reach out to a wider audience). The key findings of the surveys clearly indicate that majority of consumers have limited knowledge on food biotech, consumers seem to be most interested in information about nutritional benefits, discussions on risk introduces/create anxiety amongst participants and communications should address specific concerns, not bombard consumers with data.

3.2 Public Perceptions of GM Foods in India:

Dr. Suman Sahai, Gene Campaign

Dr. Sahai's presentation was more targeted towards the need for effective regulatory system before the GM foods are approved for commercial use. Regarding data requirements for considering the commercial use of GM crops, some of the points to be looked into urgently are methodologies and tests to be used to generate the data, mechanism to cross check the data provided by the agencies, competency of the regulatory agencies to evaluate the data, protocol for risk assessment (for human and animal health), comparative assessments between GM food and its conventional counterpart, protocol for monitoring the unintended effects and effects other than from targeted modification.

In the end of the presentation Dr. Sahai stressed on the points related to lack of technical competence in regulatory agencies, lack of transparency, no access to data to public organizations and lack of public participation in decision making with respect to biosafety issues.

She further suggested that India's regulatory framework should be divided into two levels: a multidisciplinary Advisory Committee consisting of experts from a wide range of fields with a mandate to plan and design the framework for biosafety assessment to address all relevant areas; and an independent Statutory Body of technical experts who will actually conduct the risk assessment, risk management and risk communication exercise, leading up to decision making.

3.3 Consumers Concerns with Respect to GM Foods

Dr. Sriram Khanna, Voluntary Organisation in Interest of Consumer Education (VOICE)

Dr. Khanna stated that the national consumer policy approach on GMOs would depend primarily on capacity of national governments to understand scientific issues, commitment to citizens health, ability to withstand

commercial pressure, active consumer movement to articulate citizen's concerns etc. Regarding application of GMOs in agriculture, the opponents are concerned about the environment, food safety, _____ and ethics as compared to the benefits given by the proponents of this technology. He also stated that while rich countries could afford to be critical, developing countries face a difficult trade-off position between potential risks and the need for productivity increases in food production and lower food prices. Developing countries also need to consider how GMO policy actions may affect market access, world market prices and global food demand. He listed potential risks related to GMOs under three headings- health risks, environmental hazards and ethical issues. Along with risks he also pointed out the benefits of GMOs.

Dr. Khanna also gave a brief overview of the GM food regulations in Asia, including India. He emphasized that in India clear-cut government policy on GM foods, evaluation of GMOs in food, development of infrastructure to test GM food, risk assessment methodologies based on Codex recommendation and consumer awareness need to be in place before widespread use of GM food is permitted.. He said the consumer rights include transparency in assessment, monitoring & evaluation process and to know the short and long term effects on human health and environment. He concluded the presentation by saying that careful cost benefit analysis needs to be carried out for possible advantages of GM foods. There should be laws and regulations on GM food with mandatory labeling and consumer's rights and awareness is the major issue to be taken care of.

3.4 GM Food Labeling and Traceability in Biosafety Management: Key Issues and Impact on Developing Countries

Dr. S. R. Rao, OSD to Minister of Science and Technology

Dr. Rao highlighted the status of the international biotech trade and regulations. He mentioned that labeling is often used to deliver information to consumers on characteristics of products that they are not able to evaluate. Economists refer to this type of characteristic as a credence attribute whether a product is produced with the use of biotechnology or genetic engineering is frequently difficult or impossible for the consumer to judge. He also listed the elements of GMO labeling policy, which included ingredients or products to be covered in the policy, requirements that triggers labeling, *etc*.

Dr. Rao elaborated on the labeling provisions and thresholds required for labeling. He said that highly processed food ingredients, processing aids, food additives and flavours of food are exempted from labeling. He gave an overview of labeling requirements in the Europe/Africa, Asia Pacific, Latin American and North American. Since 1997, Europe had mandatory labeling for foods with detectable DNA or protein and 1% threshold, and there are new proposals for traceability, process-based labeling of food and feed at a 0.9% threshold, whereas in Africa there mandatory labeling based on substantial equivalence like US. He said that in few countries in Asia Pacific region, labeling is mandatory with threshold levels varying from 1-5%, whereas in India labeling requirements are under developmental stage. In Argentina and Canada there is no labeling required and voluntary labels are under review. Dr. Rao presented the conclusions of a study on the costs of compliance with, and enforcement of labeling conducted by Australia- New Zealand Authority (ANZA) in September, 2003 stating that there could be 10-15% price rises for major ingredients and consumers may have to pay up to 15% more for processed food. He informed that small results were obtained in a study funded by USAID to Philippines.

He stated that traceability refers to the ability for the retrieval of the history and use or location of an article or an activity through a registered identification. He gave the biosafety status of GM food in SAARC region and said that policy making is required in these regions. He said that there was a need for standardized methods to

test the agricultural biotech products and listed the challenges for the standardization of methods for testing these products. He mentioned that the preference of urban consumers had shifted towards packaged processed food.

Dr. Rao stated that experts at national and international levels were capable of addressing consumer/regulatory issues at macro level but the challenge was how to creating awareness at grass root level is the real challenge.

He concluded that detection of GM food components and ingredients becomes costly, difficult and unreliable when GM-DNA or protein occurs at very low levels, and impossible in ingredients that do not contain such DNA or protein. Therefore, reliance on a traceable audit trail is not only expensive but also opens the floodgates to fraudulent labeling. According to him developing countries cannot afford cost increases in either domestic food production or in export food products, especially in the light of negligible premiums being paid for non-GM food.

3.5 Labelling and Traceability of Genetically Engineered Foods: The Indian Context

C. Kameswara Rao, Executive Secretary, Foundation For Biotechnology Awareness And Education

Dr. Rao began his presentation by saying that all products of agriculture and animal husbandry of 10,000 years are genetically modified (GMOs, LMOs), taking advantage of variation arising out by various procedures such as Mutation which could be natural or induced, hybridization; which could be natural or artificial and human selection; which was mostly conscious since only beneficial traits were chosen. He stated that GMO and LMO are imprecise terms for Genetically Engineered (GE) products. Dr Rao compared the classical agricultural biotechnology and genetic engineering. He said that classical agricultural biotechnology produced several thousand varieties of different crops. He pointed out that some of theses varieties were not existed in nature before. These varieties may also pose risks similar to GE products and none of these undergoes any regulatory process. He mentioned that in transgenic technology insertion of gene/s selected from any organism into the genome of any other organism, irrespective of the degree of genetic relationship is carried out. The genes and their function are precisely known, unlike in conventional agricultural technology.

