

To

July 30, 2008

Dr Manmohan Singh,  
Prime Minister of India and Minister for Environment  
Government of India

Respected Sir,

**Sub: Drop the National Biotechnology Regulatory Authority proposals mooted by the DBT immediately**

A group of fifty farmer leaders and NGO representatives from fifteen states of India met on July 24<sup>th</sup> 2008 to debate and deliberate on the proposals put forward by the Department of Biotechnology to set up a National Biotechnology Regulatory Authority [NBRA], through a new legislation proposed called the National Biotechnology Regulation Bill, 2008. In addition, civil society groups created a debate on the NBRA proposals through other means, in other cities too. Through this letter, we would like to bring to your attention our objections and concerns, keeping the national interest in mind, with regard to the NBRA.

**Civil groups and Farmer leaders from Kerala were also part of these discussions and we have come to the following conclusions.**

We object to the very process of the formulation of this draft Bill by DBT and its so-called consultative processes [run in a few cities with very little time provided for comprehensive debate and discussion on the proposals and with no involvement of primary stakeholders]. Farmers' organizations and consumer organizations have not been involved and no bottom-up processes have been used to come up with these proposals.

**After going carefully through the proposals, we demand that the NBRA proposals be dropped immediately since the draft legislation has serious shortcomings and objectionable clauses.**

1. While the Swaminathan Task Force report which first mooted the idea of an NBRA stated: *"the bottomline for any biotechnology regulatory policy should be the safety of the environment, the well being of farming families, the ecological and economic sustainability of farming systems, the health and nutrition security of consumers, safeguarding of home and external trade and the biosecurity of the nation"*, these very cornerstone recommendations do not find a place in the draft proposals. The Preamble to the draft Bill is a give-away of the blatant pro-biotech leanings of the new proposals.
2. As you know, a recent United Nations report pointed out the lack of biosafety capabilities in India (like in many other countries) especially with regard to bio-terrorism with the use of biotechnology. In this context, it would be disastrous to go in for a single-window, fast-track clearance system in the form of NBRA, just to appease the biotech industry at the expense of the security, health and environment of the nation.
3. While one of the ostensible reasons for bringing in a separate legislation and for setting up the NBRA is to remove the existing conflict of interests in the current regulatory regime, the very fact that the NBRA would be set up under the Department of Biotechnology (which has the mandate of promoting modern biotechnology) would reinforce such a conflict of interest. This is

unacceptable and totally inconsistent with the spirit of such a legislation as spelled out by Dr M S Swaminathan in his task force report. Sadly, even Dr Swaminathan has turned a blind eye to what he had said in the task force report.

4. A single-window, fast-track clearance system proposed in the NBRA draft is not at all necessary and actually leaves much space for unscientific, undemocratic and corrupt functioning with very little checks and balances. In that sense, this is a Bill that has been created by the wrong people for the wrong reasons, with wrong perspectives with potential disastrous consequences.
5. The institutional mechanism of decision-making in the NBRA, with a 4-member committee consisting of scientists taking all decisions is undemocratic and authoritarian (Section 11(1)). It has been found time and again that even a broad-based and inter-ministerial body like the Genetic Engineering Approval Committee (GEAC) is unable to address all stakes and concerns during decision-making. Even though the NBRA proposals talk about various committees and offices to be set up, all of them have been given only an advisory role and the narrow 4-member 'Products Ruling Committee' clearly is not bound by the advice and recommendations of all these various units and committees.
6. The NBRA denies and violates the constitutional right of state governments over their agriculture. There is not only no role allowed for state governments in decision-making under the NBRA, there is a denial of their state level mechanisms and regulations over their agriculture pertaining to biotechnology. This is completely unconstitutional (Section 25, 33(2)).
7. As per the provisions of Section 31 the NBRA is allowed to amend the first schedule, and this defeats the very purpose of a separate legislation for regulation and takes away the power of the elected parliamentarians over this law
8. The over-riding effect of the NBRA on other existing regulations is a matter of serious concern. It tramples upon the Biological Diversity Act, for instance. (Section 29)
9. Similarly, Section 33 (4) specifies time frame of three years for appeals on the repealed act is unacceptable as problems can arise with earlier decisions, given the imprecise and unpredictable nature of transgenic technology.
10. It is very obvious that within the NBRA, risk assessment will be on narrow technical parameters and it is not clear how all the other cornerstones of regulation laid down by the Swaminathan Task Force report will be met.
11. The NBRA proposals do not contain any clauses related to conditional approvals, for a limited period, subject to review and revoking of approvals. It appears that an approval would be valid for all time to come, irrespective of other considerations!
12. There are no provisions in the NBRA for liability, redressal and remediation. As we know from past experience from across the world, even confined trials could involve losses and damages related to contamination and recalls which

