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**RE-ENGINEERING BIOSAFETY REGULATIONS IN INDIA:
TOWARDS A CRITIQUE OF POLICY, LAW AND PRESCRIPTIONS**

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1

BACKGROUND

India's Environment Protection Act of 1986 (EPA) was an afterthought of the shocking Bhopal gas tragedy. In the matter of biosafety laws and policies, India was one of the early movers in the developing world, having introduced in the country biosafety rules even before the Convention of Biodiversity was adopted at Rio de Janeiro in 1992. Thus, the introduction of the biosafety rules in 1989 was a pioneering step that was enabled by the EPA. Eighteen years after the EPA and one and a half decades after the biosafety rules, knowledge and awareness about hazardous substances and genetic organisms has steadily percolated to the civic-community layers of Indian society. Indeed by the mid-1990s, the import of Bt cotton seeds from Monsanto provoked a serious public debate on the safety aspects of biotechnology in general and plant biotechnology in particular. This gave a major push to the country's biosafety regulations. By 2002, a constellation of legislations cognate to biosafety regulations had come into existence. This included the National Biodiversity Act 2002 (NBA), and the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR). In the course of its evolution the biosafety regulations have undergone changes. Since 2004, there have been serious discussions in India on re-engineering the structure of biosafety regulations. The primary objective of the exercise is to cut down red tape and ensure greater transparency in decision-making. Another focus of the exercise is to position single-window systems for regulatory clearances thus unifying multiple-agency layers in the decision chain. Given the sensitivities triggered by biotechnology products in India, the debate on re-engineering has proved to be a contentious affair.

All the same, India's biotechnology industry is emerging as one of the fastest growing industries, calculated in terms of the volume of investment attracted in recent years. The biotech sector market in India was \$420 million during 2002-2003. Nearly 70 per cent of this was accounted for by the bio-pharma sector.¹ As far as the remaining components were concerned, 13 per cent was accounted for by

the bio-industrial sector, 7 per cent by the bio-services sector (which covers clinical research and related contracted research programmes) and 6 per cent by the agricultural sector.²

2

FRAMEWORK OF BIOSAFETY REGULATIONS IN INDIA

Biosafety regulations in India comprise biosafety rules and guidelines. The existing legislative framework in India for biosafety regulations has followed a disaggregated approach with regulatory powers imposed in a top-down fashion. The framework legislation for biosafety regulations in India is the EPA. Three provisions of the EPA form the basis of the biosafety regulations. These are sections 6, 8, and 25. While Section 6 of the Act empowers the Central Government to make rules on procedures, safeguards, prohibition and restrictions for handling of hazardous substances, Section 8 of the Act prohibits a person from handling hazardous substances, except in accordance with procedures and after complying with safeguards. Section 25 of the EPA empowers the Central Government to lay down rules regarding procedures and safeguards for handling hazardous substances.³ Thus, the biosafety rules in India are statutory in nature as they originate from the EPA. These provisions of the EPA led to the adoption of the 1989 Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro organisms/ Genetically Engineered Organisms or Cells.⁴

India's biosafety rules apply to manufacture, import and storage of micro organisms and gene-technology products and include products made of micro organisms that are genetically engineered. The rules cover research and large-scale applications of Genetically Modified Organisms (GMOs) and products. They also deal with hazardous organisms that are not genetically modified. The rules encompass manufacture, use, import, export, storage and

[1] A. Damodaran, 'Implications of Competition Policy on Biotechnology Industry in India', in P.S. Mehta ed., *Towards a Functional Competition Policy for India* 239, 246 (New Delhi: New Delhi Academic Foundation, 2005).

[2] *Id.*

[3] The Indian Environment (Protection) Act, 1986 (N° 29 of 1986, 23 May 1986).

[4] Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells (New Delhi: Ministry of Environment & Forests, GSIR 1037(E), 5 December 1989)[hereafter 1989 Biosafety Rules].

research. Rule 8 requires previous approval of the regulatory body for production and discharge of genetically engineered organisms or cells into the environment. Rules 10 and 11 require permission and approval to be taken for substances, products and foodstuffs and additives that contain genetically-engineered organisms or cells. The most significant provision is Rule 9, which prohibits deliberate or unintentional release of genetically-engineered organisms or cells covered under the schedule for experimental purposes, except when approved as a special case by the regulatory body concerned.⁵ An interesting feature of the rules is its Schedule, which categorises animal and human pathogens in terms of their risk profile.

The biosafety rules have been supplemented by the Biotechnology Safety Guidelines issued by the Department of Biotechnology (DBT).⁶ These Guidelines have been issued in pursuance of Rule 4(2) of the Biosafety Rules, which require manuals of guidelines to be brought out by the Review Committee on Genetic Manipulation, a component of the biosafety decision-making apparatus that is serviced by the DBT. The guidelines carry detailed analysis and assessment of biosafety levels. They also provide detailed guidance on rDNA research activities, large-scale experiments, import and shipments and quality control of products produced by rDNA technology. The guidelines were initially issued by the DBT in January 1990 under the title Recombinant DNA Safety Guidelines. In 1994 the Department issued the Revised Guidelines for Safety in Biotechnology. In 1998 further revisions were effected.⁷ The 1998 amendments were made in the light of enormous progress made since the 1990s in the fields of recombinant DNA research and its applications namely, microbial strains, cell lines and transgenic plants for commercial exploitation.

The biosafety rules are driven by multi-layered decision-making structures. These structures carry their corresponding functions, details of which are described below.

2.1 Recombinant DNA Advisory Committee

The Recombinant DNA Advisory Committee (RDAC) reviews developments in biotechnology at national and international levels and recommends suitable and appropriate safety regulations in India in recombinant research, their use and applications. The RDAC is constituted by and based in the DBT.