Dr. Rao said that all countries that are developing, cultivating and marketing of GE foods, have a regulatory frame work to ensure for consumer safety. The procedures and regulations for testing GE foods for different safety parameters and mandatory labeling practices, to facilitate traceability of a food product to its genetic and production source, were now international controversies. He suggested that a uniform international policy was essential to smoothen international trade in such products.

Dr. Rao presented a brief introduction and various objectives of Codex Alimentarius Commission (CAC). For biosafety assessment and comparison Dr Rao said that it should be between the transgenic and its isogenic and confined to the biosafety of the products of the transgenes.

He stated that substantial equivalence ensures that the transgenic and its isogenic are identical in genotype, marked characteristics and performance, but for the transgenes and their anticipated characteristics. If the isogenic were safe, the transgenic would be equally safe, provided that the newly introduced transgenes do not exercise any adverse effects by themselves or through altering the expression of any other genes of the isogenic. He enumerated how substantial equivalence was evaluated in USA and the European Union. Dr Rao suggested that India should frame internationally compatible regulations on labeling and traceability of GE food products and the issues should be addressed on a case-by-case basis. He said that in India product based rules

should be framed only when authentic information on the probable datelines of open field trials of the crops, and probable products from the crop is available. Further, all stakeholders should be involved in the process in order to arrive at a wider consensus.

Dr. Rao ended his presentation by saying that rational policy on GM food should be based in science and not in appeasement politics or outdated political philosophies. He also stressed on the need of public awareness programmes for GM food, in which media can play an important role.

Technical Session III: Questions and Answers

Q: Are GM foods consumed in USA?
A: Yes, GM food products from soybean and corn are being consumed in USA.

Approved GM foods like soya, corn are being eaten in US that have been released with lot of rigorous regulatory testing and review by appointing authorities such as USDA, FDA and EPA.

Q: India has many stringent policies, committees and regulatory bodies for GM but the speakers have stated that it is not transparent. Comment on it.
A: Since, it is new area (GM foods), transparency in testing, policy and decision-making is to be shared and capacity building in this area.

Consumer confidence is extremely important and proper methodology for the marketing of GM food should be followed.

Q: How labeling will help in India, as 70% of people are illiterate and how you will elicit awareness among the public?
A: Three apprehensions are always there with labeling whenever a new type of is vegetarian/non-vegetarian is considered *e.g.* "halal" food etc., but as we go along the consumer awareness cane created.

It is agreed that consumer needs information but public participation in consultations is very poor. For example, there are only few organizations like Gene Campaign, Consumer Voice, which are involved in such discussions. We need to find mechanisms for creating wide spread awareness and motivate public participation. Reacting to lack of competitiveness in regulatory bodies, it was pointed out that regulatory bodies in India have definitely scientific and technical experts, however improvement is required for transparency. The objective of this conference is also on how we can help the regulatory agencies.

It was a Herculean task to create public awareness about GM foods. A large number of debates involving scientists, regulators, public organizations, etc. need to be involved.

Q: What is the importance of labeling and traceability of GM food in India?
A: The traceability and labeling issues are related to trade when the food is imported or marketed. The labeling and traceability issues are still being debated in the country as we need to review the cost implications before taking any decisions.

Q: Can Bangladesh and India work together for e.g. in the case of labeling issue?
A: Regional interactions need to take place through bilateral as well as regional cooperation like SAARC.

Additional Commentary:

To deal with GM food, capacity building required for human resource and development, transparency in regulatory decisions and access data and post market surveillance.

We should have interactive websites where we have FAQs for consumers. We should involve consumers and industry in our regulatory bodies. We cannot conclusively say that labeling is required for GM food unless the pros and cons are looked into seriously.

An emphasis was palced on the need for creating data on cost-benefit analysis of labeling. So far no systematic study on the subject has taken place in India. There is an urgent need to initiate such a study before any decisions on mandatory labeling are taken in India.

Technical Session IV: Challenges and Opportunities

4.1. Assessing the Safety of Nutritionally Enhanced Genetically Modified Foods:

Ian C. Munro, CANTOX Health Sciences International

Dr. Munro began his presentation by explaining that nutrition and health benefits may be introduced in GM food/crops by various ways such as increases in the content of an essential nutrient or micronutrient; increased content of a macronutrient with a compensatory decrease in another; alteration in the chemical composition of a macronutrient; increases in health-beneficial bioactive substance; reduction in anti-nutrient, toxin, or allergen; and by changes that affect bioavailability, absorption, or utilization of a nutrient. Using Golden Rice as an example, Dr. Munro noted that the nutritional value of Golden Rice Version II has been improved through increased pro-Vitamin A content. Dr. Munro also presented data on distribution of nutrient intakes in the U.S. (1994-1996) and described the general principles of biosafety.

He stated that the basic approach to safety evaluation of nutritionally improved GM foods is similar to that of first generation crops with improved agronomic traits. Analytical comparison of composition between the new variety and a suitable safe comparator provides the key data needed to assess safety; differences are then subjected to detailed assessment. Exposure assessment plays a key role in the safety evaluation of nutritionally improved GM foods. Dr. Munro explained the key elements of the safety assessment, which includes molecular characterization, safety of expressed proteins, compositional analysis (substantial equivalence), pattern of use and exposure, animal safety studies and overall evaluation. He stated that usefulness of substantial equivalence depends upon the nature of the end product, whereas some nutritionally improved foods and feeds are intended to replace traditional varieties (*e.g.*, high-lysine maize), and other GM varieties will be developed with altered levels of bioactive substances intended to be separated from the crop and sold as ingredients. Dr. Munro explained the above using a hypothetical case study for enhanced alpha-tocopherol in soybean oil.

Dr. Munro stated that in nutritionally enhanced novel foods significant change is a change in the dietary intake of a nutrient that meaningfully affects health, growth, or development. While explaining the role of animal

safety tests, he noted that animal tests need to be used on a case-by-case basis as appropriate to the product being assessed.

Dr. Munro concluded his presentation by saying that nutritionally enhanced GM foods have the potential to correct nutritional deficiencies in large populations and reduce the risk of chronic disease. The safety standard was a comparative one, whereas new nutritionally enhanced foods are compared with a suitable comparator and the differences in composition are subjected to evaluation. In addition, exposure (intake) analysis plays a big role in determining safety of nutritionally enhanced foods and animal studies are of limited value in assessing safety.

