



The Biotechnology Regulatory Authority of India Bill, 2013: An Appraisal

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ABSTRACT

India is one of the fastest growing economy & market for the products of all known goods in globe. India along with other countries of the world needs to address the issues which are related to the Health & food security. The answer to all which lies in the Biotechnology. In the last two decades, biotechnology research has reached new-fangled horizons and hundreds of genetically modified (GM) creations have procured their place in international market. To have the streamlined development & progress; India has come up with the BRAI concept. This has been recently tabled to the floor of Parliament in 2013, monsoon session, which still is pending & people have started talking about its progress & implication in future. This paperwork while giving overview of present bill has remarked upon its pros & cons along with the suggestions that if incorporated could result into fruitful Act for the most prominent demand of the time.

KEYWORDS : Biotechnology, BRAI, Genetics, Biotechnology Law

Introduction:

The growth of the biotechnology sector in India has significant implications for policy in the area of regulation. Two very important reports prepared by Ministry of Agriculture and the Ministry of Environment and Forests have evaluated the regulatory framework for products of agricultural biotechnology and recombinant pharmaceuticals.

The 2004 Report of the Task Force on the Application of Agricultural Biotechnology chaired by Prof. M.S. Swaminathan (the Swaminathan Report) recommended the establishment of an "autonomous, statutory and professionally-led National Biotechnology Regulatory Authority" (herein after NBRA) that would have "two separate wings – one dealing with food and agricultural biotechnology, and the other with medical and pharmaceutical biotechnology." The Report recommended that the "NBRA is essential for generating the necessary public, political, professional and commercial confidence in the science based regulatory mechanism in place in the country."

The 2005 Report of the Task Force on Recombinant Pharma chaired by Dr. R.A. Mashelkar (the Mashelkar Report) similarly supported the establishment of a National Biotechnology Regulatory Authority/Commission "providing a professionally managed single window mechanism for giving various clearances including biosafety issues." A model for the NBRA was proposed that "would comprise of four wings namely:

- a) Agricultural products / Transgenic Crops;
- b) Pharmaceutical/ Drugs and Industrial Products;
- c) Transgenic Foods/Feed; and
- d) Transgenic Animals/ Aquaculture"

In 2005, DBT published a draft National Biotechnology Development Strategy which elaborated a ten year vision for the future of biotechnology in India. Key policy recommendations and approaches to implement these were established through a process of multi-stakeholder consultations that focused on cross-cutting issues of relevance to all sub-sectors of the biotechnology community. Under the topic of regulatory mechanisms, the National Biotechnology Strategy recommended "a competent single National Biotechnology Regulatory Authority be established with separate divisions for agriculture products/transgenic crops, pharmaceuticals/drugs and industrial products; and transgenic food/feed and transgenic animal/aqua culture. The authority is to be governed by an independent administrative structure with common chairman. The inter-ministerial group will evolve suitable proposals for consideration of the government."

The National Biotechnology Development Strategy was approved by the Government of India in November, 2007 after a two year consultation period with multiple stakeholders including concerned ministries, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and

international bodies. As regards the regulation of biotechnology, the strategy states that the NBRA will be established as an "independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes". DBT has been given the responsibility to set up the NBRA and until such time as the NBRA is fully functional, biotechnology regulation will continue under the existing regulatory framework.

All this circumstances gave birth to the National Biotechnology Regulatory Bill, 2008. To full fill the very purpose which is discussed above, to setup NBRA will require the promulgation of new legislation. As a result of which the Government of India proposed a bill namely the "National Biotechnology Regulatory Act, 2008" or the NBR Act. This has been prepared by a Consultative Committee of experts. DBT proposed to take feedback on this document with all the concerned stakeholders through placing on the websites as well as organizing regional consultations. After that the Bill was redrafted and tabled in Parliament in 2011 in the winter session, but there could be no decision over the matter. Again the same way the matter was tabled in parliament this year with the amended portions of the bill, but this time again the bill could not be passed.

