

BRAI bill crosses stage one, industry hopeful

16 January 2014 | News | By Rahul Koul Koul

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This is one such news that the industry has been eagerly waiting to hear since a long time now. The biotechnology regulatory authority to carry out the risk assessment of all biotech products and supervise field trials of genetically modified crops was introduced in the Lok Sabha on Monday, April 22, 2013. As expected, it received an overwhelming welcome response by the industry body and experts alike.

The bill seeks to create an independent regulator called Biotechnology Regulatory Authority of India (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 central and state governments.

Hailing the decision, Mr Ram Kaundinya, chairman, Association of Biotech Led Enterprises - Agricultural Group (ABLE-AG) mentioned, "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 states policies on biotech crop regulations. "It will also enable a more formidable system of keeping science and politics separate," he added further.

The reason that makes the industry smile is that finally the government has managed to put bill through first stage amid 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 speculation 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 also, several government panels had recommended 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 BioSpetcrum 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 added further, "Ours is one of the most stringent and competent regulatory mechanisms in GEAC - with three Union ministries viz Agriculture, Science & 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."

Giving his reaction from the biosupplier industry, 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 the high time, biotech industry gets its due," he added.

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 in the first place," mentions Dr Verma.

However, the bill has come under attack severely at the draft stage from activists and certain political parties. Among the top critics are the left wing parties and Greenpeace who feel that the UPA government is trying to push the BRAI bill amidst all the confusion without much media debate or public opposition in the garb of rape incidents and Coalgate.

As the Union Science and Technology Minister, Mr S Jaipal Reddy was introducing the bill, CPM member, Mr Basudev Acharia interrupted 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, has urged UPA chairperson Ms Sonia Gandhi to intervene and hold back introduction of a bill on biotechnology in Parliament and allow further public debate on the matter .

However industry experts point toward that fact 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 a credible share of voice, BRAI will surely is expected to lead the country into the next level of development of biotechnology