Report of the
Task Force on Application of
Agricultural Biotechnology

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PREFACE

The elucidation of the double-helix structure of the Deoxy ribose Nucleic Acid (DNA) molecule in 1953 by Drs. James Watson, Francis Crick, Maurice William and Franklin Rosalind marked the beginning of what is now known as *the new genetics*. Research during the last 51 years in the fields of molecular genetics and recombinant DNA technology has opened up new opportunities in agriculture, medicine, industry and environment protection. The ability to move genes across sexual barriers has led to heightened interest in the conservation and sustainable and equitable use of biodiversity, since biodiversity is the feedstock for plant, animal and microbial breeding enterprises.

Considerable advances have been made during the last 25 years in taking advantage of the new genetics in the areas of medical research, production of vaccines, sero-diagnostics and pharmaceuticals for human and farm animal health care. The production of novel bioremediation agents as for example, the development of a new *Pseudomonas* strain for clearing oil spills in oceans, rivers and lakes by Dr. Anand Chakraborty, is also receiving priority attention because of increasing environmental and water pollution.

There has also been substantial progress in agriculture, particularly in the area of crop improvement through the use of molecular marker assisted breeding, functional genomics, and recombinant DNA technology. A wide range of crop varieties containing novel genetic combinations are now being cultivated in USA, Canada, China, Argentina and several other countries. A strain of cotton containing the *Bacillus thuringiensis* gene (Bt Cotton), which has resistance to boll woms, is now under cultivation in India based on both official and unofficial (illegal) releases.

There is little doubt that the new genetics has opened up uncommon opportunities for enhancing the productivity, profitability, sustainability and stability of major cropping systems. It has also created scope for developing crop varieties tolerant/resistant to biotic and abiotic stresses through an appropriate blend of Mendelian and molecular breeding techniques. It has led to the possibility of undertaking anticipatory breeding to meet potential changes in temperature, precipitation and sea level as a result of global warming. There are new opportunities for fostering pre-breeding and farmer-participatory breeding methods in order to continue the merits of genetic efficiency with genetic diversity.

While the benefits are clear, there are also many risks when we enter the territory of the unknown and unexplored. Such risks relate to potential harm to the environment and to human and animal health. There are also equity and ownership issues in relation to biotechnological processes and products. The following issues are the major areas of concern to the public and policy maker.

a. What is inherently wrong with the technology?
   Is the science itself safe, as for example, the use of selectable marker genes conferring antibiotic or herbicide resistance?
b. Who controls the technology?

Will it be largely in the private sector? If the technology is largely in the hands of the private sector, the overriding motive behind the choice of research problems will be private profit and not necessarily public good. If this happens, "orphans will remain orphans" with reference to choice of research priorities. Crops being cultivated in rainfed, marginal and fragile environments, which are crying for scientific attention, may continue to remain neglected.

c. Who will have access to the products of biotechnology?
   If the products arising from recombinant DNA technology are all covered by intellectual property rights (IPR), then the technology will result in social exclusion and will lead to a further enlargement of the rich-poor divide in villages.

d. What are the major biosafety issues?
   There are serious concerns about the short and long term impact of GMOs on the environment, biodiversity and human and animal health.

Thus, there is need for transparent and truthful risk-benefit analysis in relation to GMOs, on a case-by-case basis. In the coming decades, Indian farm women and men will have to produce more food and other agricultural commodities to meet home needs and to take advantage of export opportunities, under conditions of diminishing per capita availability of arable land and irrigation water and expanding abiotic and biotic stresses. The enlargement of the gene pool with which breeders work will be necessary to meet these challenges. Recombinant DNA technology provides breeders with a powerful tool for enlarging the genetic base of crop varieties and to pyramid genes for a wide range of economically important traits. The safe and responsible use of biotechnology will enlarge our capacity to meet the challenges ahead, including those caused by climate change. At the international level, the Cartagena Protocol on Biosafety provides a framework for risk assessment and aversion. At the national level, there is need for a regulatory mechanism, which inspires public, political and professional confidence.

The Union Ministry of Agriculture set up in May 2003, a Task Force to consider the above issues and offer suggestions on how Indian farm women and men can derive benefit from the new genetics, without taking unacceptable environmental, health and social risks.

The Task Force felt that **the process** of preparing recommendations is as important **as the product**. Hence, multi-stakeholder consultations were held, including with mass media representatives. Agriculture is a state subject in our country and hence considerable importance was attached to hearing and receiving the views and suggestions of State Governments. The written communications received from State Governments are included in Part B of the report, along with the reports submitted by the five Working Groups set up by the Task Force. These documents provided important inputs in the preparation of the recommendations. They are however, reports of the Working Groups and not of the Task Force.

Agriculture comprising crop and animal husbandary, fisheries, forestry and agro-processing constitutes the backbone of our food, livelihood and ecological security systems. In addition, it is fundamental to national sovereignty and to fighting the famine of jobs. Hence, it will be no exaggeration to say that "if agriculture goes wrong, nothing else will have a chance to go right". **The Task Force therefore felt that the bottom line for any biotechnology regulatory policy should be the safety of the environment, the well being of farming families, the ecological and economic sustainability of farming systems, the health and nutrition security of consumers, safeguarding of home and external trade, and the biosecurity of our nation.**

Consumers all over the world are concerned with potential health risks associated with GM foods. The nature and extent of concerns vary from country to country, depending upon the confidence the public have in the food and environmental safety regulation systems in place. For example, the Food and Drug Administration (FDA) of the United States attracts greater consumer confidence than the counterpart systems in Europe. The situation in India is similar to that in Europe. Public regard and satisfaction for the regulatory systems currently in place in the field of agricultural biotechnology are, to say the least, low.

In contrast to GM crops, 'life-saving' and 'life-enhancing' GM pharmaceutical products seem to have more ready acceptance. The socio-ethical perspective often defines the public risk perceptions. Bio-ethical norms are as important as biosafety regulations in the case of medical and pharmaceutical biotechnology. The ethical, social, gender equity and economic concerns will have to be considered along with the environmental and health safety aspects. To perform all these tasks in an objective, transparent and trustworthy mode, there is an urgent need for an autonomous, statutory and professionally led **National Biotechnology Regulatory Authority**. Such an Authority should be headed by an eminent expert well versed in the science of risk assessment and management, as well as risk communication. The Members of such a Biotechnology Regulatory Authority of India should be leading authorities in the areas of environment protection, human and animal health, ethics, gender and social equity and trade and international protocols.

The National Biotechnology Regulatory Authority could have a common Chair but two separate wings – one dealing with food and agricultural biotechnology, and the other with medical and pharmaceutical biotechnology. The mandate of our Task Force was confined to agricultural biotechnology and hence our recommendations relate only to the field of crop and animal husbandry, forestry and fisheries.

The setting up an autonomous, statutory and professionally-led National Biotechnology Regulatory Authority is a must for our country if we are to derive full benefit from this fast growing area of science, including fields like functional genomics, proteomics, bio-informatics and nano-biotechnology, in a safe and responsible manner.
Pending the establishment of a National Biotechnology Authority, with a specialized wing for Agricultural Biotechnology, the Task Force has offered suggestions for streamlining and improving the regulatory procedures now in force. These suggestions

may be given effect to immediately, so that the on-going regulatory work continues without interruption.

As mentioned earlier, agriculture is a State subject and new crop varieties are released regularly by the State Variety Release Committees. Therefore, there should be counter-part bodies in all the States and Union Territories to liase with the proposed National Biotechnology Regulatory Authority. For this purpose State Governments could set up a Biotechnology Regulatory Advisory Board at the State level, and a Biotechnology Risk Assessment and Communication Committee at the district level (this will be needed only in districts where GM crops are recommended for cultivation). The State Agricultural and Veterinary Universities should be fully involved in all the aspects connected with the evaluation, risk assessment, monitoring and extension advice relating to GMOs at the State, district and village level. They should spearhead a genetic literacy movement in villages, including information on Farmers' Rights under the Protection of Plant Varieties and Farmers' Right Act (2001).

Thus there will be a continuum of communication and common wavelength in understanding benefits and risks from the village to the national level

Progress in understanding the scientific and environmental issues relating to the safe and responsible use of biotechnology is extremely rapid. Therefore, the regulatory principles and procedures will have to be reviewed periodically by the proposed National Biotechnology Regulatory Authority so that they are based on advances in scientific knowledge.

The gratitude of the Task Force Members go to the past (Shri RCA Jain) and current (Smt Radha Singh) Secretaries of Agriculture, Shri Asish Bahaguna, Member-Secretary and Shri Sanjay Vikram Singh, Deputy Secretary, Department of Agriculture and Cooperation for their invaluable assistance in the work of the Task Force.

I thank the Union Minister for Agriculture for giving me the privilege of chairing this Task Force entrusted with the responsibility of offering recommendations in an area of supreme importance to the shaping of our agricultural future.

Chennai
26 May 2004

M S Swaminathan
Chairman
Agricultural Biotechnology Task Force

Executive Summary

1. India is rich in bioresources and biotechnology offers opportunities for converting our biological wealth into economic wealth and new employment opportunities on an environmentally and socially sustainable basis. Our agriculture now faces the challenge of having to produce more farm commodities for our growing human and farm animal populations under conditions of diminishing per capita arable land and irrigation water resources, and expanding biotic and abiotic stresses. Further, factor productivity has to be enhanced and quality and food safety have to be improved if our agriculture is to be globally competitive. To achieve these objectives, the nearly 110 million farm families of our country, most of whom own 1 or 2 hectares of land or less will have to be assisted with the best available technologies such as biotechnology and information, space, nuclear, renewable energy, and precision farming technologies and scientific organic farming methods. In order to specifically address agro-biotechnological applications in improving the productivity, profitability, sustainability and stability of the major farming systems of the country in an environmentally safe manner, the Department of Agriculture, Government of India, set up in May, 2003 a Task Force under the Chairmanship of Prof M S Swaminathan. The Task Force examined both the potentials and problems associated with biotechnology applications, with particular reference to genetically modified crops arising from the use of recombinant-DNA technology. The recommendations of the Task Force are contained in this Report.

2. The Task Force kept the following as its basic guiding principle

'The bottom line of our national agricultural biotechnology policy should be the economic well being of farm families, food security of the nation, health security of the consumer, protection of the environment and the security of our national and international trade in farm commodities'.

3. The long-term policy on Biotechnology Applications in Agriculture should aim to provide direction to research and development in relation to priorities, based on social, economic, ecological, ethical and gender equity issues, to devise a system for commercialization of transgenics/GM products, and to formulate a clear policy on GM food and feed in the country. The transgenic approach should be considered as complementary and resorted to when other options to achieve the desired objectives are either not available or not feasible. High priority should be accorded in transgenic approach to the incorporation of resistance to insect-pests and diseases including viruses and to drought and salinity (i.e. biotic and abiotic stresses). Transgenic research should

not be undertaken in crops/commodities where our international trade may be affected, e.g., Basmati rice, soybean or Darjeeling Tea.

4. The international guidelines set up by the FAO-WHO Codex Commission for assessing and managing the health risks posed by GM foods should be closely followed. These risk analysis guidelines call for safety assessments to be conducted for all GM foods prior to market approval. It will be useful to develop well-defined national food safety guidelines based on the Report of Joint Parliamentary Committee on Pesticide Residues in and Safety Standards for Soft Drinks, Fruit Juice and Other Beverages, Chaired by Shri Sharad Pawar.

5. There are regions in India which represent either primary or secondary centres of genetic diversity in major crops like rice. These areas should be conserved for posterity as **"Agro-biodiversity Sanctuaries"**. A Technical Committee may be constituted by ICAR, NBPGR, DBT, Dept of Agriculture and Ministry of Environment and Forests (Botanical, Zoological and Forest Surveys of India) to develop guidelines for earmarking areas as Agro-biodiversity Sanctuaries and Organic Farming Zones.

6. With regard to application of biotechnology to animal husbandry and fisheries, existing DBT guidelines for rDNA-based vaccines can be used for animal vaccines but the protocol for rDNA-based vaccine needs to be developed on a case-by-case basis. Appropriate mechanisms of safety should be developed for the plant-animal-human food chain. Prioritized target traits in livestock include production of pharmaceutical proteins, enhanced fertility and reproductive performance, improved quality (milk, meat, fiber, eggs) and resistance to diseases so as to reduce drug use.

7. The Government of India may provide about Rs. 1200 crores of additional funds during the remaining 3 years of the Tenth Plan period for the following purposes:

a. The Department of Agriculture may provide approximately Rs. 300 crores to develop and augment capacity building, human resource development, monitoring and surveillance, development of organic farming zones and Agro-biodiversity sanctuaries, initiating a special GMO insurance scheme, public and political understanding about applications of bio-technology in agriculture, training and retraining of extension personnel, and assisting farm and home science graduates to set up agri-clinics and agri-business centers for Agricultural Biotechnology.

b. About Rs. 200 crores may be provided during 2004-07 for venture capital.

c. The strengthening of the regulatory and surveillance mechanisms, including the setting up of a National Biotechnology Regulatory Authority may require about Rs. 150 crores during the next three years.

d. DARE/ICAR, Department of Animal Husbandary and Dairying and DBT may provide an additional Rs. 400 crores to upgrade research infrastructure, undertake human resource development, accelerate progress in research and education relating to biotechnology applications in crop and animal husbandary and inland and marine fisheries, and organize a special All India Coordinated Research Project on GM crops.

e. A provision of Rs. 150 crores may be made for the creation of infrastructure for establishing Ag-biotech Parks, on the model of the one developed by ICRISAT in Hyderabad. Atleast one such park may be established in every State during the next three years in collaboration with NABARD.

8. Biosafety and agronomic evaluations could be done concurrently. However, biosafety assessment should be done on a case-by-case basis. The Task Force has suggested changes in the existing review mechanism for approval of GM crops to prevent avoidable loss of time and promote concurrent biosafety and agronomic performance studies.

9. With rapid growth in R & D efforts in biotechnology, a statutory and autonomous National Biotechnology Regulatory Authority will soon become necessary. The NBRA should have two wings – one for agricultural and food biotechnology, and the other for medical and pharmaceutical biotechnology. NBRA is essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanisms in place in the country. The NBRA should be autonomous and professionally led but could be attached for necessary administrative support to an appropriate Ministry/Department.

10. The Monitoring and Evaluation Committees (MEC) should report to GEAC, which may continue to handle biosafety and environmental safety issues of GM crop candidates until the proposed National Agricultural Biotechnology Regulatory Authority comes into existence.

11. An All India Coordinated Research Project (AICRP) solely for the testing of GM crop varieties should be organized by ICAR with the requisite technical expertise and safety arrangements.

12. Farmers and consumers should have complete information on the benefits and risks associated with GM crops. The evaluation procedure should include farmer participatory assessment, as is the case of non-GM crop varieties. The procedure of transparent evaluation should apply equally to both private and public sector varieties. A special insurance scheme for GM crops may be devised and introduced by the Ministry of Agriculture. An integrated GM Seed-cum-Crop Insurance System will help to ensure that desirable new technologies confer benefits to resource poor small farm families, without undue risks.

13. Pre-breeding to generate novel genetic combinations at Advanced Research Centres, coupled with participatory breeding with farming families will help to de-mystify new technologies and make farm women and men effective partners in biotechnological research.

14. There are uncommon opportunities for facing successfully the current and future challenges faced by farming families through synergy between technology and public policy. There is need to strengthen both our technological capability and public policy framework especially in the areas of regulation, surveillance and monitoring, as well as in the areas of promotion, facilitation and mentoring. This is the pathway to an era of bio-happiness.

PART – A

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I. Introduction

The need for a long-term policy on applications of biotechnology in agriculture has been felt for quite sometime. This subject is, at present, being dealt in three different Ministries/Departments viz. Ministry of Agriculture, Ministry of Environment and Forests and Department of Biotechnology, Ministry of Science and Technology. It is therefore of utmost importance to formulate a long-term policy on agro-biotechnology, which could be used to prepare a blueprint for further action in this regard by the Ministries/Departments concerned.

The legislative framework on agro-biotechnology is provided under the Environment (Protection) Act. The Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Modified Organisms or Cells formulated under the Environment (Protection) Act which is administered by the Ministry of Environment and Forests provides for the following multi-tiered regulatory framework to assess and ensure biosafety of genetically engineered organisms:

(i) The Recombinant DNA Advisory Committee (RDAC) under the Department of Bio-technology to recommend appropriate safety regulations in recombinant research, use and applications.

(ii) The Review Committee on Genetic Manipulation (RCGM) under the Department of Bio-technology to monitor safety related aspects in respect of ongoing research projects and activities involving genetically engineered organisms. The RCGM lays down procedures/regulations regarding research, production, sale, import and use of genetically engineered organisms with a view to ensure environmental safety.

(iii) The Institutional Biosafety Committee (IBSC) to prepare site-specific plans for use of genetically engineered microorganisms.

(iv) The Genetic Engineering Approval Committee (GEAC) under the Ministry Environment and Forests to consider proposals relating to release of genetically engineered organisms into the environment.

(v) The State Bio-technology Coordination Committee (SBCC) to inspect, investigate and take punitive action in case of violations of safety and control measures in the handling of genetically engineered organisms.

(vi) The District Level Committee to monitor safety regulations in installations engaged in the use of genetically modified organisms and their applications in the environment.

The procedures under the Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Modified Organisms or Cells, are lengthy. With accelerated research in the area of agro-biotechnology, a spate of proposals for the commercial release of several transgenic crop varieties is likely to come up for consideration of the GEAC in the future. Hence, It is time that government reviews the existing procedures so that biosafety can be assessed concurrently with agronomic performance. The rigour of the biosafety assessment should not be compromised. The government has also to devise a policy in regard to segregation, traceability and labeling of produce/product, which would arise upon commercial release of transgenic crops. Procedures relating to biotechnology applications are already being reviewed by a Committee under the Chairmanship of Secretary, Environment & Forests in which the representatives of DAC and ICAR are also included. The Ministry of Health is also putting together a paper relating to genetically modified food for consideration of the Committee of Secretaries, which would, probably, also cover the issues of labeling and traceability.

As these committees do not cover applications of biotechnology in agriculture, the Department of Agriculture & Cooperation, set up in May,

2003 a Task Force on Application of Biotechnology in Agriculture under the Chairmanship of Prof M S Swaminathan with the following terms of reference :

i) Formulate a draft long-term policy on applications of biotechnology in agriculture.

ii) Suggest modifications in the existing administrative and procedural arrangements in order to streamline/harmonize decision making under various Ministries/Organizations.

iii) Suggest the future role of Ministry of Agriculture in view of the developments taking place in the field of agriculture biotechnology.

iv) Awareness generation on matters relating to agricultural biotechnology.

2. The order dated 14th May 2003, provides details concerning the setting up of the Task Force and its composition **(Annexure-1)**. The Task Force was asked to submit its recommendation within three months.

3. The first meeting of the Task Force was held on 11th July 2003. A decision was taken in this meeting to expand the Task Force so as to include key stakeholders like other Government Departments, Seed Industry and experts in Animal Sciences. As a result, the Government modified its earlier order regarding the Task Force to include the following as members:

i) Secretary (Health), Ministry of Health & Family Welfare
ii) Secretary, Department of Food
iii) Secretary, Department of Commerce
iv) Dr. Amrita Patel, Chairperson, National Dairy Development Board
v) Dr. Syed E. Hasnain, Director, Centre for DNA Fingerprinting & Diagnostics, Hyderabad.
vi) President, Association of Seed Industry
vii) President, Seed Association of India.

3.1 It was also felt that it would not be possible for the Task Force to submit its Report by mid July 2003 as was envisaged in the initial order in view of the immensity and complexity of the work involved. It was therefore decided to request the Government to allow the Task Force to submit its Report by 31st December 2003. The term was further extended upto 15th February 2004.

3.2 At its first meeting on 11 July 2003, the Task Force also decided to set up Working Groups to prepare base papers for each term of reference, which could be used as the starting point for discussions by the entire Task Force.

3.3 It was also decided that besides developing the long-term policy on the application of agricultural biotechnology, the Task Force would also hold discussions with other stakeholders like Industry (CII, ASSOCHAM, FICCI, etc.), State Government representations, NGOs, and Civil society Organisations, Policy Makers, Mass Media representatives and Farmers' groups so as to incorporate their views into the report of the Task Force.

4. Professor R.B. Singh, Ex-Assistant Director General, FAO also made a presentation on bio-security as a strategy for livelihood security. The presentation made a case for establishment of a National Authority for Bio-security, which would coordinate the use of the latest developments in science to provide for, enhanced and sustained productivity through the development of enabling capacities.

5. The Task Force noted the inability of Dr. (Mrs.) Kiran Mazumdar Shaw, Chairperson, Biocon India to be a member of the Task Force due to her business pre-occupation.

6. Following the decision in the first meeting, the composition of the Task Force was enlarged vide order dated July 28, 2003 and its term was extended upto 31st December 2003 **(Annexure-2)**. Five working groups were constituted. The terms of reference for the Working Groups and names of the Chairperson of the Working Groups were decided as under:

1. "Biotechnology Applications in Agriculture : Developing a long term policy" to be prepared by the by a Working Group Chaired by Prof. V.L. Chopra, President, National Academy of Agricultural Sciences and former DG, ICAR and Secretary, DARE

2. "Role of the Ministry of Agriculture" to be prepared by a Working Group Chaired by Shri R.C.A. Jain, Secretary, Department of Agriculture & Cooperation

3. "Regulatory Procedures in Agriculture" to be prepared by a Working Group under the Chairpersonship of Dr. Manju Sharma, Secretary, Department of Biotechnology

4. "Applications of Biotechnology in Animal Husbandry" to be prepared by a Working Group Chaired by Dr. Amrita Patel, Chairperson, NDDB

5. "Promoting Public Awareness on matters relating to Agricultural Biotechnology in India" to be prepared by Dr. Mangla Rai, Secretary, DARE & DG, ICAR

The base papers prepared by the above Working Groups are included in Part B of this Report. It should be emphasized that these represent only the views of the respective Working Groups.

6.1 The base papers prepared by the five working groups were discussed by the Task Force in its meetings held from time to time. Modifications as suggested on the basis of discussions among members of the Task Force were carried out by various Working Groups. The modified base papers were considered by the Task Force to develop its recommendations. In order to ensure that the recommendations of the

Task Force are based on the views held by major stakeholders, Task Force members had detailed discussions with representatives of farmers, NGOs, Associations of Seed Industry, Association of Industry, representatives of the State Governments and representatives of media. Written submissions were also made by some stakeholders, particularly, State Governments. They are included in Part B of this Report.

7. The Task Force held 11 meetings. The calendar of the meetings and the subjects discussed in those meetings are given in **Annexure-3**. Part 'A' of the report comprises of the Chairman's Preface, Executive Summary, Terms of Reference and Composition of the Task Force, and the Recommendations of the Task Force. Part 'B' comprises of Reports of the working groups addressing specific topics and submission made by various states and stakeholders.

II. Application of Biotechnology in Agriculture

1 Agriculture comprising crop and animal husbandry, fisheries, agro-forestry and agro-processing is the backbone of our national food security and rural livelihood security systems. There are about 110 million operational holdings in the country. The smaller the farm, the greater is the need for higher productivity and marketable surplus, so that the family can derive some cash income. Also, our human population is predominantly young. Youth can be attracted and retained in farming only if farming becomes intellectually satisfying and economically rewarding. This will call for a technological upgrading of our agriculture.

1.1 India is a mega-biodiversity area. Biodiversity constitutes the feedstock of the biotechnology industry. India is also endowed with a rich institutional infrastructure in the form of National and State research institutes, Agricultural, Veterinary, Rural, Women's and general Universities and a network of Krishi Vigyan Kendras (KVKs). Private sector research, particularly in the area of breeding and seed production, is fast expanding. India has already attained a position of leadership in information and communication technology, space technology and medical biotechnology.

1.2 Biotechnology provides an opportunity to convert bioresources into economic wealth. This has to be done in a manner that there is no adverse impact either on the environment or on human and animal health. *The bottom line of our national agricultural biotechnology policy should be the economic well being of farm families, food security of the nation, health security of the consumer, protection of the environment and the security of our national and international trade in farm commodities.* Recommendations of the Task Force are based on these considerations.

1.3 Infusion of new technology is necessary to maintain our agricultural enterprise competitive and remunerative. Modern science of biotechnology is relevant to various areas of agriculture including crops, animals, fisheries and agro-forestry and agro-processing. There are myriad applications of biotechnology in agriculture such as:

- Generation of transgenic crops/animals/agro-forestry plants/ microbes with improved traits
- Use of molecular markers to (i) tag genes of interest, (ii) accelerate breeding through marker assisted selection, and (iii) undertake fingerprinting of cultivars, landraces, germplasm stocks
- DNA-based diagnostics to monitor/control /manage/ eradicate pests and pathogens of crops, farm animals and fish
- Biotech-derived drugs/antibiotics/vaccines for animal husbandry and fisheries
- Assessment and monitoring of bio-resource diversity
- Plant tissue culture for large-scale multiplication of elite/disease-free planting material
- Embryo culture/transfer/cloning technology for animal breeding
- Feed biotechnology for efficient use of crop residues and oil cakes
- Food biotechnology
- Bioremediation of pollution in ground water and other effluents.
- Functional Genomics, Proteomics and Bioinformatics

In additional the Science of Nano-biotechnology is making rapid progress.