4.2 Postharvest Monitoring of Foods Modified by New Genetic Modification Techniques

Dr. Christine M. Bruhn: University of California, Davis

Dr. Bruhn highlighted the importance of cultural role of food. She said that food reflects cultural identity, plays an important role in the social life and has important religious aspects. She mentioned that to assure the safety of GM food pre-market assessment was necessary. She explained the different parameters of pre market safety assessment given by Codex, July 2003, which included direct health effects (toxicity), potential allergenicity, assessment of nutritional/toxic components, stability of inserted gene, nutritional effects of genetic modification and assessment of unintended effects. She stated that post market monitoring is resource intensive and is best used to verify health/environmental impact. Dr Bruhn pointed out that foods eaten by animals and people must be approved together. She explained principle of substantial equivalence and said that GM food is considered as safe as its conventional counterpart when potentially toxic components are comparable, nutrients are comparable and the genetic modification is considered safe.

Dr. Bruhn highlighted the importance of labeling of GM food. She said that labeling products not different from the traditional product can be misleading and may generate unwarranted fear. In contrast, labeling is appropriate for foods that are nutritionally superior to the traditional counterpart. Labeling that communicates the product's benefits will allow consumers to select the make an informed choice and will assist in post-market health evaluation. Labeling should be truthful and not misleading. People want to know why products are modified so identifying benefits conveys this information.Dr Bruhn expressed concern about mandatory testing of GM food. Currently there are no internationally accepted standard of testing and tests give variable results.

If post-market health evaluation is conducted, it should be targeted toward a specific population. The impact of GM modified product can be determined with both pre and post dietary surveys to determine the quantity of the target food consumed and measuring biomarkers in the target population to verify the impact on health. A similar approach can be conducted to measure the impact on pesticide use, water quality, natural toxins, or other targeted environment or health measures. Post market evaluation is costly, and should only be conducted when the information obtained is warranted. Dr Bruhn concluded her presentation by mentioning that public involvement and transparent decision-making will enhance likelihood of success of wider acceptance of GM food. She suggested that public education about GM potential benefits and safety can be coordinated with local schools, technical colleges, and universities.

4.3 Public Consultation in Decision Making: The Experience in Australia and New Zealand

Mrs. Lydia Buchtmann, Food Standards Australia New Zealand Mrs. Buchtmann began her presentation by saying that scientists can no longer work in isolation and industry, academics and governments must engage the public if they want innovation to be accepted and for the public to accept innovation they must perceive an advantage. Mrs. Buchtmann explained about the various activities of Food Standards Australia New Zealand (FSANZ). She mentioned that FSANZ carries out rigorous safety assessments of GM food to ensure GM food is as safe and nutritious as its conventional counterpart. In addition, food is labelled if novel protein/DNA is in final product so that consumers can make an informed choice. She mentioned that there is no report of any one falling ill from GM food as of now.

Mrs. Buchtmann highlighted the consumer concern about the GM food and said that that consumers carry out their own risk assessments. She stated that changing global situation has changed attitudes towards technology and trust. Once an attitude is formed it is very hard to change it, and an attitude will seek out confirmation of it, regardless of how unrepresentative the supporting data is. She provided information about the GM labelling surveys which was carried out in Australia and New Zealand in 2004. She stated that no non-approved GM foods were found in Australia and all foods were found to be compliant whereas in New Zealand 2 imported foods found claiming to be GM free had less than 1% GM material. Mrs. Buchtmann concluded her presentation by saying that there is a need to close the gap between real and perceived risks and emphasized about the need for extensive education programs, which will be useful for the consumers.

4.4 Challenges in Decision Making: The Indian Context

Dr. G. S. Toteja: DDG, Indian Council of Medical Research, New Delhi

Dr. Toteja started his presentation by saying that decision making is about facing a question such as "To be or not to be?" Dr. Toteja said that six steps involved in the decision making process were: defining the problem; identifying available alternative solutions to the problem; evaluating the identified alternatives; making the decision; implementing the decision and evaluating the decision. He said that policy makers, planners, bureaucrats, technocrats and researchers are mainly involved in making decisions/assist in making decision. Decisions making required information or database, clarity of thoughts and will to take decisions. For decision making issues related to biotechnology, nutrition, safety and testing, labeling ethical and public awareness were the main challenges.

Dr. Toteja submitted that there was a need for national preparedness for assessing biosafety. Towards this a National Centre as well as regional Centres for testing of GM Foods, assessing safety as well as nutritional evaluation need to be established along with availability of skilled manpower.

Regarding import of basic foods derived through GM technology Dr. Toteja pointed out that in addition to scrutinizing the biosafety data generated abroad, there was a need to generate biosafety data indigenously in view of the discrete dietary and environmental factors. He said that GM food data bank needs to be created and maintained so as to make available all the relevant information. Specific and standard protocols should be used for testing, safety and nutritional evaluation. Along with this guidelines for regulators and analysts on safety assessment and testing need to be developed.

Dr. Toteja also highlighted that the label of all packages of GM food or foods containing ingredients, derived from biotechnology or bioengineering should indicate that they have been subject to genetic modification. These provisions would be applicable to all such products both imported or domestically produced. About the ethical issues Dr. Toteja remarked that legal system should provide strong penal provisions against any un-ethical practices and provide for liability clause for any untoward effects. There was a need for developing a surveillance mechanism to monitor long term use of GM foods to study any adverse health and environmental effects. Mechanisms need to be developed to continuously update and disseminate information on al aspects of GM products, which could be made available in public domain on website. He concluded by saying that all activities by different government agencies relating to biotechnological issues concerning GM Foods/GMOs need to be coordinated and integrated.

Technical Session III: Questions and Answers

Q: Is there any standardized methods and any agency for testing GM food and whether any tracer can be added in GM food for testing?
A: We have several ICAR and CSIR laboratories, which are developing detection kits. The indigenous and imported detection kits for testing Bt cotton are already available in the country.

Q: Is there any study on bioavailability of nutrients and synergism?
A: Bioavailability and synergism between different micronutrients need to be studied. In India, we have tried to combine iron and beta-carotene together in rice to study mechanism of synergism between them.

Q: What is the approval status and which country has approved GM rice?
A: Irrespective of mode of transformation one should focus only on evaluating the GM crops with all methods of biosafety. However, Syngenta is coming out with Golden Rice-2 in US. Once it is studied that Golden Rice-2 can stand true for bioavailability of carotenoids then government should take it and distribute it to all the consumers including farmers using PDS (public distributed service) procedures. Farmers will easily access it if government accepts it and distribute it. Golden rice also has high level of alpha-tocopherol (vitamin-E), which could be beneficial for middle-class as it also has high iron content. This can be more valuable for the anemic women.

