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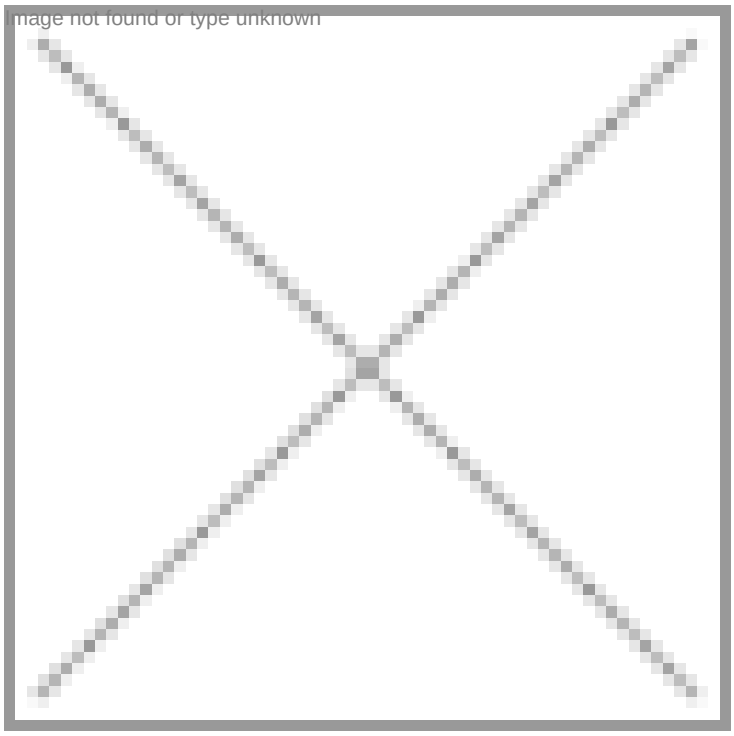

GM safety assessment guidelines in India

Biosafety regulations have been put in place by various countries including India.

The development of a GM crop involves a complex process starting from gene identification, selection, product commercialization and safety assessment has to be undertaken at all stages of its development. It begins at early gene selection phase by taking into account each gene's source, previous consumer exposure to the source, and whether there is a history of safe use for source material, the gene and its specific products. After genetic modification, specific GM crop line is selected through a variety of steps in the greenhouse and field during which the biological and agronomic equivalence of the GM crop is compared with its traditional counterpart. Biosafety regulations have been put in place by various countries including India.

The regulation of GMOs in India is governed by the "Rules for manufacture, use, import, export, and storage of hazardous microorganisms/genetically engineered organisms or cells 1989" under the environment protection Act, 1986. The two agencies primarily responsible for implementation of the 1989 rules are the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT) of the Ministry of Science and Technology. The 1989 rules define competent authorities and the composition of such authorities for handling of various aspects of the rules. Six competent authorities are listed in the rules:

- The recombinant DNA advisory committee(RDAC)
- The review committee on Genetic Manipulation(RCGM)

- The Genetic Engineering approval Committee(GEAC)
- State Biosafety Coordination Committees (SBCs)
- District Level Committees (DLCs)

The Ministry of Health and Family welfare is responsible for ensuring the quality and safety of food marketed in the country and the Prevention of food Adulteration Act enacted in 1954. The Indian Council of Medical Research acts as an advisory body on GM foods and the Ministry of Food Processing industries is involved in developing new regulations for R&D of food processing industries. In addition to MoEF and DBT, the Ministry of Agriculture is responsible for Seeds policy.

Before commercialization, GM crops undergo a detailed and specific safety assessment process. This process focuses on the safety of products associated with the introduced gene and any other likely toxicological or anti-nutritional factors associated with the source of the novel gene and the product to which it was introduced. DBT had formulated Recombinant DNA safety guidelines in 1990 which were further revised in 1994 that covered areas of research involving GMOs. In 1998, DBT brought out separate guidelines for carrying out research in transgenic plants called the “Revised guidelines for research in transgenic plants”. These also include guidelines for toxicity and allerginicity evaluation of transgenic seeds, plants and plant parts. These guidelines cover development of transgenic plants and their molecular and field evaluation along with import and shipment of GM plants for research. The guidelines include complete design of a contained greenhouse suitable for conducting research with transgenic plants and provide the basis for generating food safety information on transgenic plants and plant parts.

Acute and sub acute chronic toxicity tests have been included in the DBT guidelines. Many of these test protocols have been adopted from the OECD (Organization for Economic Cooperation and Development) guidelines and modified as per requirements. Separate protocols have been provided for transgenic seeds and vegetables. Similarly protocols have been proposed by designing appropriate experiments to gather data on allerginicity testing in the laboratory. Review Committee on genetic manipulation (RCGM) decides on the actual tests and protocols on a case by case basis.

RCGM(Review Committee on genetic manipulation) is a statutory body notified under the Rules, 1989 of environmental Protection Act, 1986 to ensure that the R&D activities undertaken by DBT are carried out in a safe and sound manner. It comprises of 29 experts from various multi-disciplinary fields. The development of GM crops (including imports for research) at the laboratory stage, contained multi-location trials and protocols for the biosafety studies require prior approval of the RCGM. Based on the results of the contained field trials and the biosafety assessment studies, RCGM then makes its recommendation to the GEAC.

An approval of GEAC is required to conduct of large-scale field trials to assess biosafety, efficacy of the variety and the agronomic benefits of transgenic seeds. The results of the contained field trials and large scale field trials are then evaluated by the state Agricultural Monitoring Committee (MEC) before recommendations on the efficacy of the transgenic are made to the GEAC. The GM crops for large scale trials are also evaluated under the Indian Council of Agriculture and Research (ICAR) testing system.

In addition all institutions involved in any work related to development or use of transgenic(including export/import) are required to set up an Institutional biosafety committee which has an expert nominated by DBT. The GEAC takes into consideration the findings of the biosafety studies and the agronomic evaluation by MEC and ICAR before according approval for the environmental release of the crop.

GEAC is the apex statutory body notified under the rules, 1989 of environmental Protection Act to evaluate environmentalrisk versus societal benefits before release of Living Modified Organisms (LMOs). Any company involved in the development of GM crop has to undertake extensive biosafety assessment which includes environmental safety assessment as well as food and feed safety. Food safety studies are conducted in public institutions such as National Dairy Research Institute, Karnal, and Indian Toxicological Research Institute, Lucknow and are further scrutinized by experts at the GEAC and independent experts as well.

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is an international agreement on biosafety, as a supplement to the Convention on Biological Diversity that seeks to protect biological diversity from the potential risks posed by living modified organisms. The Biosafety Protocol makes clear that products from new technologies must be based on the precautionary principle and allow developing nations to balance public health against economic benefits. It will for example let countries ban imports of a living modified organism if they feel there is not enough scientific evidence the product is safe and requires exporters to label shipments containing genetically altered commodities such as corn or cotton.

In accordance with the precautionary approach, contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of “living modified organisms resulting from modern biotechnology” that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements.

The number of ratifications and accessions to the Protocol grew from 143 countries to 151 (as of 15 November 2008). The countries that became Parties to the Protocol in 2008 include Guinea, Guyana, Myanmar, Suriname, Turkmenistan, Kazakhstan, Burundi and Georgia. During the year, the number of countries that finalized their first draft national biosafety frameworks funded by UNEP-GEF reached 104. September 11, 2008 marked the fifth anniversary of the entry into force of the Protocol.