1.4 A long-term policy on Biotechnology Applications in Agriculture should therefore aim at:

- Providing direction to research and development in relation to priorities, based on social, economic, ecological, ethical and equity issues.
- Devising a system for commercialization of transgenics/GM products, and
- Developing a clear policy on GM food and feed in the country

1.5 The long-term policy should also take into account the need and relevance of the technology to agriculture and should be in tune with and derived from the National Policy on Agriculture, the overall goals of which are:

- Increasing productivity, profitability, quality and total agricultural output
- Promoting environmental sustainability through natural resource conservation and enhancement
- Improving factor productivity in order to reduce the cost of production and enhance net earning from marginal and small holdings
- Ensuring food and nutrition security
- Generating employment, reducing gender and social inequality and regional imbalances in agricultural growth
- Enhancing agricultural competitiveness in relation to global standards
- Strengthening national capability in facing the potential adverse impact of climate change and sea level rise.

1.6 Since there is public, political and professional concern about transgenics with reference to their short and long term impacts on human health and the environment, their testing, evaluation and

approval have to be stringent, elaborate and science-based. The general approach in this respect, therefore, should be that:

- Biotech applications, which do not involve transgenics such as biopesticides, biofertilizers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas
- Transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible
- High priority should be accorded in transgenic approach to the incorporation of resistance to insect-pests and diseases including viruses and to drought and salinity (i.e. biotic and abiotic stresses)
- Transgenic research should not be undertaken in crops/commodities where our international trade may be affected, e.g., Basmati rice, soybean or Darjeeling Tea. Wheat exporting countries like Canada and USA are abandoning their programmes for breeding transgenic wheat varieties hybrids.
- The international guidelines being set up by the FAO-WHO Codex Commission for assessing and managing the health risks posed by GM foods should be closely followed. These risk analysis guidelines call for safety assessments to be conducted for all GM foods prior to market approval.

1.7 In addition, core information about gene exchange taking place among modern cultivars, traditional varieties and wild relatives should be gathered to assess concerns of transgene escape and establishment. Data should also be gathered on the impact of transgenics on biodiversity in crop fields, as has been done on an extensive scale in the United Kingdom.

1.8 Information emerging from genomics especially genome sequencing of model plants and other organisms should be used for allele mining from other related species.

2. Application of Biotechnology in Animal Husbandry and Fishery Sectors:

2.1 Farm animals in general are less amenable to transgenic development and as such the development of transgenics has not reached a significant stage. However, transgenic animals have been internationally developed for expression of human proteins for therapeutic use.

2.2 Despite an acute shortage of trained manpower, animal Science Research Centres are developing capacity in the area of embryo biotechnology, such as production and transfer of embryos in livestock.

2.3 Though the existing DBT guidelines for rDNA-based vaccines can be used for animal vaccines, the protocol for rDNA-based vaccine needs to be developed on a case-by-case basis. Additionally, the tests for the presence of tissue-specific distribution of the expressed product and its characterization need to be included.

2.4 Delivery system for plant based recombinant edible/injectable vaccines to the farmers need to be regulated taking into consideration the requirement of storage, in terms of temperature and other physical parameters of the edible plant including its transportation etc. Since no such regulatory mechanism is available at present, this aspect needs deliberation and early decision by the Agricultural wing of the proposed National Biotechnology Regulatory Authority.

2.5 The effects of recombinant vaccines administered to farm animals on human health need to be analysed, since human beings consume food and milk of animal origin. Appropriate mechanisms of safety should be developed for the plant-animal-human food chain

2.6 Effects of the GM feed/fodder on the animal as well as on milk, meat, eggs produced from such animals/birds on human health need to be studied before permitting commercialization of such feed/fodder.

2.7 For conducting clinical trials on GM feeds like genetically modified maize, soybean etc., as well as on GM edible vaccines and other recombinant vaccines for livestock and poultry, the facilities at IVRI authorized by DCGI/ICAR need to be strengthened by providing adequate infrastructure.

2.8 Quality control laboratories for GM products for livestock are very essential. In view of this, the existing quality control laboratories under D&C Act 1940 need to be strengthened to handle GMOs. This will be better than establishing new laboratories, which will be expensive, and time consuming. However, it should include the facilities being developed at Baghpat at the National Veterinary Biological Products Quality Control Centre.

2.9 Regarding the role of ICAR, DBT and GEAC, it has to be clearly spelt out that ICAR and DBT would get the feed analysis done through IVRI or other approved institutes for chemical composition, evaluation for equivalence with counterpart, small animal/ruminant/canine/poultry, safety trials and target animal production trials. Based on the results, ICAR should offer its recommendation on the use of GM crop or GM crop products in animal feed to GEAC. The GEAC should take decisions on

the use of GM crop/product for animal use on the basis of the ICAR data.

2.10 Quarantine facilities for the import of aquatic live animals, biologicals, bioremediation materials and probiotics etc. are critical and must be set up speedily. Off-shore quarantine facilities may also be created for this purpose, as for example in an unmanned island in the Lakshadweep group of islands.

2.11 Extensive biosafety guidelines should be developed for undertaking rDNA work on transgenic animals including biosafety aspects for consumption.

2.12 Various biosafety issues for release of GM fish/marine animals in the environment need careful research.

3 Biotechnology in Fisheries

Clear benefits are perceived with respect to a transgenic approach for increasing production and productivity of fishes at the global level. In India, experimental transgenic *rohu, zebra fish* and *singhi* have been produced recently. At present, there is well-trained but very limited human capacity available for transgenic fish research and production. Genes, promoters and vectors of indigenous origin are available only for two species (*rohu* and *singhi*) for engineering growth. Though protocols are available for transformation of a few fish species, infrastructure for transgenic fish production is highly limited and biosafety testing procedures, specific to aquatic animals, are not in place.

4 Prioritization of the target crops/animal/fish and traits

4.1.0 There is a need to prioritize and reorient our research programmes relating to transgenic research in crops, animals and fishes, in order to maximize benefits from limited resources in areas of relevance to food, livelihood and ecological security.

4.1.1 Prioritization should be on the basis of the importance of target crop/animal/fish to the nation in terms of (i) food, nutrition and health security; (ii) stability and sustainability of production (iii) social and environmental impact (iv) trade-related comparative advantages, including marketability of the transgenic product; (iv) technological options and (v) institutional capacity and expertise.

4.1.2 An illustrative but not exhaustive list of specific targets/ traits, keeping in view the above mentioned criteria is given below. This may be further revised/expanded on the basis of national and international data.

4.2 Prioritized target traits in crop plants

4.2.1 Insect pest resistance

- Lepidoptera
- Sucking pests
- Coleoptera and Diptera

4.2.2 Disease resistance

- Viruses
- Fungi (blights; wilts)
- Bacteria

4.2.3 Abiotic stress tolerance

- Drought
- Salinity
- Excessive moisture and water logging

4.2.4 Quality improvement

- Macro – nutrients
- Micro – nutrients
- Processing quality
- Consumer preferences

4.2.5 Enhancing shelf-life

4.2.6 Engineering male sterility (with strategy for fertility restoration) for breeding hybrids in self-pollinated crops

4.2.7 Development of apomictic hybrids the seeds of which farmers can save and plant.

4.3 Prioritized target traits in livestock

- Production of pharmaceutical proteins
- Enhanced fertility and reproductive performance
- Improved quality - milk, meat, fiber, eggs
- Resistance to diseases for reduced drug use.

4.4 Specific areas for transgenic livestock:

- Transgenic animals need to be developed for production of vaccines, biochemicals, specialized proteins for human and animal health.
- The genes for fast growth, high fecundity, milk quality and disease resistance should be identified, isolated and cloned.
- Development of gene constructs carrying these genes followed by validation for their expression before using them for animal improvement need to be taken up.
- Livestock genomics and proteomics should be initiated taking buffaloes as a model.

- Research on stem-cell cloning and development of animal clones with special genes as donors for tissue/organ transplant may be taken up.

4.5 Prioritized target traits in fishes

- Auto-transgenesis in commercially important species with growth hormone gene
- Production of pharmaceutical and other industrial products
- Fish 'biosensors' for monitoring aquatic pollution

4.6 Specific areas for transgenic fish:

- Field-testing of transgenic *Labeo rohita* as per biosafety protocol.
- Development of auto-transgenic *magur*
- Transgenic 'biosensor' teleost species to monitor aquatic pollution.
- Development of multi-coloured, endemic ornamental " glow fish" such as *Puntius denisonii, P. jerdoni* and other species
- "Bio-reactor" fish to produce Omega-3 fatty acids through recombinant DNA technology.
- Isolation and characterization of genes for quality black and golden pearls, and pearl production through trangenics.

5 Choice of Research Problems :

- Research and extension systems should be sensitive to the biodiversity conservation and socio-economic contexts of our composite agrarian system.
- Biotechnological applications should be viewed comprehensively. Both r-DNA and non-r-DNA applications such

as fermentation, bio-processing, bio-pesticides, bio-fertilizers, tissue-culture, micro-propagation, and related technological components which are important for Indian agriculture including animal husbandry and fisheries should be viewed as integral components of the planning and promotion of biotechnological applications in agriculture.

- Public investment in the area of biotechnology, particularly with reference to recombinant DNA technology, should be to address problems, which are socially and ecologically relevant. Diversified farming systems which can help provide much needed macro- and micro-nutrients to children and adults from locally adapted crops, including those which are underutilized presently, like millets, legumes, tuber crops and leafy vegetables should be fostered. Nutrition security at the level of each individual should be an important consideration in the design of farming systems. A food based and not a drug-based approach is needed to overcome hidden hunger caused by deficiency in the diet of micronutrients such as iron, zinc, iodine and Vitamin A.
- Viable alternatives available for meeting the food/feed and nutritional needs should be viewed comprehensively before resorting to recombinant DNA technology.
- There should be an equal thrust to develop both GM varieties and GM hybrids in priority crops. The varieties, in contrast to hybrids, are preferred by small farmers because they can use their own farm-saved seeds for at least 3-4 years. In the case of hybrids, research on the introduction of genetic factors for apomixis should be supported, so that resource poor farmers can derive benefit from hybrid vigour without having to buy expensive hybrid seeds every crop season. Public-good research

should also cover under-utilized or "orphan crops" like millets, legumes and tuber crops cultivated in dry farming and fragile environments. Arid and hill zone crops need attention. These often serve as "life-saving crops" under conditions of drought or other natural calamities.

- Such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. Breeding for herbicide tolerance, for example, may have low priority on this account in several parts of India where there are large numbers of landless labour families. The priorities will have to be determined both on the basis of agro-climatic and socio-economic factors, region by region.

5.1 Capacity building for Priority setting in Genetic Engineering Research in Agriculture

5.1.1 A Standing Committee on Agricultural Biotechnology comprising of the Secretaries under M/o Agriculture with Secretary (A&C), as Chair and Secretary (DARE) and Secretary, Animal Husbandry & Dairying and Secretary, Food Processing Industries, Secretary, Water Resources and Secretary, Biotechnology as Members may be set up to address issues of strategic importance to the agriculture sector including providing direction to focus public good research in areas of national priority.

5.1.2 There should be an agro-climatic region/location-specific R&D agenda for sustainable agriculture with State Agricultural and Veterinary Universities taking the lead role in setting such an agenda. SAUs should develop a strategy for bio-security in their

respective areas and get it implemented through the respective State Government.

5.1.3 DAC and ICAR could organize an Orientation Workshop on Priority Setting in Recombinant DNA Research in Crop Plants, Animal Husbandry and Fisheries for Project Leaders engaged in research in the area of Molecular Breeding in Crop Plant, Animal Husbandry and Fisheries. Such an orientation workshop could help to develop a code of conduct of "dos" and "donts" in relation to choice of research problems and investment priorities in the public and private sectors.

5.1.4 Capacity building may be carried out at the field level, in areas such as genetic literacy, bio-safety and bio-ethics. Effective involvement of HRD/Trainings and infrastructure would be needed.

6 New Generation of Applications : Framework for Technological Assessment:

6.1 Department of Agriculture should set up a joint inter-ministerial working group in association with ICAR, ICMR, DBT, NIN and Ministries and Departments associated with delivery of health systems to examine the most cost-effective and nutritionally desirable manner of overcoming hidden hunger caused by the deficiency of micronutrients like iron, zinc, iodine and Vitamin A in the diet.

6.2 There is need for greater attention to assess the potential uses of technologies like bio-fortification and conservation tillage in a contained and holistic manner. There is evidence from recent studies carried out in the U.K. that excessive use of herbicides leads to a reduction in field biodiversity.

6.3 Department of Agriculture and ICAR should set up an expert group for examining biotechnological applications in relation to anticipatory research for meeting the challenges of global warming, climate change and sea level rise.

6.4 Global trends in preferences among consumers and industries in the area of farm commodities should be continuously monitored.

7 Conservation and Protection of Centres of Genetic Diversity:

7.1 As India is endowed with rich agro-bio diversity, important centres of origin and diversity should be protected so as to conserve precious agro-biodiversity in their pristine purity. A case in point is the Jeypore tract of Orissa, which is very rich in rice genetic resources. Such areas should be earmarked as "**Agro-Biodiversity Sanctuaries**", along the pattern of wild life sanctuaries and National Parks. In such areas, the cultivation of GM crops should be prohibited. Financial support should be extended to the local tribal and rural families from the National Gene Fund proposed under the Protection of Plant Varieties and Farmers' Rights Act (2001) to compensate them from losses in yield and income due to their maintaining field gene banks (ie *in situ* on-farm conservation) in public interest.

7.2 Mega-biodiversity centers and hot spots of agro-biodiversity viz. Western and Eastern Ghats and NE Region should also be preserved. Areas within these, such as parts of Uttaranchal, may be declared as "Organic Region" or even "Organic States" and may also be kept free from GM crops/plants until more data are available on the long-term impact of the introgression of transgenic material into native biodiversity. The National Institute for Organic Farming and Certification proposed to be set up during the Tenth Five Year Plan period can undertake such

studies and develop guidelines for declaring specific areas as, "Organic Farming Zones". **A Technical Committee may be constituted by ICAR, NBPGR, DBT, Dept of Agriculture and Ministry of Environment and Forests (Botanical, Zoological and Forest Surveys of India) to develop guidelines for earmarking areas as Agro-biodiversity Sanctuaries and Organic Farming Zones.**

8 Promotion of Organic Farming Zones :

There is a need for developing a consensus on the role of biotechnology in organic farming. The linkages between organic farming and biotechnology should be studied on the lines indicated in **Figure I**. Organic farming zones should be protected from potential cross-pollination by GM crops. This will be particularly important for horticultural crops and medicinal plants. Certification procedures for organically produced food should be standardized and agencies identified for issuing such certificates.

9 Pest Management Systems:

GM crops should be fitted into an Integrated Pest Management (IPM) system. Bollworm affects not only cotton but several other crops. Bollworm is now migrating from Bt cotton to cauliflower and other vegetable crops**.** The illegal spread of GM varieties is likely to result in serious problems of pest resistance to Bt toxins. ICAR and Department of Agriculture should review the situation and develop guidelines for preventing bio-disasters arising from the lack of a scientifically sound integrated pest management strategy. Non-GM components such as biofertilizers, biopesticides, Integrated Pest Management etc. should be equally promoted along with GM components, for sustainable agriculture. As part of the scientific literacy movement, the need for

"refugia" (i.e., concurrent cultivation of non GM varieties) should be explained to farm families. A genetic literacy movement should be launched and Genome clubs may be organized in schools in biodiversity rich areas. Regulation, education and social mobilization with all, will be necessary to prevent illegal plantings and to promote the safe use of GM crops.

10 Expeditious commercialization of Biotech Products

10.1 At present, biotech research is conducted in a project mode. To achieve the goals of developing commercial products, a mission-mode approach may be followed. Programmes of five-year duration defining goals and strategies, and involving multi-disciplinary partners should be considered for funding. Adequate funding should be ensured and clear time schedules of activities prepared and monitored. It will be useful to organize mini-networks of concerned scientists to accelerate progress by mobilizing the power of partnership. Convergence and synergy among various funding agencies need to be developed to avoid duplication and to promote synergy. Databases of projects at various stages of funding and implementation by different agencies should be developed and maintained at the proposed National Resource Centre for the Safe and Responsible use of agricultural biotechnology.

10.2 Our public research system is expected to extend the benefits of the development of agricultural biotechnology to the farmers. The private sector may supplement this function. A symbiotic public- private partnership for research and product development should be encouraged. Alliances between the public research system and public and private companies in the area of production and marketing of GM seeds also need to be established and strengthened. **The existing extension personnel should be retrained and retooled to equip them**

to enter the age of Functional Genomics, Proteomics, recombinant DNA technology, and Nano-biotechnology. They should be capable of imparting genetic, quality and trade literacy among farm women and men.

10.3 The development of GM technology is expensive. Innovators who evolve new GM seeds may not always be in a position to provide the resources to commercialize their product. It is, therefore, suggested to set up a venture capital fund to help commercialize research breakthroughs in the development of GM seeds/crops. The different links between discovery and field delivery need integrated attention.

10.4 Considerable investments have been made during the last 20 years and hence necessary facilities to carry out biotechnological research and training are available in several parts of the country. Many Universities have started M.Sc. and Ph.D. programmes in biotechnology. Funding for specific equipments and maintenance and improvement of existing facilities may be considered on a case-by-case basis. The aim should be to generate a critical mass of inter-disciplinary effort and create inter-disciplinary centers staffed by outstanding young professionals in all fields of biotechnology. Indian private sector companies may also be encouraged to make greater investments in R & D

10.4 A preliminary assessment by the Task Force of fund requirement for implementing our recommendations and for giving a push to the application of bio-technology on the basis of the work being done in the public sector indicates that in all Rs. 1200 crores of additional funds may be needed during the remaining three years of the Tenth plan period. **Out of this, the Department of Agriculture may provide approximately Rs. 300 crores to develop and augment capacity building, human resource development, monitoring and**

surveillance, development of organic farming zones and Agro-biodiversity sanctuaries, initiating a special GMO insurance scheme, public and political understanding about applications of bio-technology in agriculture, training and retraining of extension personnel, and assisting farm and home science graduates to set up agri-clinics and agri-business centers for Agricultural Biotechnology. About Rs. 200 crores may be provided during 2004-07 for venture capital. The strengthening of the regulatory and surveillance mechanisms, including the setting up of a National Biotechnology Regulatory Authority may require about Rs. 150 crores during the next three years. In addition, DARE/ICAR, Department of Animal Husbandary and Dairying and DBT may provide an additional Rs. 400 crores to upgrade research infrastructure, undertake human resource development, accelerate progress in research and education relating to biotechnology applications in crop and animal husbandary and inland and marine fisheries, and organize a special All India Coordinated Research Project on GM crops. A provision of Rs. 150 crores may be made for the creation of infrastructure for establishing Ag-biotech Parks, on the model of the one developed by ICRISAT in Hyderabad. Atleast one such park may be established in every State during the next three years in collaboration with NABARD. Requirement of funds for the current year may be assessed by the Ministry of Agriculture and proposed to Government for funding in the regular budget of 2004-05.

10.5 The AG-biotech Parks should provide the necessary infrastructure and common facilities like e-commerce, website, brand name, etc., to agricultural, veterinary fisheries, home science and forestry graduates who wish to start agri-clinics and agri-business centers in the area of agricultural and food biotechnology. Decentralised market-driven enterprises supported by core common facilities will have

the advantage of low transaction costs and lateral learning among the Ag-biotech Park community. 2004 has been designated by the United Nations as the International year of Rice. **Hence, a few Rice Bio-Parks designed to produce value-added commodities from the rice straw, bran and husk can be started during this year under the national grid of Ag-Biotech Parks.**

11 Policy framework for commercialization

11.1 Various legislative instruments govern the cultivation, evaluation and commercial release of crop varieties and animal feeds. Harmony among these instruments should to be ensured for developing a seamless conduit for commercialization of technology. Policies and procedures pertaining to linking discovery at the laboratory level to delivery at the field level need attention. Towards this end, a clear policy document should be brought out by DAC and DARE specifying products and delivery systems:

i) A robust product development ensuring and profitability at farm level.

ii) Facilitating rapid testing/evaluation towards release

iii) Fostering partnership for product delivery through contracts, franchises, licenses, MOUs, consortia of public and private sectors and through Agri-business centers operated by self-employment farm graduates.

iv) Policies relating to intellectual property rights and patenting including defensive patenting.

12 Regulatory Mechanisms for Bio-Safety Evaluation and release system/protocol

12.1 After analyzing the current procedures for biosafety evaluation/ protocol, the Task Force came to the conclusion that the existing system of approval of GM Varieties for cultivation needs review and rationalization. The Task Force recognizes the need for reduction in the levels and number of steps required in evaluation and environmental clearance of GM products/transgenics and the need for transparency and professionalism in the regulatory process.

12.2 The Task Force is, of the view that the implementation of the procedures under the Rules for the Manufacture, on Use/Import/Export and Storage of Hazardous Micro-organisms/ Genetically Modified Organisms or Cells, formulated under the EPA 1986, involves avoidable loss of time. It will be appropriate to review the existing procedures so that biosafety can be assessed concurrently with agronomic performance. There is a need for streamlining the procedures for commercial release of genetically modified crops, without compromising on principles of bio- and environmental safety. The urgency is further highlighted by mushrooming of illegal varieties of Bt. Cotton seed in Gujarat, which is reported to have spread to Andhra Pradesh, Maharashtra, Madhya Pradesh and Punjab as well. The production and sale of unauthorised Bt. Cotton seed also underscores the need for a further strengthening of the relevant provisions of law under the Seed Act and Environment (Protection) Act. The provision of mandatory registration under the proposed Seed Act is a welcome step in this direction. The provisions relating to breeders' rights under PPV&FR Act will also to some extent, help in addressing the problem. There is, however, need for constant vigil and monitoring and for initiating measures to plug the loopholes in collaboration with State level authorities.

12.3 It is suggested that while the present system of granting approval for contained and open field trials for biosafety may continue to rest with the RCGM, the multilocational farmer's field trials for Value for Cultivation and Use (VCU) should be the sole responsibility of ICAR and the concerned company / institution. **The Monitoring and Evaluation Committees (MEC) should report to GEAC, which may continue to handle biosafety and environmental safety issues of GM crop candidates until the proposed National Agricultural Biotechnology Regulatory Authority comes into existence.** 'Commercial release' /notification/registration, however, should be with ICAR/DAC as the release for use by farmers comes under the domain of the Ministry of Agriculture. No GM crop variety should be allowed to be released for use by farmers by any agency other than ICAR/DAC who have a system of VCU evaluation and also a regulatory mechanism for release and notification of varieties. ICAR would devise a mechanism to concurrently run the VCU trial of such GM crop candidates for which GEAC clearance has been given and for which large-scale seed production/multiplication has been recommended by GEAC. **An All India Coordinated Research Project (AICRP) solely for the testing of GM crop varieties should be organized by ICAR with the requisite technical expertise.** Multilocational/regional testing should be carried out with the help of the concerned State Agricultural University centers under the AICRPs. The Agricultural Production Commissioner of the concerned State should be given full details of trials with GMOs in the respective State

12.4 The above suggestions are represented in the flow chart given below :

Protocol-I: For New Transgenic Event

Institutional Biosafety Committee (IBSC)

Preparation and/submission of application data

⇩

Review Committee on Genetic Manipulation (RCGM)

Evaluation of application data from Institutional Bio-safety Committee (IBSC)*;

Approval for Laboratory and Green House Trials & contained field trials for generation of environmental, toxicity and allergenicity data.

Evaluation/monitoring of contained field Trials through

Monitoring-cum-Evaluation Committee (MEC)

⇩

Genetic Engineering Approval Committee (GEAC)

Approval for large scale Field Trials and Evaluation Protocol**

⇩ ⇩

Concurrent

Farmer's Field trials by **Company** ⟺ **ICAR** trials for VCU Involving SAUs and other appropriate State Agencies

⇩

GEAC

Evaluation of data

Environmental clearance of the event/gene

⇩

Ministry of Agriculture

Approval for commercial release/notification/registration of variety(ies)/hybrid(s)

by **DAC/ICAR**

⇩

DAC/ICAR

Ministry of Agriculture & State Governments

Post-release monitoring and vigilance

* Representatives to be nominated by DBT. However, DBT officials should not be part of IBSC.

** i) GEAC to issue permission to applicant for (a) multi-location coordinated trials to be conducted by ICAR (b) conduct of field trials by applicant at suitable locations in different agro ecological zones as per approval of GEAC.

ii) The applicants will hand over the seed/planting material of requisite quantity to ICAR for coordinated trials. GEAC should inform all stakeholders including State Govts. In case of conduct of large-scale trials of transgenic crops, the experimental design and the number shall be decided by GEAC in collaboration with ICAR.

12.5 Once an extant/transgene has been declared bio-safe, its derivatives need not always be evaluated for bio-safety to the same extent again. Such derivative crop varieties may be considered for biosafety clearance after case verification and need-based trial by RCGM. Studies on gene stability and expression levels will however have to be repeated for new varieties. Thereafter, such varieties (derivative) GM Crop varieties

can be evaluated through large-scale trials by ICAR and released after satisfactory VCU performance, provided no adverse linkages are observed. For example, cotton Cry 1Ac gene has been found to be safe. Therefore, the use of this gene for improvement of other varieties in the same crop need not be subjected to the same degree of biosafety assessment as in case of a new transgenic event in case the gene does not show a position effect. **This should be done on a case-by-case basis**. After the biosafety of a new transgenic crop is established, it could be allowed to be cultivated after evaluating its agronomic potential and genetic behaviour because of the presence of the gene in a new genetic background. In such cases where both the gene and the genetic background/ initial variety have been earlier approved/ released, even the VCU testing by company could be for one season/year only. Trials for biosafety and agronomic evaluation should be conducted in tandem in order to save time and resources. Also, the commercial release of GM crops should rest with respective Ministry viz. the Ministry of Agriculture which would deal with release and notifications/registration of GM crops. State Variety Release Committees should be involved appropriately.

