BRAI BILL:
A THREAT TO OUR FOOD AND FARMING

A LEGAL ASSESSMENT OF THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA (BRAI) BILL,2011.

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Cover Image:
A wholesale vegetable market known as Okhla Mandi in New Delhi.
The Okhla Mandi is an important wholesale market in New Delhi.

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INTRODUCTION

The Biotechnology Regulatory Authority of India Bill 2011 ('BRAI Bill') has been proposed by the Ministry of Science and Technology, Government of India. It is a Bill 'to promote safe use of biotechnology' and to set up a new regulatory mechanism for matters connected to biotechnology including research, use, trade and manufacture. The present regulatory mechanism for genetically engineered organisms in the country is the *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells 1989,* which were issued by the Ministry of Environment and Forests under the Environment (Protection) Act, 1986. The nodal agency for approval of Genetically Modified Organisms (GMOs) for research, manufacture, use, export or import is the Genetic Engineering Appraisal Committee (GEAC) which is located within the Ministry of Environment and Forests. The BRAI Bill, if enacted, would replace these Rules and completely revamp the existing regulatory structure. The Bill has not been tabled in the Parliament as yet.

It is essential to understand the context in which the BRAI Bill is being proposed. There is an unprecedented debate around Genetically Modified (GM) crops, one of the products of modern biotechnology, in India at this point. This debate started with the introduction of Bt Cotton, the only GM crop which is commercially cultivated in the country, but has reached its heights when the existing regulatory system was on the verge of approving Bt Brinjal, the first GM food crop. This debate which is happening across the world is grounded on the various scientific studies which points at the potential harm to health and environment from environmental release of GM crops.[1]

The public consultations on Bt Brinjal that the then Minister for Environment and Forests organised in 7 cities across the country in 2010 saw a wide cross section of the Indian society, Scientists, farmer unions, environmental groups, consumer groups, political parties and lawyers opposing its introduction due to its potential to harm the health of human beings, impact biodiversity, lead to corporate control of our seed and agriculture. The Central Government also received formal letters of opposition from several state governments. Taking into account these varied concerns, on the 9 February 2010, introduction of Bt Brinjal was put under an indefinite moratorium by the Ministry of Environment and Forests[2]. The consultations brought to light the inadequacies in the existing assessments for GM crops and also raised fundamental questions on the need for such risky technologies.

The Ministry of Science and Technology has all along shown its support for GM crops in general and the Bt Brinjal in particular. In fact the then Minister for Science and Technology had publicly expressed his displeasure at the moratorium on Bt Brinjal. The first Bill setting up the Biotechnology Regulatory Authority of India by the Ministry of Science and Technology surfaced in the media in April 2010 and created a lot of controversy as it had clauses which were highly undemocratic and unconstitutional in nature. The revised bill, the BRAI Bill, 2011, had been scheduled for introduction in the Parliament, during the monsoon and winter sessions of 2011. Both times there was opposition inside and outside the Parliament.

Given the wide ranging concerns about GMOs and the lack of trust in the Ministry of Science and Technology to constitute an impartial, independent and comprehensive regulatory system which will prioritise biosafety over introduction of GMOs, an indepth analysis of the proposed BRAI Bill, 2011 with a focus on open release of GMOs is very important.

A close analysis of the Bill reveals that there is an urgent need to question several aspects of the Bill and to reconsider the mechanism proposed. The Bill, apparently drafted to meet India's international obligations under the Convention on

[1]Greenpeace, Environmental and Health Impacts of GM crops - the Science, 2011, available at http://www.greenpeace.org/eu-unit/en/Publications/2011/impacts-the-science/
[2]Ministry of Environment and Forests, Decision on Commercialisation of Bt-Brinjal, 9 February 2010, available at moef.nic.in/downloads/public-information/minister_REPORT.pdf

Biological Diversity 1992 and the Cartagena Protocol on Biosafety 2000, and to ensure 'safe and responsible use of biotechnology', falls significantly short on both accounts. Furthermore, provisions of the Bill do not conform with several principles which form the core of Indian and international environmental jurisprudence – absolute liability for hazardous and dangerous activities, polluter pays principle, precautionary principle, onus of proof on those who want to change the status quo, effective public participation in environmental decision making and access to biosafety information.

It is absolutely crucial that before the Government of India decides to table this Bill in the Parliament, there is rigorous public debate and engagement with all stakeholders to suitably amend the provisions of the Bill.

A giant banner reading 'Save our Rice' is displayed in a rice field. The banner is a protest against genetically engineered rice field trials in the region.
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WEAK JUSTIFICATION FOR SETTING UP BRAI AND INTRODUCING THE BILL

The preliminary issue that has not been addressed by the new Bill is the justification for enacting a new law and setting up a new regulatory mechanism – the Biotechnology Regulatory Authority of India (BRAI). The existing legal framework under the 1989 Rules issued by the Ministry of Environment and Forests have been criticized previously on grounds of there not being adequate safeguard against potentially irreversible harm that can be caused due to release of GMOs. Objections have also been raised with regard to the working of the GEAC.

