



CONTENTS

- Context and importance of the problem
 - Introduction to biotechnology
 - Genetically modified crops vs. conventionally bred crops
 - Potential costs and benefits of genetically modified crops
- Current approach
 - Existing regulatory framework
 - Weaknesses in the current approach
- Policy recommendations
 - Product-based vs. process-based processes
 - Institutionally autonomous
 - Independent and qualified regulators
 - Reliable and transparent information
 - Harmonization with international standards
 - Biotechnology Regulatory Authority of India bill, 2009

Strengthening Agricultural Biotechnology Regulation in India

Highlights

The recent decision by the Ministry of Environment and Forests to place an indefinite moratorium on the release of Bt Brinjal for commercial agriculture has brought sharp focus on the stridently polarized views across the scientific community and civil society on the benefits and costs of genetically modified crops. Although agricultural biotechnology has significant potential to address India's food security, public debate has reflected concerns that the full range of potential consequences of these transgenic plants on human health, environment, and farmers' livelihoods must be understood adequately before releasing these plants for commercial agriculture.

Because of the controversy surrounding agricultural biotechnology, it is crucial that India has a strong, transparent, and independent biotechnology regulatory regime that upholds rigorous safety standards without compromising efficiency. However, India's current regulatory regime is a fragmented system with several flaws. This policy brief outlines the crucial elements of a strong biotechnology regulatory regime in India, namely, a process-based regulatory system, an autonomous regulatory body, independent and qualified regulators, reliable information, transparent processes, and harmonization with international standards.

Context and importance of the problem

Introduction to biotechnology

The UN Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".¹ In biotechnology, organisms can be

designed with the aid of genetic engineering so as to introduce desirable traits into a species, creating a specialized organism with specific traits. Genetically modified products include various types of medicines, vaccines, food products, food ingredients, fibre, and feeds. Specific examples range from pest-resistant crops to synthetic insulin to genetically modified algae for use in biofuel.²

Genetically modified crops vs. conventionally bred crops

A genetically modified crop differs in several ways from one that is developed through conventional cross-breeding methods. In conventional plant breeding, genes can be introduced from species that are closely related (as well as from different varieties of the same species), and after repeated back-crossings and large-scale field evaluation, individuals with desired traits can be selected. However, there is little or no guarantee of obtaining any particular gene combination. In contrast, genetic engineering is able to precisely introduce specific desirable traits into a species, using the techniques of molecular cloning and transformation to directly alter the structure and characteristics of genes. Crops produced through this process are called “transgenic” or “genetically engineered/modified” crops.

In genetic engineering, genetic traits from any species—bacteria, virus, fungi, plants or animals—can be introduced into a desired plant species; this is different from conventional breeding in which plant breeders can only work with closely related plant species. For example, the “Bt” widely used in genetically modified crops is *Bacillus thuringiensis*, a common bacterium that produces insecticidal proteins.³ By introducing the bacterium’s gene for toxin production into brinjal, for example, BT Brinjal acquires the ability to intrinsically repel insects,

reducing the burden on farmers to use insecticide against pests, and consequently enabling consumers to benefit from a crop that has been grown with the use of fewer chemicals.

Potential costs and benefits of genetically modified crops

Agricultural biotechnology has significant potential in addressing India’s food security needs. Proponents of biotechnology argue that it has the potential to introduce crops with increased yields and nutritional values; improved resistance to diseases, pests, and herbicides; improved tolerance to climatic variations; reduced maturation period; longer shelf-lives; reduced consumption of pesticides/other agricultural chemicals; and so on. These improved varieties of crops would clearly have an important and lasting effect on India’s food security. However, biotech crops that have largely been developed till now are characterized by herbicide and pesticide tolerance only.

Potential benefits

Genetically modified crops have the potential to contribute to food security through the following characteristics.

- Increased yields, nutritional value, quality
- Improved resistance to diseases, pests, and herbicides
- Improved tolerance to stresses such as cold and heat, drought, and salinity
- Reduced maturation period
- Food products have longer shelf life.
- Food products have considerable health benefits.
- Reduced use of pesticides/other agricultural chemicals

¹ Food and Agriculture Organization of the United Nations. Biotechnology in Food and Agriculture. Details available at <<http://www.fao.org/biotech/stat.asp>>, last accessed on 12 August 2010.

