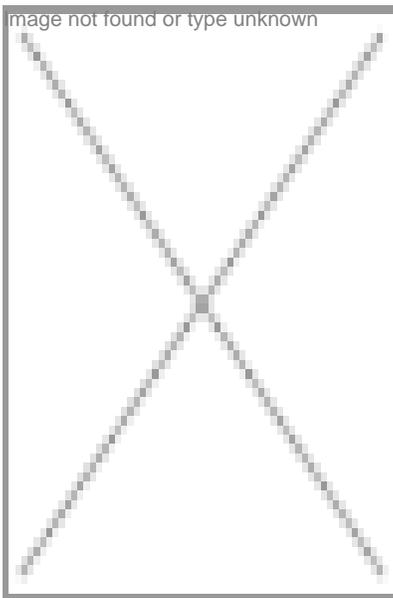


BRAI Bill hangs fire, industry is hopeful

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The Biotechnology Regulatory Authority of India as a single window system can help in streamlining the regulatory process. Despite being drafted a decade ago, it is yet to see the light of day



The Biotech Regulatory Authority of India (BRAI) bill, which is a revised version of the earlier National Biotechnology Regulatory Authority (NBRA) bill, was scheduled to be tabled in Parliament on August 17, 2011, by Mr Vilasrao Deshmukh, who became the fourth Science, Technology and Earth Sciences Minister in the last 18 months. This did not happen due to the disturbances in Parliament over Anna Hazare's fast in support of the

Ever since the government came up with the proposal for a new regulatory body in the form of BRAI, which is expected to promote safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures, the bill has received mixed reaction with the academia and the industry pushing for the bill while the anti-

st it. The bill proposes to set up a five-member Biotechnology Regulatory Authority of India, of which two would be part-time members, under the Ministry of Science and Technology. BRAI will take all decisions related to research, transport, import, manufacture and use of organisms and products created through modern biotechnology. All the other institutions proposed as part of the regulatory system like the Inter Ministerial Governing Board and the Biotechnology Advisory Council are all advisory or supportive in nature. The bill also

checks the state government's role in permitting open air field trials of GM crops.

"Biotechnology offers one way out of this dilemma of growing more with less. With more than 90 percent of India's cotton farmers taking advantage of biotechnology, I would appeal to the government to replicate the benefits to other crops by expediting the process of its creation."

- **Mr Ravinder Singh**, A farmer leader from Punjab

"We are committed as an industry to prove the safety of biotech crops and adhere to very robust trial rules laid out by the Government of India. Our compliance to the regulatory processes is complete and sacrosanct. It is certainly great if we have a single window regulator in the country."

- **Dr Bharat Char**, Lead Biotechnology, Mahyco & ABLE-AG member

"Extensive studies examining the safety of biotech crops have been conducted by various independent bodies, including the World Health Organization. These bodies have overwhelmingly concluded that there are no adverse effects on human health. It is high time to establish this authority."

Mr Bhupen Dubey, Head, Integrated Business, UPL/Advanta and Member, ABLE-AG

"As illustrated by the success of Bt Cotton, the benefits are clearly in favor of Indian farmers, whose earnings have improved considerably, commensurated with dramatic increases in cotton yields over the past decade."

Dr P Anand Kumar, Principal scientist, National Research Center on Plant Biotechnology (NRCPB), Indian Agriculture Research Institute (IARI), Ministry of Agriculture

"We have seen a definite positive shift in the lifestyles of numerous farmers and the changes were clearly linked to increase in their incomes after adoption of Bt cotton. The BRAI can help in decreasing the timelines in the approval of such crops with enormous profits."

Dr N Chandrasekhara Rao, Associate professor, Center for Economic & Social Studies, Hyderabad

livelinessâ€?. â€œThe bill in its current form is a classic case of conflicting interests where the ministry, which is supposed to promote GM crops, has been asked to regulate it for safety.â€?

Similarly, Greenpeace noted in its release that Mr Basudev Acharya, CPI(M) party leader in Lok Sabha who found the proposed BRAI objectionable, said that there were â€œnumerous concerns with relation to the health and environmental safety of GM cropsâ€?. Acharya, who is also the chairman of the Parliamentary Standing Committee on Agriculture, further opined in the House that â€œthis bill read along with other legislations like the seed bill, that is up for tabling in this session, shows the government's real intent of siding with the biotech seed corporations against the farmers and consumers of our countryâ€?.

The BRAI is expected to be a dedicated authority comprising five members including a chairman. According to the proposal, it will also have an inter-ministerial governing body. There would be three divisions to address the core areas of

Farmers, who have tasted the success of the Bt cotton crop in India, along with scientists and the agri-biotech industry, came together under the umbrella of the Association of Biotechnology Led Enterprises-Agricultural Group (ABLE-AG) to appeal to the policy makers to expedite the process of establishment of the single-window regulatory authority in biotechnology. They agreed that use of new technologies in agriculture was the only hope for farmers and was a solution to address the challenges of food security. They also emphasized on expeditious approvals of biotech crop trials and commercialization under the existing system, till the BRAI was

Favoring the introduction of the BRAI bill, former Environment minister, Mr Jairam Ramesh, who placed Bt Brinjal under moratorium during his tenure in February 2010, had on record said that the BRAI bill would be a huge step forward in maintaining the integrity of environmental assessment processes. â€œI believe that when the bill will be introduced, it will address the concerns that have been expressed by the civil society groups that it will open floodgates for all GM foods. It's just a exaggerated notion of non-reading of the bill,â€?st 2010.

Expressing objections to the proposed bill, Mr Kapil Mishra, sustainable agriculture campaigner of Greenpeace India, said, â€œThe sly and hasty manner in which the government is trying to table the bill in Parliament, without even putting the draft bill in the public domain for any discussion, is a commentary on the complete lack of transparency and accountability of our government.â€? He expressed shock at the sweeping powers being given to the proposed authority even to override the Right to Information Act 2005. â€œThe BRAI will take away the people's right to information on things as essential as biosafety assessment of GM crops,â€? he

Greenpeace has urged the members of Parliament not to approve any proposal on a regulatory framework for modern biotechnology and its applications/products that â€œoverlooks biosafety of citizens and the environmentâ€?. â€œInstead the government should table a legislation to protect and enhance biosafety and to ensure democratic processes are adhered to when dealing with issues as important as

Dr Raghuvansh Prasad Singh, former Union minister for Rural Development and a member of Parliament from Bihar, while stating his opposition to the BRAI bill in Lok Sabha, called it â€œa threat to food safety and a recipe for destruction of agriculture and rural

biotechnology, including agriculture, biopharma and environment. There are enough provisions for public feedback in the bill and also an appellate tribunal (law ministry) to take care of objections. Besides, it is inclusive of experts from agriculture, commerce and other fields. The empowered board is expected to have secretaries from all the ministries including, science, commerce, environment and others concerned. Administrative work will be overseen by an empowered chairman, with a stakeholder forum and state biotech committees present to give ideas. There will be separate bodies to deal with the issue of commercialization of the biotech products and the BRAI is expected to deal comprehensively and credibly with all the issues of biosafety.

According to critics, it is not a technology matter but a social issue that scientists often look down upon. Sources in the government told BioSpectrum that the new bill, with many amendments, maintains the integrity of the social issues and public consultation done in different cities last year to seek opinion of the members of the civil society.

The successful passage of the bill in Parliament can lead to the establishment of the highest biotech regulatory authority and subsequent streamlining of the prevalent chaos. The biotechnology industry and scientists are pinning their hopes on an early introduction of the bill in Parliament.

Rahul Koul in NewDelhi