The Statement of Objects and Reasons of the BRAI Bill, while recognizing the rapidity with which the science and industry of biotechnology is advancing, and that there are several public concerns associated with biosafety, does not give a justification for enacting a new law and setting up the BRAI. It also does not acknowledge the concerns that have been raised with regard to the 1989 Rules. It makes reference to the reports of the Task Force on the Application of Agricultural Biotechnology constituted by the Ministry of Agriculture in 2003 and that of the Task Force constituted on the recombinant pharma – both of which recommended the establishment of an 'autonomous, statutory and professionally led authority' for 'generating the necessary public, political, professional and commercial confidence in the science-based regulatory mechanism'. Neither the Preamble to the Bill nor the Statement of Objects and Reasons explain how the new authority would be better than the existing system and why changes cannot be made to the existing regulatory framework to meet the objectives which are being set out for the new Bill. New legislative enactments cannot be used as a camouflage for reluctance to make any effective change in the existing laws and rules. To ensure that this does not happen, it is important for the government to first properly justify the reasons for introducing a new law and what is the real change that it is likely to lead to.

The Cartagena Protocol came into force in 2003 and as a signatory to it, India is under an obligation to ensure that its domestic laws are in compliance with the provisions of the Protocol. The objective of the Protocol is –

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

The objective clearly mentions the potential risks associated with modern biotechnology and the need for 'adequate level of protection' and the necessity for following the Precautionary Principle. The BRAI Bill in its long title does not make any reference to the risks associated with 'modern biotechnology' and its potentially adverse effects on biological diversity and human health. While efficiency and effectiveness of the regulatory procedure are important goals in themselves, the statute must first set out the objective of the regulatory procedure ex ante, as that would define the criteria to determine the extent of efficiency and effectiveness of the regulatory procedure. The statute must lay out a framework which ensures greater vigilance over the use of modern biotechnology in the country.

It appears from the preamble that the Bill intents an adaptive approach – i.e. reducing the risks by taking measures for safe and responsible use of modern biotechnology and assumes that products of modern biotechnology are a *fait accompli.* Instead, the main focus of the Bill should be the prevention of risk arising from the use of modern biotechnology as there may be threats of serious or irreversible damage associated with it. The Precautionary Approach/ Principle should be the overall focus of the regulatory regime.

CONFLICT OF INTEREST

The mandate of the Department of Biotechnology (DBT), under the Ministry of Science and Technology, which has proposed the Bill includes the promotion of biotechnology in the country including the promotion of the biotechnology industry and a 'well directed effort, significant investment for generation of products, processes and technologies'.[3] The Ministry through DBT has made significant investments in the field of biotechnology, with or without private partnership and supports various institutions involved in genetic engineering related research.[4] It is thus very much interested in ensuring that decisions are taken in favour of propagation of genetic engineering in the country. In this scenario, for an independent regulatory authority to function properly, without any form of perceived or actual influence, and in an unbiased manner, it has to be entirely disassociated from government departments and institutions involved in the development of biotechnology.

With the DBT through the Ministry of Science and Technology proposing the regulator of the sector, a situation has been created wherein the foremost promoter of biotechnology in the country would play a major role in constituting the sector regulator and also assisting in its functioning. For instance, Clause 7(1) of the Bill provides the members of the selection committee for the Chairperson and the Members of the BRAI and includes the secretary-in-charge of the Department of Biotechnology and a scientist from the same department is required to convene the meetings of the selection committee.

It is a principle of natural justice that justice should not only be done, but manifestly and undoubtedly seen to be done. This principle has been upheld by the Supreme Court in catena of cases. The Supreme Court has held that 'what is objectionable … is not that the decision is actually tainted with bias but that the circumstances are such as to create a reasonable apprehension in the mind of others that there is a likelihood of bias affecting the decision'.[5] As one of the functions of the BRAI is to consider applications for initiating research, transport, import, use or manufacture of GMOs, the BRAI would often have to consider applications with which the Ministry of Science and Technology and the Department of Biotechnology is either directly or indirectly associated. Therefore, the decision making of BRAI, irrespective of whether there has been any actual instance of bias, would be viewed with the apprehension of bias.

It would be advisable for a different Ministry of the Government which is not involved in promoting biotechnology to be the nodal agency for the regulation of GMOs. It is suggested that the Ministry of Environment and Forests, which is currently the parent ministry for GEAC, be the nodal agency for such a regulatory body.

[3] See Official website of Department of Biotechnology, available at http://dbtindia.nic.in/uniquepage.asp?id_pk=83
[4] See for information Annual Report 2009-2010 of Department of Biotechnology, Ministry of Science and Technology, available at http://dbtindia.nic.in/annualreports/DBT-An-Re-2009-10.pdf
[5] Ashok Kumar Yadav v. State of Haryana (1985) 4 SCC 417

ROLE OF THE STATE GOVERNMENTS

The current Bill reduces the role of the State Governments to a recommendatory capacity in the form of the State Biotechnology Regulatory Advisory Committee set up under Clause 35 of the Bill. In its 111th meeting held in 6 July 2011, the GEAC had decided-

'After detailed deliberation, it was agreed that agriculture being a State subject, it is important to take the views of the State Government on board and to promote their involvement in activities pertaining to GM crop field trials especially its effective monitoring. It was decided that in respect of all GM crop field trials, the GEAC/RCGM would issue the approval letter only on receipt of NOC from the respective State Department of Agriculture.'[6] This is a significant way in which states are able assert their decision with regard to GMOs. In 2011, the State Governments of Karnataka, Tamil Nadu, Maharashtra, Bihar, West Bengal, Uttar Pradesh, Rajasthan, Bihar and Punjab denied No Objection Certificates (NOCs) to field trial applications in their states for both *kharif* and *rabi* seasons.

