Decision on Bt-Brinjal: Legal Issues

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The recent decision of the government of India to impose a moratorium on the release of Bt-Brinjal has been hailed by civil society and scientists alike as a victory for transparency and has demonstrated that the government is responsive to societal demands. This decision is also important since it could set a precedent within environmental regulation with reference to technologies with significant environmental risks. However, the decision also reflects a clear departure from procedure and its legal basis is tenuous and therefore the risk of it being reversed remains. This establishes a clear case for ensuring legal certainty in environmental regulations especially in the case of technologies with significant risks attached to it.

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On 9 February 2010, the Ministry of Environment and Forests (MOEF) in its decision on the commercialisation of Bt-Brinjal[1] quoted the GEAC, which stated,

> as this decision of the Genetic Engineering Approval Committee (GEAC) has very important policy implication at the national level, the GEAC decided its recommendation for environmental release may be put to the Government for taking final view on the matter.[2]

The GEAC, therefore, in its own decision of granting approval to the release of Bt-Brinjal, had also recommended that the government of India (GOI) may review the matter, given the policy implications. It is important to note that the minister's report mentions this recommendation by the GEAC upfront, precisely because this recommendation provided the moral basis for the government to introduce a process of review of the GEAC decision leading up to the final decision on moratorium on the commercialisation of Bt-Brinjal. The decision of the MOEF is, in the nature of an executive order that has very tenuous legal basis and is, therefore open to judicial review.

The process of arriving at this decision itself had attracted its fair share of media attention, given that the MOEF held a series of public meetings in Kolkata, Bhubaneswar, Ahmedabad, Nagpur, Chandigarh, Hyderabad and Bangalore. These meetings were attended by a wide variety of stakeholders including farmers, farmers' organisations, scientists, state agriculture department officials, non-governmental organisations, consumer groups, allopathic and ayurvedic doctors, students and housewives, with the striking exception of agricultural biotechnology companies. This was unprecedented in two ways, first the decision of MOEF to launch a process of public consultation on an issue that has been essentially viewed as a "scientific" issue (Carter and Gruère 2006: 465-68); and second, the massive public response, witnessed by the participation of nearly 8,000 persons.[3] Thus, this almost referendum like process of public consultation would seem to establish certain important parameters for environmental regulation in the country. First, that decisions involving large-scale utilisation of technologies that bear an environmental and/or public health risk, should not only be based on scientific risk assessment but also should undergo a process of public engagement (stakeholder consultation) in order to gauge the social acceptance of that technology. Second, that the scientific assessment report of expert committees on such technologies should be made public and comments invited on the report prior to a decision being taken. The decision, therefore, seems to establish two critical parameters – social engagement and transparency in environmental regulation and has, therefore, been lauded as a "wise decision" by a number of experts in India.[4]

Legal Basis and Role of MOEF

Despite this decision being cited as marking a watershed in environmental regulation, there are certain inherent legal problems with this decision. First, it is important to question the legal basis for this decision. As mentioned above, the minister's decision on the commercialisation of Bt-Brinjal is based on the recommendation by the GEAC that since its decision as an important policy implication nationally, the government may review it in order to take a final decision. The question which arises is whether the GOI has the legal authority to review/revise/overturn the decision of the GEAC? In other words, if the GEAC had not recommended its decision for review by the GOI, could the GOI suo motu authorise this process of review of GEAC decision? In order to answer this question it would be prudent to briefly outline the legal mandate and scope of functioning of the GEAC under the statute.

The GEAC was set up as a statutory body under the 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (1989 Rules), that was notified under the Environmental Protection Act 1986 (EPA). The 1989 Rules created a hierarchical structure of

competent authorities to oversee the regulation and policymaking vis-à-vis hazardous microorganisms including genetically engineered organisms. The Recombinant DNA Advisory Committee (RDAC) and the Review Committee on Genetic Manipulation (RCGM) were set up within the department of biotechnology with the mandate to monitor safety aspects of ongoing research projects and activities involving such genetically engineered organisms and also to recommend appropriate safety regulations for India. At the institutional level, every facility involved in research or handling of such substances is liable to constitute an Institutional Biosafety Committee (IBSC) in order to prepare and implement an on-site emergency evacuation plan. Further, at the district level, district level committees (DLC) and at the state level, state biotechnology coordination committees (SBCC) would also be constituted wherever necessary to monitor the safety regulations in installations or handling of such substances and with powers to inspect, investigate and take punitive action in terms of non-compliance with statutory provisions.

