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Biosafety Issues and Preparedness for GMOs

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Rapid advances in biotechnology have opened up countless opportunities for practically all sectors of economy, such as pharmaceutical and drugs, agriculture, industrial processes, environment and biodiversity conservation. In modern biotechnology, a Genetically Modified Organism (GMO) is that in which the basic genetic material (DNA) has been artificially altered or modified to improve the attributes or make it perform new functions. Common GMOs include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases e.g. Bt cotton, incorporating a gene from a bacterium *Bacillus thuriengiensis* effective against the American Bollworm, a major pest on cotton. In the context of International Agrobiodiversity Congress, the focus of this paper is on GM crops only.

Although the development of GM crops using recombinant DNA techniques is relatively recent, their applications and use is increasing because of advantages over the conventional crops. However as more and more GM crops are being released for field-testing and commercialization, concerns have been expressed regarding the risks arising from their use due to potential risks to both human health and environment. These apprehensions arise because GM technology crosses the species barrier as compared to classical selection techniques, thereby permitting the gene transfer among microorganisms, plants and animals. There is no evidence that any unique hazards exist in the development of GM crops, because of novel combinations of genes. It is not true that all GM crops are toxic or are likely to proliferate in the environment. However, specific crops may be harmful by virtue of novel combinations of traits they possess. This means that the concerns associated with use of GMOs can differ greatly depending on the particular gene-organism combination and therefore a case-by-case approach is required for assessment of safety concerns.

Evaluating the safety of a GM crop is a comprehensive process that involves several steps. Systematic safety assessment methodologies are in place that have been agreed on years of consultations under the aegis of international organizations and agreements viz. FAO, WHO, Codex Alimentarius, OECD and Cartagena Protocol on Biosafety. The potential changes introduced using genetic engineering are assessed using comparative risk assessment approach The underline assumption of this comparative approach is that traditionally cultivated crop has a history of safe use and thus serves as the comparator. As a consequence, safety assessment process gives conclusion on whether or not the GE plant is as safe as its conventional non-GE counterpart. Safety assessment studies required for commercial release of a GE plant comprise of food and feed safety assessment and the environmental risk assessment coupled with information through the molecular characterization of the GE plant and characterization of the expressed, transgenic proteins.

Safety assessment requirements have led to the development of regulatory regimes in various countries for research, testing, safe use and handling of GM crops and their products. Regulatory framework in India governing GM crops is based on the "Rules for the manufacture, use, import, export & storage of hazardous microorganisms, genetically engineered organisms or cells, 1989 notified under the Environment (Protection) Act, 1986. These rules are the apex rules for regulation of all activities related to genetically engineered organisms and products thereof. These rules are implemented by the Ministry of Environment, Forest & Climate Change (MoEFCC), the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and State Governments. Six competent authorities and their composition and roles have been notified under the rules. These include Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). Various

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sub-committees and Expert committees are set up by RCGM and GEAC on a case by case basis and comprise of experts from various disciplines drawn from public sector institutions to prepare and review various guidelines and biosafety data. Central Compliance Committees are also set up for monitoring of confined field trials on case by case basis.

A series of biosafety guidelines have been issued by the regulatory authorities to deal with various aspects such as contained research, confined field trials, food safety assessment, environmental risk assessment etc. with a view to minimize any adverse impact that the GE plants may have GMOs and product thereof would have on the environment as well as human and animal health. These include:

- Recombinant DNA Safety Guidelines, 1990
- Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants - 2008
- Guideline for the Monitoring of Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008.
- Protocols for Food and Feed Safety Assessment of GE crops, 2008
- Guidelines and handbook for Institutional Biosafety Committees (IBSCs), 2011

In continuation to these efforts, MoEFCC in association with the Department of Biotechnology (DBT) have prepared a set of three documents to strengthen the environmental risk assessment of genetically engineered plants in India. These include Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders and Risk Analysis Framework, 2016.

The ERA Guidelines for GE Plants provided a comprehensive, and science-based framework for identification of potential harms, collection of relevant scientific data pertaining to the nature and severity of any harms, and characterize the level of risk posed by GE plants. The accompanying Guide for Stakeholders has been prepared to provide additional explanatory material, illustrative examples, and references to scientific literature to provide a better understanding. The Risk Analysis Framework (RAF) describes the principles of risk analysis to be used by the Regulatory Agencies to protect human health and safety, and the environment. RAF also includes concepts related to, risk management, and risk communication in addition to risk assessment. The three documents put together provides a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-Ill of the Cartagena Protocol on Biosafety, to which India is a Party.

Besides other issues, the guidelines deal with potential effects on biodiversity and ecosystems. The comparison of phenotypic and agronomic characteristics of the GE plants is used to determine whether they are substantially different from those of the know GM plant and whether any of these difference could have significant adverse environmental impacts on biodiversity.

Table 1. An indicative list of GE plants under research and development/ field trials in India

S.No.	Plant	Trait
1.	Banana	Antimicrobial peptide (AMP) gene
2.	Brinjal	Insect resistance
3.	Cabbage	Insect resistance
4.	Castor	Insect resistance
5.	Cauliflower	Insect resistance
6.	Chickpea	Abiotic stress tolerance, insect resistance
7.	Corn	Insect resistance, herbicide tolerance
8.	Cotton	Insect resistance, herbicide tolerance
9.	Groundnut	Virus resistance, abiotic stress tolerance
10.	Mustard	Hybrid seed production
11.	Okra	Insect resistance
12.	Papaya	Virus resistance
13.	Pigeonpea	Insect resistance
14.	Potato	Tuber sweetening, fungal resistance
15.	Rice	Insect resistance, diseases resistance, hybrid seed production, nutritional enhancement
16.	Rubber	Abiotic stress tolerance
17.	Sorghum	Insect resistance, abiotic stress tolerance
18.	Sugarcane	Insect resistance
19.	Tomato	Insect resistance, virus resistance, fruit ripening
20.	Watermelon	Virus resistance
21.	Wheat	Effect of mutant strains Azotobacter

As on date Bt cotton is the only GM crop approved for commercial cultivation in India. The total area under Bt cotton has increased from 0.05 million hectares in 2002 to 11.6 million hectares in 2014. Bt cotton is cultivated in more than 90% of the area under cotton.

Several public and private sector institutions are involved in the research and development of GE plants in India. More than 20 plants with varying traits such as hybrid seed production, insect resistance, herbicide tolerance etc. are under various stages of field trials.

As per the regulatory requirements, developers of GE plants from both public and private sector test their products according to the biosafety regulatory requirements which include detailed documentation of testing. Regulatory authorities undertake thorough analysis of the data and the protocols used to ensure the validity of the results. In view of the above, India is well prepared to take forward the GE plants under research and development through the biosafety regulations for the benefit of society and farmers.

References

MoEF and BCIL, 2007, Biosafety Information Kit.

MoEFCC and BCIL, 2015, Biosafety Resource Kit.

MoEFCC and DBT, 2016, Environmental Risk Assessment of Genetically Engineered Plants.