However, the BRAI Bill does not give any power to the State Governments to reject the introduction of any GMOs, including experimental releases through field trials, in their state. When the issue of Bt Brinjal introduction in various parts of India was being considered, the State governments of Kerala, Karnataka, Tamil Nadu, Andhra Pradesh, Chhattisgarh, Madhya Pradesh, Odisha, Bihar, West Bengal, Uttarakhand, Gujarat and Himachal Pradesh had at different points of time formally and through media statements opposed the introduction of Bt Brinjal in their respective states. Kerala, Bihar, Madhya Pradesh, West Bengal and Chhattisgarh have formally written to the Central Government not to permit field trials of any GM crop in their respective states.[7]

While the Central Government has the power to legislate a law on the regulation of biotechnology, to completely take away the authority of State Governments to decide on behalf of the people of their state, goes against the spirit of the federal structure of the Constitution. The Bill will affect issues which are on the State list such as public health and agriculture and therefore it should give certain decision making powers to states with regard to what actions can or cannot be taken in their territory.

In other environmental laws such as the Wildlife (Protection) Act, 1972, the Forest (Conservation) Act 1980, the Environment (Protection) Act 1986, the Biological Diversity Act 2002, and the Scheduled Tribes and Other Forest Dwellers (Recognition of Forest Rights) Act, 2006 departments in the State Government or state-level committees have been given certain decision making powers. Under the Water (Prevention and Control of Pollution) Act 1974 and the Air (Prevention and Control of Pollution) Act 1981, the State Pollution Control Boards retain the power to grant the Consent to Establish and Consent to Operate to industries. Without these consents, even industries, operations or processes, approved by the central Ministry of Environment and Forests cannot be set up.

It is therefore recommended that the State-level Biosafety Protection Committee headed by the Chief Secretary of the state or the Principal Secretary, Department of Environment be created which will have certain decision making powers and not just a recommendatory role. For instance, the Committee should be given the power to decide whether a field trial should be permitted to start in the territory of the State or not. The Committee should also be given the power to decide whether there is a need for a particular GMO in that state given the existing situation (e.g. existence of other viable alternatives, risks of the products).

[6]Decisions taken in the 111th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 06 July 2011 is available at http://moef.nic.in/divisions/csurv/geac/decision-jul-111.pdf.
[7]See Nitin Sethi, Chhattisgarh says no to GM crop trials, Times of India, 11 August 2011, available at http://articles.timesofindia.indiatimes.com/2011-08-11/india/29875780_1_field-trials-gm-crop-genetic-engineering-appraisal-committee; and Reema Narendran, Government 'No' to GM crops in Kerala, Express Buzz, 7 January 2012, available at http://expressbuzz.com/states/kerala/government-%E2%80%98no%E2%80%99-to-gm-crops-in-kerala/350835.html.

INADEQUACIES IN THE COMPOSITION OF STATUTORY COMMITTEES/COUNCILS

The committees and councils constituted under the BRAI Bill are dominated by government officials and those with a purely technical background. As the use of modern biotechnology has repercussions which are social, cultural, economic, ethical and ecological in nature, the committees and councils constituted under the Bill, including the BRAI itself, whether it is to give recommendations, make decisions or selection, should be broad-based with members bringing in varied expertise and representing different sectors and stakeholders.

Clause 6(2) of the Bill provides the qualifications of persons who can be appointed as members to the proposed BRAI. The qualifications mentioned here are very limited and exclude those representing social sciences, anthropology, public health, economics etc. Such persons bring a necessary diversity and expertise to the decision making process which ensures that a decision is based not only on science related to molecular biology, genetics or biotechnology but takes into account the social, economic and ecological realities of the area which would be affected by the decision. Without this nature of diversity, decisions of the BRAI would not be based on holistic assessment. Even the Risk Assessment Unit is expected to undertake a limited evaluation ('science based evaluation') which does not include assessment of social, economical and cultural impacts.

The Forest Advisory Committee constituted under the Forest (Conservation) Act, 1980 performs a crucial role of giving recommendations to the Central Government on applications for diversion of forest land for non-forestry purposes. This Committee, although seemingly performing a 'scientific' task has included a social activist, an environmental historian and civil society representatives. Similar is the case of the National Board for Wildlife which is a statutory body and comprises of wildlife scientists and government officials as well as wildlife activists, environmentalists, and NGOs.

It is recommended that the committees and councils constituted to regulate GMOs should also include persons who have expertise to understand the social, cultural and economic impacts of the use of modern biotechnology products like GMOs and represent the various sectors.

INDEPENDENT LONG-TERM ASSESSMENT OF BIOSAFETY OF GMOS MISSING

Given that there is a strong body of evidence on the potential impacts of GM crops on human health and environment, it is essential for any regulatory mechanism for GM crops to ensure long term, independent biosafety assessments before environmental releases of any kind [field trials or commercialisation] can be considered. The BRAI Bill does not provide for this kind of long term independent assessments. In fact it allows the applicant to undertake the biosafety assessment itself which would then be reviewed by different assessment units under the BRAI. The quality and credibility of the assessment is highly suspect in such a scenario as the applicant is an interested party.