2.2 Review Committee on Genetic Manipulation

The Review Committee on Genetic Manipulation (RCGM) is also constituted by and based in the DBT. It monitors safety-related aspects of ongoing research projects and activities involving genetically engineered organisms. The Committee is entrusted with the responsibility of bringing out guidelines, specifying procedures and processes for activities involving genetically engineered organisms in research, use and applications, all with the objective of ensuring environmental safety. All high risk category products, controlled field experiments and containment conditions are reviewed by this committee which also lays down procedures for respecting or prohibiting production, sale, importation and use of genetically engineered organisms or cells as listed in the schedule. Industries carrying out genetic research and projects come under the purview of the Committee.

2.3 Institutional Biosafety Committee

The Institutional Biosafety Committee (IBSC) is constituted by the institution conducting research that handles micro-organisms/genetically-engineered organisms. The committee comprises the Head of the institution involved in research, scientists engaged in DNA work, a medical expert and a nominee of the DBT. The institutions involved in the process are required to prepare, with the assistance of the Institutional Biosafety Committee (IBSC), an up-to-date on-site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

[5] *Id.*

[6] Revised Guidelines for Research in Transgenic Plants (New Delhi: Department of Biotechnology and Government of India, 1998).

[7] Biotech Consortium India Limited, New Delhi and Department of Biotechnology Ministry of Science & Technology, Background Document for Workshop on Biosafety Issues Emanating from Use of Genetically Modified Organisms (GMOs) (September 1998).

2.4 Genetic Engineering Approval Committee

The Genetic Engineering Approval Committee (GEAC) is constituted and based in the Ministry for Environment and Forests (MoEF). It gives approvals for activities involving large-scale commercial use and release of hazardous micro organisms including imports of GMOs and recombinants in research and industrial production from the environmental angle. Where necessary, the Committee also restricts or prohibits production, sale, import or use of GMOs.

2.5 State Biotechnology Co-ordination Committee (SBCC)

The State Biotechnology Coordination Committee (SBCC) is located at the state level constituted by the respective State Governments. It acts as the nodal agency at the State-level to assess damages, if any, from the release of GMOs. It has the powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee is also required to periodically review the safety and control measures in various industries and institutions handling genetically engineered organisms or hazardous micro-organisms and take on-site control measures.

2.6 District Level Committees

The District Level Biotechnology Committee (DLC) is constituted below the State Government level in the district where biotechnology projects function. It is headed by the District Collector (who is the chief executive of the Government at this level of administration) and monitors safety regulations in installations engaged in the use of GMOs and hazardous substances. The Committee investigates compliance with rDNA guidelines and reports violations to the SBCC or the GEAC. The Committee also coordinates activities with a view to meeting emergency situations arising from accidental releases.

2.7 Monitoring and Evaluation Committee

This committee is required to undertake field visits at experiment sites, suggest remedial measures to adjust original trial design, assist the RCGM in collecting and analysing field data and collect or cause to collect information on comparative agronomic advantages of transgenic plants.

The structure of the biosafety decision-making structure in India is depicted in Figure 1. As Figure 1 illustrates, there are four domains involved in the life-cycle of a biotech product that is based on GMOs. These are the pre-research, research, release and post-release domains. A product runs through the four domains, which are characterised by the presence of the six structures described above. The RDAC is in the pre-research domain as it triggers research through its initial approval mechanisms. The RCGM functions in the research domain, closely monitoring the process of research and experimental releases. Commercial releases of organisms or biotech products containing GMOs come under the purview of the GEAC, a body that dominates the release domain. The Monitoring and Evaluation Committee and the SBCC and DLC basically occupy the post-release domain, although they contribute to the research domain activities through data-provisioning to the RCGM. The IBSC undertakes monitoring and implementation of safeguards at the R&D sites, under the close supervision of the RCGM, the SBCC and the DLC.

It is noteworthy that the decision-making circle in Figure 1 does not include the participation of the industry, civil society or consumer groups.

3

PRESSURE POINTS FOR THE BIOSAFETY REGULATIONS

The growth of India's biotechnology sector has been unparalleled since 2002, when the GEAC approved the commercial release of the Monsanto-Mahyco Bt cotton. During the period from April 2002 to April 2004, four Bt cotton hybrids were approved for commercial release.⁸ A host

[8] D.D. Verma, National Biotechnology Policy and Structural Arrangements, Presentation at FICCI – MSSRF International Conference on Agricultural Biotechnology: Ushering in the Second Green Revolution, New Delhi, 10-12 August 2004.

of other Bt cotton hybrids were in the pipeline. During the same period the GEAC approved import of refined vegetable soy oil and crude degummed soyabean oil. In the year 2004, nearly 15 rDNA drugs, pharmaceuticals and therapeutics were also under consideration for approval by the GEAC.⁹ These included insulin, streptokinase and interferons. There have been instances where requests have been rejected by the GEAC. These include the release of Mech 915 Bt cotton hybrid and the import of a corn-soya blend. Despite this trend of approvals and rejections, the functioning of biosafety regulations have been subjected to criticism both by industry and civil society groups. While industry associations consider these regulations as affecting their growth, civil society groups consider biosafety regulations as not being strong enough to check the introduction of potentially harmful biotechnology products. As a result, the regulations have undergone changes. Some of these changes were effected to allay industry apprehensions, while in some cases they were brought in to address civil society concerns.

The amendments or changes that have favoured the industry relate to changes in the 1998 revised guidelines for research in transgenic plants, whereupon a relaxation was permitted regarding the concept of deliberate release. This amendment, by conferring powers to the RCGM to permit limited conduct of field trials in multi-locations, was at variance with the 1989 Rules that prohibited deliberate or unintentional release for experimental purposes, except where the GEAC approved it as a special case. Indeed as Gupta points out,¹⁰ the distinction between small-scale and large-scale releases brought about by the changed guidelines, was unusual and was designed to ensure the control of the DBT and the RCGM over initial field-testing of transgenic crops. The change was triggered by a case filed by the Research Foundation for Science, Technology and Ecology before the Supreme Court in January 1999, challenging the field trials authorised by the RCGM to Monsanto-Mahyco for their Bt cotton variety. The argument of the petitioner was that the RCGM had no right, as per the 1989 Biosafety Rules, to authorise field trials of transgenics, as it amounted to unintentional release. According to the petitioner, the power to authorise field trials vested only with the GEAC.