12.6 Post-release monitoring should be ensured by Department of Agriculture & Cooperation and ICAR and the concerned State Agricultural Universities. Such monitoring would include aspects such as gene flow to wild relatives and non-targeted crop species, building up of resistance, observance of maintenance of refuge and other post-release requisites. The above procedure is represented in the flow chart given below :

Protocol - II: For Released Event

Institutional Biosafety Committee (IBSC)

Preparation/submission of application data

⇩

RCGM

Case verification and Bio-safety clearance

(Need based trials)

⇩

Genetic Engineering Approval Committee (GEAC)

Approval for large scale Field Trials and Evaluation Protocol*

⇩ ⇩

Farmer's Field trials by **Company/** Institutions ⟺ **ICAR** trials for VCU

⇩

GEAC

Evaluation of data

Environmental clearance of the event/gene

⇩

DAC/ICAR, **Ministry of Agriculture**

Approval for commercial release/notification/registration of our variety(ies)/hybrid(s)

⇩

DAC/ICAR, Ministry of Agriculture & State Governments

Post-release monitoring

- GEAC should issue permission to applicant for (a) multi-location coordinated trials to be conducted by ICAR and (b) conduct of field trials by applicant at suitable locations in different agro-ecological zones as per approval of GEAC. The applicants will hand over the seed/planting material of requisite quantity to ICAR for coordinated trials. GEAC should inform all stakeholders including State Governments. In case of conduct of large scale trials of transgenic crop, the experimental design and the number shall be decided by GEAC in collaboration with ICAR. ICAR should organize a separate All-India Coordinated Programme for testing GM crop varieties. The coordinators of this programme should have expertise both in biotechnology and agriculture.

12.7 Realising the need for rationalization of the information needed to be collected/ generated by the applicants on transgenic crops while applying to the Review Committee on Genetic Manipulation (RCGM), the Task Force set up an Expert Committee comprising representatives from Ministry of Agriculture, ICAR and DBT for rationalization of parameters for development of transgenic crops by incorporating bio-safety and agronomic evaluation requirements and environmental safety aspects. The Task Force approved the recommendations submitted by the Group of Experts. The Task Force recommends the following general, biosafety and agronomic parameters on which information by applicants needs to be submitted to RCGM.

A. General Information

- Rationale for development of transgenic crop

- Description of the host plant
- Mode of Pollination
- Centres of origin/diversity of the crop species
- Geographical distribution of the target crop and sexually compatible plant species including wild relatives

B. Biosafety Parameters:

1. Genetic and Molecular parameters

- Genetic analysis including copy number of inserts;
- Stability of the gene;
- Level, site(s) and duration of expression gene product;
- Efficacy/utility of gene product;
- Compositional analysis

2. Environmental Parameters

- Gene flow
- Implications of out-crossing
- Effect on target and non-target organisms
- Effect on soil biota

3. Toxicity parameters including histo-pathological studies (need based)

Food/feed safety evaluation in animals such as

- Effect on small laboratory animals
- Effect on livestock animals (representative goat studies of large animals)
- Effect of birds/avian species
- Effect on fish

4. Allergenicity parameters (need based)

- Primary skin irritation test in rabbit/guinea pigs

- Irritation of mucous membrane test in rabbit/guinea pig
- Immunological responses in a suitable animal system

C. Agronomic Parameters

- Efficacy of the gene at phenotypic level
- Yield
- Growth and developmental parameters
- Responses to major diseases and insect-pests
- Quality parameters
- Economic evaluation/cost: benefit ratio

(Operational protocols to be developed by RCGM for **'B'** and by ICAR for **'C'** depending upon the host crop). **A case by case analysis will be needed**

National Biotechnology Regulatory Authority

12.8 With regard to the institutional arrangements, the Task Force is of the view that GEAC should consist of members with the requisite expertise and should be headed by an outstanding biosafety and biotechnology experts. The structure of the Atomic Energy Regulatory Board could be suitably adapted for establishing an autonomous statutory National Biotechnology Regulatory Authority (NBRA) in the place of the existing GEAC. **With rapid growth in R & D efforts in biotechnology, a statutory and autonomous National Biotechnology Regulatory Authority will soon become necessary. The NBRA should have two wings – one for agricultural and food biotechnology and the other for medical and pharmaceutical biotechnology. NBRA is essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory**

mechanism in place in the country. The chairperson of NBRA could provide guidance and oversight to both the agricultural and medical wings. The members could be different in the case of the two wings. Having a common NBRA with two distinct wings will be useful to consider bio- and food safety issues in an integrated manner, in the case of products like crop-based oral vaccines and neutraceuticals.

12.9 Until an autonomous statutory NBRA comes into existence, GEAC may have two wings/committees to deal with agricultural applications and pharmaceutical applications separately and exclusively.

12.10 Evaluation of the field performance of GM crops should be transparent. Unfavourable results should also be highlighted. Evaluation mechanisms should enjoy functional independence and high scientific and public credibility. Mandatory maintenance of detailed record notebooks should be enforced which could be examined as and when needed.

12.11 The Task Force feels that in the process of evaluation and commercial release of GM crops/ products, the following should also be kept in view.

- The Set of bio-safety data necessary for seeking approval should be clearly established.
- As far as possible, data and protocols pertaining to bio-safety testing from International sources should be harmonized.
- Additional accredited laboratories should be identified/created for evaluating claims and verifying biosafety standards, the existing ones should be further strengthened
- Agronomic evaluation in terms of traits to be considered, years of testing and agencies responsible for testing need to be clearly spelt

out for each crop. This should be a priority task of the proposed ICAR All India Coordinated Project responsible for the evaluation of GM crops and varieties.

- Provisions of PPV&FR Act and Seeds Act for protecting IPRs should become better known.
- Periodicity of meetings of Committees concerned with various approvals should be regular and conducted on a well-scheduled annual calendar basis. A crop-season should not be lost due to avoidable delays in the decision making process.
- Bio-safety evaluation procedure should be suitably adapted in cases where two or more deregulated transgenic events are pyramided through conventional breeding. However, gene expression concerned with combined effects of the two genes along with VCU should be evaluated.
- Various evaluation reports and approval, once finalized, should be made public in a transparent manner and placed on a designated website.
- A clear policy/guidelines on feeding of GM foods to livestock and use of livestock products from animals fed with GM food should be developed and enforced.
- Concerted efforts should be made to educate the public about transgenic technology. Civil Society organizations, Womens' Associations, Home Science Colleges, KVKs and other agencies/stakeholders should be involved in this task.
- Rules for procurement of chemicals/equipments for biotechnology research in Govt. research Institutes should be simplified so that the pace of research can be accelerated.

13 Food Safety and Quality Literacy

13.1 There is need to put in place food safety standards. Ministry of Science and Technology along with ICMR and M/o Health should take the lead and play a greater role in setting *codex alimentarius* standards in the area of GM foods. The safety impact should be assessed in the case of both animal feeds and human foods. DBT, ICMR, ICAR, CFTRI (CSIR), Ministry of Environment and Forests, Ministries of Agriculture and Health and the Law Ministry should jointly develop a **National Food Safety Protocol**, which covers both the production and post-harvest (processing and consumption) phases of GM crops. The protocol should cover all stages in the production, processing, marketing and consumption chain. It should take into account the potential impact of GM crops on the environment and the health of human and animal populations. As a signatory to the Cartagena Protocol, (i) Biosafety clearance of these mechanisms may be expeditiously provided and operationalised, (ii) A Biosafety Data Base System be established and (iii) the trans-boundary movement of Living Modified Organisms (LMO) be monitored/ regulated and provisions of the Advanced Informed Agreement (AIA) etc. be effectively executed.

13.2 There is a need for putting in place a mechanism to facilitate segregation, identity preservation and certification and labelling of GM/non-GM products.

13.3 Food quality literacy is presently very weak in the country. The Year 2004 has been declared by the Government of India as "Year of Scientific Awareness". It will be appropriate for the Department of Agriculture, ICAR, DBT, ICMR (National Institute of Nutrition), CSIR (Central Food Technological Research Institute) and the Ministry of Food Processing to launch a Quality Literacy Movement among farm women and men during this year.

14 Human Resource Development

At present, quality training in agricultural biotechnology is available in a limited number of institutes and laboratories. To avoid mushrooming of substandard institutes in both public and private sectors, there is need for considering accreditation of institutions for training in agro-biotechnology. Also, a proper balance between sector-wise demand and supply should be ensured to avoid unemployment and in efficient use of training facilities. Training in bioinformatics, functional genomics and Nano-biotechnology should be strengthened. Training should also include issues related to intellectual property, regulatory affairs and commercialization. International training for technical updating in specific areas should be undertaken on a substantial scale.

The contents of training courses, including hands on skill training should be standardized. An appropriate mechanism/ institution should be identified to consider the accreditation process. Projections for manpower needs in this sector for the coming decade and beyond need to be prepared.

15 Right to Information:

Farmers should have complete information on the benefits and risks associated with GM crops. The evaluation procedure should include farmer participatory assessment, as is the case of non-GM crop varieties. The procedure of transparent evaluation should apply equally to both private and public sector varieties.

16 National Biotechnology Regulatory Authority (NBRA)

16.1 Keeping in view the rapid strides being taken in the area of agro- and food biotechnology research and application, there is a need for setting up a **National Biotechnology Regulatory Authority**. NBRA should be chaired by an eminent biotechnologist well known for expertise in biotechnology and biosafety assessment. NBRA should have a wing for Agricultural Biotechnology. The Agricultural Biotechnology Regulatory Wing may have five part-time Members dealing with the following areas.

- Member (Agriculture ie, crop and animal husbandry, fisheries and forestry),
- Member (Health) and Food Safety
- Member (Environment)
- Member (Social and Gender Audit)
- Member (IPR and Legal Affairs - obligations under international protocols and national legislation)

16.2 The National Biotechnology Regulatory Authority may review the different protocols from time to time. NBRA will also be responsible for setting up policy guidelines and ensuring need based periodical evaluation of regulatory mechanism.

16.3 NBRA should have a Standing Advisory Committee consisting of nominees of State Governments, so as to maintain close liaison with State Governments in matters relating to the release and monitoring of GM strains of crops, farm animals and fish.

16.4 **The NBRA should be autonomous and professionally led but could be attached for necessary administrative support to an appropriate Ministry/Department.**

16.5 The NBRA should submit an Annual Report to Government on the status of GM crop varieties submitted for approval for commercial cultivation. Such a report should contain a synoptic overview of the situation relating to GM crops and foods worldwide.

16.6 Since agriculture is a state subject it will be desirable to establish a State Agricultural Biotechnology Regulatory Advisory Board in each State to maintain liaison with NBRA and to ensure that steps are taken to prevent the illegal release and proliferation of GM seeds. The State Agricultural Biotechnology Regulatory Advisory Board will also take steps to ensure that farmers are properly educated on the raising of refugia and the adoption of IPM procedures, so that the pest resistance properties of GM crops do not break down. It can also help to supervise the trials conducted with GM strains within the State.

16.7 Since India is a large and agro-ecologically diverse country, it is desirable that Agricultural Biotechnology Advisory Committees are set up at the district levels. The three tier regulatory structure thus consists of:

a. National Level : National Biotechnology Regulatory Authority (with a separate wing for Agricultural Biotechnology)
b. State Level : State Agricultural Biotechnology Regulatory Advisory Board
c. District Level : Biotechnology Risk Assessment and Communication Committee

16.8 The national level Agricultural Biotechnology Regulatory Authority will be largely concerned with genetically modified crops, animals and fishes resulting from recombinant DNA technology. The State and

District level structures should however also promote actively the non-GM applications of biotechnology like the manufacture and sale by self-help groups of biofertilizers, biopesticides, botanical pesticides, vermiculture, etc. District level Agricultural Biotechnology Risk Assessment and Communication Committees can help to establish Genome Clubs in Schools, Colleges and Krishi Vigyan Kendras and promote genetic literacy in Panchayats. Since biodiversity is the feed stock for the biotechnology industry, the institutional structures at the above three levels should maintain close coordination with the National Biodiversity Authority, State Biodiversity Board and the local level Biodiversity Management Committee. This will enable the scientific conversion of agro-biodiversity into social upliftment through jobs and income.

16.9 **Media Resource Centre for the Safe and Responsible Use of Biotechnology.**

There is need for a single window information centre on all aspects of GM crop varieties, bioethics, biosafety and biodiversity legislation like the Biodiversity Act and Protection of Plant Varieties and Farmers' Rights Act. A Media Resource Centre needs to be organized by DAC and DARE to provide media with authentic and timely information relating to genetic modification in agriculture, medicine and industry. This could be linked to the recent initiative of DAC in the area of dedicated Krishi Radio Channel for general and dynamic farm information. A designated web site should also be created and operated by DAC.

17 Promoting Public Awareness on matters relating to Agricultural Biotechnology

17.1 Clear and understandable consumer information is a very important part of the public acceptance process. Besides media, research organizations and scientific institutions concerned with crop improvement must also take up the responsibility for promoting awareness among the public about the applications of genetic engineering in agriculture and their potential benefits as well as risks and constraints. Media serve as a bridge between science and society and they should be enabled to play an important role in fostering the technological upgradation of Indian agriculture, thereby enhancing our agricultural competitiveness.

17.2 An effective communication strategy must be developed and a cohesive mechanism established to ensure that messages are consistent with National policy on agricultural biotechnology and also that all target groups are reached. Education and development communication must receive high priority.

17.3 Field research may be required to ensure that the concerns of various groups of population are understood and addressed to see that the messages are evidence based, simple and effective. Transparency in communication should be the bottom line.

17.4 The issues in regard to the release of GM crops are not understood correctly owing to the lack of information on this subject even amongst the otherwise well-informed members of the public. An information campaign needs to be conducted to generate public awareness on the benefits and risks associated with biotechnology and the social, ethical, economic, scientific, environmental and health issues which are addressed by regulatory bodies before allowing the cultivation of GM crops.

17.5 A scheme should be formulated by DAC/ICAR to hold workshops, seminars, media campaigns (including through the proposed Krishi Channel) to provide information to the public on matters relating to agricultural biotechnology. The Media Resource Centre proposed earlier will have to perform an important role in ensuring information flow to the public through the mass media (internet, Cable TV, Radio and vernacular press).

17.6 The National Academy of Agricultural Sciences (NAAS) may be assisted to set up a committee on the Public Understanding of Agricultural Biotechnology.

18 Addressing the Factors Influencing Public Opinions on Biotechnology

The media can play a pivotal role in the public debate about agro biotechnology by facilitating two-way communication among the various stakeholders affected by the technology. The management of the proposed Media Resource Centre should involve representatives of the conventional and new media.

19 Establishing Channels of Communication with the Public

Scientific demonstrations of biosafety of transgenic crops and review by government agencies are extremely important in gaining public acceptance. The Ag-biotech Parks, recommended earlier, can also serve as windows into the Genome age.

20 Launching an Integrated and Intensive Campaign to generate public awareness

20.1 An intensive and highly integrated campaign needs to be launched, with active cooperation of various scientific organizations/institutions/ universities/NGOs to generate public awareness in the country on the following specific aspects of agricultural biotechnology:

- Concept of plant breeding, pressures on modern plant breeding and the need for novel genetic enhancement strategies
- Introduction to genetic engineering technology
- The benefits, risks and constraints of agricultural biotechnology
- Current status of national and global GM crops and other biotechnological applications in agriculture
- Risk assessment procedures (regulatory mechanisms) for environmental and food safety, and related legislations
- Social, economic, ethical, scientific, environmental and health issues which are addressed by regulatory bodies before allowing release of GM crops.
- Current GM products under evaluation in India under biosafety, VCU and other regulatory trials
- Community and Farmers' Rights and benefit sharing related to agro-biotechnological applications
- Post-release monitoring and management of GM crops and their products, such as insect resistance management, transgene stability at the farm level, use of transgenic diagnostic kits, and maintenance of transgenic seed quality, should be organized with effective involvement of State Level and District Level Coordination Committees of the existing transgenic biosafety evaluation and management mechanism.

21 Strategy to enhance Public Trust and Confidence in Agricultural Biotechnology

1) Participation of the stakeholders in formulating the research agenda in agricultural biotechnology so as to ensure a proper match between needs at the field level and research priorities.
2) Assessing the potential and socio-economic benefits of products from agricultural biotechnologies vis-à-vis other available alternatives for specific objectives (for example, biofortification; biotic stress resistance etc.) in the context of the regional and national values, ethics and concerns
3) Development of biotechnological products that directly help the farmers environment and the society
4) Facilitating reliable and independent assessment of socio-economic impacts of agro-biotechnological products
5) Public opinion-based periodic improvisation of the existing biosafety system to enhance transparency, efficiency and trust
6) Investment in training effective spokespersons, particularly transfer-of-technology and extension personnel and public relation officials of various organizations on agricultural biotechnology applications and biosafety aspects
7) Capitalizing on the inter-ministerial and inter-organizational capabilities to form an information network to promote agricultural biotechnology, wherever the will in our country's interest
8) Pre-breeding to generate novel genetic combinations at Advanced Research Centres, coupled with participatory breeding with farming families will help to de-mystify new technologies and make farm women and men effective partners in biotechnological research.

22 Seed Registration:

Registration of kinds/varieties/seeds sold to farmers must be made mandatory for all varieties. The illegal proliferation of GM varieties, as is

happening in some States, must cease or else the bio-safety regulations will be rendered meaningless.

23 Liability and Compensation:

The Protection of Plant Varieties and Farmers' Rights Act (2001) provides a liability clause. The cost of GM seeds being high, farmers will get indebted if crops fail. **A special insurance scheme for GM crops may therefore be devised and introduced by the Ministry of Agriculture.** There is a need to explore the possibility of the seed company selling GM seeds providing farmers with an insurance cover, so that they may get some relief if crops fail. Switzerland adopted in 2003 a Gene Technology Law with a strong liability regime. A similar procedure may be advisable since a vast majority of farmers in India have smallholdings with no or poor risk taking capacity. A Technical Task Force may be set up by DAC for developing an insurance system for GM crops and animals. Companies selling GM seeds to small and marginal farmers should also provide them with insurance cover. An insurance system for GM crops needs to be developed speedily, so that small farmers who take institutional credit for buying expensive seeds do not suffer in case of crop failure. **An integrated GM Seed-cum-Crop Insurance System will help to ensure that desirable new technologies confer benefits to resource poor small farm families.**

24 Biosecurity Compact

It will be advisable for the Government of India to prepare a **Biosecurity Compact**, comprising precise action plans to face the following challenges

- Invasive Alien Species (introduced with the import of food grains and seeds)
- Sanitary and Phytosanitary measures to avoid mycotoxins, salmonella and other forms of infections in food
- Food, environment, and bio-safety relating to GMOs
- Bio-ethical considerations in research

An integrated Biosecurity Compact will help to county to take anticipatory action against potential bio-perils and to promote bio-happiness arising from the risk free applications of new technologies. A Task Force may be set-up to prepare a draft Biosecurity Compact for India.

Conclusion

The Task Force is of the view that the speedy and effective implementation of the recommendations made in this report will help to accelerate the pace of progress in biotechnology research and application in the field of agriculture, by enhancing public, political and professional confidence in our national capability to harness the tools of GM technology in a safe and responsible manner. This in turn will help to enhance our agricultural competitiveness as well as our ability to insulate food security from the adverse impact of climate change and sea level rise and to cope with the challenges arising from market factors.

ANNEXURE – I

F.No. 11-5/2002/SD-V.
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation
*****

Krishi Bhavan, New Delhi.
Dated the 14th May, 2003.

OFFICE MEMORANDUM

Subject : Task Force on Agriculture Biotechnology.

It has been decided to set up a Task Force on Agricultural Biotechnology. The composition of Task Force shall be as follows :

i)	Dr. M. S. Swaminathan Chairman, M. S. Swaminathan Research Foundation, Chennai.	Chairman
ii)	Prof. V. L. Chopra Former DG, ICAR, Krishi Bhavan, New Delhi.	Member
iii)	Secretary(Agriculture & Cooperation) Department of Agriculture & Cooperation Krishi Bhavan, New Delhi.	Member
iv)	Director General (ICAR) & Secretary (DARE) ICAR, Krishi Bhavan, New Delhi.	Member
v)	Secretary, Ministry of Environment & Forests Paryavaran Bhavan, CGO Complex, New Delhi.	Member
vi)	Secretary, Department of Biotechnology, CGO Complex, New Delhi.	Member
vii)	Secretary, Department of Animal Husbandry & Dairying Krishi Bhavan, New Delhi.	Member
viii)	Dr. (Ms.) Kiran Mazumdar Shaw Chairperson, Biocon India, Bangalore	Member

ix)	Dr. J.B. Chaudhary Ex. Vice Chancellor, G.B. Pant University, Pantnagar.	Member
x)	Joint Secretary(Seeds) Department of Agriculture & Cooperation Ministry of Agriculture, Krishi Bhavan, New Delhi.	Member Secretary

2. The Task Force shall have the following terms of reference :

(i) To formulate a draft long term policy on agro-biotechnology.

(ii) To suggest modifications in the existing administrative and procedural arrangements in order to streamline/harmonize decision making under various Ministries/Organizations.

(iii) To suggest the future role of the Ministry of Agriculture in view of the developments taking place in the field of agriculture biotechnology.

(iv) To promote public awareness on matters relating to agriculture biotechnology.

3. The Task Force shall submit its report within a period of three months from the date of its setting up.

4. The expenditure on TA/DA for the Chairman and other non official members of the Task Force and other contingent expenditure will be met from the Central Sector Scheme for Implementation of Protection of Plant Varieties & Farmers' Rights Legislation.

(Sanjay Vikram Singh)
Director(Seeds)

Copy to : All concerned.

ANNEXURE – II

F.No. 11-5/2002/SD-V.
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation
*****

Krishi Bhavan, New Delhi.
Dated the July 28, 2003.

OFFICE MEMORANDUM

Subject : Task Force on Agriculture Biotechnology.

The undersigned is directed to refer to this Department's O.M. of even number dated 14th May, 2003 and to reconstitute the Task Force on Applications of Agricultural Biotechnology as follows :

i) Dr. M.S. Swaminathan, Chairman
M.S. Swaminathan Research Foundation, Chennai.

ii) Secretary, Department of Agriculture & Cooperation (Shri R.C.A. Jain)

iii) Director General (ICAR) & Secretary, Department of Agricultural Research & Education.

iv) Secretary, Ministry of Environment & Forests (Shri K.C. Mishra)

v) Secretary, Department of Biotechnology (Dr. (Mrs.) Manju Sharma)

vi) Secretary, Department of Animal Husbandry & Dairying (Smt. Binoo Sen)

vii) Secretary, Health, Ministry of Health & Family Welfare (Dr. J.V.R. Prasada Rao)

viii) Secretary, Department of Food & Public Distribution (Shri Arun Bhatnagar)

ix) Secretary, Department of Commerce (Shri Deepak Chatterjee)

x) Prof. V.L. Chopra, Former DG, ICAR.

xi) Dr. J.B. Chaudhary, Ex. Vice Chancellor, G.B. Pant University, Pantnagar.

xii) Dr. Amrita Patel, Chairman, National Dairy Development Board, Gujarat.

xiii) Dr. Syed E. Hasnain, Director, Centre for DNA Fingerprinting & Diagnostics, Hyderabad.

xiv) President, Association of Seed Industry.

xv) President, Seed Association of India.

xvi) Joint Secretary(Seeds), DAC, Ministry of Agriculture

2. The first term of reference of the Task Force may be amended to read as follows :

"To formulate a draft long term policy on application of agricultural biotechnology".

3. The Task Force shall submit its report by 31st December, 2003.

(Sanjay Vikram Singh)
Director(Seeds)

Distribution to : ALL CONERNED.

ANNEXURE-III.

Calendar of the Task Force Meetings and the Decisions Taken.

Sl.No	Date	Venue	Subject
1st.	11.07.2003	New Delhi	It was decided to expand the Task Force so as to include key stakeholders like other Government departments, Seed Industry and experts in Animal Sciences etc. Extending the term of Task Force up to 31st. December, 2003 was also recommended.
2nd	26.08.2003	New Delhi	Decided to set up five Working Groups to prepare base papers for each terms of reference as under: 1. "Role of the Ministry of Agriculture" by Working Group under the chairmanship of Shri RCA Jain, Secretary, Department of Agriculture & Cooperation. 2. "Biotechnology Applications in Agriculture : Developing a long term policy" by Working Group under the chairmanship of Prof. V.L. Chopra, President, National Academy of Agricultural Sciences. 3. "Regulatory Procedures in Agriculture" by Working Group under the chairmanship of Dr. Manju Sharma, Secretary, Department of Biotechnology. 4. "Applications of Biotechnology in Animal Husbandry" by Working Group under Dr. Amrita Patel, Chairperson, NDDB.