Concerns have been raised on the short term and inadequate nature of the protocols followed by the current regulatory system for assessing biosafety of GMOs before environmental release. What is also missing in the existing system is the precautionary approach where even the slightest abnormality found should be taken seriously and rectified before going ahead with any environmental release of the particular GMO. All these issues had come up during the public consultation around the Bt Brinjal and were reflected in the subsequent moratorium order of the Ministry of Environment and Forests. The BRAI Bill does not seem to make any effort to address these concerns and unambiguously put forth independent long term biosafety assessments before environmental release of any GMO as its main mandate.

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NEED ASSESSMENT OF A PRODUCT MISSING

For authorizations for research, transport, import, manufacture or use of GM products and organisms under Clause 24 and Clause 27, the applicant has to submit an application along with such information and documents as may be prescribed in the regulations. This application is then forwarded to the Risk Assessment Unit by the BRAI. The Unit is supposed to undertake a science-based evaluation of the application and then submit its risk assessment report to the BRAI.

The afore-mentioned procedure misses a very critical step –an assessment of the very need of the specific GMO. Although the information to be provided with the application is to be elaborated in the regulations, it appears from the present drafting that the submission of the application would immediately trigger a risk assessment process, even before assessing whether the GMO is at all needed and/ or will be an additional benefit to the society.

Article 26 of the Cartagena Protocol requires parties to keep in view, while implementing obligations under the Protocol, the 'socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities'. The Norwegian Gene Technology Act, 1993 states that significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

The BRAI Bill must contain a provision which requires the applicant to first submit a report on the need of the GMO before even submitting its risk assessment report on the GMO. This *Need Assessment Report* should be assessed by the Risk Assessment Unit . If the Unit finds that there was no adequate justification for introducing the GMO, the application should be rejected at this preliminary stage itself, without going into risk assessment. The need assessment would include an assessment of the socio-economic considerations which would arise from the impact of the GMOs.

The EIA Notification 2006 issued under the Environment (Protection) Act 1986 requires applicants for environmental clearance to first submit basic information about the project in Form 1 which is appended to the Notification. This form

has to include information on the alternatives that have been considered to this project. Theoretically, this could include the alternative of 'no project'. Additionally, the Environment Impact Assessment (EIA) report which has to be submitted for appraisal has to include information on the *need for the project* as well as technology and site *alternatives* that have been considered.

There should be a need assessment of the particular GMO proposed as a first step where the Risk Assessment Unit has to ascertain whether there is no other ecologically and socially sustainable alternative for the problem that the GMO claims to solve.

LIMITED DISCLOSURE OF INFORMATION

Several legislations such as the National Sports Development Bill 2011 and the National Nuclear Safety Authority Bill 2011 which have been drafted after the introduction of the RTI Act 2005 have included provisions to curtail the application of the RTI Act to information/bodies under them. The BRAI Bill is another example of this curtailment. Clause 28 of the Bill states that the provisions of the Right to Information Act, 2005, would not apply to confidential commercial information submitted under the provisions of the Act. Clause 28(2) allows the BRAI to disclose confidential commercial information if it is in public interest and does not harm any person.

Clause 28 seems entirely unnecessary as the provisions of the RTI Act are adequate to provide protection from disclosure of information which is of the nature of '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 RTI Act, 2005]. This exemption clause can be overridden by the relevant competent authority if it finds larger public interest in disclosing the information. Section 8(2) of the RTI Act, 2005, further provides 'a public authority may allow access to information, if public interest in disclosure outweighs the harm to the protected interests'. Very often it is seen that this balancing act of private interest versus public interest is not undertaken by the public authority and the information is denied to citizens under Section 8(1)(d). In such cases, the power lies with the concerned State or Central Information Commission to decide on the matter and direct disclosure of the information after assessing the countervailing interests.

The Central Information Commission has had to intervene on a previous occasion in a case relating to the Department of Biotechnology. Information was sought from the Department on the locations where genetic engineering (GE) field trials were being conducted, data on health and environment safety tests conducted on GE crops, and the minutes of the Review Committee of Genetic Manipulation's (RCGM) meetings. Information was denied on the ground of Section 8(1)(d) of the RTI Act. However, the disclosure of this information was in public interest as the farmers and consumers could be aware and protect their seed and food from contamination and people could know what crops are being approved and the rationale for the approval. The Central Information Commission decided that the information was not exempt from disclosure and it was in public interest to make it available publicly.[8] Although the Commission directed the Department to disclose the information, it did not comply. Instead the decision was challenged in the Delhi High Court. The court directed the case back to CIC which reconfirmed the need for making public the information.[9]

[8]Decision of the Central Information Commission in Divya Raghunandan v. Department of Biotechnology, Appeal No.CIC/WB/A/2006/00548, dated 13.04.2007, available at http://cic.gov.in/CIC-Orders/Decision_13042007_04.pdf

[9]Decision of the Central Information Commission in in Divya Raghunandan v. Department of Biotechnology, Adjunct to Appeal No.CIC/WB/A/2006/00548 and Appeal No. CIC/WB/A/2009/000668, dated 26.6.2009, available at rti.india.gov.in/cic_decisions/WB-26062009-01.pdf

The Bill provides for public disclosure of information – i.e. authorizations granted by the BRAI under Clause 24 and Clause 27 – within ten days of the decision being taken. However, there is no statutory requirement for other decisions of BRAI to be made public. For instance, the decision of the BRAI to suspend or cancel authorizations under Clause 24(5) and Clause 27(8) which are very important and their disclosure would be in public interest, are not required to be disclosed within a stipulated period of time to the public.