The GEAC was constituted as a statutory body under the department of environment, forests and wildlife of the MOEF, for

> approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle.[5]

The GEAC has also been made responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.[6] Further, the GEAC also has the power to take punitive action under the EPA. The 1989 Rules also provide approval, licensing and prohibition powers to the GEAC in terms of all activities that relate to import, export, transport, manufacture, process, use or sale of any such substances.[7] In the case of production, in which such substances are generated or used, cannot commence without the consent of the GEAC.[8] In the case of conditional approvals, the GEAC may also supervise the implementation of the terms and conditions through the SBCC and/or DLC. The decisions of the GEAC can be challenged within a period of 30 days through an appellate authority appointed by the MOEF. Since the appellate authority has to date not been set up by the MOEF, any such challenge can be filed in either the high court or the Supreme Court via a civil writ petition. This brief overview of the range of powers that the GEAC exercises over almost all activities relating to the handling of such substances, illustrates the extensive coverage of issue areas and the immense scope of its functioning. The 1989 Rules do not provide for any scope of review of the approvals granted by the GEAC other than via individual judicial appeals. Thus, it is necessary to underline that although judicial challenges can be mounted against approvals or any other regulatory decisions granted by the GEAC, there is no legal basis provided under the statute (in this case the 1989 Rules) to take suo motu action to review or revise its decisions by an executive order of the MOEF.

The other important aspect is the relationship between the MOEF and the GEAC. The GEAC was set up as a statutory body to oversee regulatory approvals of genetically engineered substances and products. However, unlike statutory bodies which by definition are structurally and functionally independent regulatory authorities – the GEAC functions under the department of environmental forests and wildlife of the MOEF. Such an institutional linkage is bound to influence and to an extent undermine the independent mandate of the GEAC. This is reflected within the statute by way of Rule 20 of the 1989 Rules that provides for a blanket exemption clause. It empowers the MOEF to grant an exemption to any occupier handling a particular microorganism or genetics engineered organisms from the obligations stated under Rule 7-11. Thus, although the 1989 Rules do not provide for any review/revision of the GEAC decisions on approvals/prohibitions by the executive, by empowering the MOEF to grant absolute waivers from regulatory approvals of the GEAC, it does create an impression that the GEAC is functioning under the authority of the MOEF. This power has also been used by the MOEF to provide for subject specific waivers[9] and has, thereafter, also been challenged in the court.[10] This underlines that although the GEAC has been given the statutory mandate to function as the regulatory authority when it comes to approvals for genetically engineered substances or products, this mandate has been severely curtailed by the executive power as provided under Rule 20 of the 1989 Rules. It could be argued that another implication of such an institutional linkage is also that the MOEF may become vicariously liable for any failings of the GEAC, given that it is the parent body under which the GEAC is functioning. The contention here is that it is

imperative that the GEAC be reconstituted as a separate regulatory authority with an independent mandate and functioning purview (similar to Telecom Regulatory Authority of India) and there should be no institutional linkage between the MOEF and the GEAC. The present manner of functioning of the GEAC creates circumstances wherein its regulatory authority can be eroded or even nullified by an executive order of the MOEF and could also lead to the arbitrary use of that power by the MOEF. On the other hand, the functioning of the GEAC has been criticised by the MOEF in this moratorium decision and has been identified as one of the grounds to review the GEAC decision – since the present status of the latter is only that of a committee functioning under the department of environment, forests and wildlife, the MOEF should hold itself liable for any gaps in the functioning of the GEAC.[11] It is indeed intemperate that the MOEF would in the first place, by an executive order (with insufficient legal basis), revise the decision of the GEAC to grant approval. This is clearly not envisaged within the present statutory law. On the other hand, if one defends this decision of the MOEF on the basis of the institutional linkage between the MOEF and the GEAC (and, therefore, based on the recommendation made by the latter), then a case can be made for a closer supervision of the GEAC by the MOEF at an earlier stage so as to ensure that it functioned in an impartial and transparent manner. Thus the MOEF stands on a slippery slope ground vis-à-vis its rationale for adopting a moratorium on the commercialisation of Bt-Brinjal in India.