The Supreme Court initially gave an interim ruling, placing a temporary injunction on field trials of transgenic cotton until such time as the rules and guidelines were amended to ensure protection for the environment, biodiversity and human health. In response to the Supreme Court order, an amendment was made by the DBT in September 1999 conferring rights to the RCGM to approve small experimental field trials for research, limited to a total area of 20 acres in multi-locations with any one location not exceeding one acre. Through this amendment the DBT delinked small experimental trials for research, from the deliberate release clause of the 1989 rules.

The changes that have been made to accommodate civil society concerns are basically two-fold. The first relates to the formation of the Monitoring and Evaluation Committee by the DBT in 1998 in order to closely and objectively monitor private sector biosafety data and through the mandatory involvement of state-level agricultural university scientists.¹¹ The second change, which was induced by the Bt cotton controversy in India, has been the introduction of allergenicity tests of transgenic seeds, leaves and vegetables on rodents, rabbits, guinea pigs and goats in the 1998 version of the Biotechnology Safety Guidelines. This precautionary step is viewed by the industry as having contributed to the delay in the regulatory approval for Bt cotton.¹²

During 2003-2004, India's biosafety regulations came into fresh scrutiny following controversies related to biomedicines and new transgenic crops. The biosafety regulatory mechanism in India had approved the commercial release of genetically modified (GM) plants and biotech medicines including Bt cotton hybrids expressing the cryIAC gene, interferon alpha and insulin. This caused concern to the civil society. In some cases the GEAC had insisted on certain data from the industry, which was resented by the latter. Thus, both the industry and civil society groups have been critical of the regulators. This triggered a debate on the revamping of biosafety regulations. Even the MoEF, which services the GEAC, has come forward with proposals for changes in the regulatory set-up to overcome what it views to be its limitations. In the meantime, the DBT has initiated a system of single window clearance for streamlining activities falling within its domain.

[9] *Id.*

[10] A. Gupta, 'The Role of Knowledge Flows in Bridging North-South Technological Divides: A Case Analysis of Biotechnology in Indian Agriculture', in *Knowledge Flows and Knowledge Collectives: Understanding the Role of Science and Technology Policies in Development*, Synthesis Report of a Project for the Global Inclusion Program of the Rockefeller Foundation 99, 130 (Washington, DC: Centre for Science, Policy and Outcome (CSPO), 2003).

[11] *Id.*

[12] A. Damodaran, 'Economic Implications of Global Conventions and India's Regulatory Environment on Plant Biotechnology Industry', 393, *I.R.F. Series* (Japan: Institute of Developing Economies, Japan External Trade Organization, 2004).

The positions advocated by the stated stakeholders are discussed below:

3.1 Civil Society

The civil society proposals, which are based on Sahai, highlight the following:¹³

- Regulatory processes are not tight enough, do not rely on precautionary principles and give in easily to new biotech products of dubious nature.
- An independent advisory body comprising representatives of scientific disciplines, adivasis (tribals), panchayat-raj institutions (local self government) and the legal profession may be constituted.
- A statutory body may be set up to conduct environment assessment, facilitate risk management and risk communication so as to foster decision-making about the safety of a GM crop from an environmental, human and animal health perspective. It is further suggested that the same body may be entrusted with the responsibility of post-release monitoring.
- Data on field trials should be made available to the public, which needs to be involved in decision-making. Annual review reports on GM products also need to be submitted to Parliament.
- Greater attention may be paid to the views of the SBCC and DLCs, prior to giving approval for GM crops.

The demands voiced by civil society groups have been illustrated in Figure 2.

3.2 Industry

The proposals mooted by the industry, as contained in Suresh, stress the following:¹⁴

- The present decision-making apparatus is dilatory and elongated. A case in point is the time-lag in the release of the Monsanto–Mahyco Bt cotton case where a period of 7 years elapsed before the final approval for commercial release was obtained from the regulatory authorities.

- The GEAC gets into matters which are not purely biosafety concerns. Thus, the insistence of the GEAC on evaluating the economic performance of Bt cotton and its decision to hold an inquiry into Shanta Biotech's clinical trial data for the company's recombinant Streptokinase drug, are quoted as instances of the body dabbling with issues other than core biosafety concerns.

The Association of Biotechnology Led Enterprises (ABLE) has demanded the introduction of a modified procedure that reduces the existing multilayers of biosafety decision-making. The Association has suggested removal of the GEAC from its apex status and elimination of its independent role in approving human clinical trials data for rDNA medicines. ABLE wants the GEAC to approve commercial release of rDNA drugs based on documentation submitted by the RDAC and the RCGM for environmental clearance. Figure 3 illustrates the structural implications of the industry proposal.

3.3. Ministry of Environment and Forests

The proposals of the Ministry of Environment and Forests (MoEF) as highlighted in Verma, centre on the following points:¹⁵

- Concedes that there are delays and problems in the approval of GM products;
- The IBSC may be eliminated and the collection, analysis and submission of greenhouse data may be made by the research unit directly to the RCGM;
- The MEC currently submits reports directly to GEAC, for all the three stages being, large fields trials, commercial release based on data collected by the Indian Council for Agricultural Research (ICAR) and post-release monitoring. The GEAC, in turn provided the monitoring data to the RCGM. The MoEF wants the GEAC to shed commercial release and post-release monitoring functions to the Department of Agriculture and the ICAR respectively.¹⁶

Figure 4 illustrates the structural implications of the MoEF on the biosafety decision-making structures.

[13] S. Sahai, 'Urgent Need to Overhaul GEAC', 2(1) *Biospectrum* 39 (January 2004).

[14] N. Suresh, 'GEAC needs a make over', 2 (1) *Biospectrum* 35, 40 (January 2004).

[15] Verma, note 8 above.

[16] As pointed out earlier the GEAC has already shed its powers of approval for research related experimental releases to the RCGM, following the amendments to the biotechnology safety guidelines made in 1999. The present proposal is for further reducing the significance of the GEAC as the apex decision-making body in the biosafety regulatory system.