Access to information is part of the fundamental right to speech and expression under Article 19(1)(a) of the Constitution of India.[10] The Supreme Court of India is various judgments has reiterated importance of the right to know and transparency and accountability in governance. The Supreme Court has observed –

"To ensure the continued participation of the people in the democratic process, they must kept informed of the vital decisions taken by the Government and the basis thereof. Democracy, therefore, expects openness and openness is a concomitant of a free society. Sunlight is the best disinfectant".[11]

The Supreme Court has held that "the right to participate in the affairs of the country is meaningless unless the citizens are well informed of all sides of the issues, in respect of which they are called upon to express their views. One sided information, disinformation, misinformation and non information, all equally create an uninformed citizenry which makes democracy a farce when the medium of information is monopolized by the partisan central authority or by private individuals or oligarchic organizations".[12]

The right to information has also been incorporated in various international legal instruments to which India is a party including the Universal Declaration of Human Rights 1948 and the International Covenant on Civil and Political Rights 1966. Principle 10 of the Rio Declaration emphasizes on the importance of access to information in the environmental context.

In the regulatory regime on GMOs, information disclosure should be made a norm and confidentiality should be made an exception. For instance, the decision of the Risk Assessment Unit or the State Biotechnology Regulatory Committee on the need assessment should be made public as soon as possible. The Supreme Court and the High Courts have emphasised on the need for reasoned decisions.[13] Under the RTI Act 2005, citizens have the right to know the reasons for any administrative or quasi judicial body. Therefore information such as minutes of meetings and recommendations of committees and councils should be mandatorily disclosed under the Bill.

In any regulatory regime on GMOs, information disclosure should be made a norm and confidentiality should be made an exception. All the decisions of the all units and committees of the regulatory system should be made public as soon as possible.

[10]People's Union for Civil Liberties v. Union of India (2004) 2 SCC 476.
[11]Dinesh Trivedi v. Union of India (1997) 3 SCC 306.
[12]Secretary, Ministry of Information and Broadcasting v. Cricket Association of Bengal (1995) 2SCC 161.
[13]MJ Sivani and Others v. State of Karnataka AIR 1995 SC 1770; Utkarsh Mandal v. Union of India 2009 (10) AD (Delhi) 365.

PARTICIPATION OF THE PUBLIC IN DECISION MAKING CURTAILED

The BRAI Bill provides for public participation in the decision making process at one stage only - Clause 27(5) places an obligation on the BRAI to obtain objections and suggestions from the public when an application for authorization for manufacture or use of organisms and products specified in the Clause is received. However, besides this specific provision, the Bill does not provide any other opportunity to the public to raise its concerns and to seek clarification.

There is no provision for public participation under Clause 24. The BRAI is expected to base its decision to grant authorization under Clause 24 on the evaluation of the Risk Assessment Unit and after considering 'all relevant matters'. There must be a process of mandatory public consultation before such an authorization is granted as accidental contamination during research and transport or from stored imported products can lead to extensive damage and people likely to get affected must have a say in the decision making. Similarly, there is no provision for public participation/ seeking public comments before authorization is given for conducting clinical trials or field trials under Clause 34.

The Risk Assessment Unit, the Enforcement Unit, the Product Rulings Committee and the Environment Appraisal Panel perform important recommendatory and monitoring functions under the Bill. But these bodies have no provision to seek public comments before making recommendations. The Supreme Court of India has underscored the importance of effective Public Participation in environmental decision making and held that:

"The rights to information and community participation for protection of environment and human health is also a right which flows from Article 21. The Government and authorities have, thus to motivate the public participation."[14]

The process of public consultation has not been explained any further in the Bill. If the same is going to be provided in the rules/notification, it must be ensured that the process is based on internationally and nationally accepted norms on public participation. Article 23 of the Cartagena Protocol, Principle 10 of the Rio Declaration, Item 23.2 of the Agenda 21 and the UNEP- Guidelines for the Development of National Legislation on Access to Information, Public Participation and Access to Justice in Environmental Matters 2010, identify effective public participation to be an important component of environmental decision making. One of the principles of the National Environment Policy, 2006 of the Government of India is 'equity' which has been defined as – 'Equity, in the context of this policy refers to both equity in entitlements to, and participation of, the relevant publics, in processes of decision-making over use of environmental resources'.

Since impacts from products of modern biotechnology, like GMOs, are far and wide, effective public participation in decision making should be a mandatory component of any regulatory regime on modern biotechnology and GM products. There should be a mechanism to take public views at every step of decision making and especially before any environmental release including experimental ones is permitted.

