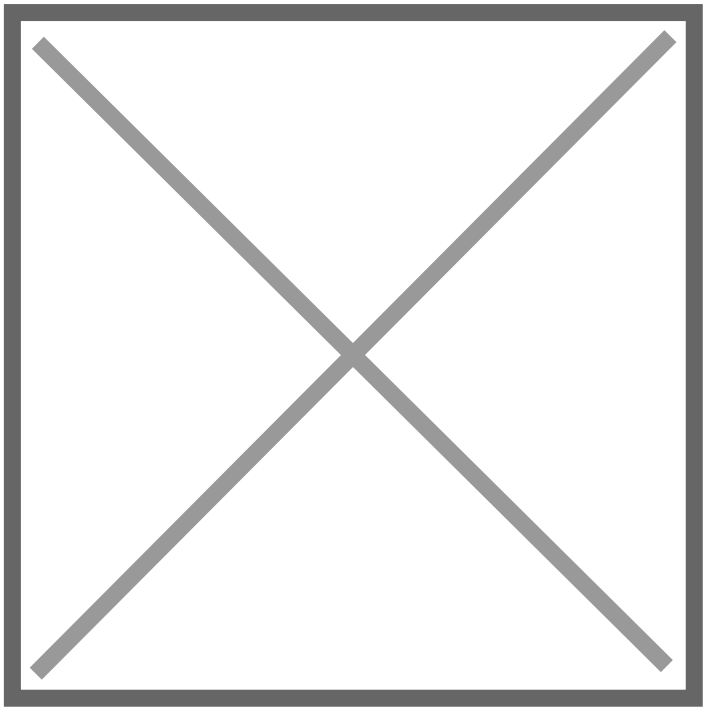
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The politics of GM food

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Law Offices of Jafa & Javali is a full fledged corporate law firm with niche expertise in IPR & Biotech law, with offices in New Delhi, Bangalore and Mumbai

Genetically modified crops have been at the center of controversy for quite some time now, both nationally and internationally. Despite a fair amount of debate and discussions, no consensus appears to be in sight.

Understanding agricultural history is a good starting point in allievating people's unease about GM foods. Humans have been modifying crops for thousands of years, and without human care many of today's crops would cease to exist. Globally, the US and Canada are all for genetically modified crops, while the European Union is not.

In India, it is still early to say whether genetically modified food would be fully accepted. The process of introduction of genetically modified food involves a series of field trials before it is released for commercial use.

GM food generally raises the concerns of environmental issues, right to information, and biosafety regulations

Environmental issues

One major concern is that genetically modified seeds, which have been engineered to insecticide or herbicide resistance, may escape into the wild and therefore, may endanger biodiversity. Proponents of transgenic crops argue that these crops requires much less herbicides and insecticides and are therefore, more environment-friendly.

Nevertheless, scientific research aimed at risk analysis, prediction and prevention, combined with adequate monitoring and stewardship, must continue so that negative ecological impact from GM crops will be kept to a minimum. Most problems raised by science can be solved by science itself.

Right to Information

Societal acceptance is essential to the continued development and application of biotechnology in food and agriculture.

The issue for consideration is whether GM food can endanger health and whether the consumer should have the right to have detailed information through proper labeling so that they can decide rationally whether they should buy such GM foods. The purpose of labels is two-fold: they contain the nutrition information and they warn against presence of allergens.

The EU and Japan are both in favor of giving GMO related information on product labels on a mandatory basis. The EU had introduced a Regulation (EC) 258/1997 and Regulation (EC) 50/2000 of the European Parliament, which makes the labeling of foods containing GM additives and flavorings mandatory. The US and Canada are opposed to mandatory GMO labeling, due to any possible adverse public reaction to their GMO-based product exports.

Bio-safety regulations

In the US, three government agencies namely the Environmental Protection Agency, United States Department of Agriculture, and the Federal Drug Administration are responsible for commercializing GM foods. In the European Union, the approval for commercialization of GM foods consists of a process outlined by Directive 90/220/EEC on the release of GMOs into the environment.

In India, the planting of GM crops is a regulated item. These crops can be planted only in the open fields with the prior permission from the Department of Biotechnology (DBT), which is under the Ministry of Science and Technology. A number of committees are involved in the regulation of GM crops.