3.4 Department of Biotechnology

With a view to reducing red tape and prevent delays, the DBT has entrusted the responsibility of permitting small-scale release of GMOs to the RCGM for experimental purposes and has also instituted a single window clearance process for applications coming before the RCGM.¹⁷

3.5 The Swaminathan Task Force Recommendations

The Ministry of Agriculture had set up a task force under the chairmanship of Dr. M. S. Swaminathan in May 2003 to examine the potential and problems of biotechnology applications, particularly GM crops. The task force recommended the setting up of an independent and professional watchdog, namely the National Biotechnology Regulatory Authority (NBRA), to generate public confidence in the use of GMOs. The task force has suggested that the role of the GEAC may be confined to biosafety and environmental safety till the formation of the authority. It has suggested that the monitoring and evaluation committee (MEC) should report to the GEAC on biosafety and environment safety issues. Further, the committee calls upon the Indian Council of Agricultural Research under the Union Agriculture Ministry, to organise testing of GM crops through an All-India Coordinated Research Project. The report is yet to be accepted by the Government of India.

4

ASSESSMENT OF PROPOSALS FOR STRUCTURAL CHANGE

Suggestions for streamlining biosafety regulations have followed their unique patterns, depending upon the sources from which they have emanated. The solutions proposed by industry and NGOs are contrasted. While the first one would aim to short-circuit the regulatory process, the latter seeks elongation of the process to the maximum extent through an inclusive and participatory approach. Thus, the proposal of civil society groups seeks structural changes

whereby civil society groups and independent experts play a major role in decision-making, monitoring of research and post-release activities. In this simplified structure, an independent advisory body would guide all stages of the biotech product cycle. Under this scheme, while industry will be kept out of the process, the present set of statutory committees being the RDAC, the RCGM, the IBSC and the GEAC would also be eliminated.

On the other hand, the proposal of the industry for restricting biosafety regulations recognises the roles assigned to the existing committees, but would like to have the same in a simplified decision-making framework, taking the form of a single window clearance system. Clearly as per this proposal, industry would be integrated into the decision-making process. The proposal of the MoEF is still rooted in the principle of hierarchy in decision-making. The sole industry-based body, the IBSC, would be removed from the decision chain. At the same time, the proposal seeks to shed the existing regulatory responsibilities of the GEAC, by shifting its assigned function of approving commercial releases and post-release monitoring functions to the Department of Agriculture and the Indian Council of Agriculture Research. In this manner the MoEF seeks to add a new element in the regulatory hierarchy in the shape of the Department of Agriculture, which will now occupy the apex of the decision-making chain in place of the GEAC. However, the proposal involves only a tinkering of intra-governmental boundaries and spheres of regulation.

Similarly, the decision of the DBT in 1998 to revise the biotechnology safety guidelines and permit the RCGM to approve limited release of GMOs to RCGM for experimental purposes is at variance with the Biosafety Rules as adopted in 1989. Further, the single window clearance system initiated by the DBT is sub-systemic in nature, confined as it is to the pre-research and research cycles of the product.

By contrast, the Swaminathan Task Force report has suggested an independent regulatory set-up that completely eliminates the existing structure of decision-making. This approach has not met with the approval of the civil society as it goes against the idea of the latter to have an independent body, which does not provide for the representation of the industry in the biosafety regulatory process.

[17] Department of Biotechnology, Regulatory Mechanisms for GMO and Products thereof (2003), available at <http://www.dbtindia.nic.in/publication.html>.

5

RE-ENGINEERING REGULATORY GOVERNANCE: CRITIQUE OF EXISTING APPROACHES

The Vision Statement on Biotechnology of the Government of India states that the objective of India's biotechnology policy is attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice, especially for the welfare of the poor.¹⁸

By contrast, the stated aim of the 1989 Biosafety Rules is to protect the environment, nature and health in connection with the application of gene technology and micro organisms.¹⁹

The position of the industry on biotechnologies has been formulated in the light of its experience with the regulatory approval in the case of Mahyco-Monsanto Bt cotton. It was after considerable debate and a series of multiple species and multi-vocational field trials that the Government of India approved Bt cotton for release. The entire process involved a period of 6 years, of which 4 years was spent on environmental safety studies. For the industry this represented a long project-cycle, which was not desirable for a capital-intensive sector like biotechnology.²⁰

The philosophical approach of civil society towards environment (including biotechnology) is based on criticisms of the reductionist approaches, characteristic of science pioneered by Bacon in the 16th century.²¹ Reductionism in turn is stated to have promoted gender marginalisation and non-inclusive approaches to problem-solving. Consequently civil society advocates a cautious and more inclusive approach to environment. This then forms the basis for civil society to demand precautionary and inclusive approaches to environmental governance. In the context of the Cartagena Protocol there have been considerable debates regarding the desirability of precautionary principles vis-à-vis precautionary approaches, that convey a softer stance towards biotechnology products undergoing transboundary movements. Civil society has always been for the application of the precautionary principle in relation to biotechnological products. At the same time the proposals of the civil society for restructuring India's bio-safety regulations do not subscribe to a strong version of the precautionary principle that calls for absolute proof of safety before allowing new technologies to be adopted. This is evident from the emphasis of the civil society proposal on post-release monitoring.

The key regulatory issue for the MoEF is the balance between growth objectives and biosafety concerns.²² In practical terms, this means balancing the interests of the industry with that of civil society and consumers farmers or other consumers of biotech products. This has been a tough proposition given the fractious nature of the debates on biosafety in India.

Nevertheless, it is clear that India's biosafety regulations have undergone major adjustments in their process of evolution. These adjustments have swung from accommodation of industry concerns to that of integrating civil society apprehensions. An interesting trend has been that, while statutory rules have not undergone amendments, the guidelines have undergone changes in a manner that is seemingly contrary to the rules. It is also apparent that these changes have been brought about to accommodate the demands of both industry and civil society groups that have no formal role to play in the decision-making process associated with biosafety management.

[18] Department of Biotechnology, *Biotechnology – A Vision (Ten Year Perspective)* (2001), available at <http://www.dbtindia.nic.in/policy/reg.html>.