			5. "Promoting Public Awareness on matters relating to Agricultural Biotechnology in India" by Dr. Mangla Rai, Secretary, DARE & DG, ICAR.
3rd	04.09.2003	New Delhi	Presentation made by Seed Industry, CII, ASI, SAI, ANSIA, etc.
4th	18.11.2003	New Delhi	Presentation made by NGOs/ environmentalists, etc.
5th	26.11.2003	New Delhi	Base Paper presented by Prof. V.L. Chopra, Dr. Mangla Rai and Shri RCA Jain, Secretary (A&C).
6th	14.12.2003	Hyderabad	Interface with State Governments. Task Force decided to constitute to a sub group to rationalize the regulatory protocols for transgenic crop.
7th	22.12.2003	New Delhi	Rationalization of parameters for regulatory protocols for transgenic crop under the chairmanship of Agriculture Commissioner.
8th	06.01.2004	New Delhi	Dr. Manju Sharma, Secretary, DBT made presentation of Base Paper about regulatory mechanism before Task Force.
9th	24.01.2004	Chennai	Presentation by Secretary, MOEF and Interaction with the representatives of Press & Media.
10th	06.02.2004	New Delhi	Task Force took stock of development in all the meetings of Task Force. Secretary, AH&D, Dr. Prodipto Ghosh, Secretary, MOEF made their presentations.
11th	22.03.2004	New Delhi	Task Force discussed the final draft and authorized the Chairman to submit it after suitable editing

PART – B

INDEX

Report of the Working Group - I

"Biotechnology Applications in Agriculture: Developing a long-term policy"

Chair: Prof. V. L. Chopra

1. Preamble

Infusion of new technology is necessary to maintain our agricultural enterprise competitive and remunerative. Modern science using biotechnological tools is relevant to various areas of agriculture including crops, animals, fisheries and agro-forestry and agro-processing. Specific applications include :

- Generation of transgenic crops/animals/agro-forestry plants/microbes with improved traits
- Use of molecular markers to tag genes of interest, accelerating breeding, fingerprinting of cultivars, landraces, germplasm stocks
- DNA-based diagnostics to monitor/control/eradicate pests and pathogens of crops, farm animals
- Biotech-derived drugs/antibiotics/vaccines for animal husbandry and fisheries
    - Assessment and monitoring of bio-resource diversity
- Plant tissue culture for large-scale multiplication of disease-free planting material
    - Embryo culture/transfer/cloning technology for animal breeding
    - Feed biotechnology for efficient use of crop residues and oil cakes
    - Food biotechnology

Bioremediation of pollution in ground water and other effluents.

2. Objectives

A long-term policy on Biotechnology Applications in Agriculture is intended to :

i. Provide direction to research and development, and
ii. Devise a system for commercialization of products
iii. Develop a clear policy on GM food and feed in the country

This long-term policy should be based on need and relevance of the technology to agriculture and should be in tune with and derived from the National Policy on Agriculture whose overall goals are :

a. Increasing productivity, profitability and total agricultural output
b. Promoting sustainability, natural resource conservation
c. Ensuring food and nutrition security
d. Generating employment, reducing inequality and regional imbalance in growth

3. Setting Priority

A detailed sector-wise priorities, identifying the problems to be tackled and the approaches to be followed should be prepared. Specific inputs from the concerned specialists should be used in this exercise (See Table 1 and 2).

Since there is public concern about transgenics with reference to their short and long term impacts on human health and the environment and their testing and approval are consequently more stringent and elaborate than conventionally bred varieties, the general directives in this respect are

- Biotech applications that do not involve transgenics should be accorded high priority, such as biofertilizers, bio-pesticides and bioremediation

- Transgenic approach should be considered when other options to achieve the objectives are either not available or not feasible
- In transgenic approach, incorporation of pathogen-derived resistance to plant viruses and to drought and salinity should be accorded high priority
- No transgenics should be developed in crops/commodities where our international trade may be affected, e.g., Basmati rice or Darjeeling Tea.

In addition, core information about gene exchange taking place among modern cultivars, traditional varieties and wild relatives should be gathered to assess concerns of transgene escape and establishment. Data should also be gathered on the impact of transgenics on biodiversity in crop fields.

Information emerging from genome sequencing of model plants and other organisms should be used for gene mining from other related species.

4. Programme planning

At present, biotech researches are conducted in project mode. To achieve the goals of developing commercial products, a mission-mode approach should be followed. Programmes of five-year duration defining goals and strategies, and involving various players should be considered for funding. Adequate funding should be ensured and clear time schedules of activities should be prepared and monitored. It will be useful to organise mini-networks of concerned scientists to accelerate progress by mobilizing the power of partnership.

Convergence and synergy among various funding agencies should be developed to avoid duplication and to promote complementation of efforts

(Database of projects at various stages funding and implementation by different agencies should be developed).

A symbiotic public-private partnership for research and product development should be encouraged.

6. Infrastructure development

Considerable investments have been made during the last 20 years and hence necessary facilities to carry out biotech research are available in most parts of the country. Funding for specific equipments and maintenance of existing facilities may be considered on a case-by-case basis.

7. Policy framework for commercialization

A number of different policies such as PVP, New Seed Act, EPA etc. govern release and commercial cultivation of crop varieties and animal breeds. A harmony among these various policies should to be ensured for developing a seamless conduit for commercialization of technology. In particular, policies pertaining to transgenics need attention.

- A clear GMO policy document should be brought out by the Government specifying the i) crops and traits permitted to be modified, and

  ii) the selection markers allowed to be used in generating transgenics
- Bio-safety data necessary for seeking approval should be clearly established
- As far as possible, data and protocols pertaining to bio-safety testing from International sources should be harmonized
- Accredited labs should be identified/created for evaluating claims and testifying biosafety standards

- Agronomic evaluation in terms of traits to be considered, years of testing and agencies responsible for testing need to be clearly spelt out for each crop
- Provisions of Seed Act for protecting IPR should be considered
- Periodicity of meetings of Committees concerned with various approvals should be increased and conducted on a fixed annual calendar basis.
- Requirement of full-scale bio-safety evaluation should not be mandatory if two or more deregulated transgenic events are pyramided through conventional breeding. However, safety aspects concerned with combined effects of the two genes may be evaluated.
- Various aspects of evaluation and approval should be made more transparent
- A clear policy/guidelines on feeding of GM foods to livestock and use of livestock products from animals fed with GM food should be drawn.
- Concerted efforts should be made to educate the public about transgenic technology. Enlisting NGO support should be considered. Also KVKs should be involved in this task.
- Rules for procurement of chemicals/equipments for biotech research in Govt. research Institutes should be simplified.

8. Human resource development

At present, quality training in agriculture biotechnology is available in limited institutes and labs. To avoid mushrooming of substandard institutes in both public and private sectors, Ministry should consider accreditation of Institutions for training in agro-biotechnology. Also, a proper balance between sector-wise demand and supply should be ensured to avoid unemployment and proper use of training facilities.

Training in Bioinformatics/Genomics should be strengthened. International training for technical updating should be encouraged.

Table 1. Priority Areas for Biotech Applications in Agriculture

Crop	**Trait**		**Proposed biotech strategy**
Rice	Insect pests	Stem borer, Brown plant hopper,	Transgenics
	Insect pest	Gall midge	Mol. Breeding
	Diseases	Blast, Blight	Mol. Breeding
	Abiotic stress	Salinity, High temperature	Transgenic/Mol. Breeding
		Water stress: drought, submergence	Mol. Breeding
	Quality	Cooking quality/Aroma (Basmati rice)	Mol. Breeding
		Nutrient enrichment: Vit. A, Iron (non-Basmati, local varieties only)	Transgenic
	Productivity	QTL pyramiding for yield	Mol. Breeding
Wheat	Diseases	Leaf rust, spot blotch, leaf blight, Karnal bunt, Stripe rust, Loose smut	Mol. Breeding
	Quality	For various end uses	Mol. Breeding
Maize	Insect pests	Asian stem borer, Pink stem borer, Weevil	Transgenic
	Diseases	Maydis leaf blight, Downy mildew	Mol. Breeding
	Quality	Protein	Mol. Breeding
	Abiotic stress	Waterlogging	Transgenic
Sorghum	Insect pests	Shoot fly, Stem borer, Midge	Transgenic
	Diseases	Charcoal rot, Grain mold	Transgenic(?)
Pigeonpea	Insect pests	Pod boere, Pod fly	Transgenic
	Diseases	Fusarium, Phytophthora	Mol. Breeding
		Sterility mosaic virus	Transgenic
Chickpea	Insect pests	Pod borer	Transgenic
	Diseases	Fusarium wilt	Transgenic
		Aschochyta blight	Mol. Breeding
Mungbean	Disease	Mungbean yellow mosaic	Transgenic

		virus	
		Powdery mildew, Cercospora	Mol. Reeding
	Physiology	Preharvest sprouting	Transgenic
Groundnut	Disease	Bud necrosis	Transgenic
		Tikka	Mol. Breeding
		Afloatoxin	Transgenic(?)
Mustard	Disease	Alternaria	Mol. Breeding(?), Transgenic
		White rust	Mol. Breeding
	Pest	Aphid	Transgenic
	Quality	Oil and meal	Mol. Markers
Soybean	Disease	Yellow mosaic virus	Transgenic
	Insect pest	Stem borer, Green semi looper	Transgenic
Cotton	Insect pests	American boll worm, Pink boll worm, Spotted boll worm	Transgenic
		Jassids, white fly	Mol. Breeding
	Disease	Bacterial blight	Mol. Markers
		Cotton Leaf curl virus	Transgenic
	Quality	Fibre	Mol. Breeding
		Oil quality	Transgenic/ Mol. Breeding
Sugarcane	Insect pests	Borers	Transgenic
	Disease	Smut	Mol. Breedog
		Red rot	Transgenic/Mol. Breeding
		Viruses, bacteria	Mol. Diagnostics
	Yield	Sugar, yield contributing traits	Mol. Breeding
	Stress tolerance	Waterlogging	Mol. Breeding
Tomato	Disease	Leaf curl virus	Transgenic
	Insect pest	Fruit borer	Transgenic
	Quality	Total solids, lycopene	Mol. Breeding
		Shelf-life	Transgenic
Potato	Diseases	Viruses	Transgenic
		Late blight	Mol. Breeding/Transgenic

	Quality	Starch	Transgenic
	Abiotic stress	Drought, salinity	Transgenic
Cole crops	Insect pests	Plutella	Transgenic
Banana	Diseases	BBTV, BBMV	Transgenic
		Sigatoka	Mol. Breeding
	Pests	Weevil, Nematode	Transgenic
Papaya	Disease	Papaya Ring spot virus	Transgenic
	Sex determination		Mol. Breeding
Citrus	Diseases	Viruses, Bacteria	Transgenic
		Crop improvement	Mol. Breeding/ Micropropagation
Fisheries			
Carps	Growth		Mol. Breeding
	Disease resistance	Aeromonas	Mol. Breeding
	Resource management		Genomics
Tiger shrimp	Growth		Mol. Breeding
	Disease	White spot	Mol. Breeding
Fresh water prawn	Disease	White muscle disease	Mol. Breeding
Carp and Shrimp	Disease monitoring		Mol. Diagnostics
Agroforestry			
Casuarina, Teak, Acacia, Albizia, Diptro-carpus, Eucalyptus, Gmelina, Terminalia, Pines, Bamboos	Germplasm fingerprinting Diversity assessment Mass multiplication		Molecular markers Tissue culture

Table 2. Priority Areas for Biotech Applications in Livestock

Species/ Activity	Trait	Proposed Biotech strategy
Sheep, Buffalo, Cattle	Fertility augmentation	Molecular markers
Production of superior animals (all species)	All economic traits	Embryo biotechnology, cloning, transgenic
Genetic analysis of MHC	Disease resistance, production traits	Molecular breeding
Buffalo	Genomic analysis	Genomics
Dairy foods	Control of food borne pathogens	Molecular diagnostics
	Production of bioactive recombinant peptides	r-DNA approach
	Development of dairy culture for health food	r-DNA approach
Feed Biotechnology	Manipulation of rumen eco-system with particular reference to rumen microbes for cell wall digestibility	r-DNA approach
	Development of recombinant bacteria and fungi for breakdown of lignin ring in plant cell wall in crop residues. For preservation of carbohydrates fermentation mechanism needs to evolved. Neutralizing toxins and other incriminating factors in oil cakes	r-DNA technology
Vaccines and diagnostics	For monitoring and control of various diseases of livestock	r-DNA technology

Report of the Working Group - II

"Role of the Ministry of Agriculture"

Chair: Shri R. C. A. Jain

The Convention on Biological Diversity (CBD) defines biotechnology as *"any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"*. This definition of biotechnology covers many of the tools and techniques that are commonplace in agriculture and food production. Cross breeding of plants to improve their yields, taste and quantity and increase their ability to withstand pests, diseases and inhospitable environments has been taking place for centuries, and is not commonly considered as biotechnology. A narrower, but more frequently used, interpretation of biotechnology would cover only the new DNA techniques, molecular biology and reproductive technological applications such as gene manipulation/transfer, DNA typing and cloning of plants and animals.

2. Biotechnology allows farmers around the world help feed a growing population. It helps increase yields while decreasing the need for inputs such as water and fertilizer. It provides improved pest control methods that are more compatible with the environment, including drastic reductions in the need for pesticides. And it helps to produce more with less – less land use, less labor and less risk of total crop loss, a key issue in many parts of the world. Biotechnology thus provides powerful tools for the sustainable development of agriculture, fisheries, forestry, and the food industry. Biotechnology, when appropriately integrated with other technologies for the production of food and agricultural products, can help in meeting the needs of an expanding and increasingly urbanized population in the new millennium.

3. While there is little controversy about many aspects of biotechnology and its applications, genetically modified organisms (GMOs) have become the target of a very intensive and, at times, emotionally charged debate in spite of being one of the most extensively reviewed agricultural advancements to date. Genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. It could lead to higher yields on marginal lands to provide food security in regions that today cannot grow enough food. Rice has been genetically engineered to contain pro-vitamin A (beta carotene) and iron, which could improve the health of many low-income communities. Other biotechnological methods have led to organisms that improve food quality and consistency. Tissue culture has produced plants that are increasing crop yields by providing farmers with healthier planting material. Marker-assisted selection and DNA fingerprinting allow a faster and targeted development of improved genotypes for all living species. The new techniques will enable scientists to increase the efficiency of breeding to restore agronomic problems such as drought resistance.

4. However, there is also concern about the potential risks posed by biotechnology. These risks fall into two basic categories: the effects on human and animal health and the environmental consequences. Caution must be exercised in order to reduce the risks of transferring toxins from one life form to another, of creating new toxins or of transferring allergenic compounds from one species to another, which could result in unexpected allergic reactions. Risks to the environment include the possibility of outcrossing, which could lead to the development of more aggressive weeds or wild relatives with increased resistance to diseases or environmental stresses, upsetting the ecosystem balance. Biodiversity may also be lost as a result of the displacement of traditional cultivars by a small number of genetically modified cultivars.

5. A science-based evaluation is called for that would objectively determine the benefits and risks of each individual GMO. This calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release. The possible effects on biodiversity, the environment and food safety need to be evaluated, and the extent to which the benefits of the product or process outweigh its risks assessed. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals and the environment.

6. Global investment in biotechnological research is generally concentrated in the private sector and oriented towards agriculture in higher-income countries where there is purchasing power for its products. In view of the potential contribution of biotechnology for increasing food supply and overcoming food insecurity and vulnerability, efforts have to be made to ensure that resource-poor farmers benefit more from biotechnological research, while continuing to have access to a diversity of sources of genetic material. This has to be addressed through increased public funding and dialogue between the public and private sectors.

Global Status of GM Crops in 2002 :

7. In 2002, the global area of GM crops was 58.7 million ha. or 145 million acres, grown in 16 countries by 6 million farmers. Of these 5 million are said to be resource-poor in developing countries. GM crop area has grown 35 fold between 1996 and 2002 as one of the highest rates of adoption of any technology in agriculture. The US was the largest grower of GM crops (68%) followed by Argentina (23%), Canada (6%) and China (4%) with the balance grown by other 12 countries. India, Colombia, Honduras grew GM crops for the first time in 2002. The principal GM crops continued to be soybean, maize, cotton and canola. On a global basis 51% of the 72 million

ha. of soybean, 20% of the 34 million ha. of cotton, 9% of 140 million ha. of maize and 12% of the 25 million ha. of Canola was GM. Herbicide tolerance continued to be the most dominant trait occupying 75% of the GM global area in 2002 followed by insect resistance (17%). GM crops represent approximately 13% of the $30 billion global commercial seed market in 2001.

8. Global R&D expenditure in the private and public sectors is $4.4 billion with over 95% of the total in the industrial countries, led by the US. China is the leading investor in R&D crop biotechnology in the developing countries, followed by India.

Biosafety :

9. Biosafety concerns have prompted both developing as well as industrialized countries to implement biosafety guidelines governing testing, safe use and handling of GMOs. A national biosafety system to regulate production and release of genetically modified organisms is considered essential in any country with a biotechnology programme. A brief overview of the biosafety regulations in various countries is presented below:

- *Biosafety regulations in various countries* :

(a) **USA**: The US regulatory system operates in a coordinated framework involving three government agencies: (1) Environmental Protection Agency (EPA), (2) United States Department of Agriculture (USDA) and (3) Federal Drug Administration (FDA). EPA takes the lead role in the commercialization process when the transgenic product is pesticidal. The transgenic products along with conventional pesticides are regulated under existing Federal Insecticide, Fungicide and Rodenticide Act and no new laws has been enacted for such products derived from biotechnology. If the transgenic product is herbicide tolerant, then EPA regulates the herbicide but not the transgene and the USDA is the lead agency. An Inter

Agency Working Group (EPA and USDA) has been constituted to deal with this type of situation. USDA grants import permits, and field trial authorization (under 10 acres for transgenic crops) whereas for field trials over 10 acres, EPA is the responsible agency. Regardless of whether the transgene is herbicide tolerant or pesticidal, a submission to FDA has to be made. FDA's focus is on whether or not the introduced transgene has in any way made the new food substantially different and whether it is safe for consumption. FDA is also the regulatory agency for approvals in case of recombinant DNA products having applications in healthcare.

One of the major reasons for high acceptability of GM crops in United States is the enormous faith US public has in their regulatory system which is very transparent and participatory. This kind of trust unfortunately is totally lacking in Europe particularly in the aftermath of madcow disease.

(b) **European Union**: The EU introduced community biotechnology legislation in the 1990s as part of an effort to address the issues of GMOs and genetically modified microorganisms (GMMs). The EU framework is implemented by the EU institutions (the European Commission, the European Parliament and the Council of Ministers) and the member countries (National Competent Authorities).

The main instrument for giving consent to experimental releases and for placing on the market of GMOs in the community is Directive 90/220/EEC on the deliberate release of GMOs into the environment. Essentially, approval for commercialization requires: (i) case-by-case environmental and health risk assessment (to be completed before notification to a national authority), and (ii) a step-by-step authorization procedure after notification has been received. The EU system requires mandatory labeling of GM foods containing novel DNA/protein.

(c) **China**: China's first biosafety guidelines were produced by the State Science and Technology Commission in December 1993, under which the administrative responsibility for biosafety of various products has been assigned to the relevant administrative departments. In 2002, China has established rules on GMOs to strengthen the safety and management of GMO products. Besides other detailed procedures, these rules require all GM products to be labeled.

(d) **Australia**: In Australia, research, manufacture, production, commercial release and import of GMOs are regulated under the Gene Technology Act, 2003 by the Gene Technology Regulator (GTR). Every dealing with a GMO needs to be licensed by GTR, unless the dealing is an Exempt dealing, a Notifiable Low Risk Dealing or on the Register of GMOs. Three advisory committees, the Gene Technology Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC) and the Gene Technology Ethics Committee (GTEC), provide advice to GTR and the Ministerial Council. Dealings with GMOs and GM products are also regulated by a number of other regulatory agencies where they are to be used for specified purposes.

Regulatory regime in India :

10. The legislative framework on agro-biotechnology is provided under the Environment (Protection) Act. The Rules for the Manufacture, Use/Import/ Export and Storage of Hazardous Micro Organisms/Genetically Modified Organisms or Cells formulated under the Environment (Protection) Act provide for the following multi-tiered regulatory framework to assess and ensure bio safety of genetically engineered organisms:

- The Recombinant DNA Advisory Committee (RDAC), under the Department of Bio-technology to recommend appropriate safety regulations in recombinant research, use and applications.

- The Review Committee on Genetic Manipulation (RCGM), under the Department of Bio-technology, to monitor safety related aspects in respect of ongoing research projects and activities involving genetically engineered organisms. The RCGM lays down procedures/regulations regarding research, production, sale, import and use of genetically engineered organisms with a view to ensuring environmental safety.

- The Institutional Biosafety Committee (IBSC), to prepare site emergency plans for use of genetically engineered micro-organisms.

- The Genetic Engineering Approval Committee (GEAC), under the Ministry of Environment and Forests, to consider proposals relating to release of genetically engineered organisms into the environment.

- The State Bio-technology Coordination Committee (SBCC), to inspect, investigate and take punitive action in case of violations of safety and control measures in the handling of genetically engineered organisms.

- The District Level Committee, to monitor safety regulations in installations engaged in the use of genetically modified organisms and their applications in the environment.

The procedures under the Rules for the Manufacture, on Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Modified Organisms or Cells, are lengthy and cumbersome, as is evident from the time taken for release of Bt. Cotton after 7 long years of trials. It is high time that the existing procedures are reviewed so that bio safety can be

assessed along with agronomic performance in order to cut down on wastage of time.

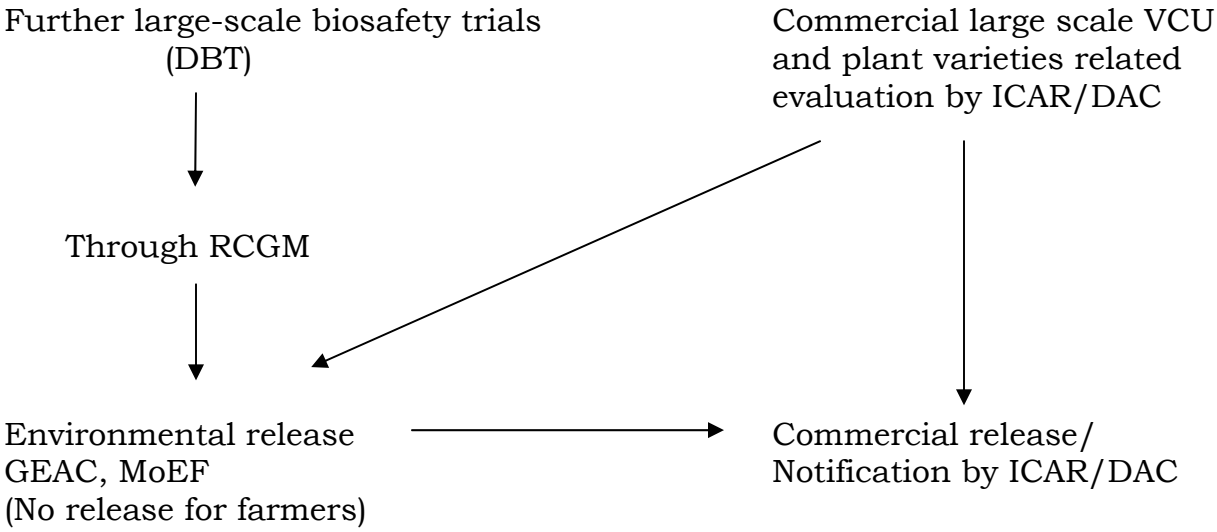
11. It is suggested that while the present system of granting approval for contained and open field trials for biosafety may continue to rest with the RCGM, the multilocational field trials for biodiversity issues and for Value for Cultivation and Use (VCU) should be the sole responsibility of ICAR/DAC rather than of MEC which functions as an arm of RCGM. Further, GEAC may continue to handle biosafety and environmental safety issues of GM crop candidates but 'commercial release' should be with ICAR/DAC as the release for use by farmers comes under the domain of Ministry of Agriculture. No GM crop varieties should be allowed to be released for use by farmers by any agency other than ICAR/DAC who have a system of VCU evaluation and also a regulatory mechanism for release and notification of varieties. Ministry of Agriculture would devise a mechanism to concurrently run the VCU trial of such GM crop candidates for which RCGM clearance has been given and for which large-scale seed production/multiplication has been recommended by GEAC. Such trials would be carried out under the All India Coordinated Trials of the ICAR for multilocational/regional testing and also involving other stakeholders as and when needed. The suggestion made above have been shown below.

Institutional Biosafety Committee with DBT Nominee and experts
(Examines lab and greenhouse studies)

↓

RCGM
(For contained open field trials & generation of biosafety data)
(Time taken of 2-3 months after received the application)
Report submitted to RCGM

↙ ↘



12. Also, once an event has been found to be safe for a particular crop, the subsequent use of that gene for improvement of other varieties/hybrids in the same crop should be free from bio safety concerns. In the case of cotton Cry 1Ac gene has been found to be safe. Therefore, use of this gene for improvement of other varieties should not be subjected to same bio safety concerns. Once the bio safety of a new transgenic crop is established, it should be allowed to be released into the environment after evaluating its agronomic potential. Trials for bio safety and agronomic evaluation should be conducted in tandem in order to save time and resources. Also, the responsibilities of GEAC in respect of proposals relating to the release of GM crops could be transferred to the parent/user Ministry viz. the Ministry of Agriculture which would be better equipped to deal with these issues. In addition, post release monitoring should be ensured by Department of Agriculture & Cooperation and ICAR. Such monitoring would include gene flow to wild relatives and non-targeted crop species, building up of resistance, observance of maintenance of refuge and other post release requisites.

13. The need for streamlining the procedure for commercial release of genetically modified crops is further highlighted by mushrooming of illegal

varieties of Bt. Cotton seed in Gujarat, which is reported to have spread to Andhra Pradesh, Maharashtra, Madhya Pradesh and Punjab as well. The production and sale of spurious Bt. Cotton seed also underscores the need for further strengthening relevant provisions of law under the Seed Act and Environment (Protection) Act. The provision of mandatory registration of crop varieties under the proposed Seed Act is a welcome step in this direction. The provisions relating to breeders' rights under PPV&FR Act also will to some extent help in addressing the problem. There is, however, need for constant monitoring and initiating measures to plug the loopholes in the legal regime governing GM crops.

