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To

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Sub: Draft: National Biotechnology Regulatory Bill, 2008

Ref: Regional Consultation Meeting on the proposed NBRA  
held on June 20, 2008 at Poribesh Bhavan, Salt Lake , Kolkata.

The Bill & NBRA are projected to “safeguard the health and safety of the people of India and to protect Environment by identifying potential risks posed by, or as a result of, modern Biotechnology.

However, the Bill, as it is presented, raises a number of pertinent questions. Some of these are given below.

- 1. Vide Chapter 1, Section 1:** There is no explicit definition of ‘safety’ ‘protection’ and ‘hazards’. The most important lacuna in the draft Bill is that there is no mention of the word “Biosafety” in the entire document, nor is there any mention of the well recorded hazards (e.g. transgenic cross-pollination, toxic effects on non-target organisms, allergenicity in humans, etc.) from transgenics that need to be checked.
- 2.** Furthermore, there is no mention of any biosafety testing methodology and preventive measures.
- 3.** The Draft seems to have been written on the gross assumption that open testing and cultivation of transgenics need not be controlled in the first place. This is strengthened by the **Second Schedule, para 1**, which suggests amendment of the Rules for the manufacture, use, import, export & storage of hazardous micro organisms, genetically engineered organisms or cells, 1989 under the EPA 1986. It escapes scientific reason as well as commonsensical explanation why “hazardous micro-organisms and genetically engineered organisms” should be *excluded* from a law that deals with biosafety of specifically these organisms.

**4. Vide Chapter II, Section 6(3):** The institution of an Inter-Ministerial Advisory Board, and the National Biotechnology Advisory Council is not justified if “they have no authority to intervene on product-specific decisions made by the NBRA.” This confers upon the NBRA an absolute power of decision making, immune from the public, including scientists and public representatives.

**5. Vide Chapter III, Section 9 (8):** It transpires that the NBRA may take some regulatory actions, and after that will convene Scientific Advisory Panels “on and as needed basis” to recommend on “issues that may result from regulatory actions [that have already been taken] that could impact on human and animal health and environment.” This provision further begs the question of the selection of the scientific “experts” who are to be hand-picked by NBRA, instead of by an independent authority. Finally, the NBRA wields the absolute power to disobey any recommendations from any Advisory body, perforce of Section 28.

**6. Vide Chapter IV, Section 11 (6):** The decision-making power of the Product Ruling Committee is vested on “reasonable grounds for believing” something, a ground that is vague and ludicrous in a regulation that is supposed to deal with serious scientific data.

**7. Vide Chapter X, Section 26, 27, 28:** The absolute autocratic power of NBRA is reinforced by such provisions: It is evident that even in case of any corruption / serious mistakes / false information being made / provided by the NBRA, no legal action can be taken by the Civil Society under the extant laws, thereby violating the Citizen’s Fundamental Rights as guaranteed under the constitution.

**8. Vide Chapter X, Section 29:** The absolute autocracy of NBRA is further reinforced by this illegal provision of having effect “notwithstanding any inconsistency therewith contained in any other law” etc. This is a singular offence to the existing legal framework and the constitution.

**9. Vide Chapter VI, Section 14:** It is stated that the selection of the laboratory will be exclusively be done by the Authority. In case of any question being raised on the result provided by the Government chosen laboratory, no power has been given to the civil society to take safeguard, thereby violating the very objective of the bill and purpose of setting up NBRA.

**10. Vide Second Schedule, para 1:** We fail to understand why this action is necessary and why both the legal provisions for safety should not be made inclusive for public safety

**11. Vide Second Schedule, para 2 (b) / Section 22(2):** It is absolutely irrational as to why the genetically engineered or modified food and food ingredients should be excluded from the definition? This must be included rather than excluded. Please refer in conjunction to our point 5 above.

**12. Vide Second Schedule, para 5:** The Seed Bill 2004, has been opposed widely by the Civil Society and is not in force. We fail to understand why a reference to the said

Bill has been made, when it has been refuted by the Civil Society and has not been approved in the Indian Parliament for the last **four years**.

**13. Vide Chapter III, Section 9 [3 (d)] and 9 [3 (n)]:** It is not clearly stated as to whose ‘safety’ is sought by such regulation – the product, or the public and the environment. Similarly, “ensuring that the level of protection adopted” does not clarify the object to be protected – the product, the manufacturer, the producer, the consumer, the general public or the environment. This combined with the vagueness mentioned in our point 3 above, indicates a sloppy attitude toward biosafety and a hurry to regularize the bio-hazardous products with absolute authority, at the cost of scientific reason and judgement.

**14.** We consider that the existence of GEAC and RCGM are more competent than a single clearance window like the NBRA. We suggest that biosafety of modern biotechnological products can be ensured by strengthening the existing regulatory bodies, in addition to the EPA rules, and by enhancing the transparency of regulatory procedures – not by replacing them with an autocratic single-window clearance authority like the NBRA.

We consider that, the proposed bill need to be scrapped and the setting up of the NBRA needs further critical examination by the Civil Society. We would like to urge upon the Government of India to provide at least six months more time to analyze the ramifications of the proposed Bill. It seems it has been drafted in a haste without concern for public health and biosafety.

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