² It is important that any independent biotechnology regulatory regime, such as the one described in this brief, regulate all types of biotechnology products: (1) crops, (2) pharmaceuticals developed for humans and animals, and (3) genetically modified organisms (GMOs) with industrial applications. However, since agricultural biotechnology has very specific set of perceived benefits and costs, this policy brief is targeted only towards agricultural biotechnology, with the implicit understanding that the regulatory regime described should also have separate branches to regulate pharmaceuticals and GMOs with industrial applications.

³ T M Manjunath. Q & A on Bt-cotton in India. All India Crop Biotechnology Association. 2007. Different varieties of Bt produce different insecticidal proteins, and each of these proteins affects only a narrow range of insects belonging to a particular group.

Principal concerns
<p>The major concerns about genetically modified crops are as follows.</p> <ul style="list-style-type: none"> ■ Potential impact on human health, especially due to allergens and the transfer of antibiotic-resistant markers ■ Potential impact on the environment, especially due to the potential movement of genes from genetically modified plants into conventional crops or species in the wild ("outcrossing") and the possibility of the development of resistance ■ Difficulty in labelling ■ Ethical objections to introducing animal genes in plants ■ Debate over the cost of seed issue ■ Debate over the effects on farmers' livelihoods ■ Issues of access and intellectual property rights ■ Strong hold of multinationals over the entire process

Coupled with these significant potential benefits is a range of concerns associated with genetically modified crops. There is a need to ensure that the adverse impacts of biotechnology on ecology, biodiversity, and human health are minimal. For example, there is a fear that the transfer of antibiotic-resistant markers and the cross-breeding of biotech crops with conventional crops will have negative effects on the environment and human health. In addition, evidence points towards the fact that pest populations may develop resistance to biotech crops that are designed to resist pests. This could result in an evolved variety of pests that may be difficult to control using traditional methods, and will require that farmers incur additional costs to address the very problem that was originally intended to be alleviated by developing biotech crops.

The difficulty of labelling biotech crops has also been flagged as a concern. Some consumers worry about the health effects of genetically modified crops, while others cite ethical/religious objections

to consuming animal genes contained in plants. Whatever the motivation, the public has the right to know what they are consuming. However, the cost of keeping biotechnology products properly segregated from non-Bt crops all the way till the marketplace may be too high. Furthermore, such segregation may not even be feasible due to the fact that many crops are produced on small-scale farms.

Furthermore, there is debate about the possible impact on farmers' livelihoods. Opponents of biotechnology argue that despite higher yields, the high cost of biotech seeds will adversely affect the livelihoods of small-scale farmers. Some poor farmers may not be able to afford biotech seed, which may result in the further widening of the gap between rich and poor farmers. Those who can may become dependent on biotech seeds and then will be forced to continually repurchase them due to strict patent laws and the fact that many biotech seeds are engineered to prevent reuse.⁴ However, proponents of biotechnology have a counter-argument about the cost of seed, as the seed cost is only a fraction of the total investment. Many Indian state governments have implemented state-level price caps on biotech seeds, which limit the ability of firms to charge accurate market prices. This non-market-based pricing, proponents argue, is a disincentive for the commercialization of biotechnology in India and, therefore, limits the potential benefits of biotechnology on food security.⁵

While there is a clear imperative to develop crops that are high-yielding, resistant to pests, and tolerant to climatic stresses like drought, it is equally important to ensure that rigorous biosafety standards be complied with and that the socio-economic concerns such as impacts on livelihoods are factored into policy-makers' decisions. A significant focus of any regulation in this sector is to develop adequate testing standards for assessing the long-term health and environmental impacts of these transgenic products, establish a workable administrative system that can implement these standards in practice, and impose credible sanctions on violators of testing norms.

⁴ United Nations Division on Investment, Technology and Enterprise Development. Key issues in biotechnology (New York: 2002). Details available at <www.unctad.org/en/docs/poitetebd10.en.pdf>, last accessed on 29 July 2010.

⁵ Linton K and Torsekar M. Innovation in biotechnology seeds: public and private initiatives in India and China. United States International Trade Commission Journal of International Commerce and Economics. Details available at <www.usitc.gov/publications/332/journals/biotechnology_seeds.pdf>, last accessed on 15 August 2010.