The Indian government first issued rules and procedures for handling GM organisms in December 1989 by way of The Hazardous Micro-Organisms and Genetically Modified Organisms Rules, 1989 under the Environment Protection Act, 1986 (EPA). Guidelines for Safety in Biotechnology were laid down by the DBT in 1994 which describe the bio-safety measures that must be undertaken in India both for contained research activities and also for large-scale open environmental release of genetically altered agricultural and pharmaceutical materials. A subsequent 1998 revision of the guidelines elaborated procedures for screening transgenic plants and seeds for toxicity and allergenicity. India's crop biosafety guidelines were written to require a screening of GM crop technologies for scientifically demonstrated risks.

The guidelines create two separate review committees: a Review Committee on Genetic Manipulation (RCGM), which is empowered to approve (or not approve) applications for all small-scale research activities in India designed to generate information on transgenic organisms, and a Genetic Engineering Approval Committee (GEAC) empowered to approve (or not) large scale research activities, plus actual industrial use or environmental release of all GM organisms.

The GEAC is thus India's most powerful biosafety policy gatekeeper. It is the lead inter-ministerial body empowered to shape by consensus - the government's final disposition toward large-scale use and environmental release of GM organisms. The GEAC is empowered to authorize or prohibit, conditionally or unconditionally, the import, export, transport, manufacture, processing, use, or sale of any GM organism.

Therefore, the GEAC requires that in the area of GM plants, basic information must be provided through lab, growth chamber, greenhouse and field trials and evaluations must be generated by applicants regarding toxicity and pathogenicity, possibility and extent of transgenic pollen escape and transfer to wild relatives, and consequences for both the environment and human and animal health.

Viewpoint

As mentioned above, the Genetic Engineering Approval Committee (GEAC) is a body appointed by the Ministry of Environment and Forests and is the regulatory body assigned to monitor the manufacture, use, import, export and storage of hazardous micro-organism and genetically engineered organism and cells. It is also responsible for granting commercial approval of proposals relating to the release of genetically engineered organisms and products into the environment, including experimental field trials.

An important point for consideration which has arisen in recent times, in relation to the field trials which have been conducted by companies is whether the field trials conducted by the companies and data collected by the authorities in respect of Bt cotton or in respect of proposed genetically modified food products such as okra and brinjal should be released under the Right to Information (RTI) Act or should the commercial interests of the companies be protected or for reasons of public health, whether the information should be released remains a matter to be decided.

It is argued that companies involved in research and development (R&D) spend a considerable amount of time and money on innovation of new products. It is further added that the disclosure of the biosafety information of transgenic crops will affect the commercial interests of the company. For, biosafety data falls under the protected confidential information covered by the Trade Related Aspects of Intellectual Property Rights (TRIPS) regime and is to be considered an intellectual property of the company. In any event protection available under Intellectual Property laws requires them to disclose the information publicly and later grants them exclusivity for a very limited period of time.

Welfare groups have been seeking details of the safety test conducted by the companies who have been granted commercial approval and to bring the data in the public domain from the concerned authorities. It is argued that the data being sought is not for commercial purposes but to ascertain the risks that transgenic crops pose, particularly when open air field trials are being conducted in several places across the country.

It can be argued that once the authorities have granted the regulatory clearance for conducting trials and commercial license has been granted after proper scrutiny then in such an event genetically modified products pose no threat to health hazards.

The Act permits the government to refuse disclosure of data, which exempts from disclosure information, including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party. (Section 8 (1)(d) of Act)

The object of the Act is to provide for setting out the practical regime for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority.

It can be argued that public health should not be compromised at any cost, however, if information has been submitted to respective committees which are designated by the government of India for appropriate review and analysis under the appropriate rules and regulations prescribed, then the company's data should not be released unless a company has bypassed or concealed any vital information which may have bearing on public health or the products prove to be otherwise, then in that event, data should be released and the matter must be investigated to its logical end.

Disclosure of information has to be balanced with preservation of confidentiality of sensitive information and protecting the interest of the public. How this can be achieved remains to be seen since the facts and circumstances in every case is different.