Q: In countries like Bangladesh, India and Sri Lanka there is no reported risk for farmers, once they feel its cost benefit and good they will use it but in Mrs. L. Buchtmann's presentation, in Australia, once people have perceived risks, are they ready to take GM food?
A: It is very difficult to convince about the perceived risk in the consumer's mind as they are all educated and will need time to work it out.

Q. Is GM potato and other GM foods in Australia labeled?
A: Yes, Australia has a mandatory labeling policy.

Q: What is the annual sale of GM food in Australia and New Zealand?
A: The figures are not available.

Q. Why the repetition of the tests of GM food for biosafety need to be carried out if the information is available?
A: This recommendation has been made by a sub-committee and will be reviewed by ICMR and MOHFW.

Q: Is ICMR coming out with any study on public perception and responses of different stakeholders on GM crops and food?
A: In principle, ICMR is in agreement with the need for such study, individuals have done some study. Efforts will be made for initiating the same with the relevant departments of ICMR.

The conference concluded with a vote of thanks by Dr. G.S. Toteja.

The Regulation of Genetically Modified Organisms/ Food in India

Dr. Vibha Ahuja, Deputy General Manager, Biotech Consortium India Limited and Dr. Geeta Jotwani, Senior Research Officer, Indian Council of Medical Research

Introduction

The global demand for food is increasing because of the growing world population and decreasing arable land. At the same time food and agricultural systems have to respond to several changes such as increasing international competition, globalization and rising consumer demands for improved food quality, safety, health enhancement and convenience. Modern biotechnology involving the use of rDNA technology/genetic engineering has emerged as a powerful tool with many potential application for improving the quantity and quality of food supply. Foods derived from genetically modified crops, commonly referred to as genetically modified food and food ingredients have already become available worldwide with aim of enhancing productivity, decreasing the use of certain agricultural chemicals, modifying the inherent properties of crops, improving the nutritional value or even increasing shelf life.

As more and more GM crops are being developed and released for field-testing and commercialization, concerns have been expressed about the potential risks associated with their impact to human health, environment and biological diversity. These apprehensions arise because genetic engineering crosses the species barrier as compared to classical selection techniques, thereby permitting the gene transfer among microorganisms, plants and animals, although there is no evidence that any unique hazards exist in the development of GM, because of novel combinations of genes.

Further the concerns in agriculture do not necessarily lie with the characteristics of the products but rather with the way it is produced particularly in case of food crops. Any innovation in the process of production of crops particularly the food crops, raises suspicion particularly with consumers and food experts.

Therefore biosafety legislation and regulatory institutions to implement them have been put in place by many countries including India, both for research and trade of GM crops and food and food ingredients derived from them. There are elaborate steps to manage these risks and it is the responsibility of the scientists, industry, and the government to assure the public of the safety of the novel food products commercialized.

A brief overview of rules and regulations in India relevant for foods derived for GM crops (GM foods) is presented here:

Government Rules for GMOs

The regulatory framework for transgenic crops in India consists of the following rules and guidelines.

1.	Rules and policies	• Rules 1989 under Environment Protection Act (1986) • Seed Policy 2002
2.	Guidelines	• Recombinant DNA guidelines, 1990 • Guidelines for research in transgenic crops, 1998

Rules, 1989

The Ministry of Environment & Forests, Government of India notified the rules and procedures for the manufacture, import, use, research and release of genetically modified organisms (GMOs) as well as products made by the use of such organisms on December 5, 1989 under the Environmental Protection Act 1986 (EPA). These rules and regulations, commonly referred as Rules 1989 cover the areas of research as well as large scale applications of GMOs and products made therefrom throughout India. A copy of the rules can be accessed at http://envfor.nic.in.

The Rules, 1989 order compliance of the safeguards through regulatory approach and any violation and non-compliance including non-reporting of the activity in this area attracts punitive action provided under the EPA.

The two main agencies responsible for implementation of the rules are the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT), Government of India. The rules have also defined competent authorities and the composition of such authorities for handling of various aspects of the rules. There are six competent authorities as per the rules.

i. Recombinant DNA Advisory Committee (RDAC)
ii. Review Committee on Genetic Manipulation (RCGM)
iii. Genetic Engineering Approval Committee (GEAC)
iv. Institutional Biosafety Committees (IBSC)
v. State Biosafety Coordination Committees (SBCC)
vi. District Level Committees (DLC).

Out of these, the three agencies that are involved in approval of new transgenic crops are:

1. IBSC set-up at each institution for monitoring institute level research in genetically modified organisms.
2. RCGM functioning in the DBT to monitor ongoing research activities in GMOs and small scale field trials.
3. GEAC functioning in the MoEF to authorize large-scale trials and environmental release of GMOs.

The Recombinant DNA Advisory Committee (RDAC) constituted by DBT takes note of developments in biotechnology at national and international level and prepares suitable recommendations. The State Biotechnology Coordination Committees (SBCCs) set up in each state where research and application of GMOs are contemplated, coordinate the activities related to GMOs in the state with the central ministry. SBCCs have

monitoring functions and therefore have got powers to inspect, investigate and to take punitive action in case of violations. Similarly, District Level Committees (DLCs) are constituted at district level to monitor the safety regulations in installations engaged in the use of GMOs in research and application.

The approvals and prohibitions under Rules 1989 are summarized below:

1. No person shall import, export, transport, manufacture, process, use or sell any GMOs, substances or cells except with the approval of the GEAC.
2. Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notification, 1989 of the EPA, 1986.
3. Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.
4. For purpose of education, experiments on GMOs IBSC can look after, as per the guidelines of the Government of India.
5. Deliberate or unintentional release of GMOs not allowed.
6. Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC
7. GEAC supervises the implementation of rules and guidelines.
8. GEAC carries out supervision through SBCC, DLC or any authorized person.
9. If orders are not complied, SBCC/DLC may take suitable measures at the expenses of the person who is responsible.
10. In case of immediate interventions to prevent any damage, SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible.
11. All approvals shall be for a period of 4 years at first instance renewable for 2 years at a time.
12. GEAC shall have powers to revoke approvals in case of:
    i. Any new information on harmful effects of GMOs.
    ii. GMOs cause such damage to the environment as could not be envisaged when approval was given.
    iii. Non-compliance of any conditions stipulated by GEAC.

