

The long wait for NBRA

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With rapid growth in R&D efforts in biotechnology, a statutory and autonomous National Biotechnology Regulatory Authority (NBRA) is the need of the hour. The recommendations for the same had been made quite some time back but it remains to be seen how swiftly will it be formed.

The Task Force on Application of Biotechnology in Agriculture, under the chairmanship of Dr MS Swaminathan, submitted its report in June 2004. One of the most important recommendations of the Task Force was on the setting up of a National Biotechnology Regulatory Authority (NBRA) for promotion and regulation of application of biotechnology in agriculture. According to the report, the NBRA should be an apex body, which would put an end to the multiplicity of overseers. The Authority would have a common chair but two separate wings—one dealing with food and agricultural biotechnology and the other with medical and pharma biotech, the report said.

After the inter-ministerial consultations on the recommendations of the MS Swaminathan Task Force report, the Department of Agriculture and Cooperation had identified some areas for prioritized action and subsequently, the note for setting up the NBRA was mooted in the Cabinet by the Ministry of Agriculture. A meeting of the Committee of Secretaries (COS) was held in this regard in March this year.

Even the Indian President, Dr APJ Abdul Kalam, reiterated the present government's commitment to the setting up of the NBRA. Addressing a joint session of the Parliament in February this year, he said, "My government is in the process of

setting up of a National Biotechnology Regulatory Authority which will be the nodal authority for release, import and post-release monitoring of GM crops and seeds." Kalam noted that quality control is an important issue, and the National Biotechnology Regulatory Authority will boost and strengthen the GM seed testing laboratories.

Later in August, this year, while replying to a question on the status of NBRA, in the Lok Sabha, Kapil Sibal, Union Minister for Science and Technology, confirmed that the government will set up a National Bio-technology Regulatory Authority. Updating the members on the situation, he stated "The Ministry of Agriculture, Department of Agriculture & Cooperation had submitted a Note for the Cabinet for setting up of National Biotechnology Regulatory Authority (NBRA) and has resubmitted revised Note for the Cabinet after the proposal was considered by the Committee of Secretaries (COS). The Government department to serve as a nodal Ministry will be decided by the Union Cabinet. If the proposal is approved by the Cabinet, the Department of Agriculture and Cooperation would send the whole report to the identified Department for setting up of NBRA and taking follow up action." "Thus no specific time frame (for setting up the NBRA) can be committed at this moment," he replied when asked about the time by which it is likely to come into existence.

Making the case for NBRA stronger, the Department of Biotechnology has also made the recommendation for setting the Authority in the National Biotechnology Draft Strategy Report which is currently in the Cabinet for approval. According to Dr Bhan, "I believe that the NBRA proposal will be considered by the Cabinet in the near future."

Giving the rationale behind the NBRA, Prof MS Swaminathan said, "In order to facilitate the Second Green Revolution, the Government should do what I recommended more than two years ago in my report on agricultural biotechnology. First, we must have a credible mechanism accepted by the public, by the media, a transparent, credible mechanism of risk benefit analysis-the social cost and the social benefit. Here the social cost includes the environment and the health. Hence I had recommended, like our election commission, an autonomous biotechnology regulatory authority, which will be run professionally by leading professionals, that is, a member recommended as chairperson who will be common for two wings-medical and pharmaceutical biotechnology and agricultural and veterinary biotechnology. There could be two vice-chairs. The overall chairman should be a leading authority on biosafety, bioethics and should not be appointed on an ad hoc basis."

But unfortunately, the setting up of the NBRA has essentially become a turf war, as to who will control the Authority. "The idea of an autonomous body is that it should not be controlled," said Prof Swaminathan while expressing his disappointment at the enormous delay.

The setting up of an autonomous and professionally-led regulator is essential for deriving the full benefits from this fast-growing area of science and the need of the hour is that the government should quickly act on it.

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