

IN THE SUPREME COURT OF INDIA

WRIT PETITION (CIVIL) NO. 115 OF 2004

**In the matter of:**

Gene Campaign & Another                      ....                      Petitioners

Versus

Union of India & Others                      ...                      Respondents

APPLICATION FOR DIRECTIONS

TO  
THE HON'BLE CHIEF JUSTICE OF SUPREME COURT OF INDIA AND  
HIS HON'BLE COMPANION JUSTICES.

THE PETITIONERS MOST RESPECTFULLY SHEWETH: -

1. That the above Writ Petition was filed as early as 7th January, 2004 pointing out that the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells 1989 (hereinafter referred to as the Rules of 1989) do not address themselves to the protection of environment and public health which is a part of Article 21 of the Constitution and that the regulatory regime which exist in the outdated 1989 Rules do not incorporate the necessary environmental principles, namely, Precautionary Principle, Polluter Pays Principle, and Inter-generational Principle etc., which have been accepted by the International Conventions. The Petitioners in support of the Writ Petition had enclosed the international conventions including Bio-

safety Protocol which are binding as well as the regulatory regimes which exist in other countries.

2. That after notice was issued in the above Writ Petition, counter-affidavit as well as rejoinder and additional affidavits have been filed. The Writ Petition was directed to be listed for final hearing but the same could not be heard. There is enough material brought on record to show the potential health and environmental hazards of Genetically Modified (GM) crops, its social and economic implications, lacunae, inadequacies and changes required in the regulatory framework under the Rules of 1989 and the requirement of complying with the international obligations which are binding. Looking at the present regulatory regime, a moratorium is required to be imposed on any field trial till proper controlling and regulatory mechanism exist to check the potential health and environmental hazards of Genetically Modified Organisms (GMOs).
3. That the Petitioners have been seeking information under the Right to Information Act (RTI), 2005 about trials that have been conducted before they are approved for commercial cultivation. The Petitioners are enclosing in a tabular form information which were sought to which no reply whatsoever was given as **ANNEXURE –A**. The Petitioners had, therefore, filed an Appeal under RTI Act, 2005 which was replied to by the Department of Bio-technology, Government of India on 3rd February, 2006. The reply, inter-alia, reads as follows: -

"Under the guidelines of RCGM, the toxicity and allergenicity data being generated on transgenic crops that are yet to get the approval for commercial cultivation, is the intellectual

property of the applicant. It also has commercial value and the disclosure of information on the same is likely to adversely affect the competitive advantage of the applicant generating the data as it can be taken as publicly available information by competitors in the same field. Therefore, the information sought by you on crops other than the already released Bt. Cotton cannot be provided under Section 8(1)(d) of the RTI Act."

A true and correct copy of the reply dated 3.2.2006 under RTI Act, 2005 by Department of Biotechnology, Government of India is

**ANNEXURE – B.**

4. That the above reply saying that the data with regard to toxicity and allergenicity on transgenic crops that are yet to get the approval for commercial cultivation is the intellectual property of the applicant is absolutely untenable and makes a mockery of public health and environment which the Rules seek to protect.

The following steps are undertaken under the existing Rules before granting approval for commercial cultivation of GM Crops: -

- i) Laboratory tests and tests under controlled conditions on the genetically engineered plants of the particular variety, to determine inter alia, if any new elements have been created that could be toxic or create allergies. The data generated on the potential of the newly engineered plants to be toxic or allergenic is of prime importance as far as public health is concerned. If the genetically engineered plants show indications of toxicity or allergenicity, they must be abandoned and new plants engineered to try to get toxin

free and allergen free plants. If indications of toxicity or allergenicity persist in the plants subjected to genetic engineering, further trials cannot be permitted.

- ii) The data on toxicity and allergenicity in genetically engineered plants should necessarily be in the public domain.
- iii) However, the guidelines framed by RCGM, which are not in consonance with the Rules of 1989, are being quoted to withhold data which ought to be in public domain. If a plant persists in showing toxicity and allergenicity, applying the precautionary principle, all further trials should be stopped.
- iv) It is only after trials have been conducted under controlled conditions and data shown to be satisfactory, that large-scale trials and thereafter commercial cultivation approval can be granted. Once large-scale trials are permitted for genetically engineered plants that have not cleared the allergenicity and toxicity tests, such plants will enter the open field and can cause damage to the public health and environment. It has been widely reported that failure to contain field trials has resulted in trial crops like Bt Okra and Bt brinjal being sold in the open market.
- v) It is shocking that information that has a bearing on public health and safety can be kept confidential according to the current rules. This lack of transparency makes the regulatory regime extremely weak and completely inadequate to protect the public from grave health hazards. It is therefore imperative that data related to public health, like toxicity and

allergenicity is made publicly available in the early stages, before the GE plants go into field trials and large scale trials.

Equally, data must be generated and made available on the impact of GE plants on the rich biodiversity in Indian agriculture, the wild relatives of cultivated crops and the complex web of beneficial insects and birds that interact in our agricultural ecosystem to keep agriculture viable and sustainable. The responses obtained under the Right to Information Act reveal that a lot of critical information relating to environmental and health safety of GE plants has simply not been provided by the companies to the GEAC. Yet the GEAC is sanctioning field trials and large scale trials of insufficiently tested plants.

A stringent and transparent regulatory regime is urgently required to ensure that

### **PRAYER**

The Petitioners, therefore, pray that in the facts and circumstances of the case, this Hon'ble Court may be pleased to: -

1. Direct the concerned authorities to make public all data that is relevant to determining environment and health safety, including toxicity and allergenicity data, of a genetically engineered variety under trial.
2. Direct a moratorium on commercialization of GE varieties until a competent regulatory structure and rules are put in place since there is ample evidence of mismanagement and mishandling of field trials by the regulatory agencies.

3. pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

DRAFTED AND FILED BY

(ANITHA SHENOY)  
ADVOCATE FOR THE PETITIONERS

NEW DELHI

DATED : -10-2006