[19] 'As Juma observes, failure to bring a large number of developing countries into the global trading system serves to create a "genetic divide" among countries, which in turn, is likely to intensify public opposition to biotechnology. Juma considers national regulation of biotechnology as a critical factor in this regard. See C. Juma, 'The New Genetic Divide: Biotechnology in a Globalizing world', *Biosafety and Trade: Issues For Developing Countries*, Briefing Papers, *Biotechnology* 1,10, available at www.ictsd.org/dlo/gue/2001-07-19/Full_Briefings_Paper.pdf (2001).

[20] Damodaran, note 12 above.

[21] V. Shiva, 'Western Science and its Destruction of Local Knowledge', in Rahnama, Majid, Bawtree and Victoria eds, *The Post-Development Reader* 161, 167 (Dhaka: The University Press, 1997).

[22] Damodaran, note 1 above.

The pattern of recommendations is thus centred on changing the structure of decision-making from hierarchical systems to horizontal systems, with government supporting the former and the industry and civil society the latter.

Apart from proposals of re-engineering that have attempted to influence the structure of decision-making, there has been a major proposal to re-vamp the biosafety regulations from a functional perspective. This proposal calls for a shift in the focus of decision-making from process to products. The proposal, which emanated from the Confederation of Indian Industry (CII) in 2002, suggests the setting-up of an end-product categorization system for biotech products based on rDNA techniques. Such a scheme it is argued would be helpful in declaring the nature of the end product containing GMOs in a transparent manner.²³ Similar steps have been initiated in other parts of the world.

In countries like Canada the shift in regulatory emphasis from end-product to process is reported for biotech products.²⁴ In the USA, the four principles of regulatory review aim to cut down delays and transaction costs by stressing on performance standards.²⁵ These principles extend to both products and processes. In India, the pre-

research and research phases qualify to be subjected to standards that could be developed on the basis of the 1998 Guidelines on Biotechnology. This could in turn reduce the transaction costs of daily monitoring of research activities by the RCGM through the MEC, SBCC and DLC. Indeed the Model National Biosafety Law proposed by the Third World Network prescribes systems of identification and labelling of biotechnology products in the larger interests of consumer information.²⁶ Hence, for example, the Brazilian Biosafety law passed on 24 March 2005 provides for 'safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of genetically modified organisms – GMOs and their by-products, guided by the drive for attaining scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and the compliance with the principle of environmental precaution'.²⁷ Though law also legalises the sale, planting and marketing of transgenic glyphosate-resistant soybean (articles 35 and 36) the emphasis on 'norm' or standard laying is implicit in these laws. To a large extent decision making on release of biotechnology products could be facilitated by a 'norm laying approach', in case civil society concerns are internalised by decision makers.

The functional vision based on product standards, if integrated in single window systems of regulatory approvals, can facilitate greater acceptance of the regulatory mechanism by both civil society and industry groups. It is possible for a single window system to employ the criteria of familiarity and confinement to screen through new GM crops that are close cousins of the approved ones. The twin criteria could facilitate development of systemic single window systems for biosafety that can cut down on protocol rigours associated with a first-time biotech product. However, for this advantage to accrue, the single window regulatory system needs to be both stacked and horizontal, besides being systemic. Currently, since decisions in India are taken sequentially and independently by different agencies in the biosafety chain, protocol-related tests tend to be superfluously employed. Also, if a single window system does not enjoy participation by NGOs, industry representatives and the consumers, their decision-making tends

[23] A. Krishnan, 'Call to Categorise biotech products', *Business Line*, 3 October 2002.

[24] J.E. Hollebone and L. Duke, 'Canadian Approaches to Biotechnology Regulation', in A.F. Krattiger and A. Rosemarin eds, *Biosafety for Sustainable Agriculture: Sharing Biotechnology Regulatory Experiences of the Western Hemisphere* 79, 90 (Ithaca: ISAAA, 1994).

[25] The four principles of regulatory review in the USA are: (1) federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product and not the process by which it is created; (2) for biotechnology products that require review, regulatory review should be designed to minimise regulatory burden while assuring protection of public health and welfare; (3) regulatory programs should be designed to accommodate the rapid advances in biotechnology; and (4) in order to create opportunities for the application of innovative new biotechnology products, all regulations in the environmental and health areas should use performance standards rather than specifying rigid controls or specific designs for compliance. The goal of these principles is to ensure that regulations and guidelines affecting biotechnology are based solely on the potential risks and are carefully constructed and monitored to avoid excessive restrictions that curtail the benefits of biotechnology of the society. See T.L. Medley, 'A Regulatory Perspective on Harmonization of Regulations and Public Perception', in A.F. Krattiger and A. Rosemarin eds, *Biosafety for Sustainable Agriculture: Sharing Biotechnology Regulatory Experiences of the Western Hemisphere* 71, 73 (Ithaca: ISAAA, 1994). In terms of principle, performance standards are seen as giving up on case-to-case approaches that tend to specify rigid designs for compliance.

[26] G.S Nijar, *Model National Biosafety Law* (Kuala Lumpur: Third World Network, 2003).

[27] *Brazilian Biosafety law passed on 24 March 2005* available at http://www.ctnbio.gov.br/index.php?action=/content/view&cod_objeto=1296.

to be overtly circumspect.²⁸ This is more so since the criterion of familiarity requires systematic incorporation of perspectives of local communities who have cultivated the approved GM crop. Therefore, a stacked single window will not achieve the desired results of efficiency and effectiveness, unless it is also horizontally broad-based.²⁹

Another serious inadequacy of India's biosafety regulations and the various proposals to amend them is its non-emphasis in considering the role of cognate legislations in guiding the fortunes of the biotechnology industry. Apart from biosafety regulations, at least 5 cognate legislations or regulations have their impacts on the life cycle of biotechnology products in India. These include the Prevention of Food Adulteration Act, the Seed Act, the Biosecurity regulations, the PPVFR and the NBA.³⁰ Apart from these Acts, the Patents Act, 1970 also carries provisions for providing protection against possible adverse impacts of biotechnology products. Thus, section 3 (b) of the Patents Act declares an invention which causes serious prejudice to human, animal or plant life or health or the environment, as not patentable within the meaning of the act.