Recombinant DNA Guidelines, 1990:

With the advancement of research in biotechnology initiated by various Indian institutions and industry, Department of Biotechnology had formulated Recombinant DNA Guidelines in 1990. These guidelines were further revised in 1994 to cover R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research.

For research, the guidelines have been classified into three categories, based on the level of the associated risk and requirement for the approval of competent authority.

- Category I activities include those experiments involving self cloning using strains and also inter-species cloning belonging to organism in the same exchanger group which are exempt for the purpose of intimation and approval of competent authority.
- Category II activities which require prior intimation of competent authority and include experiments falling under containment levels II, III and IV (details of each containment level provided separately in the guidelines).

- Category III activities that require review and approval of competent authority before commencement include experiments involving toxin gene cloning, cloning of genes for vaccine production, and other experiments as mentioned in the guidelines.

The levels of risk and classification of the organisms within these categories have been defined in these guidelines. Appropriate practices, equipment and facilities necessary for safeguards in handling organisms, plants and animals in various risk groups have been recommended. The guidelines employ the concept of physical and biological containment and the principle of good laboratory practices.

For containment facilities and biosafety practices, recommendations in the WHO laboratory safety manual on genetic engineering techniques involving microorganisms of different risk groups have been incorporated therein.

The guidelines categorize experiments beyond 20 liters capacity for research and industrial purposes as large-scale. In case of cultivation of plants, this limit is 20 acres area. The guidelines give principles of occupational safety and hygiene for large-scale practice and containment. Safety criteria have also been defined in the guidelines. Physical containment conditions that should be ensured for large-scale experiments and production have been specified in the guidelines.

For release to the environment the guidelines specify appropriate containment facilities depending on the type of organisms handled and potential risks involved. The guidelines require the interested party to evaluate rDNA modified organism for potential risk prior to application in agriculture and environment like properties of the organism, possible interaction with other disease causing agents and the infected wild plant species. An independent review of potential risks should be conducted on a case-to-case basis. A copy of the guidelines can be accessed at http://www.dbtindia.nic.in.

Guidelines for Research in Transgenic Plants, 1998:

In 1998, DBT brought out separate guidelines for carrying out research in transgenic plants called the Revised Guidelines for Research in Transgenic Plants. These also include the guidelines for toxicity and allergenicity of transgenic seeds, plants and plant parts.

These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research purposes.

Genetic engineering experiments on plants have been grouped under three categories.

- Category I includes routine cloning of defined genes, defined non-coding stretches of DNA and open reading frames in defined genes in E. coli or other bacterial/fungal hosts which are generally considered as safe to human, animals and plants.
- Category II experiments include experiments carried out in lab and green house/net house using defined DNA fragments non-pathogenic to human and animals for genetic transformation of plants, both model species and crop species.
- Category III includes experiments having high risk where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, plants and animals by

dispersing new genetic traits the effects of which cannot be judged precisely. This also includes experiments having risks mentioned above conducted in green houses and open field conditions.

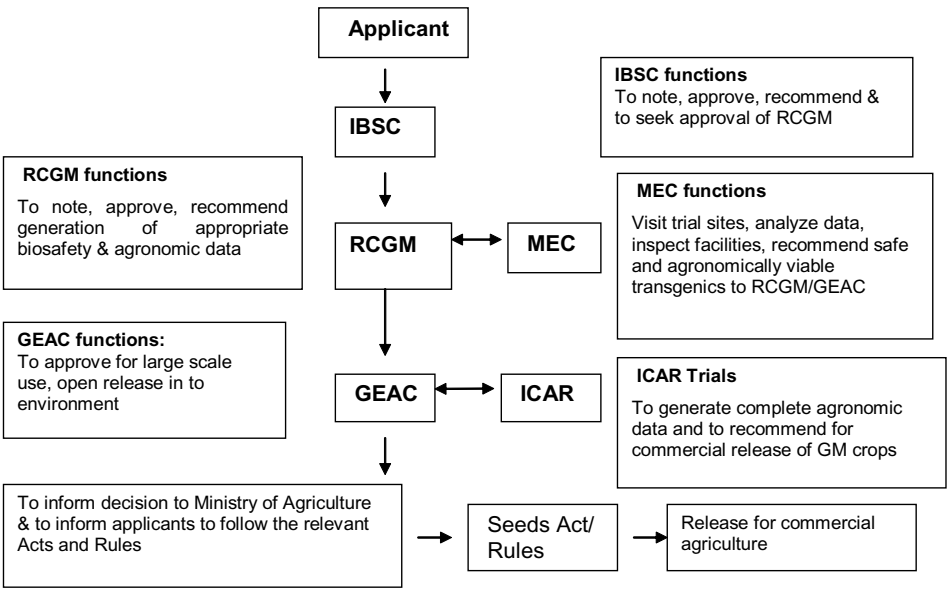
To monitor the impact of transgenic plants on the environment over a period of time, a special Monitoring cum Evaluation Committee (MEC) has been set up by the RCGM. The committee undertakes field visits at the experimental sites and suggests remedial measures to adjust the trial design, if required, based on the on-the-spot situation. This committee also collects and reviews information on the comparative agronomic advantages of the transgenic plants and advises the RCGM on the risks and benefits from the use of transgenic plants under evaluation.

The guidelines include complete design of a contained green house suitable for conducting research with transgenic plants. Besides, it provides the basis for generating food safety information on transgenic plants and plant parts.

A copy of the guidelines can be accessed at http://www.dbtindia.nic.in.

Seed Policy, 2002

The Seed Policy 2002 issued by Ministry of Agriculture, Government of India contains a separate section (No. 6) on transgenic plant varieties. It has been stated that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations on guidelines of the EPA, 1986. Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986. Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released in the market. After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act. After commercial release of a



transgenic plant variety, its performance in the field, will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.

It has also been mentioned that transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation. A copy of seed policy can be accessed at http://agricoop.nic.in/seedpolicy.htm.

The procedures involved in the approval of GM crops in India are summarized in the following flow chart:

Food Control System

As the Government has the prime responsibility for the establishment and operation of national food safety programs and quality control systems that must ensure safe and wholesome food to meet the nutritional needs of consumers and do not endanger the consumer's health through chemical, biological or other contaminants, it has set up a 'food control system' that includes the national, state and municipal organizations involved in either the regulation, inspection or analysis of food and agricultural products, together with their supporting legislation and rules and compliance activities.