Public protest against the introduction of Bt Brinjal in the country. © Greenpeace

[14] Research Foundation for Science Technology National Resource Policy v. Union of India and another 2003 (9) SCALE 303.

THE NEED FOR A NEW GRIEVANCE REDRESSAL MECHANISM?

The Bill proposes the setting up of a Biotechnology Regulatory Appellate Tribunal (BRAT). Any person aggrieved by a decision/order or directions of the BRAI may file an appeal in the Tribunal. A pertinent question arises as to whether there is actually a need for a separate Appellate Tribunal for Biotechnology at all, given the fact that the National Green Tribunal set up under the National Green Tribunal Act, 2010, is functional and has a wide jurisdiction. Although the Bill gives detailed provisions regarding the Tribunal, its members and its functioning, the responsibility to decide the substantive issue such as *locus standi* to approach the Tribunal has been left to the Central Government to draft. Most legislations setting up new quasi-judicial bodies clearly lay down which category of persons can approach the said body to avoid future ambiguity.

The Bill provides that the Tribunal 'shall have jurisdiction over all civil cases where a substantial question relating to modern biotechnology is involved…'. **The setting up of a new Appellate Tribunal appears to be unnecessary and a replication of the National Green Tribunal's powers –**

- Currently, the National Green Tribunal has jurisdiction over all civil cases raising a substantial question relating to the environment which arises out of the implementation of certain stipulated legislations, including the Environment (Protection) Act, 1986 and the Biological Diversity Act, 2002.

- The experience of setting up the National Green Tribunal shows that even if a law provides for a quasi-judicial body, the setting up of such body is extremely difficult and affected persons may be left without a grievance redressal forum for months or even years. There are several procedural hurdles in the process of arranging the adequate infrastructure for the body to function, to provide accommodation to the chairperson and members of the body and in appointing the staff.

- Although the National Green Tribunal Act 2010 was passed in June 2010 and the Act was enacted in October 2010, the Tribunal did not start functioning properly till July 2011. Till date, the circuit benches of the Tribunal have not been set up in different cities across the country as envisaged in the Act. Only the principle Bench in Delhi and one Circuit Bench is functioning with two judicial and four expert members. Even to reach this stage of operation, regular intervention of the Supreme Court through directions to the Ministry of Environment and Forests and other departments were required.[15] The Supreme Court continues to supervise the operationalisation of the Tribunal. Creating the Appellate Tribunal under the BRAI Bill would also have financial implications.

- Given the fact that a specialized body in the form of the National Green Tribunal already exists, expenditure on another similar body would be an unnecessary burden on the exchequer.

- The National Green Tribunal has the power to award relief and compensation to victims of environmental damage as well as direct restitution of property damaged (Section 15). Such extensive powers have not been granted to the BRAT under the Bill. Furthermore, an application for relief and compensation can be filed in the National Green Tribunal within five years from the date on which the cause of action first arose. This time limit allows much greater access to justice than the 2 years permitted under Clause 56(3) of the BRAI Bill for taking up any substantial questioning of modern biotechnology.

- The qualifications for expert members of the National Green Tribunal are far more diverse than the set of qualifications for expert members of the BRAT. Experts from varied backgrounds would ensure that the social, economic, and ecological aspects of any grievance before the Tribunal would also be considered appropriately.

The National Green Tribunal Act can be suitably amended to include within the jurisdiction of the Tribunal appeals and applications pertaining to matters pertaining to regulation of GMOs as well. From the current trend of cases before the National Green Tribunal, an additional category of cases relating to GM regulation would not significantly burden the Tribunal's workload.

[15] See orders of the Supreme Court in Union of India v. Vimal Bhai, SLP No. 12065 of 2009.

The Tribunal has jurisdiction over all civil cases involving a substantial question relating to environment which arises out of the implementation of the enactments listed in Schedule I to the Act. By the application of Section 34(1) of the National Green Tribunal Act, Schedule I can be amended by the Central Government through a notification to include the any new regulatory system on GMOs in it. If it is deemed necessary, of the ten expert members that are to be appointed to the Tribunal, a fixed number (two or three) can be those with the qualifications which have been prescribed for expert members of BRAT.

The regulatory system for GMOs would have to include a clause identifying the National Green Tribunal Act as the appropriate grievance redressal forum. Necessary amendments to the sections of the National Green Tribunal Act can be made by adding a clause in any new legislation for regulating GMOs.

DILUTED STANDARD OF LEGAL LIABILITY

Clauses 62 to 66 identify certain offences under the BRAI Bill. The Bill also provides that liability for the offences may be fixed on companies, societies, trusts or universities through every person who at the time of the offence was in charge of and responsible to the company, societies, trusts or universities for the conduct of business of the entity. The liability may extend to any director, manager, secretary, governor, vice chancellor, committee, trustees, etc. if the offence has been committed with the consent or connivance of such person.

A Department of the Government can also be found to be liable for an offence and in such a case the Head of the Department shall be liable to be proceeded against or any other officer with whose consent or connivance the offence has been committed (Clauses 67 to 69).

a. Need for penalty to have deterrence effect

Clause 62 provides that -

If a person, in connection with a requirement or direction under this Act, provides any information or produces any document that the person knows is false or misleading, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

This clause must include an explanation which clearly states that 'person' includes those who are responsible for preparing false or misleading data/ assessment which forms part of or is the basis of an application for authorization which has been made to the proposed BRAI. Such a provision would ensure that third-party consultants hired by the company would be extremely cautious while undertaking assessments for the company.