Genetically modified organisms need to be assessed for a number of issues, including their potential toxicity to other species, to humans, and to the environment at large; their potential to cause health problems such as allergies; their effect on non-target beneficial organisms, including biological control agents; their impact on feed safety (since animal feed links directly to the human food chain); along with the effect of cross pollination on a range of issues, including yields, and indirectly on global prices (and therefore farmer incomes).

Current approach

Existing regulatory framework

The Ministry of Environment and Forests (MoEF) has notified the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/ Genetically Engineered Organisms or Cells 1989 under the umbrella legislation Environment (Protection) Act, 1986. Box 1 gives a list of the institutions established through the 1989 Rules, along with their functions and the ministries in which they are housed, to establish policy guidelines, monitor and review experiments, and issue approvals under the existing regulatory structure. Most of these institutions operate under the Ministry of Science and Technology (MoST), with the notable exception of the Genetic Engineering Approval Committee (GEAC), which is housed within the MoEF (however, except for the Chair, the members of GEAC are from institutions not under the MoEF).

Procedure for the development of transgenic crops⁶

Figure 1 presents an indicative procedure for the development of transgenic crops under the existing system.

Weaknesses in the current approach

In light of the dual goals of rigorous safety and efficiency, the current regulatory approach has several major flaws. First, the current regulatory regime is spread across three different ministries

Box 1 Competent authorities dealing with genetically modified organisms and their functions

Regulations/guidelines

- Recombinant DNA Advisory Committee (RDAC) under the Ministry of Science and Technology (MoST):
Regulations/guidelines

Monitoring, review, and approvals

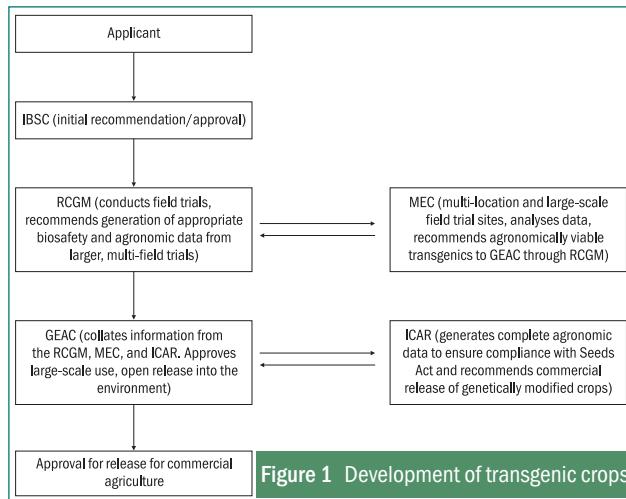
- Institutional Biosafety Committee (IBSC) under MoST:
Prepares site-specific plans
- Review Committee on Genetic Manipulation (RCGM) under MoST: Monitors safety-related aspects of ongoing research projects
- Monitoring-cum-Evaluation Committee (MEC) under MoST:
Conducts large scale, multi-site field trials
- Indian Council of Agricultural Research (ICAR) under the Ministry of Agriculture (MoA): Generates complete agro-nomic data, recommends genetically modified crops for commercial release
- Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests (MoEF): Gives approvals for release into the environment, commercial agriculture

Punitive actions

- State Biotechnology Coordination Committee (SBCC):
Addresses violations of safety and control measures
- District Level Committee (DLC): Monitors safety regulations and takes appropriate measures

and departments: the Ministry of Agriculture (MoA), Ministry of Environment and Forests (MoEF), and the Department of Biotechnology in the Ministry of Science and Technology (MoST). Although it can be argued that this structure ensures that the regulatory process is independent from any one Ministry, a better design would be an entirely separate and independent regulatory regime. Furthermore, as competent authorities are housed in different ministries, the procedure for the development of transgenic crops is not streamlined. Second, because the regulatory institutions are not part of a separate regulatory body, the regime lacks autonomy and credibility. In addition, the individuals themselves are not independent; rather, serving government officials are individual

⁶ Adapted from tables provided in the Department of Biotechnology, Ministry of Science and Technology website, <<http://dbtbiosafety.nic.in/>>, version 20 May 2006.



