

GENE CAMPAIGN'S PUBLIC INTEREST LITIGATION IN THE SUPREME COURT OF INDIA WITH RESPECT TO THE GM REGULATORY REGIME

On 7th January 2004, Gene Campaign filed a Writ Petition in the form of a Public Interest Litigation (PIL) in the Supreme Court against the Government of India, seeking a moratorium on the commercial release of GM crops until an 'effective' oversight mechanism is put in place. The Supreme Court then issued a notice to the Government of India through the Ministries of Environment and Forests, Science & Technology and Agriculture on 29th March 2004.

This is a brief note illustrating:

- the reason for filing the PIL;
- approach and contents of the PIL;
- grounds raised in the PIL;
- remedies sought vide the PIL; and
- Status and update of the matter in the Hon'ble Supreme Court.

However, prior to going into the reasons for the PIL, an overview of the regulatory regime governing GMOs in India is most essential.

The Indian Regulatory Regime on Genetically Modified Organisms (GMOs)

The present Indian GM regulatory regime consists of the following legal documents:

- i. Environmental Protection Act, 1986 (Parent legislation)
- ii. Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms and Genetically Engineered Organisms or Cells, 1989 (Secondary legislation). These Rules were issued by the Ministry of Environment and Forests (MoEF) "with a view to protecting the environment, nature and health, in connection with the application of genetechnology and micro-organisms".
- iii. Recombinant Safety Guidelines, 1990 issued by the Department of Biotechnology (DBT), in pursuance of the Rules of 1989.
- iv. Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and
- v. Allergenicity, Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998 by the DBT.

Under the current regulatory regime, the following decision- making structures have been created:

- i. **Recombinant DNA Advisory Committee**, based in the DBT. It reviews developments in biotechnology at national and

international levels and recommends suitable and appropriate safety regulations in India in recombinant research, their use and applications.

- ii. **Review Committee on Genetic Manipulation (RCGM)**- Constituted by and based in the DBT, it **monitors** safety- related aspects of ongoing research projects and activities involving GMOs and brings out guidelines specifying procedures and processes for such activities.
- iii. **Institutional Biosafety Committee (IBSC)**, constituted by the institution conducting research involving GMOs. Required to prepare an up-to-date on-site emergency plan according to the manuals/ guidelines of the RCGM and make available copies to the District Level Committee/ State Biotechnology Co- ordination Committee and the Genetic Engineering Approval Committee.
- iv. **Genetic Engineering Approval Committee (GEAC)** constituted and based in the Ministry of Environment and Forests. It is responsible for '**approval**' of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.
- v. **State Biotechnology Co- ordination Committee (SBCC)** located at the state level constituted by respective state governments. Acts as nodal agency at State level to assess damages, with powers to inspect, investigate and take punitive action in case of violations.
- vi. **District Level Committees (DLC)** constituted in the district where biotechnology projects function. It monitors safety regulations in installations and compliance with guidelines and reports violations to the SBCC or the GEAC.
- vii. **Monitoring and Evaluation Committee (MEC)**, required to undertake field visits at experiment sites, suggest remedial measures to adjust original trial design, assist RCGM in collecting and analyzing field data etc.

Why this PIL?

Biotechnology is being promoted in India as the next revolution for bringing food security and economic growth. Agriculture is one of the major sectors where biotechnology, particularly GM crops, is being promoted. However, this is being done in an *ad hoc* manner and without the adequate precautions or regulations prescribed by international practice and convention. There is neither a clear-cut policy nor an effective oversight mechanism.

The Rules of 1989 governing GMOs have considerable lacunae and are confused and ambiguous. That apart, the concurrent guidelines issued by the DBT (particularly the 1998 guidelines) are in apparent violation of these statutory Rules. The Revised Guidelines for Research in Transgenic Plants, 1998 has given the RCGM the power to authorize or grant approval to applicants to conduct limited field trials in multi- locations

in the country. This is an encroachment on the territory of the GEAC: the GEAC has been given the sole mandate by the Rules to grant approval.

Rule 12 of the 1989 Rules provides that GEAC is to determine certain guidelines to be followed by the applicant to submit information and make examinations, including examinations according to specific directions and at specific laboratories. However, the GEAC is yet to disclose the guidelines followed by it while granting approvals.

With agriculture being a subject on the State List, SBCCs and DLCs could constitutionally speaking, intervene decisively in the processes leading to field trials and commercialization of GM crops. However, till date, SBCCs have been constituted in only three states- Andhra Pradesh, Himachal Pradesh and Karnataka. No DLCs have yet been constituted under the said Rules.