Rationale for the Moratorium

A detailed analysis of the MOEF decision on the commercialisation of Bt-Brinjal is a prerequisite in identifying the underlying rationale and the future plan of action which is expected to be pursued. First, it has been stated that this decision relates to Bt-Brinjal alone and does not have any implication for the issues of genetic engineering and agricultural biotechnology in general.[12] Semantically speaking there is some truth in this, since the decision per se has resulted in the adoption of a moratorium to the commercialisation of Bt-Brinjal. However, the controversy preceding this decision along with the process of public consultations justifying this decision on the basis of the precautionary principle and other aspects of this decision do carry precedential value. Although the moratorium is only applicable to Bt-Brinjal but the process of arriving at this decision will have an implication for any public policy decision on the regulation of large-scale utilisation of technologies that bear an environmental and/or public health risk. Second, the decision was not only based on public consultations conducted in the cities which were selected on the basis of their importance in brinjal cultivation, but also the state governments were given an opportunity to submit their views on this issue. Specifically, the fact that agriculture is a state subject and, therefore, the views of the state would have to be considered in the case of regulation of technologies having an agricultural implication, has been accepted.

Third, the decision also refers to the question of public utility of the technology to be accepted for commercialisation.[13] This is an important aspect of the technology assessment exercise that is followed in Europe as a standard public policy procedure in the case of commercialisation of new technologies that may bear potential environment, health and social risks.[14] In this case, it makes a point that "Bt-biotechnology is not the only route for reducing pesticide use"[15]. It refers to non-pesticide management (NPM) that has been adopted by many districts in Andhra Pradesh as an example of a technology that completely eliminates chemical pesticide use and, therefore, is a viable alternative to Bt-Brinjal that only reduces the pesticide usage. The presence of a viable alternative is an important factor that has to be considered in decisions for commercialisation of technologies that have potential environmental and public health risks associated with it.

Fourth, reference is also made to the fact that legitimate doubts can be raised as to reliability of the tests relating to human safety of Bt-Brinjal since they were carried out by the applicants themselves and not by independent laboratory. It needs to be clarified that the current regulatory regime does not mandate independent tests and, in fact, it is upon the applicant to conduct tests in order to prove the safety of the product. It is the GEAC which is supposed to authenticate these tests. This system needs to be overhauled. Either in the case of tests conducted by the applicant independent third party supervision/oversight should be required to verify the tests or the tests should be conducted by independent laboratories in the first place. In both the cases the GEAC will be the final authority to validate the tests

and therefore needs to be equipped with the necessary resources to conduct this authorisation.