will cost a lot in terms of redressal and remediation. NBRA makes no mention of making the GM developer liable for redressal and remediation.

13. Even the penalty clauses have been left to be evolved in the Rules. Section 16 related to penalties and offences, an offence is narrowly defined to include only offenders “who knowingly fail to comply” and leaves room for misuse.
14. Under Section (8), no wrongful decision of the NBRA can be invalidated and leaves room to justify almost anything.
15. The scope of the NBRA, for some inexplicable reason, does not cover storage, distribution and export of GMOs and products thereof. This leaves a vast area of regulation out of the scope.
16. The NBRA proposals don't talk about any mandatory prior informed public consent in its decision-making; this is a violation of the principle enshrined in the Cartagena Protocol. The NBRA proposes to make only decisions of the body public, but not the bases on which decision-making took place; it also does not talk about how public will be involved in decision-making. All of this will only reinforce the current non-credible, opaque functioning of regulators.
17. The NBRA seems to negate and discount the existing systems of seed assessment and regulation by having over-arching and over-riding decision-making authority.
18. The NBRA seeks to make amendments to the Food Safety & Standards Act with regard to clauses that govern GM foods' regulation. The proposal to alter the definition of GM foods under the FSSA is obviously a way to scuttle the labeling regime of GM foods and this is objectionable.
19. The Appellate Tribunal proposed to be set up under the NBRA is not acceptable in its constitution and is not broad based to include farmers' and consumers' representatives. Further, an appeal to be filed within 30 days is unreasonable - given that GM technology is unpredictable and any appeals mechanism cannot be time-bound with such technologies. Further, bar on judicial reviews on decisions taken by the Appellate Tribunal is objectionable (Section 20(2), (4), 26).

Given all the above unacceptable clauses and proposals in the NBRA, we demand that the NBRA proposals be dropped immediately. What we in fact need is utmost consideration to be given to protecting and conserving our biodiversity, environment and health, with due consideration also to ethical, social and cultural issues involved with the application of modern biotechnology. There is a dire need to go beyond narrow risk assessment. There is a need to uphold the rights of states and citizens to remain GM-Free.

We believe that what India needs is not the NBRA but a statutory framework with the mandate of protecting and conserving the environment and health, food and nutrition security, farmers' rights and livelihoods and ensuring social justice (from the application of modern biotechnology) and such a framework should be based on the Precautionary Principle.

It is important for the Government of India to note and learn that across the world, intense scientific processes like the IAASTD (International Assessment of Agricultural

Science & Technology for Development) are concluding that Genetically Modified crops and foods are not the way forward and that ecological agriculture is the way forward. Any proposal like the NBRA would therefore be unwise and incongruous and we urge you to intervene and get the current proposals dropped immediately.

Sincerely,

Sd/- as below.