14. The issues in regard to the release of GM crops have at times been hijacked by vested interests. This has been compounded by the lack of information on this subject amongst even the otherwise informed members of the public. A campaign needs to be conducted to generate public awareness on the benefits and risks associated with biotechnology and the social, economic, scientific, environmental and health issues which are addressed by regulatory bodies before allowing release of GM crops. A scheme should be formulated by DAC/ICAR to hold workshops, seminars, media campaigns (including through the proposed Krishi Channel) to educate the public on matters relating to agricultural biotechnology.

15. Our public research system is expected to provide major breakthroughs in the development of agricultural biotechnology. The traits of such R&D are not, however, being able to be effectively disseminated to the farmers. It is expected that the private sector may in many ways be in a better position to perform this function. DAC/ICAR should therefore broker alliances between the public research system and private companies for production and marketing of GM seeds.

16. The development of GM technology is very expensive. Innovators who evolve new GM seeds may not always be in a position to provide the resources to commercialize their product. GOI should therefore set up a venture capital fund to help commercialize research breakthroughs in development of GM seeds/crops and a bio safety consortium may also be considered along with Department of Biotechnology. A Standing Committee comprising of the Secretaries under M/o Agriculture viz. Secretary (A&C), Secretary (DARE) and Secretary, Animal Husbandry & Dairying may be set up to address issues of strategic importance to the agriculture sector including providing direction to focus research in areas of national priority viz. development of droughts resistant seeds etc.

17. Considering the fact that many countries have strict laws against import of genetically modified products, absence of a policy relating to segregation, labeling and tracing may affect our exports. There is, therefore, a need for a clear policy on segregation and/or identity preservation, labeling and tracing of genetically modified produce. The first step towards this should be to identify a certification agency, which should have well equipped labs. There is also a need for synergy in approach adopted by the various concerned Ministries on these issues. The costs involved in implementing policy relating to identity preservation/segregation, labeling and tracing would also need to be studied. Trade, Marketing and Seeds Division of Department of Agriculture & Cooperation, D/o Animal Husbandry & Dairying & DARE would need to discuss the implications of these issues to formulate the views of the Ministry of Agriculture before discussing with other Department viz. Commerce, Health, Food Processing, etc. in the Government of India.

Report of the Working Group - III

"Regulatory Procedures in Agriculture"

Chair: Dr. Manju Sharma

1. The Ministry of Agriculture & Cooperation vide its Notification No. 11-5/2002/SD-V dated 14.05.2003 has constituted a Task Force on Agricultural Biotechnology under the Chairmanship of Dr. M.S. Swaminathan, MSSRF, Chennai. During its Meeting held on 11.07.2003, it was decided to set up a working group under the Chairpersonship of Dr. (Mrs.) Manju Sharma, Secretary, DBT to suggest modifications in the existing administrative and procedural arrangements in order to streamline/ harmonize rules, procedures, guidelines etc. related to application of Agricultural Biotechnology. The constitution of the working group is at **Annexure-I.**

2. The Working Group on regulatory procedures in agriculture met on 23rd September 2003. The list of members, who attended the meeting is at **Annexure-2.** The background note circulated for the meeting provided details of the existing procedures for recombinant DNA drugs and pharmaceuticals, transgenic crops and also the proposed modifications in the regulatory procedures.

3. The existing procedures are as follows:

A). rDNA Drugs, Pharmaceuticals and Therapeutics:

Proposal

↓

Institutional Biosafety Committee with DBT Nominee

↓

RCGM's approval

↓

Based on the pre-clinical data, RCGM conveys its recommendations to the applicant and copy to the DCG(I) and to GEAC

↓

rDNA Advisory Committee (RDAC) approves the protocol and recommends for conducting human clinical trials

↓

IBSC examines the human clinical trial data and sends it for RCGM and DCG(I) for Recommendation to GEAC for environmental release

↓

GEAC approval for Environmental Release

The applicant is to follow the provisions of the Drugs Act for commercial release of the product. This shall include inspection of the production facilities, according temporary license to produce trial batches, sending products from 5 trial batches to CRI, Kasauli or CDL, Kolkata, receiving the test report by DCG(I) and finally granting approval to manufacture and marketing the product.

B) Steps to be followed for developing Transgenic Crops with new gene in new gene cassette

Proposal

↓

Institutional Biosafety Committee with DBT Nominee

↓

RCGM's approval for Lab & Green House Experiments (one acre per location; maximum 20 locations per crop season) & Generation of relevant data

↓

RCGM's approval for Contained open field trials

& Generation of biosafety data

↓

RCGM's approval for Multi-location trials under RCGM & ICAR trials for generation of biosafety and agronomic data

↓

Large scale field trials under GEAC & ICAR
Trials for generation of biosafety and agronomic data

↓

Commercialization of seeds as per the relevant Acts & Rules

C. GM Foods

As far as GM food products are concerned the application is directly entertained by the GEAC from the importer or exporter of the GM food products, since in India so far no GM food is produced commercially. Similar is the case for industrial products produced through GMOs like enzymes, organic acids, microbial consortia etc.

4. After the detailed discussions, the following step-wise procedures and recommendations were adopted by the Working Group to improve and further streamline the procedures to speedup the decision making process.

Going forward, we need clear regulatory procedures

5. **Revised Regulatory Framework for rDNA Products from all sources (plants, animals, micro-organisms etc.)**

It is proposed that the following steps for the release of rDNA products including drugs, pharmaceuticals, therapeutics and other products from all biological sources be adopted :

rDNA Drugs, Pharmaceuticals, Therapeutics and other products

Proposal/Application to IBSC

↓

RCGM's recommendations

↓

Based on the pre-clinical data, RCGM conveys its recommendations to

↓

Recombinant Drug Advisory Committee (RDAC)
(Approve all clinical trial protocols, examine human clinical trial data etc.)

↓

Drugs Controller General (India) (DCGI)
and
Genetic Engineering Approval Committee (GEAC)

6. Development of Transgenic Crops

Protocol-I

Institutional Biosafety Committee with experts
(Examines lab and greenhouse studies)

↓

RCGM
(For Contained open field trials & Generation of biosafety data)
(Time taken of 2-3 months after receiving the application)
Report submitted to RCGM

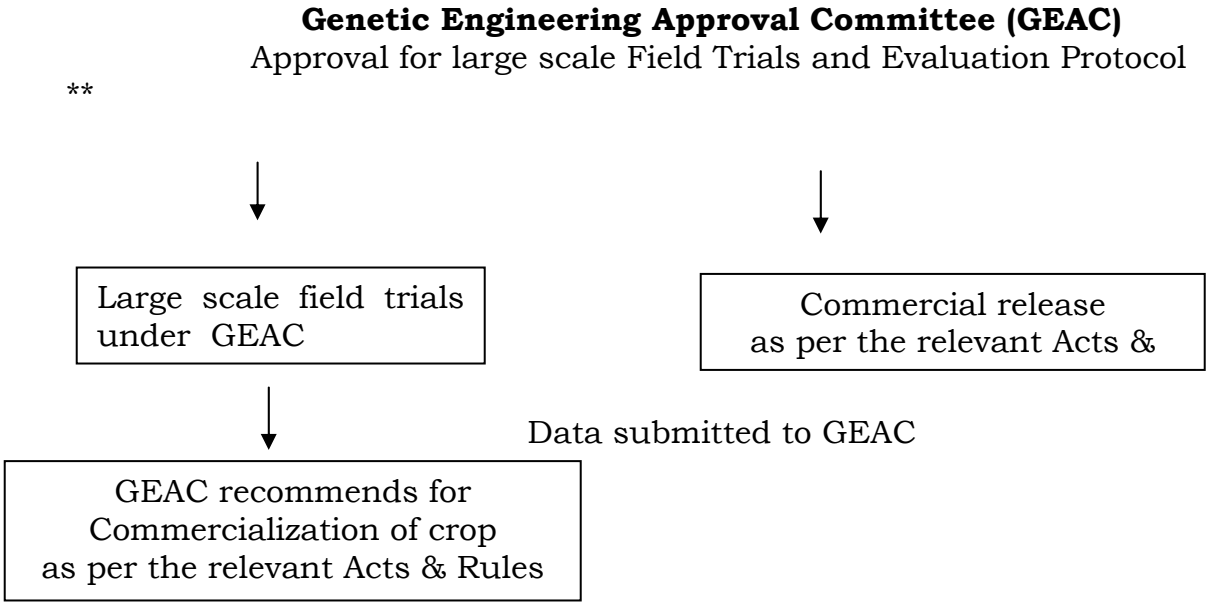
↓

→ Monitoring-cum-Evaluation Committee (MEC) (evaluation And monitoring of field trials)

↓

RCGM
Examines the results of above biosafety and agronomic trial data

↓



7. **The development and release of transgenic crops with approved gene/ gene cassette :**

When a transgenic variety developed and released based on a cassette comprising of given promoter(s) and gene(s) in a crop following all the necessary biosafety and agronomic trials, the further derivatives of this variety or its immediate transgenic parent can be released upon evaluation of one/ two year agronomic performance under All India Coordinated Crop Improvement Project (AICCIP) system and by the applicant. The necessary permission for release will be granted by GEAC upon examination of the relevant data submitted to it by AICCIP and applicant.

8. **Procedure for development and release of GM Foods**

At present GEAC directly considers the applications for the introduction of GM foods in the Indian market. So far no GM food has been introduced. In future a number of GM foods would be introduced. For this it is suggested that a Sub-Committee of GEAC which could consider all such cases for the GM food (processed/ unprocessed) and can

recommend to GEAC for the release of such products. Therefore, for regulation of GM foods the following mechanism is proposed:

Proposal/Application to IBSC

↓

RCGM's recomendations

↓

GEAC Sub Committee (GM Food Advisory Committee (GMFAC)

↓

Genetic Engineering Approval Committee (GEAC)

The Committee (GMFAC) be chaired by Co-Chairman of GEAC. Experts from Ministry of Health, Ministry of Food Processing, Ministry of Agriculture, Department of Biotechnology, ICAR and other subject specialists may be included in the Committee. Member Secretary of the GEAC can act as Member Secretary of this Committee.

9. Other recommendations

a) Post release monitoring of transgenic crops should be done by the Ministry of Agriculture and reports may be sent to GEAC for any action, if necessary.

b) The Working Group was of the view that strengthening of the present system can be a better option rather than going for a new system of "National Commission on GMOs". The existing system under EPA can be further streamlined with various recommendations made by the Working Group.

c) It was suggested that GEAC may be chaired by an eminent scientist having expertise in Molecular Biology having vast experience in rDNA technology. Accordingly, the Gazette

Notification may be modified. A highly professional Secretariat in the Ministry of Environment & Forests may be set up to service GEAC. It should also network and use the existing expertise of relevant national laboratories and academic institutions.

Annexure-I

Composition of the Working Group:

1. Dr. Manju Sharma, Secretary, DBT - Chairperson
2. Dr. C.M. Gupta, Director, CDRI, Lucknow - Member
3. Dr. S. Nagarajan, Director, IARI, New Delhi - Member
4. Dr. R.P. Sharma, Emeritus Scientist, IARI, New Delhi - Member
5. Dr. Sudhir Sopory, Scientist, ICGEB, New Delhi - Member
6. Dr. Sushil Kumar, NCPGR, New Delhi - Member
7. Mr. Navin B. Chawla, Spl. Secretary, MoE&F, New Delhi- Member
8. Shri Raju Barwale, Mahyco, Mumbai - Member
9. Dr. K.K. Narayanan, Metahelix Laboratories, Bangalore- Member

Annexure-2

List of participants:

1. Dr. Manju Sharma, Secretary, DBT
2. Dr. Sushil Kumar, NCPGR, New Delhi
3. Dr. Ranjini Warrier, Addl. Director, MoE&F, New Delhi
4. Shri Raju Barwale, Mahyco, Mumbai
5. Dr. K.K. Narayanan, Metahelix Laboratories, Bangalore
5. Dr. K.K. Tripathi, Adviser, DBT
6. Shri. Sanjay Vikram Singh, Director, Min. of Agriculture.
7. Dr. T.V. Ramanaiah, Scientist-F, DBT

Record note of the meeting of the 'Group of Scientists' on "Rationalization of the parameters for development of transgenic crops by incorporating biosafety & agronomic evaluation requirements and environmental safety aspects" held on 22.12.2003 in the Department of Biotechnology.

During the meeting of the Task Force on 'Applications of Biotechnology in Agriculture' held on 14.12.2003 at Hyderabad, the Task Force recommended to constitute a small committee comprising scientists from MoA, ICAR, DBT and other experts to discuss "Rationalization of the parameters for development of transgenic crops by incorporating biosafety & agronomic evaluation requirements and environmental safety aspects" and to submit a report to the Task Force. During the meeting, MoA, ICAR & DBT had identified the scientists to constitute the group. The list of scientists who were inducted in the 'Group of Scientists' is annexed at **Annexure-I.** DBT had organized meeting of the Group of Scientists on 22.12.2003. The list of scientists who attended the meeting

are annexed at **Annexure-II**. Dr. C.D. Mayee, Agricultural Commissioner, Ministry of Agriculture was specially invited to Chair the meeting.

At the outset of the meeting, Dr. Mayee welcomed the scientists and expressed that the procedures adopted for development of Bt cotton can taken as bench mark and with experience gained, the procedures can be further modified by bringing in all concerned authorities.

Dr. T.V. Ramanaiah, Scientist-F, DBT informed the scientists about the deliberations of the Task Force in the meeting held on 14.12.2003 at Hyderabad, the genesis and the objectives of the meeting of the Group of Scientist. Dr. S.P. Tiwari, ADG (Seeds), ICAR further supplemented the information by stating that the Group should also discuss on the reducing time limit and steps to be followed by the applicant. The Group of Scientists had discussed the parameters of biosafety and the procedures to be followed for the development of transgenic crops one after another. After considerable discussions on the subject matter, the Group recommended the following :

<u>Recommendations of the 'Group of Scientists' on the Biosafety parameters</u> :

Information needed to be collected/generated by the applicant on transgenic crop and submitted to Review Committee on Genetic Manipulation (RCGM) on the following parameters :

A. <u>General information</u> :

- Rationale for development of transgenic crop
- Description of the host plant

- Mode of pollination
- Centers of origin/diversity of the crop species
- Geographical distribution of the target crop and sexually compatible plant species including wild relatives

B. Biosafety Parameters :

1. Genetic and Molecular parameters

- Genetic analysis including copy number of inserts,
- Stability of the gene,
- Level, site(s) and duration of expression of transgene
- Characterization of expressed gene product;
- Efficacy/utility of gene product;
- Compositional analysis

2. Environmental parameters

- Gene flow
- Implications of out-crossing
- Effect on target and non-target organisms
- Effect on soil biota

3. Toxicity parameters including histo-pathological studies (need based)

Food/feed safety evaluation in animals such as

- Effect on small laboratory animals
- Effect on livestock animals (representative goat studies of large animals)
- Effect on birds/avian species
- Effect on fish

4. **Allergenicity parameters (need based)**

- Primary skin irritation test in rabbit/guinea pigs
- Irritation to mucous membrane test in rabbit/guinea pig
- Immunological responses in suitable animal system

C. Agronomic paramters

- Efficacy of the gene at phenotypic level
- Yield
- Growth and developmental parameters
- Responses to major diseases and insect-pests
- Quality parameters
- Economic evaluation/cost : benefit ratio

(Operational protocols to be developed by RCGM for 'B' and by ICAR for 'C' depending upon the host crop)

Annexure-I

1. Dr. C.D. Mayee, Commissioner of Agriculture, MoA, New Delhi.
2. Dr. S.P. Tiwari, ADG(Seeds), ICAR, New Delhi.
3. Dr. B.S. Dhillon, Director, NBPGR, New Delhi.
4. Dr. Rajendra Kumar, Head, Seed Science & Technology, IARI, New Delhi.
5. Dr. B.M. Prasanna, Division of Genetics, IARI, New Delhi.
6. Dr. K.R. Koundal, NRCPB, IARI, New Delhi.
7. Dr. America Singh, Director, NCIPM, IARI, New Delhi.
8. Dr. Sudhir Sapory, ICGEB, New Delhi.

9. Dr, Akhilesh Tyagi, UDSC, New Delhi.
10. Prof. Veluthambi, MKU, Madurai.
11. Dr. B. Arunachalam, MSSRF, Chennai
12. Dr. Ranjini Warrier, Additional Director, MoE&F, New Delhi.
13. Shri Sanjay Vikram Singh, Director, MoA, New Delhi.

Annexure-II

Participants of the meeting

1. Dr. C.D. Mayee, Commissioner of Agriculture, MoA, New Delhi.
2. Dr. S.P. Tiwari, ADG(Seeds), ICAR, New Delhi.
3. Dr. K.R. Koundal, NRCPB, IARI, New Delhi.
4. Dr. Rajendra Kumar, Head, Seed Science & Technology, IARI, New Delhi.
5. Dr. B.S. Dhillon, Director, NBPGR, New Delhi.
6. Dr. B.M. Prasanna, Division of Genetics, IARI, New Delhi.
7. Shri Sanjay Vikram Singh, Director, MoA, New Delhi.
8. Dr. K.K. Tripathi, Adviser, DBT.
9. Dr. T.V. Ramanaiah, Scientist-F, DBT.

Report of the Working Group - IV

"Application of Biotechnology in Animal Husbandry"

Chair: Dr. Amrita Patel

The Ministry of Agriculture and Cooperation, Government of India vide their notification No.11-5/2002/SD-V dated 14-05-2003, constituted a Task Force on Agriculture Biotechnology under the Chairmanship of Dr MS Swaminathan, Chairman, MSSRF, Chennai. During its meeting held on 26-08-2003, it was decided to request Dr Amrita Patel, Chairman, NDDB to chair a Working Group of Experts to prepare a base paper on

the “Application of Biotechnology in the Animal Husbandry Sector, with special reference to the use of GM Feeds and its implications on Trade”.

The list of experts in the Working Group is given in Annexure -III.

The first meeting of the Working Group was held on 21.11.2003. A background note was circulated to the members. After deliberating on the subject, sub groups of experts were set up and they were advised to co-opt additional members, if required and prepare notes covering various aspects related to the following areas.

1. Vaccines and other Biologicals produced by genetic modification of plants and organisms for use in livestock.
2. Ingredients and byproducts of GM crops used in animal feeds.
3. GM organisms and their products used in the dairy industry.

Based on the information received an interim on “Application of Biotechnology in Animal Husbandry sector, with special reference to use of Genetically Modified Feed and its implications on Trade” was prepared and forwarded to the Department of Animal Husbandry, Ministry of Agriculture, for discussions during the meeting of the Task Force held in Hyderabad, on December 14th, 03.

Copies of the interim paper were also sent to other members of the group, for their comments and suggestions, if any. The attached base paper incorporates the inputs received from the members.

BASE PAPER ON "APPLICATION OF BIOTECHNOLOGY IN ANIMAL HUSBANDRY SECTOR, WITH SPECIAL REFERENCE TO USE OF GENETICALLY MODIFIED FEED AND ITS IMPLICATIONS ON TRADE".

Introduction

Genetic Engineering is one of the most powerful biological developments made, so far. It provides tremendous opportunities for several industrial sectors such as agriculture, food manufacturing, biologicals and drugs. During the last couple of decades, molecular methods have been developed to clone genes and transfer them to other living organisms or plants, resulting into Genetically Modified Organisms (GMOs) or Genetically Enhanced Organisms (GEOs).

Tissue culture vaccines:

Tissue culture vaccines are already in use in the animal health sector for more than three decades. Various tissue culture vaccines both inactivated and live attenuated, currently in the market are:

Tissue culture inactivated viral vaccines:

1. **Avian Infectious Bronchitis Vaccine,**
2. **Canine Contagious Hepatitis Vaccine,**
3. **Canine Corona Virus Vaccine,**
4. **Canine Parvo virus Vaccine,**
5. **Egg-drop Syndrome 76 (Adenovirus) Vaccine,**
6. **Foot and Mouth Disease Vaccine,**
7. **Infectious Bursal Disease Vaccine,**
8. **Rabies Veterinary Vaccine,**

Tissue culture Live attenuated viral vaccines:

1. **Canine Contagious Hepatitis Vaccine,**

2. **Canine Distemper Vaccine,**
3. **Canine Para-influenza Virus Vaccine,**
4. **Canine Parvo-virus Vaccine,**
5. **Fowl Pox Vaccine,**
6. **Goat Pox Vaccine,**
7. **Marek's Disease Vaccine,**
8. **Sheep Pox Vaccine,**
9. **Swine Fever Vaccine,**

Vaccines and biologics from GMO:

In developing countries, plant based vaccines and other rDNA vaccines can play a major role in health improvement: increased vaccine coverage and hence improved herd immunity and disease eradication. Plant based vaccines are also an attractive, alternative mode of vaccine delivery because it does not involve the use of needles. Edible vaccines will have rapid and wide acceptance among the public if proven to be safe and effective. Thermostable vaccines produced by rDNA technology are also extremely relevant in tropical countries, where the infrastructure for cold chain is not available or affordable. The main cause of vaccination failures in developing countries is spoilage of vaccines due to exposure to high ambient temperatures, in the absence of infrastructure required for effective maintenance of cold chain.

Bio-engineered plants can be used as vehicles for veterinary vaccines/drugs and other biologics. For example plants can be modified to express vaccines and antibodies intended for specific or over all animal health improvement. Biologics are recombinant proteins designed to have a specific effect in the target species. Biologics may be administered in oral form or in parenteral form.

The following is a partial list of genetically modified plants being used in different countries to produce recombinant proteins for use in veterinary preventive medicine either in oral or par-enteral form.

- Foot-and-mouth disease peptide vaccine in alfalfa
- Foot-and-mouth disease VP1 expressed by tobacco mosaic virus

- Rinderpest hemagglutinin in peanut leaves
- Rabies vaccine (different plants)
- Bovine Herpes virus -1 glycoprotein expressed by tobacco mosaic virus
- Mink enteritis virus VP2 expressed by cowpea mosaic virus
- Canine parvo-virus VP2
- *Taenia solium,* cysticercosis peptide vaccine
- Rabbit hemorrhagic disease VP60 protein

GM crops for food and feed:

The application of recombinant technology in crops for food and feed is being pursued in the developed world and claims are being made that

(i) Significant yield increases are possible

(ii) An improvement in the nutritive value through increase in essential amino acids, minerals and vitamins as is claimed in soybean, corn and rice.

(iii) The elimination of certain allergens, anti-metabolites and toxins.

(iv) Increase in resistance to insects, bacteria, viruses and fungi leading to reduced losses.

(v) Cleaner environment due to reduction in use of chemicals for control of pests.

By the end of 1997, total 18 recombinant crops were approved in USA. USA, Canada and Argentina have started commercial scale production of some GM crops. Even in the UK, sizable quantities of GM soybean and maize are being imported from USA for use in animal feeds. Till January 2003, Canadian Food Inspection Agency had approved 29 plants with novel traits for use in livestock feeds. These include 12 corn, 11 canola, 3 cotton, 2 soybean varieties and one wheat variety. By April 2001, the US Department of Agriculture, had approved the commercial use of 52 different GM crops, which included soybean, corn, cotton, canola, sugar beat, rice etc.

During the year 2000, worldwide, GM crops were grown over an estimated area of 44.3 million hectares. The main GM crops grown commercially were soybean, maize, cotton and canola (Table 1). While varieties of GM crops are being developed in many countries including

India, their incorporation and use in commercial foods/feeds is being mainly practiced in US, Argentina, Canada and China. Maximum production of GM crops is in USA, where 30 million hectares of land was covered during the year 2000 (Table-2).

Table-1: Estimated Land Area under Coverage with GM crops, during the Year 2000.

Crops	Area (Million hectares)	GM Traits
Soybean	25.8	Herbicide resistant
Maize	10.3	Insect and herbicide resistant
Cotton	5.3	Insect and herbicide resistant
Canola	2.8	Herbicide resistant

(Reproduced from Meat and Livestock, Australia, Dec. 2001).

Table-2: Country wise Land Coverage with GM crops, during the year 2000.

Countries	Area (Million Hectares)	GM Crops
USA	30	Many crops
Argentina	10	Soybean, Corn, Cotton
Canada	3	Canola, Corn
China	0.5	Cotton, Carnation
Australia	0.2	Corn, Cotton
South Africa	0.1	Corn

(Reproduced from Meat and Livestock, Australia, 2001).

In India, research is in progress in several laboratories, but none of the transgenic crops have been commercialized, so far. Plants on which research is being conducted in various ICAR institutes are rice, mustard, cotton, potato, cabbage, tobacco, etc.

Rapeseed-Mustard (Sarson, Rai, Raida) is the second most important oilseed crop in India covering an area of over six million hectares with production touching beyond six million tonnes.

Indian mustard seed, however, has two major limitations viz., high erucic acid (up to 55%) which is not considered desirable from the nutrition viewpoint and high level of glucosinolates which affects the palatability of

the mustard cake as animal feed. Mustard meal with high glucosinolate also depresses the appetite of animals lowering their productivity through goitrogenic effects. Because of this, the Indian mustard meal fetches about half the price compared to better quality meal produced in North America or Europe in the international market.

