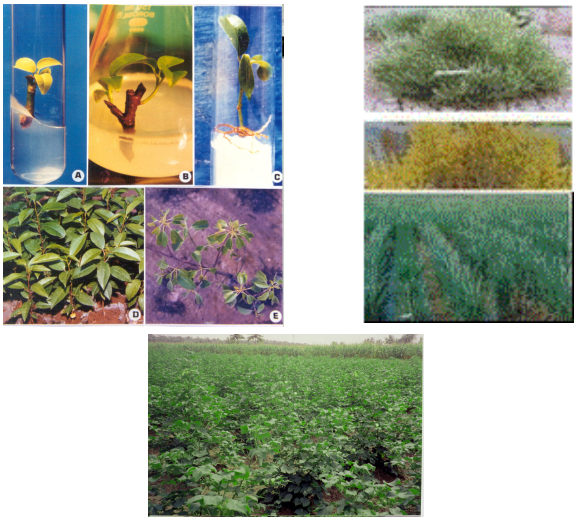
Report of the Task Force on Application of Agricultural Biotechnology

by:-
M. S. Swaminathan
Chairman, Task Force on Agricultural Biotechnology



May 2004
Ministry of Agriculture
Government of India

Next>>

[About Us] [Programmes & Schemes] [Farm Produce Prices] [Statistics] [Weather] [Documents]
[Stop Press] [Announcements] [Feedback] [Help Desk]

Last Updated On - 01 April, 2005

INDEX

Last Updated On - 01 April, 2005

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 Biotechnology to recommend appropriate safety regulations in recombinant research, use and applications.

ii. The Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology 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:

i. "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

ii. "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

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

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

v. "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.

Last Updated On - 01 April, 2005

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.

[About Us] [Programmes & Schemes] [Farm Produce Prices] [Statistics] [Weather] [Documents]
[Stop Press] [Announcements] [Feedback] [Help Desk]

Last Updated On - 01 April, 2005

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.

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.

[About Us] [Programmes & Schemes] [Farm Produce Prices] [Statistics] [Weather] [Documents] [Stop Press] [Announcements] [Feedback] [Help Desk]

Ho