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ASIA EDITION

BRAI Bill deadline extension fails to dampen biotech industry's spirits

July 11, 2013 | Regulatory | By Rahul Koul Koul



New Delhi: While, the environment activists in India welcomed the Standing Committee on Science and Technology, Environment and Forests' decision to extend the deadline for Biotechnology Regulatory Authority of India (BRAI) Bill public views and suggestions from July 10, 2013, to after 45 days, the industry continues to linger on the hopes of early passing of the Bill.

Despite stiff opposition, 11 parliament sessions, and two failed attempts in the last three years, the BRAI Bill, drafted to carry out risk assessment of all biotech products and supervise field trials of genetically modified crops in India, was tabled in the Lok Sabha on April 22, 2013. The Bill seeks to create an independent regulator called BRAI, besides a 17-member inter-ministerial governing board, to oversee the authority's performance and a Biotechnology Regulatory Appellate Tribunal, where BRAI decisions could be challenged. However, the commercialization of biotechnology products in agriculture and healthcare would be left to the central and the state governments.

The Bill was sent to the Standing Committee on Science and Technology, Environment and Forests for review due to widespread opposition to it both inside and outside the parliament. However, the Bill continues to receive an overwhelming response from the industry bodies and experts alike.

Hailing the decision, Dr Ram Kaundinya, chairman, Association of Biotech led Enterprises-Agricultural Group (ABLE-AG), says, "BRAI is a logical step forward and the government has mooted the setting up of a National Biotechnology Regulatory Authority of India to regulate the research, manufacture, importation and use of products of modern biotechnology through National Biotechnology Authority Bill."

Dr Kaundinya feels that the biggest advantage of BRAI is that it will bring single-window clearance on approvals. "We also hope this will bring about the much-needed alignment in central and state policies on biotech crop regulations. It will also enable a more formidable system of keeping science and politics separate," he adds.

The reason that made the industry smile is that, finally the government has managed to put the Bill through the first stage amidst stiff opposition from Parliament members, as also in the past, the previous science ministers were compelled to withdraw the Bill at the last moment and that too after listing it in the Lok Sabha business.

The industry experts say that the authority will be empowered to "develop and implement guidelines for risk assessment methodologies and monitor and conduct and forward messages about the safety of modern biotechnology products and processes to the central government and state governments," as per 9(3)(c) of the draft Bill. This will help create a credible system of risk assessment and put to rest many speculations being put forth about the health and environmental safety of biotech crops. Further the draft Bill also has the provision to "ensure that the process and criteria for risk assessment and risk management are easily accessible so that product developers, stakeholders, and the public can be confident that the biotechnology regulatory system is both credible and predictable," through its clause 9(3)(f).

In the past too, several government panels had recommended the creation of an independent regulatory body for the biotechnology sector. Prominent scientists such as Dr R A Mashelkar had in past expressed strong support for the Bill. In his recent interaction with *BioSpectrum*, Dr Mashelkar had noted, "It is very unfortunate that the BRAI Bill is still pending before the parliament despite it being a very important step for the growth and benefits of the industry. In fact it looks like that the government is keen to move forward in this regard. However, one has to understand that sometimes there are policy procedure delays. Yet, I am quite hopeful of its early implementation."

Dr Ram Kaundinya at the same time thinks that even as the government works on BRAI, GEAC should continue to steer decisions on trials. He adds, "Ours is one of the most stringent and competent regulatory mechanisms in GEAC-with three union ministries viz agriculture, science and technology, and biotech involved in it. Over the years GEAC as a competent regulatory agency has done a wonderful job and cleared large number of trials."

Sharing his views, Mr Neeraj Gupta, director, sales and marketing, Imperial Life Sciences, told *BioSpectrum* that it is certainly a welcome move by the government and any such decision to streamline the regulations has come at the right time when the industry needs it the most. "It is high time that biotech industry gets its due," he says.

Dr J N Verma, managing director, Life Care Innovations, called it a "brave decision". He feels strongly that BRAI must have the mandate of both regulations as well as the product development to clear the current mess. "The BRAI and directorate of health research should function in tandem and I think we must do away with Drug Controller General of India (DCGI) in the first place," says Dr Verma.

The unhappy lot

However, the activists and groups condemning the Bill argue that the Indian government is trying to push the BRAI Bill amidst confusion. "It is strange that Mr Jaipal Reddy (Indian Minister for Science & Technology and Earth Science) overlooked the concerns raised by political parties and the parliamentary standing committee report on GM, especially when the Technical Expert Committee recommendations are still pending at the Supreme Court. The UPA government is trying to push the BRAI Bill amid all the confusion without much media debate or public opposition in the garb of rape incidents and Coalgate," said National Campaign for People's Right to Information (NCPRI) in a statement.

Non-profit organization Greenpeace too in a statement demanded that the Bill should be sent to the Joint Committee of the parliament with members from all political parties from both the houses for amendments so that it does not jeopardize food safety and seed sovereignty.

Besides, as the Union Science and Technology Minister of India, Mr Jaipal Reddy, was introducing the Bill in the parliament, CPM member, Mr Basudev Acharya, interrupted the proceedings arguing the proposed Bill would help the multinational companies, and goes against the recommendations of a report made by the standing committee on agriculture headed by him. Meanwhile, Ms Aruna Roy, a member of the National Development Council, asked ruling party chairperson, Ms Sonia Gandhi, to intervene and hold back the introduction of the Bill in the parliament, and allow further public debate on the matter.

Few members of the parliament have already written to the Indian prime minister, expressing their concern over the Government of India pushing forward the BRAI Bill. Among these are the former union minister of environment, Captain Jainarain Nishad, also a Rajya Sabha MP, and Professor Anil Kumar Sahani, a Rajya Sabha MP, who pointed out that the BRAI Bill appears to be too centralized and therefore, contradictory to the principle of increasing decentralization of governance. Earlier, Ms Meneka Gandhi, from the opposition party and Dr Raghuvansh P Singh, another leading party

member, raised their concerns over the Bill.

However, some politicians supported the Bill. "Let the scientific matters be decided by the scientists and not get caught in the administrative and political non-decisiveness," was what Mr Manish Tewari, former spokesperson, ruling party, had to say last year when *BioSpectrum* had contacted him. However, industry experts say that the inclusion of the provision of "notifying the public of all applications for field and clinical trials and of all regulatory decisions made by the authority," the Bill adequately creates provisions for transparent dissemination of information.

Also the Bill makes for stringent provisions for recruitment of officials and experts for its various bodies. By roping in the scientific community and providing them with a credible share of voice, BRAI is expected to lead the country into the next level of development of biotechnology. With the civil society and opposition members up in arm against the BRAI Bill, the government would have to do a tightrope walk for its safe passage in the coming parliament sessions.