NDDB has been working on the development of double zero rapeseed-mustard varieties. The development of double zero varieties has manifold advantages. The double zero varieties will have lower glucosinolate level in (less than 30 micromoles per gram of de-fatted meal from the current level of about 180 micromoles per gram) and erucic acid below 2% (from current level of about 45-50%) in oil. With reduction in glucosinolate level and consequent reduction in pungency, the palatability of double zero meal in animal and bird feed would improve substantially. This would also encourage cultivation of rapeseed-mustard in non-traditional areas. Acceptability of double-zero oil would also improve among consumers who hitherto were consuming traditional oils like groundnut, soybean etc.

GM organisms and their products used in dairy industry:

GM microorganisms are applied for production of calf chymosine and bovine growth hormone. The calf gene for chymosine has been copies and inserted into yeast cells (*Kluyeromyces lactis* and numerous other species) which produce pure chymosine. The yeast derived enzyme is similar to animal enzyme. It was first approved for use in USA and most European countries.

Recombinant bovine somatotropin (rBST) is used to stimulate lactation resulting in increase in milk production by 10-15 percent. This therefore leads to lower cost of milk production. Around nine million dairy cows in the USA are in herds treated with rBST. Its use however is still controversial and not permitted in Europe and India.

GM starter cultures have been developed by the scientists. Phage resistant cultures have been developed by microbiolgists by inserting plasmids into DNA of bacteria to increase their viability during cheese making, providing more predictable performance and reducing the chances of financial loss from “dead vats”. Scientists have successfully employed genetic engineering techniques to enhance the flavour potential of cheese cultures. Production of bio-preservatives through GM lactic bacteria is also being attempted to increase the shelf life of dairy foods especially in warm countries.

Probiotic lactic bacteria and rumen bacteria & fungi are being targeted for genetic modification to improve the digestion and utilization of fibrous feeds and to reduce the emissions of methane by ruminant animals. Enzymes like amylase, cellulase, hemicellulase, proteinase and pectinance, etc., are being produced from GM microorganisms.

In India, NDRI Karnal has been working on the cloning and expression of buffalo chymosine genes in yeast cells i.e. *Pichia sp*. For production of this enzyme at lower costs and without killing the animals.

CONCERNS WITH REGARD TO REGULATORY MEASURES TO EVALUATE GM PRODUCTS:

While the list of applications of GM products is long, concerns have been raised globally and particularly in India, as to whether the GMOs or their products are safe, if used as food or feed or as biologics for the prevention and treatment of diseases. These concerns are mainly related to two areas, the first concerning the effect of consumption of livestock products from animals fed on GM feed on human health and the other concerning the environment. These concerns are primarily because enough attention has not been given to putting in place regulatory measures for their development including the production and commercial release of GMOs and their products.

I. **Regulatory measures being implemented in developed countries**

In some developed counties a number of bio-engineered plants and organisms have been approved for commercial use and many more are in developmental stages. Some of these Bio-engineered plants/ organisms and their products are being used or may be used as human food, animal feed or as vaccines for humans as well as animals. Many of the genetically modified crops/plants have specific resistance to pests, herbicides or plant pathogens.

In the USA and Canada different agencies are involved in the regulation of GM products, through co-ordination of various functions. The regulatory agencies and their roles in these countries are outlined below, which indicate how genetically modified plants are regulated in these countries. The following tables show the regulation of genetically modified plants / crops / organisms in US and Canada. The regulation is achieved by co-ordination between different agencies.

<u>US regulatory authorities for biotechnology products</u>

Agency	Jurisdiction
Unites States Department of Agriculture (USDA)	Plant pests, plants, veterinary biologics
Food and Drugs Administration (FDA)	Food, feed, food additives, veterinary drugs, human drugs, medical devices
Environmental Protection Agency (EPA)	Microbial and plant pesticides, new uses of existing pesticides, novel microorganisms

Canadian regulatory authorities for biotechnology products

Agency	Jurisdiction
Canadian Food Inspection Agency	Plants and seeds, including those with novel traits; animals; animal vaccines and biologics; fertilizers; livestock feeds
Environment Canada	Biotechnology products such as micro-organisms used in bioremediation; waste disposal, mineral leaching or enhanced oil recovery
Health Canada	Foods; drugs; cosmetics; medical devices; pest control products
Fisheries and Oceans	Potential environmental release of transgenic aquatic organisms

In September 2002, the US regulatory agencies prepared a draft guideline for the industry for the growth and cultivation of bio-engineered plants for preparing drugs and biologics and this draft is currently being circulated for comments. This draft guideline details the general considerations for genetically modified plants/crops/organisms, information to be furnished by the manufacturer/researcher in the application and instructions for notification, before planting GM plants/crops.

The US draft guidelines also address environmental issues, bio-safety and pre-clinical tests for allergenicity, in the case of products designed for human or animal use. A formal review process for veterinary biologics and drugs has not been instituted in the US.

In Europe and Japan, much of the debate regarding genetically modified plants is about proper labeling of foods meant for human consumption and prevention of adulteration. A formal review process for the evaluation of veterinary vaccines and biologicals does not seem to exist in these countries. No labeling is required either for foods produced from animals fed on GM feed or for products made with the help of a GM enzyme. Currently, public confidence in GMOs and GM products is at an all time

low. In European countries hardly any GM food products are seen in the super markets. The new regulation set up by EU, during November 7, 2003, requires producers and suppliers of feed and food to retain and provide information regarding traceability and transmit it through out the commercial chain, including the identity of the GMOs a product may contain. Suppliers henceforth are required to label products, if these contain GMOs. Feed additives made from a GMO also require labeling, as per the proposed new EU regulatory rules. Need to label seeds, foods, feed and the biologics having GMOs or their products, so as to inform consumers that the product is produced from genetically modified crops/plants/organisms. The onus for this should be on the producer / supplier to inform consumers that the product does or does not contain GMOs or the products of GMOs.

GM modification of food grade organisms is permitted only if all the genes come from lactic acid bacteria and the inserted DNA is integrated into the host chromosome. Recombinant bacteria are selected by their ability to grow on medium containing antibiotics. Given the possible transfer of antibiotic resistance genes to other bacteria there is absolute agreement that these should not be used in any food/feed. Products derived from fermentation using GM microbes are subjected to safety testing and regulatory procedures prescribed for GM crops.

II. Regulatory measures being implemented in India as on date for evaluation of biologicals and drugs derived from GM organisms

To the best of our knowledge, there are no policies formulated or prescribed by the Government of India for testing of bio-engineered plants/crops/ organisms designed for the production of veterinary biologics and feeds. The rDNA safety guidelines published by the Department of Biotechnology (DBT) describe in detail, the bio-safety measures, guidelines and approved procedures for research in the development of rDNA products. The DBT guidelines also describe in detail the containment, bio-safety levels and test methods required for production of rDNA organisms.

Vaccines undergo test for sterility, potency and safety as per Indian Pharmacopoeia (Veterinary). There are no regulations for the production of tissue culture vaccines. The Department of Biotechnology, Government of India, has issued safety guidelines which indicate that the Institutional Biosafety Committee (IBSC) should monitor large scale production of tissue culture vaccines particularly when the fermenter size is 20 litres or more.

This paper seeks to draw attention to the urgent need to formulate guidelines for testing of bio-engineered plants/crops/organisms for potential use in Animal Husbandry.

III. Additional regulatory measures/ guidelines, including infrastructure that need to be put in place or strengthened for effective implementation in India.

a. Scope of the guidelines:

Before approval for wide use, genetically modified plants/crops/organism need to be tested for their safety and efficacy. The manufacture of veterinary biologics and drugs in India is governed as per the Indian Pharmacopoeia (Vet). The general standards and procedures of biologicals and drugs preparation apply to bio-engineered plants as well. In cases where the biologic or drug or diagnostic reagent is to be purified from a bio-engineered plant (plant factories), sterility testing is required. In the case of bio-engineered plants designed for oral delivery of biologics and drugs, however sterility testing may be omitted. The details outlined here should be read in conjunction with the existing pharmacopoeia guidelines. The tests described in this document supplement the tests described in the Indian Pharmacopoeia (Vet).

b. General Considerations:

The manufacturer/researcher must obtain permission from the Institutional Bio-safety Committee (IBSC), as per the Guidelines prescribed by the Department of Biotechnology, Ministry of Science and Technology, Government of India, before developing a recombinant protein expressing plant/crop/organism. Laboratory scale production and testing should be carried out with strict adherence to containment and bio-security measures after obtaining approvals from the appropriate government agency. A small- scale cultivation of the crop/plant/organism should be undertaken, harvested and used for pre-clinical tests/ nutritional evaluation. The results of the in-vitro and in-vivo pre-clinical tests should be submitted to DCGI/RDAC/ICAR and only after their review and approval, should large- scale cultivation/ production should be undertaken. In the case of veterinary biologics and drugs, pre-clinical and clinical tests could be carried out concurrently, so that the duration of the approval process is shortened (see Annexure I). In the case of bio-engineered plants/organisms designed for production of a diagnostic reagent for use in in-vitro tests, the in-

vivo pre-clinical and clinical tests may be omitted. In this case in-vitro tests could be used to verify the claims of the manufacturer/researcher.

c. Pre-clinical Tests

Pre-clinical tests may be of two kinds: in-vitro tests and in-vivo tests. The proposed in-vitro tests are suggested to characterize the recombinant DNA and the expressed protein/non-protein product. The in-vivo tests are meant to check the safety of the product in laboratory animal models. The manufacturer/researcher should submit the documentation regarding the recombinant DNA methods used; nature of plasmids/vectors and the data regarding the expressed product. The manufacturer/researcher should include the following details to describe the plasmid(s) used for making the recombinant DNA in his application:

- Origin and function of all component parts of the construct, including coding regions, antibiotic resistance genes or other selection markers, origins of replicators, promoters and enhancers;

- Physical map of construct illustrating the position of each functional component;

- Method used for plasmid propagation;

- Nucleotide sequence of the insert

- Complete information regarding the coding region must be provided, including full length and truncated sense constructs, anti-sense constructs, and constructs containing ribozymes, regardless of whether or not the coding region is designed or expected to be expressed in the bio-engineered plant/organism.

- Details of transformation systems used including their origin, taxonomic classification and any changes that were made to the plasmid should be provided.

- The identity and nature of the expressed product should also be included in the application. The protocol for preparation of nucleic acid from plasmid;

- Characterization of the nucleic acid with respect to its identity with the parental genome

***(i) In-vitro tests*:**

The in-vitro pre-clinical tests should be designed to verify the claims of the manufacturer/researcher. The focus of the in-vitro pre-clinical tests should be to check the fidelity and integrity of the foreign DNA in the bio-engineered plant and the nature of the expressed product.

The manufacturer/researcher should submit in his application the number of integration sites; number of gene copies per site; promoter and/or enhancer sequences used and any other genetic element used for expression of product. If a fragment of an insert is designed for expression as fusion protein, details of the fusion protein and the parts of host tissues that produce the fusion protein must be documented. It is suggested that the pre-clinical in-vitro tests should check the integrity and fidelity of the inserted rDNA.

Proposed tests for characterization of the gene:

S. No	Proposed Test	Purpose	Comments
01	Southern hybridization using complementary sequences of the recombinant DNA	To verify presence of insert	May reveal number of copies of the inserted gene
02	Northern hybridization using complementary sequences of the mRNA produced by the inserted gene	To verify expression of product	May be used to check expression in different parts of the plant
03	Nucleotide sequencing of the insert	To verify integration of the insert DNA	May include 5' and 3' junctions of the insert
04	PCR or southern hybridization	To verify presence of gene in the fusion protein gene construct	

(ii) Tests for presence and tissue distribution of expressedproducts:

The expression of the product in the intended part of the plant must be demonstrated. Ideally the method should be quantifiable, so as to estimate the quantity of expressed product in the bio-engineered plants. The assay method and the limits of detection should be documented.

Proposed tests for presence and tissue distribution of expressed products:

S. No	Proposed Test	Purpose	Comments
01	ELISA using specific polyclonal/Monoclonal antibodies	Verifies expression of the gene product	Help in quantification of the expressed product
02	Western blot using specific polyclonal/Monoclonal antibodies	Verifies expression of the gene product	
03	ELISA using antibodies against fusion protein	Verifies expression of fusion product	Help in quantification of the expressed fusion product

Characterization of the expressed product:

The in-vitro tests for characterization of the expressed product should include identity and physico-chemical measurements.

Proposed tests for characterization of the expressed product:

S. No	Proposed Test	Purpose	Comments
01	Chromatography profiles	Molecular weight estimation	To identify the expressed product
02	Spectroscopic measurements	Physical characterization	
03	Amino acid sequencing / N-terminal amino acid sequencing	Verifies product identity	

For biologics and drugs it should be necessary to organize pre-clinical potency and safety tests

d) In vivo pre-clinical tests:

(i) Pre-clinical studies for safety:

Before approval for large- scale manufacture, bio-engineered plants/organisms need to be tested for safety in suitable laboratory animal models (rodents and/or non-rodents). This could involve

acute, sub-acute and chronic studies to determine if the bio-engineered plant and the expressed products can cause deaths and/or clinical symptoms in test animals. Established protocols should be followed for the pre-clinical studies in small laboratory animals.

(ii) Pre-clinical studies for potency:

The pre-clinical tests for potency need to be carried out concurrently with pre-clinical studies for safety. In the case of ruminants, sheep or goats may be used as animal models. In the case of poultry, chickens could be used as models for testing the potency. The potency of the product could be tested using established protocols for the recombinant biologic under test. The potency tests should be designed to confirm the manufacturer/researchers claim regarding the intended effect of the bio-engineered plant on the target species. For example bio-engineered plants expressing vaccines need to be tested using protection, sero-conversion and supplemental studies.

<u>The current measures for production of tissue culture vaccines are adequate and can continue as such.</u>

Transgenic plants/crops and feeds derived from the above would need specific evaluation for biochemical composition, nutritive value, tests for allergenicity and toxicity in laboratory animals, such as mice or guinea pigs etc, followed by trials in small ruminants in case of products advocated for ruminants, in dogs for the products advocated for canines and in chickens for the products for poultry.

IV. **Additional infrastructure required in India for testing genetically modified plants/crops/organisms:**

Conventional veterinary biologics in India are tested for safety and efficacy. Bio-engineered plants/organisms and their expressed products require methods, technical expertise and equipments different from the facilities used for testing conventional vaccines and biologics. The Indian Institute of Science, Bangalore as a premier scientific institution has the facilities and technical expertise to characterize recombinant DNA and the expressed product. Experimental bio-engineered plants/organisms have been produced in the Institute for use as vaccines. It is suggested that the Indian Institute of Science be assigned with the responsibility to conduct pre-clinical <u>in-vitro</u> tests for all biologics/diagnostics.

Adequate funds would need to be provided to them to cover the cost of the additional equipment, facilities and recurring expenses. However, the products developed at IISc could be tested at ICGEB, NII, or NRC on plant technology, where adequate infrastructure and expertise exists.

The evaluation of GM crops and feeds derived from GM crops/plants could be undertaken for nutritional parameters, biochemical composition, allergenicity and carcinogenicity, in some of the ICAR institutes, with specialization in animal nutrition. The facilities existing at Indian Veterinary Research Institute which is authorized by the DCG(I)/ICAR could be strengthened and utilized for conducting clinical trials on GM Feed. Based on the results, ICAR should recommend use of GM crop or GM crop products in animal feed to GEAC. The GEAC shall approve use of GM crop/ product for animal use.

The safety and potency testing in animals should invariably be done in Animal Science Institutes where expertise is available for such evaluation.

All such testing should be carried out in controlled environment including bio-containment both for crop production and feeding so that recycling of all organic products and wastes can be monitored.

It is likely that GM feed/vaccines will be adopted in a big way in the near future. An independent and well-equipped laboratory (more than one depending upon the geo-climatic conditions required for production of each GM crop) is required to be created. This quality control laboratory for GM products for livestock is absolutely essential. Once established, this can be sustained by payment received for testing each prospective product, irrespective of the outcome of the test.

V. **Proposed product movement through the regulatory system:**

The following table shows the recommended route for approval of a bio-engineered plant/organism designed for production of veterinary biologics and drugs and crops for use in animal feeds.

Research & Development	• Compliance with DBT guidelines for recombinant DNA; approval from IBSC

Small-scale cultivation	• Manufacturer/researcher receives the approval from the Government regulatory agency following notification (in US approval is given by Animal and Plant Health Inspection Services of the USDA) • Manufacturer/researcher complies with Government of India guidelines for growth and cultivation of bio-engineered plants/organisms
General Environmental Release	• Manufacturer/researcher applies to the Government regulatory agency for determination of non-regulated status (in US approval is given by Animal and Plant Health Inspection Services of the USDA)
Commercial manufacture Cultivation.	• Manufacturer/researcher conducts pre-clinical and clinical tests (see Annexure I) • Review of test results and approval

VI. Clinical tests for bio-engineered plants:

For clinical tests, an experimental batch of the bio-engineered plant/organism should be cultivated, properly labeled and shipped to the testing institutions. Clinical tests for bio-engineered plants/organisms and products derived from them would need to be undertaken in a systematic manner based on the intended use of the product and the target species. In the case of vaccines, animal trials would include oral or parenteral administration of the product and measurement of antibody response, confirmation of sero-conversion or decreased pathogen burden. The choice of study design, assay methods and validation will depend on the expressed product and its intended use. The scope of the clinical tests should be adequate to verify the manufacturer/researcher's claim.

Additional safety testes required would consist of

1. Comparative efficacy between conventional vaccine versus edible rDNA vaccine in terms of:

   (i) Immune response
   (ii) Protective ability (PD50)
   (iii) Duration of immunity following single/recommended amount of feeding

2. Effect on discontinuance of edible vaccine and resumption of conventional vaccine

   - ❖ Any inter-phase required ??
   - ❖ Will a subsequent conventional vaccine compromise the previously acquired immune status through edible vaccine??
   - ❖ Will there is a choice for farmers for interchange between edible vaccine and conventional vaccine (similarly between GM fodder and conventional fodder)??

3. Tests for detecting traces of new protein/antigen or product/construct in milk, meat, egg and other edible livestock products, which originated from animals fed with GM geed or edible vaccines. Long-term effect on feeding such livestock products on humans.

4. Tests for detecting traces of new protein/antigen or product/construct in excreta (dung, urine etc). Effect thereof in soil, further entry into the food chain.

5. Effect of feeding GM fodder/edible vaccine on physiological functions, e.g. reproductive, immunological, draught power and other metabolic functions.

6. Effect on progeny of animals that were fed with GM feed/edible vaccine.

7. Effect on human health.

VII. **Suggestions regarding bio-safety measures, which need to be adopted in India during the development, testing and commercial production of biological products and drugs from GM organisms, intended for use in livestock and particularly in dairy animals.**

During laboratory development of genetically modified plants and organisms, the DBT guidelines for handling of recombinant DNA and genetically modified plants/organisms should be applied. A brief mention of the important stages in the development is mentioned below.

- **Cultivation and harvesting of genetically modified plants/organisms/crops for pre-clinical/nutritional tests**

should be carried out in a green house/ high security lab with proper containment and bio-security facilities.

- **The manufacturer/researcher should ensure freedom from rodents, restricted entry of personnel and de-contamination of the farm / laboratory waste and disposed materials during the cultivation stage of the genetically modified plants/crops.**

- **Pilot scale testing may be done after review of results of pre-clinical/ nutritional evaluation tests.**

- **During storage and shipment of genetically modified plants/crops/organisms and their products appropriate and clear labeling must be provided, so that mixing with normal plants does not occur.**

- **The manufacturer/researcher must apply for a 'non-regulated status' before large- scale cultivation of the genetically modified plants/crops.**

- **The approval should be given by Government of India Agency/Department similar in function and authority, as the Animal and Plant Health Inspection Service of the USDA.**

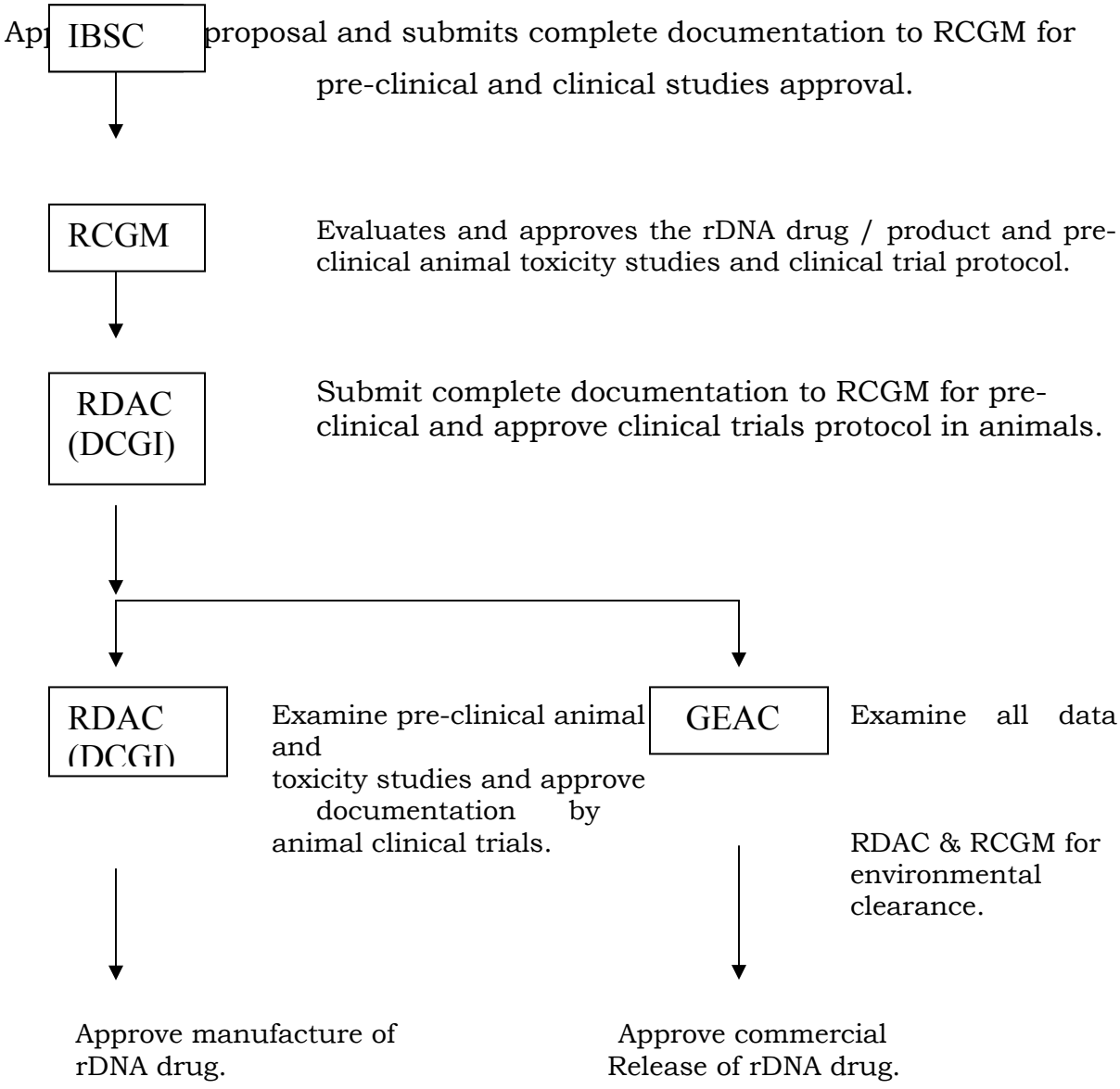
- **It also needs to be explored/addressed whether feeding GM crops or use of GM products in livestock will affect our export market for livestock products.**

- **<u>Various biosafety issues for release of GM Fish /Marine animals in the environment must be examined.</u>**

The flow charts for undertaking research and for release of recombinant biologicals and drugs and crops for incorporation in animal feed are given in Annexure I & II.

Annexure I

Recommended Protocol for genetically modified plants/ organisms for biologics in animal use.



Annexure II

Recommended Protocol for use of GM Feeds

IBSC	Approves the protocol and submits to RCGM
RCGM	Evaluates the proposal and forwards to ICAR for agronomical and nutritional trials.
GEAC & ICAR	Analysis for chemical composition, evaluation for equivalence with counterpart, small animal/ ruminant/canine/poultry, safety trials and target animal production trials. Based on the results, together approve use of GM crop or GM crop products in animal feed.

ANNEXURE – III

List and addresses of the members of the working group:

1.	Dr Amrita Patel Chairman National Dairy Development Board Anand Phone: 02692 – 260145 Fax: 02692 – 260157, 260165	Chairman
2.	Dr. V.K. Taneja Deputy Director General (AS) Indian Council of Agricultural Research Krishi Bhawan, New Delhi Phone: 011 – 2338119	Member
3.	Ms. Neerja Rajkumar Joint Secretary (PL&F) Government of India Ministry of Agriculture Deptt. of AH & Dairying Krishi Bhavan, New Delhi Phone: 011 – 23382354 Fax: 011 – 23386674	Member
4.	Dr. V.A. Srinivasan Executive Director Indian Immunologicals Limited Gachi Bowli Hyderabad - 500 019. Phone: 040 – 23000894 Fax: 040 – 23000213	Member
5.	Dr. K. Ramasamy Director Centre for Plant Molecular Biology Tamil Nadu Agricultural University Coimbatore - 641 003. Phone: 0422 – 2451078 Fax: 0422 – 2431821	Member

6. Dr. Rameshwar Singh — Member
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Indian Institute of Science
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8. Dr VV Suryanarayana — Member
Principal Scientist
Indian Veterinary Research Institute
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9. Dr D Thiagarajan — Member
Manager (R&D)
Indian Immunologicals Ltd
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10. Dr. D.K. Singh — Member
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Anand
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To Shri Ashish Bahuguna **Dated: 11-11-2003**
Joint Secretary (Seeds)
Member Secretary, Biotechnology Task Force
Ministry of Agriculture
Krishi Bhawan
New Delhi 110001

Dear Shri Bahuguna,

I am enclosing a copy of the Discussion Paper assigned to the Working Group on 'Policy for Biotechnology Applications in Agriculture'. As mentioned earlier, a draft of the paper was circulated among the members including those from the Seed Industry and their responses have been appropriately incorporated into the paper.

