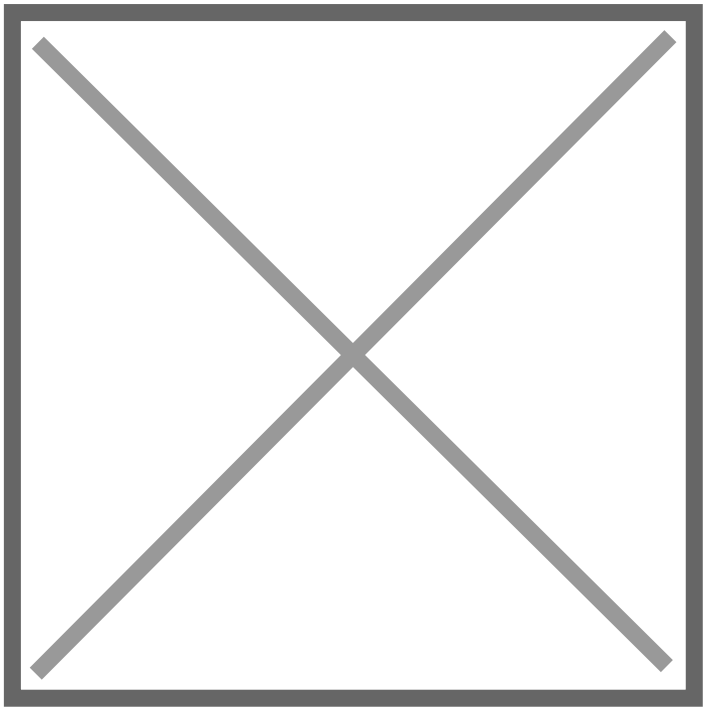
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Re-think the BioAgri Regulatory System

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LEGAL VIEW

Re-think the BioAgri Regulatory System

In evaluating the adequacy of a regulatory system, the purposes of the system must initially be considered. The primary purpose of any regulatory system is to protect against harm by assessing and managing the risks of potentially harmful products and activities.

To ensure safety of consumers, producers, farmers and environment, governments all over the world are following regulatory mechanisms and guidelines. This effort to reduce and eliminate the potential risks resulting from biotechnology and its products is often described as "Biosafety". Several recombinant DNA products have been permitted for commercial use in many countries based on these biosafety procedures and measures. Not all countries have biosafety guidelines in place. Though there are appropriate procedures in place, the nature of these guidelines varies. For example, in Asia itself, China, India, Japan, Korea, Malaysia, Philippines, and Thailand have policies and political environments that are promotional, yet precautious. On the contrary, in Sri Lanka and Bangladesh the policies are prohibitive or preventive even for imports or pilot scale experiments.

Indian Regulatory System

Since 1989, biotechnology regulatory policy has emerged in an incremental, some would say haphazard, way, prompted by a variety of factors and influenced by a range of different actors, both within and outside the formal regulatory arena.

The committees that form the regulatory administration of biotechnology in India have left room for doubt, at least on two counts. First, the nature of intervention of the State Biotechnology Coordination Committees and the District Level Committees in the regulatory process is not clear and this arises from the absence of the requisite information. In other words, although a decentralized structure has been provided for carrying out the regulatory functions, no real attempt seems to have been made to make it respond to the problem at hand. The second issue is the low level of transparency that the regulatory administration maintains.

Competent Authorities

The Rules provide for competent authorities, who have been empowered to inspect, investigate and take punitive action in case of violations of statutory provisions through the nodal department and the State Pollution Control Board or Directorate of Health & Medical Services.