Many failings in the Rules themselves as well as in their implementation, the lack of technical competence and bureaucratic nature of the regulatory agencies have been a matter of concern for civil society organizations. For a long time, Gene Campaign has been voicing concern over the arbitrariness in the application of biotechnology in food and agriculture; inadequate regulatory mechanism to control the potential environmental and health hazards due to genetically modified organisms (GMOs); lack of attention to the socio-economic and ethical aspects of the application of GM technology in food and agriculture; and lack of transparency and public participation in the decision-making process.

Unfortunately the Indian government has chosen to promote this technology without adequately responding to public concern, by showing no sensitivity to the issues raised by Gene Campaign. Gene Campaign wrote several letters to the relevant agencies, including the Genetic Engineering Approval Committee (GEAC; the key regulating body) and the Department of Biotechnology (DBT; the key body promoting biotechnology). Those letters contained suggestions for the improvement of the existing GM regulations and/or seeking field-trial data on which decisions were taken with respect to Bt cotton (India's first and so far the only approved GM crop) and GM mustard. None of the letters or phone calls was acknowledged. This was a clear infringement of the people's right to know and to participate in a matter that has considerable implications for their life and welfare.

On November 26-27, 2003, Gene Campaign organised a multi-stakeholder consultation at New Delhi in the form of a National Symposium titled "Relevance of GM Technology to Indian Agriculture and Food Security." The Symposium brought on board a wide range of views. There were participants and speakers, representing the GEAC (Genetic Engineering Approval Committee), several ministries and research councils, agricultural universities, R& D institutions, social science and policy research institutions, CSOs (farmers, consumers and environmental organizations), private sector, seed companies, Indian subsidiaries of agro-chemical TNCs and the media. Twenty key recommendations emerged from this multi-stakeholder symposium, which clearly stated that **the Indian oversight mechanism needs amendment** and that India needs a distinct National

Biotechnology Policy. These recommendations, *inter alia*, were sent to the DBT for consideration. The DBT sent a response rebutting every single recommendation. According to the DBT there is no need for a separate Biotechnology Policy and the existing regulatory regime is good enough to meet biosafety requirements.

Faced with the continuing stonewalling from government departments and seeing no possibility of dialogue, Gene Campaign decided to approach the Judiciary for relief. It filed a PIL in the Supreme Court of India on 7th January 2004.

What approach does the PIL adopt and what does it contain?

Constitutionality

The PIL challenges the constitutionality of the Rules of 1989 framed under the Environment (Protection) Act, 1986. It has been alleged that the Rules are not in consonance with the principles evolved under Article 21 (Right to Life) of the Constitution read with the Directive Principles. Various judgments by the Supreme Court have not only kept environment and human health as a part of Article 21 of the Constitution, they have also made essential principles like precautionary principle, sustainable development, polluter pays principle and intergenerational equity doctrine a part of Articles 14 (Right to Equality) and 21 of the Constitution. In the past the Court has also held that “the Right to Information and Community Participation necessary for the Protection of Environment and Human Health is an inalienable part of Article 21 and is governed by the accepted environment principles. The Government and the authorities have to motivate the public participation by formulating the necessary programmes”.

It has also been alleged that the Rules have not been brought into consonance with the International Conventions (Convention on Biological Diversity, Cartagena Protocol, etc.) when these conventions, signed/ratified by the Indian Government, can, according to the Supreme Court’s judgements, be read with the Constitutional Provisions.

Lacunae in the present regulatory regime

The PIL points out lacunae in the Rules of 1989 and the bodies set up under it, which includes GEAC. The important lacunae that have been highlighted in the PIL include:

- The Rules do not provide for qualifications/expertise required by the members of various agencies (such as GEAC). At present people who lack technical competence and the skills to perform important tasks pertaining to biosafety assessment man such agencies.
- The Rules do not provide for any protocols and/or expertise actually available to evaluate socio-economic impact of GM crops and products derived from GM technology.
- The majority of the members of the regulatory agencies, such as GEAC, are civil servants in their *ex officio* capacity, who do not have the technical competence and skill to discharge their duties.
- The GEAC, the key decision-making body, has an extremely narrow and inadequate focus in its membership. There is no broad-based scientific

competence. There are no soil scientists, entomologists, agronomists, toxicologists, allergy experts, social scientists or legal experts.

- The field agencies (State Biotechnology Coordination Committees and District Level Committees), which are endowed with supervisory and monitoring responsibilities, are either not in place or are dysfunctional.
- There is lack of transparency in the GM regulatory regime. There is no window for either public access to information or for public participation in the decision making process.
- There is no accountability or liability on the part of regulatory agencies and/or occupiers.
- There are no effective penal provisions for cases of violation of the Rules.