Of the five legislations and regulations, the NBA and the PPVFR are particularly sensitive as they are new and are yet to be operational. The PPVFR, which was adopted by Parliament in 2001, provides for plant breeders' rights over new plant varieties. The Act makes explicit provisions for registering transgenic varieties for IPR protection.³¹ It is likely that varieties that are protected through the PPVFR, may not meet the requirements of biosafety either by way of biosafety approval or by way of post-approval complications. There is no explicit provision in the PPVFR or its rules requiring plant breeders of new transgenic varieties to submit evidence of biosafety clearance prior to sub-

mitting an application for PPVFR registration.³² To avoid problems, it will be desirable to seek the mutual incorporation of the GEAC and the PPVFR in their respective decision-making processes.

The NBA came into effect in 2002. Though basically an access and benefit sharing legislation, the NBA has conservation provisions built into it, especially in local management of biodiversity. Thus, Section 41 of the Act, which provides for the constitution of Biodiversity Management Committees (BMCs), mandates the committees to preserve habitats, conserve land races, folk varieties and cultivars. Possible invasive impacts of transgenic plants on land races, folk varieties and cultivars can be a matter of concern not only to the SBCC and DLC but also to the BMCs.³³ To this extent, it is important to associate the BMC representatives in SBCC/DLC monitoring activities apart from obtaining their viewpoints at the stages of limited and large-scale deliberate releases.³⁴

To sum up, the foregoing discussions indicate that though there are stakeholder conflicts when it comes to structuring of biosafety regulations in India, there is scope for stakeholder-convergence where the decision-making processes are accommodative of industry and civil society concerns through innovative participative functions and processes. In practical terms this can be brought about by involving civil society and industry association representatives in the decision-making ring illustrated in Figure 1.

[28] Medley, note 25 above at pp. 75-76 states that the critical issue for public acceptance of the applications of biotechnology is effective communication in writings about biotechnology whereby a community acquires an improved understanding of the hazards of biotechnologies.

[29] Despite taking many decisions on commercial release of GM products, the GEAC dithers as evident from its tendency to go back to RCGM to seek further clarifications. Examples are the cases relating to ex-post facto approval for Phase -III clinical trials and permission for manufacture and marketing of r-Erythropoietin by M/S. Shantha Biotechnics, Hyderabad. Ministry of Environment and Forests, Decisions taken in the 41st Meeting of the Genetic Engineering Approval Committee (GEAC) held on 15th April 2004.

[30] Damodaran, note 12 above at p. 37.

[31] The Protection of Plant Varieties and Farmers' Rights Act, 2001, Act 53 of 2001, in Gazette of India, Ext., Pt II, S.1, 30 October 2001.

[32] Damodaran, note 7 above at p. 37.

[33] The Biological Diversity Act, 2002, Act 18 of 2003, Gazette of India, Ext., Pt.II, S.1, 5 February 2003. Invasiveness is not necessarily associated with non-indigenous species introduced into an ecosystem. As Wolfenbarger and Phifer explain, novelty created through genetic modifications, could induce an organism to behave invasively (L.L. Wolfenbarger and P.R. Phifer, The Ecological Risks and Benefits of Genetically Engineered Plants, 290 *Science*, 2000, 2088-2089 (15 December 2000).

[34] Interestingly such a step would be consistent with Article 16 of the Cartagena Protocol on Biosafety, which recognises the rights of countries to assess the impacts of imported GMOs in terms of their effects on conservation and sustainable utilisation of biodiversity. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, 39 *Int'l Leg. Mat.* 1027 (2000).

6

CONCLUSION

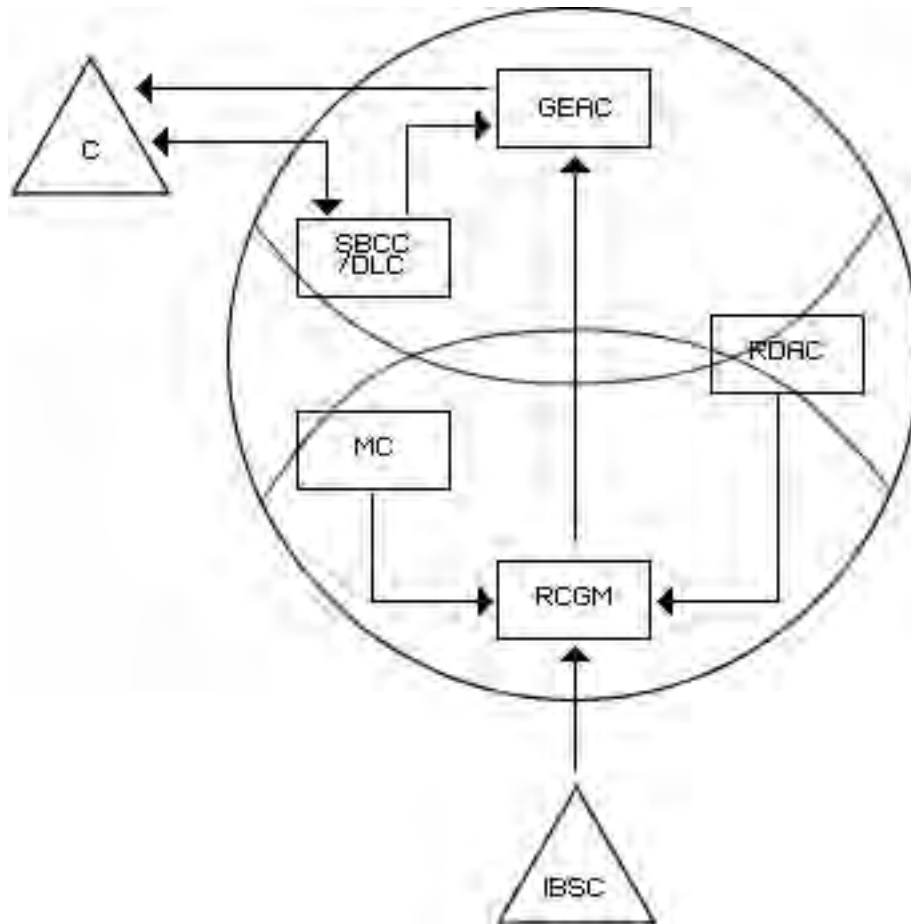
The International Service for National Agricultural Research (ISNAR) and FAO have identified four elements that are required to be considered when developing a regulatory framework for biotechnology.³⁵ The first element is a legislative framework while the second element is regarding the criteria for making a product subject to regulatory assessment. The third element concerns transparency and public involvement in decision-making while the fourth element is on approaches to risk-assessment and risk-management. India has fulfilled the first criteria by going for a mandatory legislative framework. India's biosafety regulations clearly deal with both micro organisms and gene technology products. India has also factored in the element of economic and social impacts in assessing risks arising from GMOs and GM products. India has a decision-making system, which is well structured but needs public involvement in decision making. It is this aspect that has caused problems for India's biosafety regulations.