Prevention of Food Adulteration Act:

In India, the Ministry of Health and Family Welfare (MOH&FW) in the Central Government is the nodal Ministry for ensuring the quality and safety of food marketed in the country. A comprehensive legislation called the Prevention of Food Adulteration Act (PFA Act) has been enacted in 1954, which came into effect from June 1, 1955, with the objective of assuring the quality and safety of food as well as to encourage fair trade practices.

The Act has been amended a number of times to make the provisions more practical and consumer-oriented. This Act is the basic statute intended to protect the consumer from the supply of adulterated food and it specifies food safety and quality standards for consumer protection. The definition of 'adulteration' includes the addition of cheaper or inferior substances to deceive the consumer and the presence of contaminants, which may make the food, unfit for human consumption. The objective of this legislation is, therefore, not only to ensure pure and wholesome food to the consumers, but also to prevent fraud or deception. It lays down that no person shall manufacture, sale, store, or distribute adulterated or misbranded food products not conforming to the standards laid down in the rules. The provisions apply to imported food as well as to food produced in India.

The overall infrastructure includes the local food inspectors, the public analysts, both at the municipal and state levels, their laboratory facilities, the four central food laboratories designated under the PFA Act and the central PFA Division in the MOH&FW in New Delhi. The central PFA Division is also designated as the National Codex Contact Point for India.

The responsibilities of the PFA cell in food control system are as follows:

1. Enhance the availability of safe and wholesome food.
2. Consumer protection from deception, fraud and food-borne diseases.
3. Risk analysis, risk management and risk communication.

4. Ensure safety of genetically modified food.
5. Enhance the involvement of NGOs and Home Science Institutes.
6. Educational authorities to ensure better consumer protection.
7. Promote a voluntary management system, the Code of Ethics, through principles of GMPs and the HACCP.

Regarding laboratory facilities under the PFA Act, there are approximately 80 food laboratories in the country undertaking the analysis of samples of food articles under the provisions of the PFA Act, out of which 13 are managed by local bodies (municipalities). These are known as Public Analyst Laboratories. In addition, there are four Central Food Laboratories notified under the PFA Act to carry out an analysis of appeal samples whenever the report of the public analyst is challenged in the court of law. These are situated in Kolkata, Ghaziabad, Mysore and Pune. These laboratories analyze the bulk of the samples under the PFA Act.

Regarding inspection and certification procedures for imported food, Section 5 of the PFA Act, 1954, prohibits the import of the following articles of food:

1. Food which is adulterated.
2. Food which is misbranded.
3. Food which contravenes any other provision of the PFA Act or any Rule.

The important provisions which are required to be followed essentially while importing/clearing the food products are:

1. Authorized officers to check the imported food products.
2. Section 6 of the PFA Act, 1954, authorizes the custom collector to check the imported food products.
3. The authorized officer, on suspicion, may detain any imported food product.
4. He will send the samples of the detained product to the Central Food Laboratory for analysis.

Imported food is inspected at the ports of entry by personnel of the Collectorate of Customs. If necessary, samples are further tested in the laboratories designated/notified for this purpose by the Ministry of Health and Family Welfare to verify the compliance with the requirements stipulated under the PFA Act, 1954 and Rules.

With a view to streamline the checking of imported food products, the Government of India has issued various instructions from time-to-time. Various departments of the Government of India, including Health, Revenue, Commerce and the Directorate General of Foreign Trade, have initiated several steps to streamline the checking of imported food.

Regarding procedures for food export inspection and certification, the Export Inspection Council (EIC) of the Ministry of Commerce and Industry is the official government inspection body for certifying food products for export. It carries out the inspection of several food articles such as marine, milk products, meat, honey, poultry, Basmati rice, black pepper and cashew meant for export.

The Food Safety Standards Bill, 2005

The Ministry of Food Processing Industries has introduced "The Food Safety and Standards Bill, 2005" which seeks to consolidate the laws relating to food and establish the "Food Safety and Standards Authority of India".

This step has been taken keeping in view the fact that presently eight ministries are administering food laws in diverse ways which has been found to be not conducive to the growth of the food processing industry.

The proposed "Food Safety and Standards Authority of India" would facilitate scientific standards for food articles and regulate their manufacture, storage, distribution, sale and import to ensure the availability of safe and wholesome food for human consumption. The authority will consist of members from various ministries, and representatives from State Governments, the food industry, consumer organisations and even farmers' organisations. Scientific committees and panels will assist it in fixing standards, while a Central Advisory Committee will prioritise the work.

The enforcement of the legislation will be through the State Commissioner for Food Safety and Panchayati Raj/ municipal bodies. The Food Bill not only incorporates the salient provisions of the Prevention of Food Adulteration (PFA) Act, but is also based on international legislations, instrumentalities and Codex Alimentaries Commission (related to food safety norms).

The proposed body will regulate the limits on the usage of food additives, crop contaminants, pesticide residues, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances.

It will formulate mechanisms and guidelines for the accreditation of bodies engaged in the certification of a food safety management system for the food business. It will also set up food labelling standards, including claims on health, nutrition and special dietary uses. The Bill seeks to regulate nutraceuticals and dietary supplements. It has stressed on proper labelling and has said that information should not be misleading. Imposing restrictions on advertising, it specified, "No advertisement shall be made of any food, which is misleading or contravenous to the provisions of this Act." The Bill has imposed safeguards on imports of food products. No person shall be allowed to import unsafe, misbranded or sub-standard food and importing would require a licence. Stringent penalties have also been proposed in the Bill.

The Bill has also mooted the establishment of a Food Safety Appellate Tribunal to hear the appeals of disputed parties.

The "genetically modified food" has been defined in the Bill as the food, which is produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating or having adequate human intervention or both. Techniques of Genetic Engineering or modification include, but are not limited to recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion, addition and doubling.

There is a provision for a separate scientific panel on genetically modified organisms. As per the provisions of the Bill, no person shall manufacture, process, export, import or sell genetically modified articles of food, organic foods, functional foods, neutraceuticals, health supplements *etc.* except in accordance with the regulations made-there for under this Act.

Various Acts/Orders which would stand repealed on commencement of this Act, include the Prevention of Food Adulteration and sections relating to food under the Environmental (Protection) Act, 1986 and the Environment Protection Rules, 1989.

The full text of the Food Safety and Standards Bill, 2005 can be accessed at http://www.mfpi.nic.in.