IBSC – Institutional Biosafety Committee; RCGM – Review Committee on Genetic Manipulation; MEC – Monitoring-cum-Evaluation Committee; GEAC – Genetic Engineering Approval Committee; ICAR – Indian Council of Agricultural Research

Note: IBSC has to be informed of all proposed recombinant DNA experiments. Prior permission from RCGM is required for high-risk experiments wherein the escape of transgenic traits into the open environment could cause significant alterations in the biosphere.

regulators. Third, the mandate of the regulators is not spelled out clearly. Though the regulators seem to understand their goals precisely, these should be clearly stipulated. Finally, the current regulatory approach is not harmonized with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity⁷, of which India is a signatory. In order to address these weaknesses, this policy brief outlines a number of recommendations to help ensure strong and transparent regulation.

Policy recommendations

India's biotechnology regulatory regime should reflect several key aspects.

Product-based vs. process-based processes

First, it is necessary to determine whether the regime should be product-based or process-based. In product-based regulation, which is the model of regulation employed in the United States⁸, regulation is based on the safety, quality, and efficacy of the product with no regard to the production process. Genetically engineered crops that are regulated under the product-based system are considered to be "substantially equivalent" to non-genetically modified crops; the process of genetic manipulation that led to the creation of the crop is inconsequential.⁹ In contrast, process-based regulation, the model of regulation employed in the European Union¹⁰, is based on the process (such as genetic manipulation) by which the product is created. The philosophy of the former model is preventive—harm is to be minimized

Key aspects of a strong biotech regulatory regime

- Clear understanding of the regulatory process (product- or process-based)
- Institutionally autonomous
- Independent and qualified regulators
- Reliable and transparent information
- Harmonization with international standards

⁷ "The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health." Convention on Biological Diversity. The Cartagena Protocol on Biosafety." Details available at <<http://bch.cbd.int/protocol/>>, last accessed on 20 August 2010.

⁸ The United States has not set up a separate body to regulate biotechnology, nor does it have a distinct set of laws that regulate genetically modified organisms (GMOs). Instead, GMOs are regulated by the same federal agencies that regulate conventional agricultural products, namely, the Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency.

⁹ Kysar D A. 2004. Preferences for processes: the process/product distinction and the regulation of consumer choice. Harvard Law Review 118.2. Cambridge, MA. p558.

¹⁰ Scientific opinions about the safety of genetically modified organisms (GMOs) in the European Union (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom) are given by the GMO Panel, which is part of the European Food Safety Authority (EFSA).

where it has been scientifically demonstrated—while the philosophy of the latter is precautionary, that is, anticipating environmental harms that have the potential to occur but have not occurred to date.¹¹

In order to justify a process-based regulatory system, which is by nature more cautious than a product-based system because it requires that genetically modified crops undergo special regulatory oversight, the case must be made that genetically modified crops should not be treated as substantially equivalent to crops produced in conventional breeding. Advocates of process-based systems argue that the crops should be treated differently because the potential environmental impacts of genetic modification are unknown. Unlike in conventional breeding, wherein genes are shared within a species or a genera at the most, genetic modification allows the transfer of genes even between different genera, which is an unnatural process. Furthermore, insertion of a mere single gene may influence the functioning of other genes. A genetically engineered crop can then reproduce in the natural environment, potentially creating cross-breeds with unknown genetic makeup. Because the Indian context faces a particular risk of genetic contamination,¹² it is important that the regulatory regime be cautious about these potential risks. A further argument for operating under a process-based regulatory system is that it will create greater harmony with international standards. India is a signatory to the Cartagena Protocol on Biosafety, which emphasizes the use of the precautionary principle. Thus, a process-based regulatory system that operates under the precautionary principle is in greater agreement with the Cartagena Protocol than a preventive product-based approach.¹³

Institutionally autonomous

The regulatory regime must be independent of other government departments. Therefore, it is crucial that the regulatory regime is created by a law that gives it a status of autonomy.

Independent and qualified regulators

In addition to the regulatory regime working independently, it is crucial that the regulators themselves are independent. The test of independence for individuals serving on the regulatory regime involves a number of conditions. First, the regulator should not have any pecuniary interest in a potential protagonist or antagonist. Second, regulators must have fixed tenure in office, and must not be dismissible except due to established malfeasance in regulatory duty. Finally, after an individual's term, there must be a cooling period of at least two years before the regulator can accept a position from anyone that has appeared before the regulatory committee.

In addition to their becoming independent, each member of the regulatory regime must be technically qualified in each of the areas involved in the regulation. All regulators should have the appropriate qualifications—be it a college degree or a Masters degree or a PhD degree—and all regulators must also have sufficient work experience. Further, there must be regulators who are trained in all relevant areas, including social sciences, for regulating pharmaceuticals and GMOs for industrial, health, and industrial biotechnology applications. Finally, it is important to note that for the selection process to be credible, there must be a wide catchment area and an independent selection board.