- Review Committee on Genetic Manipulation (RCGM)
- Institutional Biosafety Committee (ISBC)
- Genetic Engineering Approval Committee (GEAC)
- State Biotechnology Co-ordination Committee (SBCC)
- District Level Coordination Committee (DLCC)

This was quite evident in the process leading to approval for commercial exploitation of the first Genetically Modified (GM) crop in India. Several questions were raised with regard to the introduction of Bt cotton. The first was that the approval for the field trials did not have the requisite level of transparency. The second was that the claims pertaining to the advantages of using this variety of cotton, particularly on the grounds that it offered an environmentally safer alternative to the pesticide-intensive cotton cultivation were not quite justified. And finally, the cost of adoption of Bt cotton could be prohibitive for the small farmers. Even though all these questions were raised, the campaign against the field trials of Bt cotton was built essentially around the point about transparency of the regulatory mechanism. Two of the more pertinent questions have been the six-committee structure that constitutes the regulatory administration. It is largely nonfunctional since only two of the Committees seem to have any role to play. These are the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC). The functions of the sub-federal committees remain largely undefined. The second question was related to the framing of rules of the committees that have a role in regulatory administration of GMOs.

The regulatory administration for biotechnology in India, in the agri-biotech sector over the past several years, has suffered from the inability to set its own terms. This was despite the fact that India has been one of the first countries in the developing world to set up a mechanism for making a risk assessment of biotech products before their commercial exploitation. The setting up of the regulatory administration was even more remarkable since it took place even before the global community formally launched the process of developing the Biosafety Protocol.

MS Swaminathan Task Force Recommendations

There have been few attempts to explore the detailed interactions with the biotech companies themselves. The previous government had appointed the MS Swaminathan Task Force on Applications of Biotechnology in Agriculture. The Task Force has suggested that pending the establishment of an autonomous Agricultural Biotechnology Regulatory Authority (ABRA), the release, notification and registration of transgenic crops for commercial cultivation be done by the Indian Council of Agricultural Research (ICAR) and the Union agriculture ministry. The Task Force has limited the powers of the GEAC to "only environmental clearance".

In the run-up to the ABRA, the Task Force suggests, approval powers for contained and open field trials for biosafety should rest with RCGM, while the multi-location field trials are the sole responsibility of ICAR and the company concerned. The Monitoring-cum-Evaluation Committee (MEC) should report to the GEAC on biosafety and environmental issues, while post-release monitoring should be the responsibility of the Union agriculture ministry and ICAR. At present, GEAC is the sole authority to deny or clear a particular Bt gene on all counts, economic and environmental.

The report favors strengthening the existing Seeds Act, 1966 and Environmental (Protection) Act, 1986 to deal with the possible illegal proliferation of GM seeds. It favors mandatory registration of all released seeds and proposes a single-window information center on all aspects of bioethics and biosafety.

Issues for Consideration

Pre-market authority: A regulatory agency must have the ability to assess and approve a product's health and environmental safety before it goes to market, to prevent problems before they occur. Because different laws governing biotechnology were enacted at different times and for different purposes, the degree of pre-market authority given to the agencies under these laws varies widely.

GMO Regulation in India

In India, the use of genetic modification technology is governed by several primary legislations.

- The Environment Protection Act 1986 (EPA)
- The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells 1989 (Rules)
- The Department of Biotechnology Guidelines 1998 (DBT Guidelines 1998)

Data evaluation: A regulatory agency must have the capacity to assess the quality of those data, analyze and interpret them, and draw scientifically valid conclusions.

Avoiding unnecessary delays: Unnecessary delays in the regulatory process can keep valuable crops off the market thereby depriving consumers of low cost, high quality food. Biotechnology companies need some reasonable expectation of return on the large investment that technological innovation requires.

Monitoring and enforcement capability: There has to be an effective national monitoring and enforcement capacity. Monitoring and enforcement has to take place on a few levels. Scientific developments globally have to be tracked and monitored daily as new scientific information is a basis for the decision-making body to review its decision.

An initial criterion for an effective regulatory system is that regulatory agencies should have clear legal jurisdiction and authority over all products and activities that may pose a risk to human health or the environment. This is also important for providing the public and technology developers a clear understanding of the regulatory pathway to market.

A product should not fall through the regulatory cracks because no agency has clear jurisdiction or authority. Similarly, if a product could come under the authority of one or more agencies, the agencies need to coordinate those authorities to make their respective responsibilities clear and to function in a way that is not overly burdensome.

Whether a new legislation for the biotechnology industry is required to be drafted or the existing legislation be modified is a decision the government could consider to ensure that the entire legal system is consistent and workable and that the relationship among the various components is clear.

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