Overview of Ministries and Departments Involved in Regulation of GM Food

Several central ministries and departments are involved in India's program of food quality and safety and hence each one of them has a role to play in the activities related to GM foods in India. These include:

1. Ministry of Environment and Forest: This ministry holds the Secretariat of the Genetic Engineering Approval Committee, the apex body that gives approval for manufacture, sale, import and export of all GMOs and products thereof including foodstuff, ingredients in foodstuff and additives using genetically modified (GM) organisms or cells.
2. Department of Biotechnology: This department holds the Secretariat of the Review Committee on Genetically Modification that gives approval for research and small scale field trials involving GMOs and products thereof. It also interacts with the Institutional Biosafety Committees (IBSCs) set up in all organizations undertaking activities involves GMOs.
3. Department of Health in the Ministry of Health and Family Welfare: Department of Health is responsible for implementation of the PFA Act under which the quality and safety of food is regulated. The Directorate General of Health Services has also been designed as the nodal Ministry with the Codex Alimentarious Commission.
4. The Indian Council of Medical Research (ICMR) is the apex body in India for the formulation, coordination and promotion of biomedical research under the Ministry of Health and Family Welfare. ICMR acts as an advisory body for MoHFW on various issues including GM foods.
5. Ministry of Agriculture: Ministry of Agriculture is the nodal ministry for agriculture growth in the country. It comprises of three Departments viz. Department of Agriculture and Cooperation, Department of Agricultural Research & Education/ Indian Council of Agricultural Research (ICAR) and Department of Animal Husbandry & Dairying. The officials from ICAR and Ministry of Agriculture have an important role to play in the approval of GM crops as per Seed Policy, 2002.
6. Ministry of Commerce and Industry: This ministry is responsible for the formulation of the Export and Import (EXIM) Policy in the country. It implements a legislation prescribing a system of quality control and inspection for both export/import.
7. Ministry of Food Processing Industries: This ministry is responsible for the formulation of policy for the healthy growth of the food processing industries and provides developmental support to these industries. It encourages research and developmental activities and assists the industries in active participation in the laying down of food standards as well as their harmonization with international standards. This ministry is also the licensing authority for processed fruits and vegetable industries.

Research Institutions:

1. National Institute of Nutrition (NIN), Hyderabad is India's premier nutrition research institute working under the aegis of Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Government of India. ICMR proposes to set up a GM Food Safety Cell in NIN.
2. Central Food Technological Research Institute (CFTRI), Mysore is a premier institute working under Council of Scientific and Industrial Research. Its multi-disciplinary spread (across 16 R&D departments) covers almost every field of scientific investigation connected with foods and their relationship to humans, including the cutting edge area of food biotechnology.

3. The Defence Food Research Laboratory (DFRL), Mysore under the aegis of Defence Research Development Organization (DRDO) caters to the varied food challenges for military and para-military forces. This laboratory is engaged in research & development of traditional indigenous foods and their preservation
4. Industrial Toxicology Research Center (ITRC), Lucknow a constituent laboratory of Council of Scientific & Industrial Research (CSIR) is dedicated to provide health safeguards to industrial and agricultural workers through its rich knowledgebase, created painstakingly over the years.
5. National Bureau of Plant Genetic Resources (NBPGR), New Delhi is the nodal organisation in India for collecting, introducing, evaluating and conserving plant genetic resources. NBPGR is also responsible for plant quarantine activities relating to exotic samples.
6. Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad is an autonomous institution supported by the DBT and is engaged in providing services for DNA fingerprinting and diagnostics in addition to basic research in related areas. DNA fingerprinting services are also being provided to various government and law enforcement agencies.

Status of Development of GM Food Crops in India

Fourteen food crops have been approved for contained limited field trials in India (Table 1). The trials are being conducted by both public and private sector institutions and the target traits include insect resistance, herbicide tolerance, viral and fungal disease resistance and stress tolerance.

Table 1: Transgenic crops under development and field trials in 2005.

S. No.	Crop	Organization	Gene
1.	Brinjal	MAHYCO, Mumbai Sungrow Seeds Ltd., New Delhi IARI, New Delhi	cry1Ac cry1Ac cry1F
2.	Cabbage	Sungrow Seeds Ltd., New Delhi	cry1Ac
3.	Cauliflower	Sungrow Seeds Ltd., New Delhi	cry1Ac cry1Ac
4.	Corn	Monsanto, Mumbai Metahelix Life Sciences, Bangalore	cry1Ab Modified Mu-element (Turbo-Mu)
5.	Cotton	Ajeet Seeds, Aurangabad Ankur Seeds P. Ltd., Nagpur Bioseed Research India Pvt Ltd, Hyd Emergent Genetics India P. Ltd, Hyd Ganga Kaveri Seeds Ltd, Hyderabad Green Gold Seeds Ltd, Aurangabad JK Agri Genetics, Hyderabad Kaveri Seeds Co. P. Ltd, S'bad Krishidhan Seeds, Jalna Mahyco, Mumbai Metahelix Life Sciences, Bangalore Nandi Seeds Pvt. Ltd Mehbubnagar Namdhari Seeds Pvt. Ltd, Bangalore Nath Seeds, Aurangabad Nuziveedu Seeds, Hyderabad Prabhat Agri Biotech Ltd. Hyderabad Pravardhan Seeds Pvt. Ltd Hyderabad Proagro Seeds Co. Ltd Hyderabad Rasi Seeds Ltd., Attur Syngenta India Ltd., Pune Tulsi Seeds, Guntur UAS, Dharwad Vibha Agrotech Ltd. Hyderabad Vikki's Agrotech, Hyderabad Vikram Seeds Ltd, Ahmedabad Zuari Seeds Ltd. Bangalore	cry1Ac, cryX cry1Ac, cryX cry1Ac, cryX cry1Ac, cryX cry1Ac GFM cry1Aa cry1Ac cry1Ac cry1Ac, cryX cryX cry1Ac cry1Ac cry1Ac GFM cry1Aa cry1Ac, cryX cry1Ac cry1Ac cry1Ac cryX Vip-3A cry1Ac, cryX cry1Ac cry1Ac cry1Ac cry1Ac GFM cry1Aa
6.	Groundnut	ICRISAT, Hyderabad	Coat protein of IPCV Nucleo Capsid Protein of PBNV
7.	Mustard	UDSC, New Delhi	*barnase & barstar*

Table 1: Transgenic crops under development and field trials in 2005.