Fifth, interestingly the decision also raises issues of food sovereignty by acknowledging fears that Monsanto may control the food chain if Bt-Brinjal is granted approval[16]. It also stresses the importance of public investment in agricultural biotechnology so as to ensure there is a balance maintained when it comes to production in terms of the varieties of seeds to choose from and to prevent monopoly conditions. Food security is not the mandate of MOEF and least of GEAC. An objective risk appraisal and approval process should focus on the risks alone. The socio-economic dimensions are present in risks emanating from any technology but should not be of concern to an agency which has been established with the sole and clear function of approving activities involving use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. There is no doubt that new technologies need a holistic approach before and during their release in the society. However, such a task should be undertaken by an agency which has both the mandate and capacity to take such cross-cutting decisions. An approval committee that is formed under the Environment Protection Act, is neither suited nor capable of looking into issues such as market, monopoly and food security. This is primarily a larger public policy question that needs to be addressed by bodies like the Planning Commission that allocates public research funding nationally. It needs to be reiterated that at present the regulatory mandate of GEAC is to ensure that public health and environmental safety aspects have been addressed satisfactorily while considering applications for commercialisation of genetically engineered food crops and products. Its mandate does not include an examination of the players in the market so as to adjudge whether its decision could potentially create monopoly conditions and, therefore, could have an implication for food sovereignty. The argument here is that, prevention of monopoly conditions cannot be a regulatory objective or a criterion for granting approvals of genetically engineered food crops and products. Assessment of public health and environmental safety issues should be the only criteria for granting regulatory approval in the case of environmental regulators like the GEAC. This would imply not only the diffusion of a clear focus on environmental and health risks but also impinging upon the domains of other agencies and departments. Moreover, there are other legislation that addresses aspects that will influence larger governance of biotechnology applications, such as the Seeds Bill 2004 (this will be replace the Seeds Act, 1966), Competition Act, 2002 and the Food Safety and Standards Act, 2006. That is another issue that none of these, so far, have emerged as functional instruments capable of serving the desired purpose. However, this may serve as an opportunity to integrate the concerns around genetic engineering technology in their substantive and procedural frameworks and establish synergies amongst the various existing and proposed bodies, rather than each trying to address the issues of another.

Sixth, the decision mentions that several doubts have been raised on the integrity of the GEAC process itself (in fact this has also been mentioned by the Supreme Court[17]), and that it has violated the Cartagena Protocol on Biosafety that India is a signatory to. These are very serious charges and need to be thoroughly investigated. It needs to be reiterated that the GEAC is structurally linked to the MOEF and it functions under the supervision of the department of environment, forests and wildlife. In this context it would be the responsibility of the MOEF to closely supervise the functioning of the GEAC and in such cases that is found to be lacking, to make the necessary correction. Currently, the GEAC is not an independent regulatory authority that has a separate legal personality (also the reason why it is the GOI that has been made the respondent in the public interest litigation filed in the Supreme Court questioning the functioning of the GEAC[18]). It is, therefore, incumbent on the MOEF to make the necessary amends and not distance itself by questioning the integrity of the GEAC, as if it were a separate entity. This only obfuscates the issue of responsibility. This is an issue of national interest and the MOEF should come clean and accept failure to its own responsibility – ensuring that the GEAC functions in an impartial, transparent and effective manner.

Conclusions

A number of statements of good intention have been made within this decision – it includes the setting up of the National Biotechnology Regulatory Authority as a professional science-based, independent regulatory authority, reviewing the protocol of public health and environmental safety tests that need to be conducted, and application of a precautionary principle based approach within the regulatory approval process. The GEAC has been directed to take up follow-up action on the review of tests with appropriate protocols and to engage and interact with a number of eminent scientists on this issue. Most significantly a name change of the GEAC has been proposed in terms of replacing the word "approvals" with that of "appraisal". This semantic change is significant because it seems to underline a demotion of the role of GEAC and ensure that its decisions can only have the value of recommendations to the MOEF. The MOEF will, therefore, have an explicit right of review of GEAC decisions, which will most likely be merely appraisal reports having little or no approval authority or value. Two points need to be made here: first, that a simple semantic change in the minister's report will not be enough; as such a dilution of GEAC's role and enhancement of the MOEF's power can only be granted by amending the current legal framework. Second, such a suggestion seems to be prima facie contradictory to the statements of good intention mentioned earlier. The MOEF needs to clarify that the goal is to set up an independent

regulatory authority within a specific timeline. The role of robust assessments is central to a regulatory approval process of any technological application but it cannot be a substitute for the approval itself. The regulatory process needs to ensure independent risk assessments but that does not require watering down of GEAC's role in approving a biotechnology application. Given that there are lacunae in the design and manner of GEAC's exercise of powers and discharge of functions, the MOEF should divert its attention to removing those lacunae, rather than reserving more powers for itself. In the interim, it may set up an independent expert panel to review the entire functioning, structure and substantive process of the GEAC and also to specify distinct steps in the regulatory process to implement the precautionary principle.[19]