Given the nature of damage that could be caused if authorizations for release of organisms/products are based on incorrect/inaccurate risk assessment, the penalty for providing such incorrect/inaccurate risk assessment should be high enough to be an effective deterrent.

This recommendation is being made in view of a recent order of the National Green Tribunal in which it was found that there were several inadequacies in the Environment Impact Assessment (EIA) Report submitted by the project proponent for conducting mining operations in Maharashtra. The Tribunal observed that -

"It is baffling to notice that the EIA consultant, who is supposed to be an expert in the field, has no accountability what so ever, even if he furnishes wrong information or insufficient information, which leads to wrong conclusions that may be arrived at by the EAC as well as MoEF. The proponent generally is not an expert; he goes by the report prepared by the EIA consultant. It is always better to fix the responsibilities on the EIA consultant and made liable for taking suitable action (both civil and criminal) for

furnishing any wrong information."[16]

Soon after this judgment of the National Green Tribunal, the Ministry of Environment and Forests issued an Office Memorandum in which it stated that action would be initiated against the EIA consultant to delist it from the list of accredited consultants if it was found that it had copied information from a different EIA report.[17]

It is important that a 'minimum' period of imprisonment and fine be prescribed in all cases so as to serve as an effective deterrent. By 'minimum' is meant a term of imprisonment which shall not be less than a certain period.

The penalty imposed on unauthorized field trials under Clause 63 is imprisonment of not less than 6 months to a maximum of one year and fine of rupees two lakhs. There is a serious risk of contamination during field trials and the impacts could be irreparable and irreversible. The penalty for unauthorized field trials should be high enough to act as deterrent to companies planning to bye-pass the law. This could include placing the company on a list of companies which are prohibited from undertaking future trials.

b. Non-conformity with the principle of absolute liability

The standard for determining liability that has been laid down in Clauses 67, 68 and 69 are not in conformity with the law laid down by the Supreme Court on the issue of liability for hazardous activities. In all these four clauses it has been stated that a person would not be held liable if the 'offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence'. This standard of liability is very different from the principle of absolute liability laid down by the Supreme Court.[18] In this case, the Court was deciding the liability of a company for Oleum gas leakage and while finding the existing standards of liability insufficient for hazardous or inherently dangerous industries, it laid down the principle of absolute liability. The principle as laid down by the Court is –

"We are of the view that an enterprise which is engaged in a hazardous or inherently dangerous industry which poses a potential threat to the health and safety of the persons working in the factory and residing in the surrounding areas owes an absolute and non-delegable duty to the community to ensure that no harm results to anyone on account of hazardous or inherently dangerous nature of the activity which it has undertaken. The enterprise must be held to be under an obligation to provide that the hazardous or inherently dangerous activity in which it is engaged must be conducted with the highest standards of safety and if any harm results on account of such activity, the enterprise must be absolutely liable to compensate for such harm and it should be no answer to the enterprise to say that it had taken all reasonable care and that the harm occurred without any negligence on its part. Since the persons harmed on account of the hazardous or inherently dangerous activity carried on by the enterprise would not be in a position to isolate the process of operation from the hazardous preparation of substance or any other related element that caused the harm the enterprise must be held strictly liable for causing such harm as a part of the social cost for carrying on the hazardous or inherently dangerous activity. If the enterprise is permitted to carry on a hazardous or inherently dangerous activity for its profit, the law must presume that such permission is conditional on the enterprise absorbing the cost of any accident arising on account of such hazardous or inherently dangerous activity as an appropriate item of its over-heads. Such hazardous or inherently dangerous activity for private profit can be tolerated only on condition that the enterprise engaged in such hazardous or inherently dangerous activity indemnifies all those who suffer on account of the carrying on of such hazardous or inherently

[16]The Sarpanch, Gram Panchyat Tiroda & Others v. Ministry of Environment and Forests & Others, Appeal No. 3 of 2011, decided on 12.09.2011; available at <http://greentribunal.in/orderinpdf/3-2011(Ap)_12sept_final_order.pdf>
[17]Office memorandum dated 05.10.2011 issued by Ministry of Environment and Forests available at < http://www.moef.nic.in/downloads/public-information/OM_IA_ownershipEIA.pdf>.
[18] MC Mehta v. Union of India (1987) 1 SCC 395.

dangerous activity regardless of whether it is carried on carefully or not. This principle is also sustainable on the ground that the enterprise alone has the resource to discover and guard against hazards or dangers and to provide warning against potential hazards…

32. We would also like to point out that the measure of compensation in the kind of cases referred to in the preceding paragraph must be co-related to the magnitude and capacity of the enterprise because such compensation must have a deferent effect. The larger and more prosperous the enterprise, the greater must be the amount of compensation payable by it for the harm caused on account of an accident in the carrying on of the hazardous or inherently dangerous activity by the enterprise." (emphasis added)

The aforementioned principle of liability has been subsequently upheld by the Supreme Court in another decision.[19] The Court in this case was deciding the liability of chemical industrial plants for releasing toxic untreated waste waters which percolated through the soil thereby rendering the soil and the subterranean supply of water unfit for use. The Court held-

"… once the activity carried on is hazardous or inherently dangerous, the person carrying on such activity is liable to make good the loss caused to any other person by his activity irrespective of the fact whether he took reasonable care while carrying on his activity. The rule is premised upon the very nature of the activity carried on."