Reliable and transparent information

It is crucial that the information in the regulatory regime be reliable. The regulatory regime should verify the information given by proponents through a public system of validating the data. Independent third-party laboratories, without ties to the protagonist or antagonist, should validate the data. In case of a credible challenge to the results, the regulator must have the power to create and ask for data. Further, the protocol—such as the specific independent laboratories to be consulted—should be consistent.

¹¹ Patterson L A and Josling T. 2002. Regulating biotechnology: comparing EU and US approaches. European Policy Papers #8. Details available at <aei.pitt.edu/28/01/TransatlanticBiotech.pdf>, last accessed on 18 July 2010.

¹² The prevalence of small land-holdings across the country, along with the proximity of natural ecosystems to land under agriculture, implies that there is potential for a more rapid spread of any contaminant across the landscape.

¹³ Although TERI tends to favour the process-based approach, the product-based approach could be viable if the regulatory regime was carefully designed.

Furthermore, the transparency of the regulatory process is very important. Prior to making decisions, scientific data should be made available to both protagonists and antagonists, and both sides should be given the chance to submit responses to the data. The decision of the regulatory regime should always be given as a speaking order, in order to explain the reasoning behind the decision and to help build an institutional history.

Harmonization with international standards

The current regulatory regime does not entirely incorporate the international principles that India had accepted as part of international treaties. Any proposed biotechnology regime should attempt to give effect to the United Nations Convention on Biological Diversity and the Cartagena Protocol on Biosafety to the Convention. It should also seek to promote consistency between international and national technical standards on the regulation of biotechnology organisms and products and should operate under a more overtly crafted *precautionary principle* as per the Cartagena Protocol, which would promote a broader assessment of the factors contributing to biosafety, as compared to the current more narrow technical or scientific risk assessment principles. It should also, as advocated by the Cartagena Protocol, aim to involve relevant stakeholders in the regulatory process.

Biotechnology Regulatory Authority of India Bill, 2009 (Biotechnology Bill)

The Biotechnology Bill seeks to rationalize the regulatory space for biotechnology in India. As per its preamble, this is done with a view to making existing regulatory procedures more efficient (thereby promoting commercial development in this sector) while ensuring that biosafety norms are not compromised.

As Box 2 demonstrates, the proposed regulatory regime meets some, but not all, of the qualifications outlined in this brief ("yes" indicates those qualifications that are met in the proposed regime, "no" indicates those qualifications that are not met).

Box 2 Proposed regulatory framework: Biotechnology Regulatory Authority of India

Process-based approach

Yes Emphasis on the precautionary principle (Preamble)

Institutionally autonomous

Yes Independent structure
No Biotechnology Regulatory Authority of India established by notification, rather than a law (Ch. 2, S4)

Independent and qualified regulators

Yes Regulators must be free from pecuniary interests (Ch. 2, S9)
Yes Fixed tenures for Members (Ch. 2, S9)
Yes Cooling period of two years (Ch. 2, S10)
Yes Regulators must be technically qualified; expertise required in health care and agriculture or environment biotechnology (Ch. 2, S6)
No Chief Regulatory Officer should have greater protection specified to its tenure (no tenure specifications, etc.) (Ch.5, S2L)
No Expertise in industrial biotechnology not required for regulator (Ch.2, S6) nor selection committee (Ch. 2, S7)
No Expertise in social sciences not required for regulator (Ch. 2, S6) nor selection committee (Ch. 2, S7)

Reliable and transparent information

Yes Public to be informed of all applications for field and clinical trials and regulatory decisions (Ch. 4, S18)
Yes Power to call for information (Ch. 4, S19)
No No discussion about independence of laboratories

Harmonization with international standards

Yes Precautionary principle mentioned in Preamble
No Limited involvement of relevant stakeholders (civil society in particular) in the regulatory process as is advised by the Cartagena Protocol



This is the first in a series of policy briefs by TERI based on its research work in specific areas. These briefs are being made available to members of parliament, policy-makers, regulators, sectoral experts, civil society, and the media. The briefs are also accessible at www.teriin.org. The purpose is to focus on key issues and list our policy recommendations to encourage wider discussion and debate. We would very much value your comments and suggestions.