There are many aspects which need to be answered by the government as one can see that it is having lacunae all over the content & spirit of the issue. Secondly the fact is still there which reflects that India is still a predominantly agricultural country & having any experiment with it could result into havoc. The biggest issues which government is facing today is the origin of all this story, which is backed by the agreement of Mahyco & Monsanto dated back in 2002, which has introduced the Bt cotton in India & later approval from GEAC (Genetic Engineering Approval Committee) in 2009 of the Bt-Brinjal in India. Not only in India, but from all over the world scientist were disturbed to see that it was permitted in India with such an ease!

The technical Expert committee appointed by the Supreme Court of India also suggested that the level of the work going on in India in the relation of the Biotech products should be regulated at once & should be stopped without any delay. This shows that the way the biotech research & work is going in India need serious attention.

Analysis of the BRAI Bill, 2013:

The Bill aims to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures.

Biotechnology Regulatory Authority: The Bill establishes the Biotechnology Regulatory Authority of India (Authority). The Authority will consist of a chairperson, two full time members, and two part time members. The bill is divided into 88 sections & 14 Chapters. The bill vividly talks about the powers/functions/working of the NBRA. There is establishment of the Appellate authority which will look into the appeal provisions and there is coordination among different departments of the government. There are independent wings of the NBRA

which are regulatory divisions of the Authority. They have been created for the implementation of safety assessment procedures and processes. The divisions are:

- (i) Agriculture, forest and fisheries,
- (ii) Human health and veterinary products, and
- (iii) Industrial and environmental applications.

There is another risk assessment unit established which will further assess the risk involved in the projects/approval application. Risk Assessment Unit will appraise applications for proposed research, transport or import of an organism or product, before final approval is granted. The Product Rulings Committee will make recommendations to the Authority for the manufacture or use of organisms or products. The Environmental Appraisal Panel will make recommendations on environmental safety of organisms and products.

An Inter-Ministerial Governance Board has been established to promote inter-ministerial or departmental co-operation for the effective discharge of the functions of the Authority. A Biotechnology Advisory Council will render strategic advice to the Authority regarding developments in modern biotechnology and their implications in India.

Every care has been taken from the drafters, that the bill could safes the need of each & every concerned party. The bill has been very systematic & has covered all the queries in regard to the subject. The power & functions of the Biotechnology authority & tribunal are defined in elaborative way. The rejection & acceptance of the proposal under the Act has also been explained in a logical way. Every effort has been sorted to keep check on the biotechnological process. The appointment of the committee as well as that of the members in BRAI has been kept very neutral based on the qualification as per the Act. The only thing that can be apparently seen is the full fledged working of the BRAI, when it will be brought into effect.

The dark side of the proposed bill: States will lose their Autonomy:

Autonomy of States over subject of Agriculture has been taken away by this bill. As could be seen by the provisions of the Constitution of India that has made the agriculture to be the sole subject of the state jurisdiction, this Act demands that the sole authority to determine anything in relation to the biotechnology advance in agriculture will be determined by the Central govt. Not only that, apparently it seem that the states are also having say in the regulation of the biotechnology, but in fact it is only acting as the subordinate of the Center. When we have already passes the Food Security Act, how one can overlook the importance of the food grains provided from the states to the center?

Superseding effect of the BRAI Act:

Supreme Court of India has mentioned this in many judgments at many instances that the right to information is the fundamental to the identity of a citizen in India, but the proposed Act is having different attitude for the same. The Act (BRAI) tend to curtail this right of the citizens of India, by giving a superseding effect above the RTI. The authority can even deny to give the information whenever they feel so. Although there has been provision which says that the authority if deem fit that it is expedient to do so in the larger interest of the public can even disclose the information but that is very subjective & depend upon the discretion of the authority.

Selection of the members of the BRAI:

The selection process for the members has been made in such a manner which will definitely result in the influence of the corporate people over the public policy. Moreover it has been seen that the control of the BRAI from Ministry of Environment has been shifted to Department of Science & Technology. Latter has already given permission to the Bt-Brinjal in country which has clearly shown the influence of the corporate over its decisions. This could be further dangerous when many Multi-National Companies are coming to India. Not only that there will be issues in relation to the Bio-prospecting & bio-piracy too.