GM technology and the Indian scenario

It has been pointed out in the PIL that GM technology was developed in developed countries that have industrial economies, and where agriculture is highly mechanised and is done in vast monoculture tracts that are largely isolated from natural ecosystems. In addition, these countries are not rich in bio-diversity and are not centres of origin/diversity for major food crops. Therefore they are not as vulnerable to “genetic contamination” as are countries like India. Yet the regulatory system in most of these countries is far more rigorous and they are cautious about interphase between technology and the environment.

Most developing countries, including India, have an agrarian economy with a very rich natural and agro bio-diversity. Unlike in the developed world, in countries like India, farmers are often poor and agriculture is practiced on small land holdings. These are closely packed together and in proximity to natural ecosystems. A GM crop cultivated in one field is likely to affect neighbouring fields and natural ecosystems. Furthermore, developing countries like India are the centres of origin/diversity of important crops that form the basis of global food security. Therefore the biological environment is quite different in developing countries like India as compared to that of many developed countries with industrial economies.

India, being a centre of origin and diversity of major food crops (for instance rice), has to be extremely vigilant and show utmost caution in dealing with this new technology which is still in its early stages of evolution. Transgenic varieties of the crops for which India is a centre of origin/diversity should not be released for commercial cultivation until a sufficient body of scientific data is collected on gene flow and its impact on the gene pools of those crops. India needs a regulatory body having technical competence and demonstrable capacity to understand various aspects of GM technology and agrobiodiversity.

Systems should be put in place for studying long-term impact of the flow of foreign genes on natural and agri-ecosystems. This aspect may not be of much relevance in countries where agro-bio-diversity is minimal and where agriculture is practiced in large monocultural tracts with large land holdings, such as the US. The situation in India, however, is greatly different. Farms are small and closely packed together and agriculture

is practiced in close proximity to natural bio-diversity, often bordering forest areas or even within forest areas, where natural gene pools are found. In the absence of such precautionary measures, India will be putting its natural and agro-bio-diversity at a great risk, which has consequent implications not just for the livelihood of Indian farmers but also for national and global food security.

It is accepted that rice needs special attention, as it is a major staple food throughout the world (rice constitutes the staple food of two-thirds of the global population) and India is a major centre of origin/diversity of rice. Marshes, ditches and natural vegetation where wild relatives of rice are found typically surround rice fields in India. These wild relatives are known to cross-pollinate with cultivated varieties. Gene transfer between wild and cultivated species does happen. Therefore it is bound to happen between GM varieties and wild relatives, consequently contaminating the wild rice germplasm and hence potentially threatening the future of rice as a crop. It is, therefore, imperative that longterm studies are conducted to study the impact of the introduction of foreign genes, such as the Bt construct, into rice gene pools. Until sufficient data is collected from such studies, and the impact of introgression of foreign genes is well understood, it would be reckless to release transgenic rice into the Indian agricultural environment.

Despite this enormous potential danger, the regulatory agencies have approved research on GM rice. India does not have a policy for GM crops that could provide policy guidance to the regulatory agencies in decision-making. To arrive at our own GM policy and a regulatory design suited to our own ecological and socio-economic realities, a body constituted by experts in the field and the representatives of stakeholders should be set up. This body, after holding a series of consultations with members of *Panchayats* (local governments), farming communities and other stakeholders, should come out with a comprehensive GM policy. A panel of experts should then draft a suitable regulatory design suited to Indian ground realities, after incorporating the suggestions and comments of the multistakeholder consultation process. Till then there should be a moratorium on commercial release of GM crops.

Potential risks of GM Crops

The PIL discusses potential environmental and human health hazards as well as socioeconomic risks.

The environmental risks that have been discussed are:

- Contamination of the natural gene pool of crops for which India is a centre of origin and diversity;
- Contamination of non-GM crops and their wild relatives, and farmers' varieties;
- Proliferation of weeds and creation of new weeds due to flow of foreign genes from GM crops to non-GM crops and their wild relatives;
- Destruction of soil microorganisms due to release of toxins from genes, like Bt gene, leading to adverse impact on crop productivity;
- Destruction of microbial diversity.

Potential health risks have been discussed in the PIL through three real cases, viz.:

- The Brazil Nut case (how allergens can be transferred from one crop to another with potentially lethal consequences to sensitive people).
- The Starlink case (Starlink corn having a gene that produces proteins with allergenic properties was approved only as animal feed, but it contaminated the corn meant for human use)
- The Tryptophan case (Many people died of Eosinophilia Myalgia Syndrome (EMS) in the US in late 1980s after intake of GM tryptophan, which is a food supplement)

The socio-economic risks that have been discussed in the PIL broadly relate to intellectual property rights in the agriculture biotechnology sector and its impact on the livelihood of small and marginal farmers. Increasing control over seed supply by a few private companies can be dangerous for the Indian farming community and national food security. The petition also highlights that it is almost impossible in the present Indian condition to segregate GM crops from non-GM crops and that mixing is inevitable. This would mean infringement of the right of the consumer to choose not to eat GM food and the rights of the farmers to grow non-GM crops.