- CC: 1. Minister for Health & Family Welfare  
 2. Minister for Agriculture  
 3. Secretary, Department of Biotechnology  
 4. Dr M S Swaminathan, Member of Parliament

Sd/-:

1.	Dr Thomas Varghese, Chairman, Kerala State Agriculture Prices Board, Thiruvananthapuram, Kerala
2.	Prof M K Prasad, Chairman and MD, Information Kerala Mission, Thiruvananthapuram, Kerala
3.	Dr A S K Nair, Scientist, Centre for Earth Science Studies, Aakulam, Thiruvananthapuram, Kerala
4.	Usha S & Sreedevi Lakshmi Kutty, THANAL, Trivandrum, Kerala
5.	Sridhar R, Kerala Paddy Protection Forum, Trivandrum, Kerala
6.	Adv Daisy Phillipose, Lawyer, High Court, Kochi, Kerala
7.	Satheesh Sathyavardhan, SAMVADA, Bangalore, Karnataka
8.	C R Neelakantan, Political Activist and Environmentalist, Ernakulam, Kerala
9.	Purushan Eloor, Periyar Malineekarana Virudha Samithi, Kochi, Kerala
10.	Robin C A, Chief Editor, Keraleeyam Monthly, Thrissur, Kerala
11.	Ms Eliyamma Vijayan, Director, SAKHI Womens Resource Centre, Thiruvananthapuram, Kerala
12.	Dr Santhi, Scientist and Environmentalist, Thiruvananthapuram, Kerala
13.	Ms Deepa Gopinath, Lecturer, College of Engineering, Thiruvananthapuram, Kerala
14.	S Guruvayoorappan, Wildlife Preservation Society of India - South Zone, Palakkad, Kerala
15.	Sri Ribhurajan, President, Santhi Yoga Satsangham, Thiruvananthapuram, Kerala

1 6.	Air Commd. S Radhakrishnan (Retd.), Consultant, Thiruvananthapuram, Kerala
1 7.	Brig. Oommen John Retd.), HRD Consultant, Thiruvananthapuram, Kerala
1 8.	Varghese Thoduparambil, Karshaka Munnettam, Muriyad, Thrissur, Kerala
1 9.	Dharmarajan, Jaiva Karshaka Samithi, Thrissur, Kerala
2 0.	Sreekumar P R, GREENS, Thiruvananthapuram, Kerala
2 1.	Rony Joseph, INFACT, Pala, Kottayam, Kerala
2 2.	S Chandrasekharan Nair, Kerala Farmers Internet Forum, Thiruvananthapuram, Kerala
2 3.	Adv Pournan, General Secretary and Jacob V Lazer, Treasurer, People's Union for Civil Liberties, Kerala
2 4.	Ms Nalini Naik, General Secretary, Self Employed Womens Association (SEWA-Kerala), Thiruvananthapuram, Kerala
2 5.	Saroop Roy, Equations, Thiruvananthapuram, Kerala
2 6.	T P Padhmanabhan, SEEK, Payannur, Kannur, Kerala
2 7.	Sudheer Neeleswaram, Kasaragod Prakrithi Samrakshana Samithi, Thaikadapuram, Kasaragod, Kerala
2 8.	Dr Sarada Money, Social Scientist, Thiruvananthapuram, Kerala
2 9.	T J Babychan, Organic Bazaar, Thiruvananthapuram, Kerala
3 0.	Chittatinkara Krishna Pillai Vaidhyar, Vaidhyakalanidhi, Thiruvananthapuram, Kerala
3 1.	Dr A Latha, River Research Centre, Thrissur, Kerala
3 2.	Dr A Bijukumar, Reader, University of Kerala, Thiruvananthapuram, Kerala
3 3.	Geo Jose, National Alliance for People's Movement, Kochi, Kerala

3 4.	Hariharan, Secretary, Kissan Jyothi Farmers Club, Vaduvanchal, Wyanad, Kerala
3 5.	K Gangadharan, President, Wyanad Paddy Collective, Wyanad, Kerala
3 6.	N Badushah, Wyanad Environmental Protection Council, Naiketti, Wyanad, Kerala
3 7.	Pandiode Prabhakara, National Farmers Protection Committee, Palakkad, Kerala
3 8.	John Master, Vasundhra Organic Farmers Club, Sulthan Battery, Wyanad, Kerala
3 9.	Pradeep, Harithasena, Kuttiadi, Kozhikode, Kerala

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