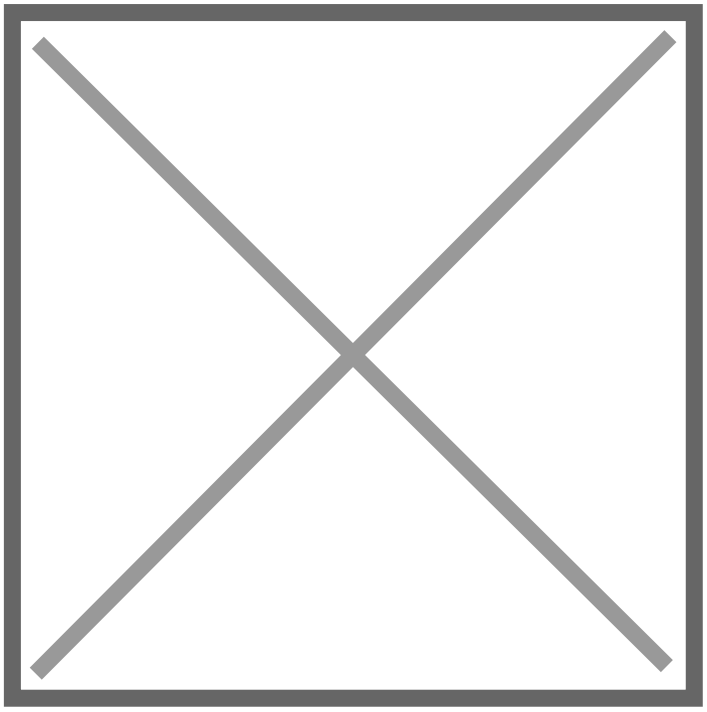
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Regulating GMOs

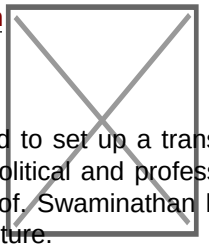
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COLUMN



Prof. MS Swaminathan



Regulating GMOs

There is an urgent need to set up a transparent regulatory mechanism to handle Genetically Modified Organisms (GMOs), which inspires public, political and professional confidence, according to Prof. MS Swaminathan, one of the world's leading agricultural scientist. Prof. Swaminathan has just submitted the report of the National Task Force chaired by him on Using Biotechnology in Agriculture.

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 worms, 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 (genetically modified organisms) 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.

Agriculture comprising crop and animal husbandry, 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 Ã¢â?¬â?? 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 liaise with the proposed National Biotechnology Regulatory Authority.

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.