The answer to the problems of biosafety regulations in India is neither simple nor straightforward. India's environmental regulatory mechanisms in the field of biotechnology were laid from above. The regulatory space is governmental. Uncertainties and gaps in the knowledge base in relation to high-tech disciplines formed the original rationale for a governmentalised biosafety regime. However, as industry and civic communities gain in knowledge and overcome their ignorance of the impacts of hi-tech products, the top-down approach needs to be re-adjusted to alter the boundaries itself and seek to alter the boundaries of regulatory exclusiveness. There are strong, distinctive proposals mooted by the Government of India, civil society groups and industry for restructuring India's biosafety regulations. However, all proposals are based on certain implicit presumptions. The first presumption is that there can be no meeting ground between those who believe in the norm of case-to-case approaches to biosafety project clearance and those who are against it. The second assumption is that biosafety regulations in India are stand-alone in nature and do not face prospects of interference from the

cognate legislations. The third assumption is that the single window approach to decision-making could lead to transparency and quick and effective results. The foregoing discussions point to the need of addressing these assumptions in the larger interests of greater stakeholder-convergence on biosafety issues. An approach that standardises processes and products can be rewarding to government, civil society and industry, if transparently designed and impartially administered. Likewise, incorporation of biodiversity conservation and PPVFR players in the biosafety processes could broad base its effective functioning. Finally, a process of inclusive regulation can render decision-making transparent and acceptable to all stakeholders. A just regulatory order is not fenceless: it lives with properly modified fences that represent change from the past. In practical terms this means that single window initiatives in the field of biosafety regulations should not only be vertically stacked but also horizontally broad-based with both civil society and industry associations accorded their due role in decision-making processes.

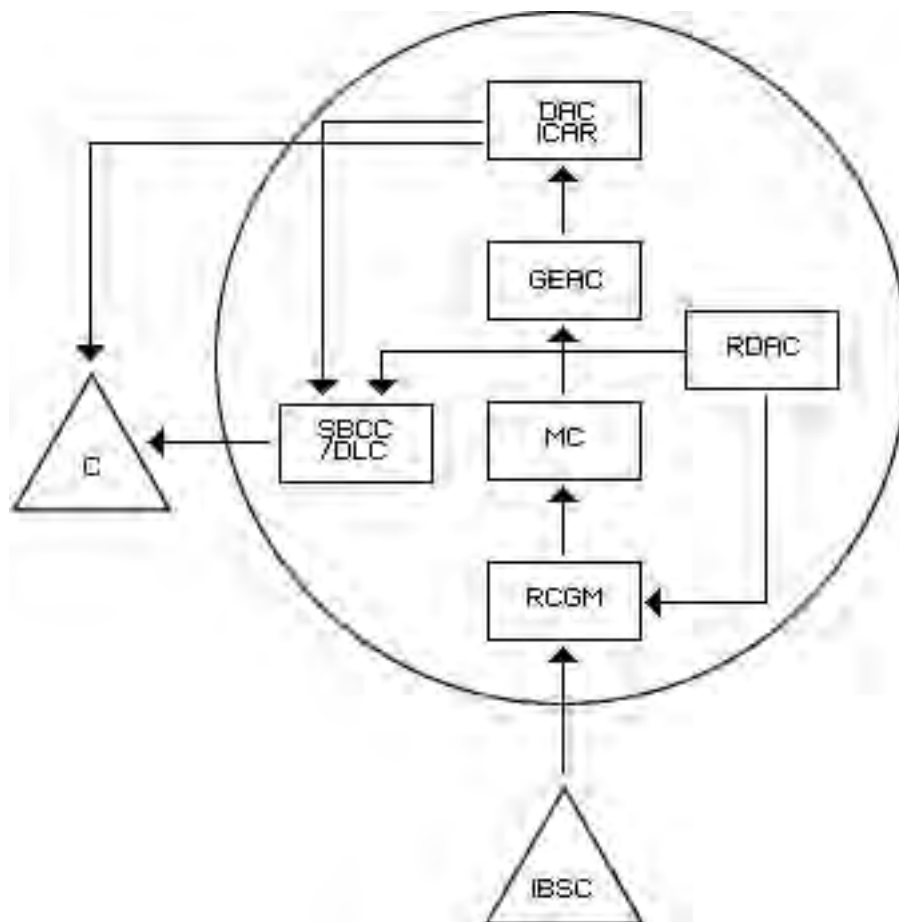
[35] Food and Agricultural Organisation, *Regulating GMOs in Developing and Transition Countries*, Background Document to Conference 9, Electronic Forum on Biotechnology in Food and Agriculture (2003), available at <http://www.fao.org/biotech/C9doc.htm>.