International developments on GM regulation

The PIL gives the details of international instruments and GM regulatory regimes in various countries in order to demonstrate how the Indian regime is lagging behind international developments. The international instruments that have been discussed are:

- Cartagena Protocol on Biosafety
- Agenda 21, Chapter 16
- Convention on Biological Diversity
- UNEP Technical Guidelines on Biosafety
- UNIDO Code of Conduct for the Release of Organisms into the Environment
- International Treaty on Plant Genetic Resources
- Draft FAO Code of Conduct on Plant Biotechnology
- Codex Draft Principles for the Risk Analysis of Food Derived from Modern Biotechnology
- Convention on Access to Information, Public Participation in Decision Making and
- Access to Justice in Environmental Matters (Aarhus Convention)

Some aspects of the GM regulatory regime of the following countries/regions have also been discussed:

- European Union/United Kingdom
- Australia
- New Zealand
- South Africa
- Indonesia
- the Philippines
- Thailand

What are the grounds raised in the PIL?

The major grounds raised in the PIL are:

- The Rules of 1989 are arbitrary and unconstitutional, and violates the Fundamental Rights of people granted under Articles 14, 19 and 21 of the Constitution of India. Various environmental principles that have been held to be part of Article 21 by the Supreme Court have not been incorporated in the Rules of 1989.
- The regulatory agencies set up under the Rules of 1989 lack technical competence, transparency, and public participation. They are not competent to deal with the potential environmental, health and socio-economic risks posed by GMOs in India.
- The Rules do not incorporate the principles and provisions given under various international instruments, like the Biosafety Protocol, Convention on Biological Diversity etc., which India has signed/ratified.
- Many countries, including developing countries, are setting up new regimes or revising the existing ones in light of new scientific evidence and latest international developments. India must do the same.

What are the remedies that have been sought through the PIL?

The following remedies have been sought from the Court through the PIL:

- The Rules of 1989 are to be brought in consonance with various provisions of the Constitution, especially Article 21 (Right to Life) that includes Right to Environment and Human Health. If the respondents (Union of India) fail to do so, then the Rules of 1989 should be declared unconstitutional.
- The Government should set up a High Powered Committee to formulate a National Policy on GMOs through a multi-stakeholder consultation process.
- The Government must observe a moratorium on various permissions/approvals/trials concerning GMOs, especially those of a commercial nature, particularly those crops for which India is a Centre of Origin/Diversity, till the Rules are amended and a sound Regulatory and Monitoring System is put in place.

Status and Update of the Matter in the Hon'ble Supreme Court.

After notice was issued in the above petition, counter- affidavit as well as rejoinder and additional affidavits have been filed. Enough material was brought on record to show the potential health and environmental hazards of 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.

The Petitioner- Gene Campaign had also been seeking information under the Right to Information Act, 2005 about trials that have been conducted before they are approved for

commercial cultivation, which was not replied to by the Department of Biotechnology. Information sought about toxicity and allergenicity were also not replied to and when petitioner filed an appeal under the RTI Act, the Department of Biotechnology replied that 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. This reply is absolutely untenable and makes a mockery of public health and environment.

Gene Campaign then made an application for directions to the Hon'ble Supreme Court on October 9, 2006 making the following prayers:

- (i) 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 plant variety under trial.
- (ii) Direct a moratorium on commercialization of genetically engineered varieties until a competent regulatory structure and rules are put in place.
- (iii) Pass such other and further orders as the Hon'ble Court may deem fit and proper.

In the Court order dated May 8, 2007, the Hon'ble Supreme Court directed the GEAC to take sufficient precautions to see that trials are not causing any contamination to the cultivation of neighboring fields. There should be at least 200 meters distance from the trial fields from the neighboring field having same type of cultivations. All the trials which are being conducted, the name of the scientist and other details who will be responsible for all aspects of the trials should be reported to GEAC and there should be regular supervision by them. Prior to bringing out the GM material from the green house for conduct of open field trials, the approved institution should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

Gene Campaign had also make submissions to the Hon'ble Supreme Court to constitute a High Powered Committee consisting of experts in the fields of biotechnology, plant breeding, plant physiology, law and environment to give detailed recommendations on some specified terms of reference.

On February 13, 2008, the three Judge Bench of the Apex Court comprising Chief Justice K.G. Balakrishnan, Justice R.V. Raveendran and Justice J.M. Panchal directed the government to include two independent scientists Prof. M.S. Swaminathan and Dr. P.M. Bhargava as "special invitees" at the time of considering the applications. Also, as suggested by Gene Campaign's counsel, the Bench ordered that guidelines followed by the GEAC while granting permissions should be disclosed.