S. No.	Crop	Organization	Gene
8.	Okra	MAHYCO, Mumbai	cry1Ac
9.	Pigeonpea	ICRISAT, Hyderabad	cry1Ac
10.	Rice	DIARI, New Delhi Mahyco, Mumbai Metahelix Life Sciences, Bangalore	cry1Ac, cry1Aa + cry1B cry1Ac NHX gene
11.	Tomato	IARI, New Delhi Mahyco, Mumbai	antisense replicase gene of tomato leaf curl virus cry1Ac

Source: Department of Biotechnology, Government of India

Labeling Issues

India, along with a number of other countries, has supported the mandatory labeling of GM food by Codex.

Out of the two options under discussion by Codex *i.e.* Option 1 requires labeling when the products obtained through biotechnology differ significantly from the corresponding food as regards the composition, nutritional value or intended use and Option 2 require the declaration of the method of production for food and ingredients composed of or containing genetically modified/engineered organisms and food or food ingredients produced from, but not containing, genetically modified/engineered organisms if they contain protein or DNA resulting from gene technology or differ significantly from the corresponding food.

The labeling of food derived from biotechnology is a major issue for India as its delegation at the CCFL has been seeking to achieve mandatory labeling as set out in Option 2. However, Option 2 has also raised a number of issues of concern including the enforcement, methodology, economic cost, consumer perception and difficulties likely to be faced.

Annex II

PROGRAMME

REGISTRATION : **9.00 A.M. – 9.30 A.M.**

INAUGURAL/OPENING SESSION : **9.30 a.m. – 10.00 a.m.**

Welcome : **Dr. Vasantha Muthuswamy,** Senior Deputy Director General, Indian Council of Medical Research

Address : **Dr. Morven A. McLean,** President AGBIOS Inc., Canada

Address : **Dr. S.R. Nair,** Managing Director, Biotech Consortium India Limited

Address : **Ms. Rita Teaotia,** Joint Secretary and **Dr. S.R. Gupta,** Joint Drug Controller General of India, Ministry of Health and Family Welfare

Address : **Shri A.N.P. Sinha,** Joint Secretary, Ministry of Food Processing Industries

Address : **Shri Desh Deepak Verma,** Joint Secretary, Ministry of Environment & Forests

Vote of Thanks : **Dr. G.S. Toteja,** Deputy Director General, Indian Council of Medical Research

Tea: 10.00 A.M. – 10.30 A.M.

Technical Session I: The Regulation of GM Foods : **10.30 A.M. – 1.00 P.M.**

Chairperson : **Shri A.N.P. Sinha,** Joint Secretary, Ministry of Food Processing Industries

10.30 Regulating GM Foods: A Global Snapshot : **Dr. Morven A. McLean,** President, AGBIOS Inc., Canada

11.00 Regulating GM Foods in India : **Dr. T.V. Ramanaiah,** Director, Department of Biotechnology

11.30 **Dr. S.R. Gupta,** Joint DCGI, Ministry of Health

12.00 Discussion and Q&A

Lunch: 13.00 P.M. – 14.00 P.M.

	Technical Session II: Key Elements in the Safety Assessment of GM Foods	:	**14.00 P.M. – 17.30 P.M.**
	Chairpersons	:	▭ **Dr. B. Sivakumar,** Director, National Institute of Nutrition
			▭ **Dr. K.K. Tripathi,** Advisor, Department of Biotechnology
14.00	The Work of the Codex Alimentarius Commission	:	▭ **Mr. Patrick Deboyser,** Minister-Counsellor (Health & Food Safety), EC
14.40			▭ **Dr. D. Chattopadhya,** Member Secretary, Shadow Committee on GM Foods of National Codex Committee of India and ADG(PFA), DGHS, Ministry of Health and Family Welfare
15.00	Allergenicity and GM Foods	:	▭ **Dr. Richard E. Goodman,** University of Nebraska Lincoln, USA
15.30			▭ **Dr. Naveen Arora,** Institute of Genomics and Integrative Biology
	Tea: 16.00 P.M. – 16.15 P.M		
16.15	Assessing Potential Toxicity	:	▭ **Dr. Willem Seinen,** Institute for Risk Assessment Science IRAS, Netherlands
16.45	Nutritional Assessment of GM Foods	:	▭ **Dr. Ian Munro,** Cantox Health Sciences International, Canada
17.15			▭ **Dr. B. Sivakumar,** Director, National Institute of Nutrition
17.45	**Discussion and Q&A**		
18.30	**Close of Day I**		
	Day 2: September 27, 2005		
	Technical Session III: Public Participation and Consumer Issues	:	**9.30 A.M. – 1.00 P.M.**
	Chairpersons	:	▭ **Shri Chaman Kumar,** Joint Secretary (CK), Department of Child and Women Development
			▭ **Dr. Kamla Krishnaswamy,** Former Director NIN and President, National Nutrition Society of India
09.30	GM Foods and Consumer Acceptance in Asia	:	▭ **Mr. Kelvin Keh,** Asian Food Information Centre, Singapore

10.00	Public Perception of GM Foods in India: Fear and Facts	:	**Dr. Suman Sahai,** Gene Campaign
10.30			**Dr. Sriram Khanna,** Consumer Voice

Tea: 11.00 A.M. – 11.15 A.M.

11.15	Consumer Labelling and Traceability Regimes	:	**Dr. S.R. Rao,** OSD to Minister of Science & Technology
11.45			**Prof. C. Kameswara Rao,** Executive Secretary, Foundation for Biotechnology Awareness And Education

12.15 Discussion and Q&A

Lunch: 13.00 P.M. – 14.00 P.M.

Technical Session IV: Challenges and Opportunities : **14.00 P.M. – 17.30 P.M.**

	Chairpersons	:	**Dr. P.S. Chauhan,** Emeritus Scientist, Department of Biosciences, Bhabha Atomic Research Station
			Dr. Vasantha Muthuswamy, Senior Deputy Director General, Indian Council of Medical Research
14.00	Assessing the Safety of Nutritionally Enhanced GM Foods	:	**Dr. Swapan Datta,** University of Calcutta
14.30			**Dr. Ian Munro,** Cantox Health Sciences International, Canada
15.00	Post-Commercial Monitoring of GM Foods	:	**Dr. Christine M. Bruhn,** Director, Center for Consumer Research, Department Food Science and Technology, University of California, USA

Tea: 15.30 P.M. - 15.45 P.M.

15.45	Challenges in Decision Making: Public Consultation in Decision Making in Australia & New Zealand	:	**Mrs. Lydia Buchtmann,** Food Standards Australia New Zealand
16.15	Challenges in Decision Making: The Indian Context	:	**Dr. G.S. Toteja,** Deputy Director General, Indian Council of Medical Research

16.45 Discussion and Q&A

17.30 Close of Conference

List of Participants

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