Impact of the US- India Knowledge Initiative over the BRAI:

India has signed an agreement with US in 2005, which is "US-India Knowledge Initiative on Agricultural Education, Teaching, Research,

Services and Commercial linkages" or the KIA agreement. As a result of this treaty, the control of the US based multi-nationals could be felt on all areas of agriculture in India, from agricultural research to the marketing and retail sale of agricultural products. As a part of this treaty, a board was established whose main objective was to implement the different aims of the agreement, and it is also a hard fact that majority of the members have their roots with the multinational giants in field of Biotechnology.

Control of the BRAI over GEAC:

It can also be seen through this proposed bill that there will be whole control of the BRAI over the committee which deals with the core aspects of the Biotechnology. Although there is no harm as to it but, still the difference is that of only few persons taking over the work of the whole well established team of the experts. Definitely this will result into the diminishing of the impact of the GEAC, which could have been avoided. GEAC is formed of the diversified people from different & important field of the subject but limiting them to the work of few 5-6 people would not yield the same desired results.

Independent research & analysis of the proposed crops:

There has been a need & demand from all corners of the scientists & environmentalists that India need an independent, erstwhile committee that can look into the projects that come for the production of the Genetically modified crops or any other advancement in field of the biotechnology. Unfortunately, nothing is done in the proposed bill in this regard. The committee that is empowered for looking into this is comprised of only three members who are not from the field of biotechnology *per se*; they are generalists who are from the department of the health, medical or agricultural field. No doubt that it is very hazy to say or to suspect the working of those specialists from their field (as the BRAI also give minimum qualification for the members), but one thing is clear that they are not the specialist who would work independently.

Role of GEAC also delimited by the Act:

It is also apparent on the face of the Act that the BRAI want to make GEAC only a recommendatory body & not the effective committee. As could be understood that the Act has made the authority a superior body over the GEAC, which would result into the channeling of the work and no one except the authority can regulate the work. As a result the very effective & efficient committee which comprises of the persons with the expertise will be discouraged to an extent that it will only remain as the recommendatory body. And this is also true with all the recommendatory bodies in India that they remain so only through their life.

Absolute authority to the BRAI over n above the usual law regulating bodies:

It can be easily seen that the authority formed under the bill has been given prominence over the rest of the regulating bodies of the land. As there is formation of the tribunal too which is not having any member from the judiciary! No matter that the present set up gives idea for the specialist determining the issues of the cases but yet no one can underestimate the importance of judicial member deciding the matters in relation to matter concerned there to. No qualm to say that this will undermine the importance of judiciary in this field. Also it is pertinent to note that the authority has been given absolute rights over the information sent to it. It seems that it is necessary to do so for the betterment of the subject matter but then there will be clash of the authority in this regard, which can be avoided.

Also the clinical trials are not kept within the ambit of the authority, which will create problem in this matter. The clinical trials, Drugs & Cosmetic Act should also be a part of this Act, so that some concrete decision could have been taken.

Punishing powers for the BRAI:

This is again a very strange fact that the proposed bill has made it within listed offences against the authority to punish person who would be attracted under the provision of the section 62- 68. While this could be seen as a welcome step but give discretionary powers to the authority to decide & refer the matter to appropriate court. This could have resulted in to desired results if the independency & neutrality of the authority could be maintained. This is not there in the bill.

Conclusion:

The Act is very ambitious project of the govt. of India, and all of our future is also connected with this. Not only this but this is the high time that govt. can realize the need to change & transform all the issues relevant thereto. The proposal is good if it can be amended so as to fit the requirement of all sections of society. This can be easily done if the govt. is ready to accept the criticism from all concerned. This is not very difficult or impossible only need is to feel that where we can improve. Else this bill could be very fruitful looking to the demand of time. This is must for Indian society that we can regulate the development in such a manner which will be not only sustainable but also with far reaching aspects.