

Regulation of Emerging Gene Technologies in India

In India, genetically modified organisms (GMOs) and products thereof are regulated under the “Rules for the manufacture, use, import, export & storage of hazardous microorganisms, genetically engineered organisms or cells, 1989” (referred to as Rules, 1989). These rules have been notified under the Environment (Protection) Act, 1986 and are administered by the Ministry of Environment, Forest and Climate Change with support from the Department of Biotechnology, Ministry of Science & Technology, Government of India. The implementation of rules is through six competent authorities, the composition of which has been notified in Rules, itself.

The Environment (Protection) Act, 1986 as an umbrella legislation that provides a holistic framework for the protection and improvement to the environment. Thereafter a series of rules were notified to address various problems such as hazardous wastes, hazardous chemicals, biomedical wastes, municipal solid wastes etc. Along with these, rules were notified for hazardous microorganisms. The genetically engineered (GE) organisms were included as part of these rules along with hazardous microorganisms. Hence, these Rules, 1989 are applicable to the manufacture, import and storage of micro-organisms and Gene-Technological products. These rules shall also apply to any substances, products and food stuffs, etc., of which such cells, organisms or tissues hereof form part. New gene technologies apart from genetic engineering have also been covered.

The Rules, 1989 are supported by series of guidelines issued from time to time to deal with contained research, biologics, confined field trials, food safety assessment, environmental risk assessment etc.

The definition of GE technology in the Rules implies that new technologies such as gene editing, gene drive etc. may be covered under the rules. Efforts have been underway to set up an independent Biotechnology Regulatory Authority of India (BRAI) through a separate Bill introduced in the Indian Parliament in 2013. However, the bill lapsed in 2014. This bill had definition of modern biotechnology derived from the Cartagena Protocol on Biosafety (CPB). There is yet no clarity on how the emerging technologies will be dealt with in India. Regarding the history of coordinating with other countries, the regulatory committees do review the experience by other countries in dealing with applications or development of new guidance.