With kind regards

Yours sincerely
V. L. Chopra
President,
National Academy of Agricultural Sciences

Report of the Working Group – V

"Promoting Public Awareness on Matters Relating to Agricultural Biotechnology in India"

Chair: Dr. Mangla Rai

Biotechnology offers a range of potential environmental, social and economic benefits. However, modern biotechnology has been under public scrutiny and is currently the focus of intense public and political debate. In democratic societies, public perceptions can both promote and hamper commercial introduction and adoption of new technologies. The issues with regard to acceptance of genetically modified (GM) crops have at times been compounded by the lack of information on this subject amongst even the otherwise informed members of the public.

Public Awareness and Acceptance of Agro-biotechnology Applications: Some Observations

Public awareness and acceptance is one of the major hurdles for the adoption of the especially the first wave of products of agricultural biotechnology as is the case in India. Huge differences also exist in intensity of the public debate on biotechnology and its applications. In general, majority of the people around the world appear to accept biotechnology in medical applications more easily than biotechnology in the field of agriculture or food processing. In some countries, the public and the scientific community hold different views on the desired balance between the regulation of research and the freedom to investigate. Even in some developed countries, particularly those in the European Union, commercialization of genetically modified crops have faced stiff

resistance. However, public acceptance is much better in the USA, and transgenic crops and their products are more widely accepted.

Public acceptance is also greatly determined by the kind of information provided by the media to the general public and various organizations concerned about farmers. Misinformed public debates on key issues related to crop biotechnology can result in erosion of public confidence and can create mistrust in the technology and its developers, irrespective whether the developers are from the public or private sector. Clear and understandable consumer information is a very important part of the public acceptance process. Besides media, research organizations and scientific institutions concerned with crop improvement must also take up the responsibility in bringing awareness in public about the applications of genetic engineering in agriculture, their potential benefits as well as constraints. The media has to play a significant and a more responsible role in creating public awareness, rather than resorting to 'sensationalism'. A recent international conference on GM crops, held at the Chennai-based M.S. Swaminathan Research Foundation, emphasized the need for information empowerment and education at all levels, starting with the farming community.

Addressing the Factors Influencing Public Opinions on Biotechnology

Analyses of public opinion surveys in many developed and developing countries reveal that consumer acceptance of biotechnology is driven by a number of inter-related factors. The major influences on public acceptance seem to be the knowledge level, awareness of benefits, confidence and trust. Surveys have also shown that global differences in support for specific applications of agricultural biotechnology are based on factors that include a country's culture and history, economic

conditions, and government initiatives or responses related to the issue. In general, there is greater acceptance of medical applications (particularly those leading to development of medicines and vaccines) than there is for food biotechnology products. Consumer opposition to genetically modified foods is driven in part by the uncertainty about possible negative health and environmental effects.

In India, the media (newspapers, televisions, radio, internet) is often the main source of information for the consumers. The media can play a pivotal role in the public debate about agro-biotechnology by facilitating two-way communication among the various stakeholders affected by the technology. Unfortunately, lopsided campaigns by some agencies have cast significant doubt in the minds of consumers as to the need and biosafety of agricultural biotechnology. Differing views on a biotechnology may reflect different beliefs about its risks and benefits, or different evaluative criteria. In the former case, suitable communications could clarify the degree of essential conflict among the parties. In the latter case, a struggle is warranted, unless it is possible to change the technology or the distributions of its costs and benefits. We need to recognize that the debate is not always about science, and therefore, understand and manage the sources of the disagreement.

Establishing Channels of Communication with the Public

Establishing and maintaining credible and viable channels of communication with the public, and creating public trust and confidence in modern technologies such as agricultural biotechnology are indeed challenging endeavours. This warrants strong linkages and cooperation amongst various organizations and agencies, as no single organization/agency can effectively fulfil the demands. Scientific

demonstrations of biosafety of transgenic crops and review by government agencies are extremely important in gaining public acceptance. What role credible experts will play in communicating the issues to the public in a realistic and effective manner can make a huge difference. Certainly, public sector scientists will be seen as more credible than those who either have direct stakes in the development and commercialization of transgenic products or individuals who work for 'advocacy groups' that have blanket dislike towards genetic engineering or its products.

Launching an Integrated and Intensive Campaign

An intensive and highly integrated campaign needs to be launched, with active cooperation of various scientific organizations/institutions/universities/NGOs to generate public awareness in the country on the following specific aspects of agricultural biotechnology:

1. Concept of plant breeding, pressures on modern plant breeding and the need for novel genetic enhancement strategies, including biotechnology
2. Introduction to genetic engineering technology
3. The benefits, risks and constraints of agricultural biotechnology
4. Current status of national and global GM crops and other biotechnological applications in agriculture
5. Risk assessment procedures (regulatory mechanisms) for environmental and food safety, and related legislations
6. Social, economic, scientific, environmental and health issues which are addressed by regulatory bodies before allowing release of GM crops.

7. Current GM products under evaluation in India under biosafety, VCU and other regulatory trials
8. Community and Farmers' Rights and benefit sharing related to agro-biotechnological applications
9. Post-release monitoring and management of GM crops and their products, such as insect resistance management, transgene stability at the farm level, use of transgenic diagnostic kits, and maintenance of transgenic seed quality, with effective involvement of State Level and District Level Coordination Committees of the existing transgenic biosafety evaluation and management mechanism.

Strategy to enhance Public Trust and Confidence in Agricultural Biotechnology

1. Participation of the stakeholders in formulating the research agenda in agricultural biotechnology to be in congruence with the public needs
2. Assessing the potential and socio-economic benefits of products from agricultural biotechnologies vis-à-vis other available alternatives for specific objectives (for example, biofortification; biotic stress resistance etc.) in the context of the regional and national values, ethics and concerns
3. Development of biotechnological products that directly help the farmers and the society
4. Facilitating reliable and independent assessment of socio-economic impacts of agro-biotechnological products
5. Public opinion-based periodic improvisation of the existing biosafety system to enhance transparency, efficiency and trust
6. Investment in training effective spokespersons, particularly transfer-of-technology and extension personnel and public relation

officials of various organizations on agricultural biotechnology applications and biosafety aspects

7. Capitalizing on the inter-ministerial and inter-organizational capabilities to form an information network to promote agricultural biotechnology

Government of Chhatisgarh

Comments on the Base Paper :

Modern biotechnology represents unique applications of science that can be used for the betterment of society through development of crops with improved nutritional quality, resistance to pests and diseases, and reduced cost of production. Biotechnology, in the form of genetic engineering, is a facet of science that has the potential to provide important benefits.

India has dramatically increased investments in molecular technologies, to increase their agricultural productivity. Molecular techniques, including gene transfer into the crops, are the basis of the next logical development in agronomy and plant breeding research. Although this technology can be viewed as an extension of traditional breeding, some people emphasize that transgenes are novel that is they do not originate from sexually compatible or closely related plants and instead can be derived from a range of organisms. Because many transgenes are new to agriculture and might result in novel phenotypes, prudence dictates that people examine the risks before wide scale deployment of transgenic crops. The development of agriculture as a science and its continual use and implementation of technology have clashed with a more idealized view in which a purity of purpose is considered on a par with scientific facts.

Chhatisgarh enjoys a unique position in the fields of agriculture, healthcare and sericulture. The assemblage of three distinct realms makes India rich and unique in biological diversity. Chhatisgarh is situated in the Deccan biogeopraphy, and therefore, houses an important part of India's biodiversity. Chhatisgarh is extremely rich in indigenous varieties of paddy and herbs with medicinal and aromatic ingredients, as well as in the mixed tropical deciduous forest, tree species. Approximately, 44% of the State is under forests.

It is our endeavour to bring technological advancement to these sectors for the overall development of society. Biotechnology as a tool has the potential to bring a sea change in the socie-economic status of the people living in this region. The positive impact will usher in a new era of food grain production coupled with food-security, significant alterations in the field of animal husbandry and fisheries leading to economic prosperity, assurance of quality food products to the consumers along with environmental protection. In order to foster international cooperation, the nascent State of Chhatisgarh has the necessary drive and desire. Chhatisgarh is a biodiversity hotspot - and is thus well poised to assume a significant and leading role in biotechnology sector.

Brief comments on the Base Papers are as follows :

Base Paper One :

Policies for the safe and responsible use of Biotechnology in Agriculture : Issues for Discussion :

The base paper covers most of the issues and is well conceived. We agree in general to the suggestions made in the base paper and would like to emphasize on few points.

a) Research areas should focus on problems which are socially and ecologically desirable such as :

1) To ensure food security and food products of high nutritional value,
2) Replacement of chemical ingredients by eco-friendly substances and to develop integrated nutrient management.
3) Lowering of present and future costs of Agricultural inputs,
4) Genetic improvement in plants/herbs that are sources of medicinal and aromatic ingredients.

b) An independent evaluation mechanism needs to be developed which should be transparent and should have high scientific and public credibility.

1. Every individual transgenic event should be evaluated for all the characters including Agro-economical and bio-safety related issues.

2. Evaluation of the transgenic lines should be at multiple locations and should be under strict guidelines as proposed by ICAR/DBT/Govt. of India.

Base Paper Two :

Biotechnology Applications in Agriculture : Development of long germ Policy :

The long-term policy has been very well thought out and covers the entire spectrum. We would like to emphasize that the policy on

Biotechnology of the Government of Chhatisgarh also covers these aspects.

With regards to infrastructure development the new state of Chhatisgarh is planning to develop Centre for Excellence with five advanced facilities. The existing facilities have been identified and these would be developed as advanced facilities for which assistance would be required.

Base Paper Three :

Regulatory procedures in Agriculture :

The regulatory mechanism as proposed is comprehensive and adequate for the present.

Base Paper Four :

Role of the Ministry of Agriculture :

The issues raised in the Base paper are adequate and have been dealt with comprehensively.

Base Paper Five :

Promoting public awareness on matters relating to Agricultural Biotechnology in India

An integrated and intensive public awareness campaign involving Government Departments, NGOs, Social activist, Educational societies, Universities is the need of the hour. This will go a long way in removing miscomprehensions and in generating public confidence.

Base Paper Six :

Applications of Biotechnology in Animal Husbandry with special reference to the use of GM feed and its implications on Trade :

The suggestions made in the base paper are agreeable and indeed is the need of the hour. A protocol for the use of GM feeds needs to implemented swiftly.

Government of Haryana

Interface of State Government representatives with the Task Force on Applications of Biotechnology in Agriculture

1. POLICY FOR SAFE & REPONSIBLE USE OF BIOTECHNOLOGY IN AGRICULTURE :

The Potential of Plant Biotechnology :

Realizing the importance of biotechnology for bringing economic benefits to the farming communities and for improved human health, the Government of India gave rightful importance to the development of not only skilled human resources in this area but also establishment of strong centres of plant molecular biology in the country. In recognition of the potential benefits, the Government of India established a separate Department of Biotechnology, which is a way guides and controls research activities in various areas of biotechnology.

The Emerging issues of Plant Biotechnology :

Except Bt. cotton, no other transgenic or genetically modified (GM) food crops has yet been commercialized in India, though extensive efforts are in progress at different laboratories across the country to develop the GM food crops. Before we reach the commercialization stage, it is imperative to build public confidence through a proper communication system, so that the public at large is well informed about the benefits (and risks, if any) of the GM foods. With regard to the use of GM food, the following issues assume importance :-

i) **Uptake of genes via the food chain** : One such fear is that the genes from the GM foods could be easily taken up by consumers when eaten and thus become part of their own genetic make up.

ii) **Antibiotic resistance genes in GM food** : Another fear concerns the transfer of antibiotic resistance from the GM food consumed by people into the bacteria inhabiting the human gut, which might result in a disease causing bacterial population to

become resistant to antibiotics. However, experiments have shown that this does not happen.

iii) **Bio- safety** : There are several related areas of concern regulating the use of genetically modified crops food. These include toxicity, alltergenicity, cardiogenicity, food intolerance and nutrition value. While supporters of the technology argue that the foods, produced through biotechnology are just as safe if not safer than conventionally produced foods because they are subjected to highly rigorous testing, critics of genetically modified food have even coined a new term Frunkstain food for genetically modified foods.

iv) **Labelling GM and non GM food** : With the kind of concerns witnessed among the public, keeping GM and non GM products separately with appropriate labelling, perhaps also through colour codes for illiterate people, may be absolutely necessary. The related issue is the need for a certification agency specializing in certifying the GM nature of a product. This is, not only necessary but essential because these food products are going to pose risks to human and animal health and this will allow consumers a choice either to use or not to use genetically modified foods for consumption.

v) **Effect on Biodiversity** : A major concern, voiced by several researchers and environmentalists, is that the commercialization of transgenic crops in general and particularly those with technologies such as 'terminator' could lead to erosion of bio-diversity and 'pollute' gene pools of endangered plant species. While many endangered plant species are indeed threatened by habitat loss and/or hybridization with cultivated plants in conventional agriculture as well, the threat level is perceived to be of higher magnetite when large-scale commercialization of transgenic crops occurs.

vi) **Public awareness** : Consumer response depends on perceptions about risks and benefits of biotechnological GM food. In order to enhance the trust of the consumer it is essential that relevant and reliable information about the genetically modified food is communicated to the consumers and stake holders. It is possible that food safety evaluation of genetically modified plant may reveal some unavoidable effects. The media, individuals or groups have the right to educate the public about such possibilities. A participatory approach is immensely required if the bio - technological products are to be accepted by the farmers and consumers.

vii) **Regulation of GMOs** : The Indian Government created the rules and procedures for dealing with GMOs in 1989 under the India EPA. India is one amongst very few countries in the developing world to have laid out detailed bio-safety guidelines for genetically engineered organisms. The guidelines are prepared by the Recombinant DNA Advisory Committee constituted by DBT, Government of India which is responsible for the development in bio technology in the country. The recombinant DNA Safety guidelines are based on the three tier system involving.

i) Institutional Bio-safety Committee (IBSC)
ii) The Review Committee on Genetic Manipulation (RCGM)
iii) The Genetic Engineering approval Committee (GEAC).

The current regulatory process for biotechnology products involving the above regulatory bodies is very lengthy and the process should be made simple but thorough, more specifically defined based on the application and method of manufacture. For example separate guidelines, procedures, forms and requirements can be set up for the following situation :-

(a) Pure research in the laboratory.

(b) Contained manufacture/fermentation, cell culture) where GMOs may be discharged after suitable treatment (e.g. chemical or steam sterilization) only as effluent and the commercial product is itself not a GMO.

(c) Where product may be GMO but is administered under medical supervision (e.g. cell therapy or viral vaccines)

(d) Environmental release where again a differentiation can be made between large animals like cows, goats, monkeys and pigs where containment is easily attained versus small animals like insects or mites where control is more difficult.

viii) **Testing and Certification** :

i) Greater interaction between the Central Government, State Government and the private agency may be

ensured during the process of field trials. Discussion of the private agencies with the State Governments regarding location of field trials would perhaps lead to better results and would assure the farmers on whose lands the field trials are to be conducted.

ii) Field trials should be carried out for at least two seasons to confirm test results.

iii) The advisability of a certification agency for GM seed/crops/fields/ may be considered.

iv) There is a need to chalk out a strategy to use this technology systematically safety and rapidly to derive maximum benefits for our country, industry and people. There may be some risks associated with the use of GM crops, in particular, the potential for adverse effect from release into environment and food safety aspects. Such risks need to be assessed and managed carefully. An effective, enforceable system of regulation is essential if consumers are to have confidence in the safety of approved GMOs and their products.

v) In fact only those GM crops should be allowed to grow in the field which have passed through extensive testing procedures and clear regulatory regimes. Further, there should be a mechanism / procedure to prevent the neighboring field from any unintended adverse effect from the fields in which GM crops are growing.

ix) **Compensation** :

i) The possibility of adverse effects of cultivation of the GM crop on neighbouring field cannot be ruled out. In addition effect of the weakening/dilution of GM seeds in subsequent generations leading to degradation of the soil and reduced production and has yet to preciously assessed and the compensation for such losses and damages and stringent penal action in case of adverse effect on health of human beings must be provided for under the relevant laws.

ii) To assure the farmers and other consumers and to assist them in claiming compensation from the private agencies, the agencies may be mandatorily required to

give full information regarding the seed/feed which they want to test on the farms or which they intend selling to the consumers.

2. BIO TECHNOLOGY APPLICATIONS IN AGRICULTURE DEVELOPING LONG-TERM POLICY :

In the past thirty years, rapid progress had been made towards the development of bio technological tools for commercial applications in agriculture, medicine and agro-based industries. Progress in the areas of tissue culture and molecular mapping of genes for biotic and abiotic stress, transfer of agronomically important genes in plant, metabolic engineering, DNA sequencing and genomics in plants as well as farm animals has been remarkable. We have now moved from a situation where a research area is no longer marred by limited information vast amount of biological information is now available in virtually every scientific area and various tools in informatics and computational science are being used to manage and interpret the available data.

(i) **Public-Private partnership** :

In addition to the public sector, private sector has now greater stakes in these research areas making a public-private sector partnership inevitable for further research progress and commercialization in agriculture.

It is vital that the public sector and the private sector forge partnerships that will allow the comparative advantage of both parties to be optimized to achieve the mutual objective of global food security. Government must ensure continued safe and effective testing and introduction of transgenic crops and implement regulatory programs that inspire public confidence. The public should be well informed and engaged in a dialogue about the impact of the technology on environment, food safety, sustainability and food security. Concerted efforts must be undertaken to investigate the identical human health and environment effects both positive and negative of GM technologies in the specific application.

(ii) **Precision breeding/farming** :

There has been a shift in paradigms of plant breeds with more emphasis on "precision breeding" to cater to the specific needs of the masses.

(iii) **Increasing Productivity** :

It is important that we should enhance farm productivity per unit land, water and capital without harming the ecosystem. Crop yields are reduced to considerable low levels because of biotic stresses e.g. pathogens and insect pests attach. Similarly, drought, salinity and temperature are the major abiotic stresses affecting crop productivity. Major network projects should be initiated to usher in transgenic technology to combat biotic and abiotic stresses and to improve the nutritive quality of foods.

(iv) **Soil management** :

Soil health has suffered to a great extant on account of intensive agriculture, large scale adoption of the rice-wheat cycle, cultivation of marginal lands and inadequate use of compost/farmyard manure. For example, the rice-wheat sequence results in a total nutrient withdrawal from the soil exceeding nutrients added by chemical fertilizers. Thus there has been a constant decline in the organic matter content of soils with the result that the efficiency of chemical fertilizer use has also declined. If the agriculture production system is to be sustainable, soil health needs to be restored and therefore, organic farming will be encouraged. In so doing farmers can be expected to benefit from both an increasing market for organic produce and a more balanced diet. Integrated soil management will have to be practiced and the use of bio-fertilizers/herbicides, progressively increased.

The popularization of the cheapest and most established form of biotechnology, tissue culture, restoring the health of degraded soils by organic farming and integrated soil management can only be achieved through diversification of crop cycles. This means agricultural and horticultural cropping patterns will be integrated.

To extend micro propagation technology to the maximum possible extent for the benefit of farmers and the State and therefore :

- to ensure the availability of quality planting material.
- to create all conditions necessary for its acceptance and successful adoption.

To promote organic farming and therefore :

- to reduce the use of chemicals
- to bring about crop diversification
- to use biological tools for pest and crop management.

3. REGULATORY PROCEDURES IN AGRICULTURE :

i) Plant/Animal Variety Protection/Breeders Rights :

Plant/Animal Variety Protection (PVP), also known as Breeders rights (BR), is a special form of IPR tailored to the needs of Plant/Animal Breeding in its traditional form.

ii) Protection to microbiological inventions :

Indian patent laws do not patent animals and plants. However, industrial process using miroorganisms such as in fermentation, antibiotics, waste matter degradation etc. can be patented.

iii) Bio-diversity Protection :

a) In the International Convention on Bio-diversity (CBD) signed at Rio in 1992, nations agreed to recognize the sovereign rights of nations with respect to their genetic resources. The transfers of genetic resources will be made under material transfer agreements designed to protect source nations' interests in any resulting profits.

b) **Trade Secret** : In addition to the farmers' statutory scheme of intellectual property protection, there is the trade secret approach based on the investor's ability to keep information secret. To assist in the process, law often provides for enforcement of a trade secret and also offers remedies against improper acquisition of a trade secret.

iv) **Protection of undisclosed information/Traditional Wisdom** :

The knowhow at grass root level in respect of medicinal herbs, various traditional practices, customs, cultures, secret ideas on bio fungicide and foods etc. which may lead to new innovations, has been handed down for generations orally and has barely been documented. Modalities for protection of such information/practice could be worked out.

4. ROLE OF MINISTRY OF AGRICULTURE :

i) Need for Reorientation of the Educational System through EDUCATION CELL of Ministry of Agriculture :

While we are proud of developing one of the most sound human resources development systems which has delivered in the past, yet in view of the future challenges, a revision and reorientation of the present system of agricultural education is required so that graduates coming out are job providers rather than job seekers. This necessitates the concept of higher education of practical nature which addresses the problems of the farming sector. The institutions have to develop modern and precision farming technology suited to small and marginal farmers and which lead to improvement in the quality of inputs and managerial practices. It is well recognized that growth in agriculture propels higher industrial growth and brings economic uplift for vast segments of our population. The development in science and technology which are revolutionary need to be harnessed to bring economic benefits to our people. This is possible if necessary structural changes are introduced which reflect modern realities, challenges and opportunities. The institutional system must be relevant towards issues and concerns, reinvigorate its commitment to the linkages among teaching, research and public service and must organize its programmes in keeping with national requirements in agriculture.

The agricultural education system in India has to take note of vast changes taking places rapidly in national and international environment of agriculture and prepare its graduates to face this new environment with confidence and faith in their ability to benefit from new opportunities arising from these changes.

Challenges in future go far beyond simply addressing the needs of our increasing population. In addition to providing more food, agriculture will have to address important issues of sustainability of farming system, improving productivity from the land, nutritional and food security, enhancement in nutritional density of crops and achieving those and other goals in a way that does not degrade the environment.

ii) Curriculum and syllabus :

The Education Division of ICAR (Under the Ministry of Agriculture) has developed course curriculum and syllabi for all the UG programme except Veterinary Science and most PG programmes of agricultural and allied sciences. These programmes have been developed by the participation of eminent subject matter specialists in the country. The course curriculum has to be practical-oriented and focused on development of human resources.

Curriculum delivery is another important aspect which needs greater attention. Learning needs of students should be the focus. This would require a shift from the traditional and conventional mode of teaching.

The agencies funding biotechnology education and research must address themselves to the new needs of the students and require that the curriculum and syllabi are tailored to suit the emerging needs in this field.

In view of globalization a tremendous opportunity lies in wait for biotechnology education in not only ensuring higher agricultural growth, sustainability of farming system, reduction of poverty, ensuring food and nutritional security but also in contributing its share for making India a developed nation by 2020.

5. APPLICATION OF BIOTECHNOLOGY IN ANIMAL HUSBANDRY WITH SPECIAL REFERENCE TO USE OF GM FEED AND ITS IMPLICATIONS OF TRADE :

GM Animal Feed :

Feed for intensively farmed animals take up a considerable proportion of the world's crops. At least one third of the world's cereal crops goes into animal feed, around 95% of the Soya Crop and 70% of the maize crop. The huge market for non-human feed has been the major target of biotech companies producing GM crops for farming. By 1999 it was estimated that upto 50% of the Soya and Maize crops world- wide was genetically modified, mainly for herbicide resistance. Feed is also being genetically engineered to include special nutrients and so increase farm animal's growth rate.

Implications for consumers :

The potential risks to human health from GM animal feed come from the possibility of increasing antibiotic resistance and from risks to people consuming the transgene in animal product. Antibiotic resistance gene from bacteria plasmid are sold in GM crops as 'markers'. Antibiotic resistance, a major threat to human and animal health, can be transferred between bacteria through gene transfer and in some circumstances bacteria can transfer genes to mammalian cells.

There is already evidence that part of transgenes from GM feed could be eaten people. There are conflicting results from studies about whether fragments of foreign DNA, such as in Bt.-Maize, can be detected in chickens. Plant DNA fragments were also detected in muscle, liver, spleen and kidney of chickens (although specific DNA from the transgene itself was not detected in the chickens or the cows).

Implications for farm animals :

All the evidence to date is that most consumers would not be prepared to eat genetically modified and cloned meat, mild and egg. Animals should not be used as a sales outlet for agricultural products or bio-products that can be used alongside. Farm animals should have a access to balanced food appropriate to their species, an important part of maintaining animal health.

One of the greatest challenges facing the biotechnology industries is to convince the public of the safety of its products. The best way of allaying public concerns regarding GM Food/feeds would be to invest on 'complete' evaluation of their use in animal feeding. Long term studies, with large number of animals, will be necessary to demonstrate that these feeds are both effective and safe and not affecting their health and reproduction, then public is more likely to be assured of the safety of these advances.