The other critical question is whether this decision creates any precedent as far as regulatory approvals vis-à-vis technologies with potential public health and environmental safety risks are concerned. The response to this question would be in affirmative.[20] The decision has underlined a number of imperatives that would need to be internalised within the regulatory structure. These include, inter alia, the necessity of undertaking wide-ranging stakeholder consultations at the pre-approval stage, undertaking a public utility assessment of technology, and application of the precautionary principle. In reality, the effect of adopting such a decision has been that it has generated wide-ranging public debates on this issue and has opened up the regulatory process to questioning. It is, therefore, unfortunate that the legal basis for this decision is questionable. It is important at this stage not to create uncertainty by indulging in semantic juggling, given that agricultural biotechnology is an important area of long-term research investment and, therefore, it is important to create legal certainty[21] and transparency in regulatory policymaking on this issue in India.

NOTES

1 Decision regarding Bt Brinjal. Minister's Report, Ministry of Environment and Forests, GOI (9 February). Viewed on 20 February 2010 (http://moef.nic.in/downloads/public-information/minister_REPORT.pdf).

2 GEAC 97th Meeting, 14 October 2009.

3 See Centre for Environment Education (2010), Complete Report of the National Consultation on Bt Brinjal.

4 See Press Trust of India (2010), "Moratorium on Bt Brinjal Wise Decision: Experts", 9 February 2010, Viewed on 20 February 2010 (http://www.hindustantimes.com/newdelhi/Moratorium-on-Bt-brinjal-wise-decision-experts/507896/H1-Article1-507080.aspx).

5 Section 4(4) of the Rules for the Manufacture, Use, import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 5 December 1989, under the Environment Protection Act of 1986.

6 Section 4(4), ibid.

7 Section 7, ibid.

8 Section 8, ibid.

9 See MOEF Notification GSR 616(E) of 20 September 2006 and SO1519(E) of 23 August 2007 (although this has been kept in abeyance until issue of further notification by the Ministry of Health and Family Welfare regarding regulation of GM processed foods by the Food Safety and Standards Authority – via, SO 411(E). MOEF Notification of 25 February 2008).

10 Civil Writ Petition No 608/2007 filed in the Supreme Court of India to stop the deregulation of import restrictions on GM food via MOEF notification SO 1519(E). of 23 August 2007.

11 In the case of Bt Cotton – the MOEF Report of the Subcommittee on Bt Cotton and Related Issues (June 2006), referred to the need to investigate the reported irregularities in the field trials of Bt Cotton and had given recommendations to streamline the current regulatory framework. There was no follow-up and therefore the MOEF should take the responsibility of repeated failings of the GEAC, as has been highlighted in the case of Bt Brinjal. Viewed on 20 February 2010 (http://www.envfor.nic.in/divisions/csurv/geac/mayee_report.pdf).

12 See Supra Note 1, point 7, p 3.

13 Another aspect of public utility would be to address economic impact aspects, See Bennett et al (2004: 96-100).

14 European Parliament, Annual Report 2008, Science and Technology Options Assessment, Director General for Internal Policies, Brussels, March 2009. Viewed on 17 February 2010 (http://www.europarl.europa.eu/stoa/publications/annual_report/2008_en.pdf).

15 See Supra Note 1, point 9, p 5.

16 See Supra Note 1, point 11, p 6.

17 Orders given in the Civil Writ Petition No 115/2004 filed in the Supreme Court of India, *Gene Campaign & Another vs Union of India & Others*.

18 See Supra Note, 11.

19 See for a detailed discussion, Chowdhury and Sabhapandit (2007: 281-300).

20 It should be mentioned that the application of the precautionary principle and the value of public consultation have been accepted as acceptable practices within environmental regulation both by the courts and by the executive in India.

21 Legal certainty refers to predictability, applicability and coherence of the regulatory system.

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