The Court found the polluting industries 'absolutely liable to compensate for the harm caused by them to villagers in the affected area, to the soil and to the underground water' and directed the industries to take all necessary measures to remove sludge and other pollutants lying in the affected areas.

The absolute liability principle is a type of no fault liability and is different from the conventional principle of fault liability because it removes the defence of having taken 'reasonable care' and the defence that there was 'no fault' of the person undertaking the activity. What this means is, that given the nature of hazardous/dangerous activities, it is not relevant whether care has been taken or not and whether there was any intent to cause harm or not. The entity causing the harm would be found *absolutely* liable for the harm and would have to compensate for the same even if the entity had taken reasonable care to prevent the harm.

The standard of no fault liability has been adopted in the National Green Tribunal Act, 2010 and the Motor Vehicles Act, 1988. In the BRAI Bill the standard of liability has been considerably watered down by first, introducing an element of *mens rea* – the requirement that the offence must have been committed with the knowledge of the persons; and second, by allowing the defence of 'due diligence' having been exercised. This dilution of the standard of liability goes against the established principle of absolute liability for hazardous and dangerous activities which is undoubtedly applicable to cases of contamination relating to use of modern biotechnology.

c. Polluter pays principle not adopted

The amount of penalty that has been laid down in the Bill for the afore-mentioned offences appears to be in the form of punitive damages. However, there is no discretion granted to the deciding authority (the courts) to grant compensation for the harm caused and to direct payment of costs for restoration of the environment. The Supreme Court has explained the 'polluter pays principle' which is part of the Indian municipal law as follows:

"The "Polluter Pays" principle as interpreted by this Court means that the absolute liability for harm to the environment extends not only to compensate the victims of pollution but also the cost of restoring the environmental degradation. Remediation of the damaged environment is part of the process of "Sustainable Development" and as such polluter is liable to pay the cost to the individual sufferers as well as the cost of reversing the damaged ecology."[20]

[19] Indian Council for Enviro-Legal Action v. Union of India (1996) 3 SCC 212.
[20] Vellore Citizens Forum v Union of India (1996) 5 SCC 647.

In Clause 27(9), the proposed BRAI has the power to suspend or cancel an authorization granted under that Clause for the purpose of manufacture or use, of certain identified organisms and products if it is found that any condition in the authorization has been violated. No other penalty is imposed on the person responsible for violating the conditions of the authorization. However, Clause 66 of the Bill lays down the amount of penalty to be imposed for offences for which no penalty has been specified elsewhere – imprisonment upto two years and fine upto ten lakh rupees. Assuming that a person violating the conditions of an authorization can be penalized under Clause 66, the situation still remains highly unsatisfactory as there is no discretion with the deciding authority. The penalty amount would have to be varied according to the nature and gravity of the condition and the corresponding violation. Further, there must also be an option for the deciding authority to direct payment of costs for damage caused to the environment due to the violation of the condition and compensation to persons to whom any harm may have been caused.

Given the nature of damage that can be caused, the regulatory regime should include penalties which are high enough to have a deterrent effect. Absolute liability and polluter pays principle should be the cornerstones of such liability clauses on regulation of GMOs.

CONCLUSION

Given that there is an inherent risk involved in modern biotechnology and its products, the main mandate of the regulatory system should be to safeguard the health of citizens, the environment and consider the various social, economic and cultural aspects. The decision making in such a system should follow the basic principles of Indian and international environmental jurisprudence like precautionary principle, absolute liability for hazardous and dangerous activities, polluter pays principle, effective public participation in environmental decision making and access to information.

The current BRAI Bill 2011 fails to incorporate these principles and hence needs to be revised before it is tabled before the Parliament. The amendments to the Bill have to be made after engaging in a rigorous public debate with all stakeholders.

Greenpeace activists protest outside the Indian Parliament against the tabling of the controversial Biotechnology Regulatory Authority of India Bill 2011 (BRAI). Five activists (wearing T-shirts bearing the message "Don't Corrupt Our Food, Stop BRAI Bill.") were later stopped and detained by the police for attempting to unfurl a banner conveying the same message.

Greenpeace is a global organisation that uses non-violent direct action to tackle the most crucial threats to our planet's biodiversity and environment. Greenpeace is a non-profit organisation, present in 40 countries across Europe, The Americas, Asia and the Pacific.

It speaks for 2.8 million supporters worldwide, and inspires many millions more to take action every day. To maintain its independence, Greenpeace does not accept donations from governments or corporations but relies on contributions from individual supporters and foundation grants.

Greenpeace has been campaigning against environmental degradation since 1971 when a small boat of volunteers and journalists sailed into Amchitka, an area north of Alaska, where the US Government was conducting underground nuclear tests. This tradition of 'bearing witness' in a non-violent manner continues today, and ships are an important part of all its campaign work.

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