Most of the transgenic fodder crops have been developed in technological advanced countries and evaluated their safety aspects in terms of animal, human and environmental health in their own ecological situation. To the best of our knowledge no transgenic fodder crop has been developed in India. Therefore, it is very important that any international agency/company, which intends to introduce GM fodder crops in India,

must not be allowed to do so until and unless solid scientific data based on long term ecological, human and animal health studies are available.

Government of Himachal Pradesh on the issues related to formulation of a long term National Policy on Application of Agri-Biotechnology.

We have gone through the documents supplied by Department of Agriculture & Cooperation for our comments; related to formulation of a draft long-term policy on the applications of Biotechnology in Agriculture by Government of India. The base papers prepared by various working groups of Task Force on Agriculture-Biotechnology i.e. i) Policies for the safe & responsible use of Biotechnology in Agriculture; ii) Biotechnology Applications in Agriculture; iii) Regulatory 'Procedures in Agriculture; iv) Applications of Biotechnology in Animal Husbandry were also studies in details.

Many important points though, have already been included in the draft policy documents but we would like to supplement following points with the hope that these will be given thorough consideration and important points will be included in the National Policy on Agri-Biotechnology in the interest of the mountain states and the country as a whole :-

1. We in hills have reservation about resistant crops especially cold, drought and pest resistant crops are needed alongwith longer shelf life. Production of transgenic seeds especially of vegetable crops having quality attributes, insect pest and other disease resistant traits which can withstand biotic and abiotic stresses. Diversified farming that too with indigenous promising crops which we have neglected should be promoted and continuous improvement be made through technological interventions.

2. The evaluation system as suggested for GM crops is acceptable but more transparency is needed in the system. Awakening of common man, NGO's and farmers regarding pros and cons of using transgenic is of paramount importance since there is a uncertainty in the mind of farmers and several misconceptions which need to be clarified so that he accepts these crops. Research on indigenous crops is needed for selecting best ones and also to go for transgenic.

3. Since mountains can serve as deal isolated ecological niches for transgenic trials and seed production. These aspects be given serious thought and provision be made for providing finance to mountain state especially for the purpose.

4. Organic Food Certification has become necessity and is needed almost in every crop. The proposed facility being highly expensive, the R&D Institutes within the States should be strengthened through appropriate funding, training and other latest technical know-how.

5. Regarding seed certification there is necessity of a fool proof mechanism to supply seed for the purpose of demonstration to the R&D Institutes so that any improvements if needed can also be attended simultaneously.

6. Crop damage especially in relation to hills be considered seriously i.e. biotehnological interventions to fight the serious diseases in Ginger, Potato, other fruits and vegetable crops be given top priority and special financial provision be made in the Policy.

7. As far as Biodiversity conservation centres are concerned, medicinal & aromatic plants alongwith other high value drug plants must be included in this category. Moreover, there are Biodiversity/Medicinal Plant Boards throughout India and

their inputs will be highly useful in farming new guidelines for the country.

8. More researches are required for new crops including promising indigenous crops and the regulatory mechanisms.

9. Regarding Agri-Biotechnology, all concerned Department must contribute with multi-disciplinary holistic approach.

10. More emphasis should be on spreading the idea of Transgenics/GM crops through various advertising/ electronic media including Radio schools, Tele Schools etc. There has been negative effect of various awareness campaigns so far, therefore, full proof mechanism is needed to project Biotechnology as a major component of new Agri-Biotech. The Krishi Vigyan Kendras (KVK's), ATIC's can play a major role to motivate farmers and change their negativity towards transgenic and other technologies. A separate cell in KVK's, ATIC's etc. should be created specially for dealing with Agri-Biotech sector.

11. We have failed in implementing our schemes since the message which reached Farmers was either wrongly interpreted or was not conveyed properly. Therefore, there is a necessity of a strong mechanism which can not only satisfy the farmers but can also clear the doubts, if any in the mind if a consumer.

12. Regarding selection of species as already mentioned, medicinal aromatic plants and other high value drug plants must be included. Production of disease free planting material of Ginger & Potato which can help the farmers to sustain is needed. Poplars have been missing from the list of trees needs to be included. Similarly several fodder trees were also not included which form the important component of the farming systems in mountains.

13. A brief assessment of the draft policy documents supplied indicates that although most of the suggestions are reasonable valid and as per the demand, but it seems that like many other previous policies at National level, mountainous regions have been neglected which contribute around 18% of total geographical area and 6% of total Biodiversity. Himalayan region in particular needs special attention in the National Agri-biotechnology Policy.

14. Apple, the backbone of the economy of Himachal Pradesh is missing although it has been playing a major role in the societal transformation of hills states. The old orchards, which have become prone to several diseases besides reduced productivity and low quality produce need immediate attention so that this sector can be rejuvenated through improved varieties which produce quality produce on sustainable basis through Biotechnological interventions. The story of many other fruit crop is also no different and needs preventive measures for sustaining the future pressures.

15. Besides apple, stone fruits and other fruits need to be included and appropriate arrangement in the policy be made for these important crops. Hazelnut and other high mountain crops also need more attention.

16. The medicinal & aromatic plants, the major tools for the transformation of economy through diversification of farming also need to be included in the National Policy. The processing of medicinal & aromatic plants should also be given top priority and be included.

17. Nutraceuticals, the major potent health food supplements have also been found missing from the document. These should also be included in the policy keeping in view their role in human health especially for kids, women and others, which can solve the problem of malnutrition without having other side effects of drugs used for curing several ailments.

18. Few important multipurpose industrial plants, indigenous to the hills need special attention, which have adapted to the harsh conditions of the hills and other introduction trials have met repeated failures. The need is to plan the developmental strategies for harnessing the benefits from these valuable resources e.g. Seabuckthorn (Hippophae I.), native to high hills has great potential to develop as a major industrial plant. China has made best use of this wonder plant among other countries. This plant has sustained the harsh conditions since long and other plants could not survive. This should be included in the Policy.

19. Floriculture as a major source of income, which has good potential in hills, also needs special attention in the Proposed Policy. Orchids too have been found missing and need to be

included in the list, as it can become a major sources of income.

The proposed policy should keep in mind both short-term as well as long-term policy implications with necessities of farmers and consumers given top priority.

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COMMENTS OF GOVERNMENT OF JAMMU & KASHMIR
(Department of Animal & Sheep Husbandry)

Potential of Biotechnology in increasing Agricultural Productivity

Jammu and Kashmir State is blessed by nature with varying agro climatic conditions thus making it suitable for growing of wide variety of crop plants and fruit crops under sub tropical, intermediate and temperate zones. Major emphasis was earlier given to achieve self-sufficiency in food grains. This is evident from the fact that the food grain production increased from 54.92 million tones in 1949-50 to 211.32 million tones in 2001-2002. But the population in India is growing at an alarming rate of around 2.5 percent per year. This makes it necessary that the food grain production should also increase at least at the same rate or even at a faster rate. The green revolution has, therefore, undoubtedly assured of food security. The importance of fruits in human diet and their cultivation for economic

upliftment of people also need not to be overemphasized. In fact, fruit cultivation is the only cropping system which not only helps in improving biological productivity and nutritional standards but also assists in maintaining ecological sustainability, earning foreign exchange and providing direct and indirect employment opportunities. Biotechnology has rapidly emerged as an area of activity having a marked realized as well as potential impact on virtually all domains of human welfare, ranging from food processing, protecting the environment, to human health. Considerable progress has been made during the last decade in many areas of plant molecular biology. Engineering plants with noval genes is the most important application that has resulted in the development of transgenic plants. The ability to introduce noval genes from diverse sources, including bacteria, fungi and wild relatives, opened up many opportunities which were not available earlier through any of the classical approaches like mutation and conventional breeding. These approaches are largely focussed on traits such as fruit ripening, floral development, disease resistance, insect resistance response to stresses, such as drought, cold or freezing. It is now proved beyond doubt that foreign DNA can be transferred into plants and can be expressed in a particular tissue and at specific development stage. The production of transgenic plants depends on the stable introduction of foreign DNA into the plant genome, followed by regeneration to produce intact plants. The importance of biotechnology to human welfare would become obvious from some examples. For the protection of human health, production of monoclonal antibodies, DNA probes, artificial vaccines, rare and highly valuable drugs, such as, human interferon, insulin etc. and the technology for gene therapy are some of the notable achievements. Microorganisms are being employed, since several decades, for the large-scale production of a variety of biochemical ranging from alcohol to antibiotics and in processing of foods and feeds. But enzymes, isolated mainly from microorganism and immobilized in suitable polymers are preferred over the whole of organism for a variety or reasons. These are becoming increasingly popular in many commercial ventures, e.g. for the production of high fructose corn syrup using immobilized enzyme glucose isomerase. Several biological agents, such as, viruses, fungi, amoebae, bacteria etc., are being exploited for the control of plant diseases and insect pests.

Harmone-induced super ovulation and/or embryo splitting coupled with embryo transfer are being used for rapid multiplication of farm animals, particularly cattle. Genetic Engineering is being employed to develop transgenic animals resistant to certain diseases, capable of faster growth rates and more efficient feed conversion, and with capacity to produce certain valuable biochemicals and excreting them in milk, urine or blood from which they are isolated and purified.

In agriculture, rapid and economic clonal multiplication of fruit and forest trees, production of virus-free stocks of clonal crops, creation of noval genetic variations through somaclonal and gametoclonal variations and transfer of novel and highly valuable genes usually for herbicide and insect resistance through genetic engineering have opened up exciting possibilities in crop production, protection and improvement. The two basic techniques used in plant biotechnology are (I) plant tissue culture and (ii) genetic engineering. Fruit crops have now been transformed by continuous selection to such an extent that these are far removed from their wild progenitors. As fruit production is gradually becoming important to national economy, there is greater dependence on a few cultivars only for each fruit crop. The present fruit industry is also based on relatively selected genotypes, few in numbers, which represents desired combinations of attributes. Thus reliance upon a narrow genetic base for production of fruit crops, in all likelihood, imperil production. So far, in most cases, the genetic improvement of fruit crops has been achieved by selection from natural seedling populations. Thus intense selection and testing coupled with fixation of unique genotypes by vegetative propagation has led to a narrow germplasm base for many fruit crops. Many fruit crops are vegetatively propagated perennials, barring few exceptions like banana and strawberry, cross pollinated and are highly heterozygous. Many cultivars are interspecific hybrids and complex polyploids. Thus, great difficulty has been faced in the attempts of intergration of specific traits from plant genetic resources into improved cultivars through conventional breeding techniques. Success in genetic improvement of fruit crops like plum, peach, strawberry, grapes, apricot, sweet cherry, etc. has been quite significant through long term breeding progrmmes. But conventional plant breeding has several restraints with special reference to vegetatively propagated, long duration fruit crops. These restraints are :

1. Reliance on naturally occurring variation and induced mutations are often deleterious, random and unstable.

2. Detection of infrequent or rare recombinants is difficult during selection.

3. Inability of sexual system to incorporate variation from unrelated species.

4. Long duration of process for generating cycles of recombination, lack of sufficient space to grow necessary population to recover superior recombinations to select, identify and evaluate the desirable combinations.

The potential of biotechnological manipulations like cell and tissue culture techniques and molecular genetic techniques, including embryo rescue, protoplast fusion and recombinant DNA technology (genetic engineering), can

provide many strategies to overcome the limitations of sexual system. Majority of initial tissue culture studies have been confined to herbaceous plants and only a few years ago, woody fruit crops were considered to be difficult to regenerate in *vitro*. It is only recently that the regeneration procedures of many woody fruit crops have been possible.

Potential application to important fruit crops :

Mango : Mango is an allopolyploid out breeding species. Considerable variability has been observed within certain important cultivars which may be attributed to the effect of non-uniform mono embryonic root-stocks or to somatic mutations. Generally, majority of mono embryonic cultivars are vegetatively propagated by grafting or budding onto mono or poly-embryonic seedling stocks while poly embryonic seedling stocks. The conventional breeding programmes have resulted in development of promising compact and regular bearing hybrids. Conventional breeding in mango with specific objectives is a long term process due to lengthy juvenile period, i.e. 6-8 years. Besides, mango cultivars are highly heterozygous. Thus, pursuing defined objectives through conventional breeding sometimes ends up in futile exercise due to loss of quantitatively inherited traits in F_1 generations. The inflorescence in mango is a determinate panicle developing only from terminal buds and can contain a high proportion of staminate to perfect flowers. Irregular bearing (or alternate) is a common feature in most of the Indian cultivars. Dropping of perfect flowers and young fruits is as high as 99% in mono embryonic cultivars. Hence, it is due to the reasons, viz (I) large number of flowers within a mango panicle, (ii) disproportionate number of staminate flowers, (iii) inefficient fruit setting and (iv) difficulty in hand pollination, the majority of outstanding mango cultivars are chance seedlings and have not come up via breeding programmes. Other important breeding priorities in mango are disease resistance, irregular bearing, post harvest disorders cold tolerance and management of canopy shape and size. Therefore, bio technological approaches for mango improvement will have to be directed to alter qualitatively one of more traits in important mango cultivars.

Citrus : The mode of inheritances and genetic nature of majority of desirable traits in citrus are still unknown which is a great impediment in genetic improvement. In fact, it is difficult to achieve desired objectives when complete understanding of these genetic factors is lacking. The problem gets further compounded due to great heterozygosity of most of the citrus clones which result in considerable character segregation in hybrid progeny. Citrus fruits occupy a place of considerable importance in fruit economy of the country but

commercial production has been challenged by citrus decline or die back. Development of new strains with all the desired characters of established cultivars and additional traits like higher yields, improvement in fruit quality, etc. will have a significant impact on citrus industry. In view of the limitations of conventional breeding methods, developments of biotechnological methods of genetic manipulations provide an excellent opportunity.

Apple : Apple belongs to genus Malus and family Rosaceae, and has 122 species and sub specie4s. Apple accounts for more tan 50 percent of deciduous fruit production of world. In India, apple cultivation is mainly confined to J&K and H.P. Although fruit forms the backbone of J&K economy, yet the yield compared to western countries is very low and there is a need to have cultivars which give high yield, quality fruit with long shelf and storage life, firm fruits, compact trees resistant to cold, diseases and insect pests. The breeding programmes which can be taken for these have certain limitations like long juvenile period of fruit trees, self incompatibility, compatible root stock, large lands required for segregating generations and seed dormancy.

Walnut : Walnuts, after apple, are the major earner for J&K. Walnuts, covering large hilly and uncovered lands of temperate and mid-zone regions, have problems like low yields, low quality of kernel, thick shell, big massive trees which take more space and make natural operations difficult, long juvenile period of trees, paucity of uniform high quality plant material. Existing plant propagation techniques have a high percentage of failure. To overcome some of these problems, fruits biotechnology can play an important role as it has emerged as a major field in science and technology. Raising production per unit ares and have quality fruit is main focus of horticulture research. Bio-technology can be used in processes like (I) rapid multiplication of existing desirable cultivars, (ii) conserving germ plasm, (iii) cryopreservation, (iv) exchange of germplasm, (v) overcoming crossability barriers, (vi) creating somoclonal variation, (vii) somatic hybridization and (viii) genetic engineering/genetic manipulation. The gene insertion has a vast potential as resistance against diseases and pests can be imparted in desired cvs. Genes which reduce enzyme activity can be introduced to prolong shelf life of fruits. Thus, it can safely, be assumed that in future major role will be played by biotechnology in increasing fruit yield per unit area, increasing diseases and pest resistance and the improvement will take shorter period as compared to long period required for conventional fruit breeding programmes.

Pulses and Oilseeds : The genus *Brassica* includes several economically important species which are known world over for oilseeds and as vegetables. A substantial amount of work has been done on various species and varieties of *Brassica* with special reference to plant regeneration. Vegetable oils play a major role in human nutrition. These oils provide twice the energy of carbohydrates or proteins, furnish essential fatty acids, serve as carrier of fat-soluble vitamins and improve the palatability of the food. Seed oils are mainly triglycerides. Mutation breeding has demonstrated the plasticity of seed oil quality with significant alterations in fatty acid composition and no visible detrimental effects on the crop agronomics. Lipid metabolism in plants has opened new area for genetic engineering to produce varieties with the required oil composition for food and industrial uses. It was now realized that transgenic crops can serve as biological factories for upscaling production of premium lipids via molecular farming. Vegetable oils possessing higher amount of polyunsaturated fatty acids, in particular linolenic acid, are easily oxidized which reduces their "shelf life". Nutritional toxic effects are due to oxidized fatty acids and peroxides fatty acids cause "green taste" or flavour reversion of the products. The storage life of the oil can be enhanced by increasing oleic acid. Therefore, long linolenic and high oleic acid contents are important quality traits of oil seeds. Rape seed and mustard produce oils which are edible and also can be used for industrial purposes. These oils differ from most other vegetable oils in containing significant (50%) amount of long chain fatty acids called erucic acid. In animals, erucic acid has shown to retard growth and induce changes in various organs. It is felt to effect a change over to new low erucic acid varieties. Besides, high olecic and linoleic, low linoleic acid could be the major improvement in the quality of rape seed mustard.

Future prospects :

It is well known fact that plant biotechnology does not develop varieties but only creates genetic variation. It can also assist in selection, and rapid multiplication of the desired lines through micro- propagation. The variation generated by it must be subjected to atleast selection and evaluation before it can be used as a variety. In coming years, embryo and meristem culture may be expected to continue maturing the same contributions to plant breeding efforts as they do today. Several transgenic crop varieties are already in cultivation. Slow ripening variety

of tomato was first cultivated in 1995 and some insect resistant maize and cotton varieties were grown in large scale in USA. Therefore, biotechnology would help in :

1. **Introduction of Bt gene** : Introduction of bacterial gene from Bacillus thuringiensis (Bt) synthesizes an insecticidal crystal protein, which resides in the bodies produced by Bacillus during sporulation. This crystal protein when ingested by insect larvae is solublized in the alkaline conditions of the midgut of insect and processed by midgut protease to produce a protease-resistant polypeptide which is toxic to the insect. The use of redesigned synthetic Bt. gene has also been used in tobacco, tomato, cotton, potato, rice and maize. Some of such transgenic have been released.

2. **Herbicide resistance** : Weeds present in the fields compete with crop plants and reduce their yields. Since herbicides are very selective, so their current use relies on different uptake between the weed and crop plant or an application of the herbicide before planting in field. Now with the ability to introduce DNA into plants, it is possible to create on herbicide-resistant crops.

3. **Insect resistance** : In addition to the insect resistance genes found in some crops plants, a gene (cry) from a bacterium may rescue many crops from insect attack, e.g. pod borer attack on chickpea. Efforts are on to transfer the cry gene into chickpea and other pulse crops in order to protect them from damage from insect pests for which sources of resistance are not available. Bio-technology can also be utilized for developing virus-resistant crop varieties.

4. **Seed storage proteins** : Transfer of genes for seed storage proteins both from cereals and legumes into tobacco have been made possible. Example of such gene transfers are : Wheat glutenin, barley hordein, rajma phaseolin into tobacco; and maize zein gene into sunflower. Thus, gene transfers have opened up possibilities for using this approach to correct the amino acid deficiencies in both cereal (lysine deficient) and pulses (deficient in tryptophan and sulphur-containing amino acids) is seed storage proteins.

Suggestions of Government of Punjab on the draft policy on 'Applications of Biotechnology in Agriculture'

The State of Punjab is in Agreement, in principle, with the draft policy of the 'Application of Biotechnology in Agriculture' prepared by Prof. M.S. Swaminathan, Chairman of the Task Force. For promoting the application of biotechnology in agriculture, the state of Punjab feels that the following suggestions may also be taken into consideration :-

1. The draft document suggests the setting up of the National Institute for the Evaluation of GM Crops Varieties. It is suggested that such institutes be set up in all the States of country leading in agriculture or at least in each zone so that the farmers, agri-product producers and exporters have testing facilities at one place and within a reasonable distance.

2. The state of Punjab is in agreement with the suggestion of setting up of a 3 tier regulatory bodies at national, state and district level for promoting the application of biotechnology in agriculture. It is suggested that all the states may set up boards which are empowered and can take decisions for the application of biotechnology in the areas of interest to the state/region.

3. The time taken for clearing a product from the stage one to commercialization for consumption by consumer is quite long. In the case of agriculture products it takes 7-8 years. The state of Punjab which is the leading agriculture state in the country, feels that the Task Force should consider simplifying the regulations so that the time taken for clearing of agri-products is reduced.

4. The state of Punjab appreciates the clause '9' of the document i.e. Liability and Compensation. It is suggested that a clause be put into the document to provide for insurance cover for agriculture. It would certainly help to build the confidence of the farmers for shifting from conventional to the cultivation of innovative crops including GM crops.

5. The document may spell out the policies for creating public awareness about biotechnology in general and application of

biotechnology in agriculture/agro-processing, GM crops etc in particular.

Comments of the Government of Tamil Nadu on the Applications of Biotechnology in Agriculture and Animal Husbandry Sector

I. Policies for the safe and responsible use of Biotechnology in Agriculture :

(1) The paper regarding Evaluation of GM Crops, has clearly brought the policy level issues that are to be examined, with regard to GM crops.

(2) Establishing an autonomous body for evaluation, giving approval to GM crops etc. should be decided by Government of India. However, it is felt that a structure is to be formed by Government of India, suitably including the Members from Government of India, Ministry of Environment & Forests, Ministry of Biotechnology, ICAR, Ministry of Agriculture for deciding the approval of GM varieties and to assess the risks and benefits of GM crops.

(3) Evaluation procedures should be transparent.

(4) Providing insurance coverages for GM crops by the Company selling GM seeds is an encouraging part in the case of farmers.

(5) A suitable regulatory structure/body should also be formed for registration, certification and to have control on the sale of GM seeds.

II. Base Paper on Biotechnology Applications in Agriculture - Developing a long term Policy :

(a) As far as agriculture is concerned, there are priority areas for the bio-tech application in crops. The strategies, like transgenics, molecular breeding, tissue culture, molecular diagnostics may be used for bio tech Research.

(b) Bio tech Researches should be strengthened by proper funding.

(c) A clear policy document of GMO should be brought out by Government.

(d) Policies pertaining to GM Crops need attention and it is pointed out here that the various aspects of evaluation and approval should be made more transparent.

III. Base Paper on Regulatory Procedures in Agriculture :

a) The revised procedures discussed in the Base Paper for development of transgenic crops may be considered.

b) However, it is suggested that, the points discussed by Dr. M.S. Swaminathan, regarding the restructuring of GEAC, may be examined again, so that public or scientific or commercial confidence can be inspired.

c) The concerned firm should be instructed properly for providing all field level data to the Department of Agriculture, (State) maintaining coordination with the Department officials, for proper monitoring of the field trials. The field trials that will be laid down by the firm, should be supervised by the district level authority. At every stage of inspection by the firm staff, the Departmental functioning should also be involved.

d) Without the involvement of the Department of Agriculture (State) the firms are not to be allowed to distribute the GM seeds.

e) Hence, strict conditions are to be derived for the firms that develop and commercialize GM seeds.

IV. Role of Ministry of Agriculture in the Application of Biotechnology in Agriculture :

1. The suggestion of Ministry of Agriculture regarding multi locational field trials may be examined in detail.

2. As the present system of release and notification aspects of various crops is dealt by Ministry of Agriculture, the Ministry of Agriculture should also be consulted, discussed for release and notification of GM crops.

3. The suggestion with regard to conducting campaigns, Seminars, Workshops to educate the public on Biotechnology before allowing GM crops may be considered.

V. Application of Biotechnology in Animal Husbandry sector with reference to the use of Genetically Modified feeds and its implications on the trade :

Biotechnology is very much useful in the Animal Husbandry sector to improve the health and productivity of the livestock of poultry which will ultimately help create food security of the growing population of out country. If biotechnology is put into use in a regulated manner, it will help to produce food with genetically modified products by converting the bio factors of living organism. Nutritional value can also be improved.

The role of biotechnology in preparation of various vaccines is significant to improve Animal Husbandry immunity and disease eradication. At present, foot and mouth and Rinderpest disease are taking the lives of thousands of animals in our country. Therefore, if biotechnology is used to prepare the veterinary vaccines products, we can seek better health improvement besides producing disease resistance livestock. The cost of vaccines will also be affordable. Nowadays eggs, which are low in cholesterol, are being produced with the help of biotechnology. The genetic modified organisms can also help to produce animal feed which is the need of the day in this sector as we are not having sufficient quality of food for the requirement of livestock and poultry. This will certainly help to improve milk potential in this State.

The main concern will be, on the side of regulation of the production of genetically modified products and its trade. Special stems/measures will have to be taken by the

concerned authorities to have regulatory measures to avoid future problem.

Use of Bio technology in Agriculture is gaining importance due to its varied applications in different stages of Agricultural application such as seeds, pest management, development of new varieties, tissue culture etc. It has great implications for increasing food productivity and ensuring livelihood security. Though most of the applications will be beneficial in the long run, in the immediate after math of introduction of Bio Technology, there may be some unexpected short-term side effects. It is suggested that in a developing country like India where vast majority of the population is dependant on agriculture a graded response to introduction of Biotechnology in Agriculture may be adopted.

Care may also be taken to ensure that Bt does not lead to replacement of Agricultural labour or destruction of traditional agricultural practices. Bio Technology may be put to profitable use in areas such as post harvest management, storage, creation of infrastructure, logistics and effective marketing. High-tech precision farming is the need of the times for which there is a biotechnology policy already announced by the Government of Tamil Nadu. Greater efforts may be directed towards cost reduction of Biotechnology seeds and reuse of such terminated seeds. Over all Biotechnology can be harnessed for increasing farm productivity and improving rural incomes.