Figure 1: Existing Processes and Procedures for Biosafety Approvals



C	Consumers
GEAC	Genetic Engineering Approval Committee
SBCC	State Biotechnology Co-ordination Committee
DLC	District Level Committees
RDAC	Recombinant DNA Advisory Committee
RCGM	Review Committee on Genetic Manipulation
MC	Monitoring Committee
IBSC	Institutional Biosafety Committee

Figure 2: Proposal of the Ministry of Environment & Forests for Restructuring Process



C	Consumers
GEAC	Genetic Engineering Approval Committee
SBCC	State Biotechnology Co-ordination Committee
DLC	District Level Committees
RDAC	Recombinant DNA Advisory Committee
RCGM	Review Committee on Genetic Manipulation
MC	Monitoring Committee
IBSC	Institutional Biosafety Committee
ICAR	Indian Council for Agricultural Research
DAC	Department of Agriculture and Cooperation

Figure 3: Proposal of the Civil Society for Restructuring Biosafety Approval Process

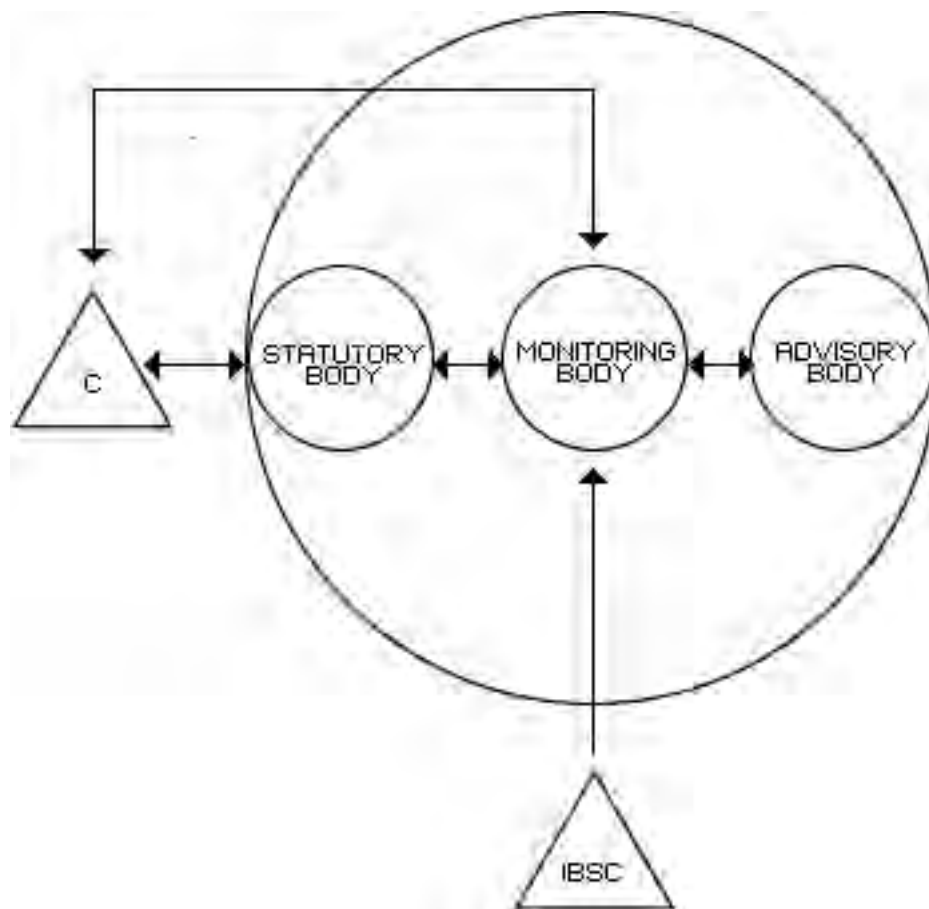
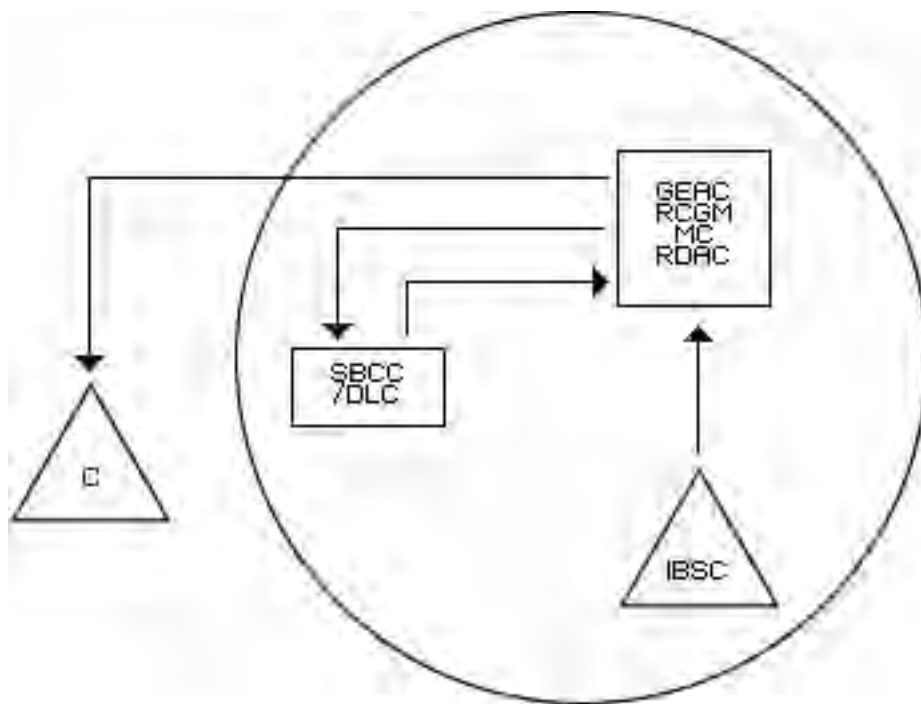


Figure 4: Proposal of the Industry for Restructuring Biosafety Approval Process



C	Consumers
GEAC	Genetic Engineering Approval Committee
SBCC	State Biotechnology Co-ordination Committee
DLC	District Level Committees
RDAC	Recombinant DNA Advisory Committee
RCGM	Review Committee on Genetic Manipulation
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