GENE CAMPAIGN'S ADVOCACY ACTIONS ON GMOS

Need for Advocacy on GMOs: India's need to consider the effects of GM crops arises inter alia from its interests in the international market for products like GM free soybean and traditional Basmati rice which are major exports. India's trade concerns need to be placed in the context of the international trade dynamics, determined by overlapping and conflicting regulatory principles as embodied in the two multilateral paradigms- the World Trade Organisation (WTO) and the Cartagena Protocol on Biosafety (CBD).For countries to protect domestic trade interests, it is necessary to achieve clarity on the specifics of international trade in GE agricultural produce and GE foods within the WTO framework and in bilateral trade agreements. In addition, it is necessary to develop a policy structure that would regulate trade in GE products in a way that public interest related to environmental and health security as well as access to safe and adequate food is ensured. A key step in this direction would be the development of a regime for Liability and Redress both for cultivation and import of GM crops and foods.

Gene Campaign's advocacy strategies include a range of options, all or some of which may be used depending on the requirement. Successful approaches made by GC range from grassroots to policy making like research and analysis, stakeholder consultation, policy recommendations, spreading awareness through simple literature, education and capacity building, active participation in related events nationally and internationally, organization of workshops etc.

Advocacy at the COP-MOP- Bonn, 12-16 May 2008

Gene Campaign wished to use the platform afforded by the Fourth Meeting of the Parties to the Biosafety Protocol (COP-MOP 4), to highlight the right of developing countries to regulate the trade in GM crops and foods in a manner that does not go against their efforts to achieve food and nutritional security for their people. The Biosafety Protocol affords accredited agencies the opportunity to play a role in the global negotiations on biosafety and the transboundary trade of GMOs, and to help influence the outcome in favor of developing countries. GC has been creating awareness about need for biosafety and has been pressing for a strong liability and redress regime for GMOs and continued to do so after.

Pre COP-MOP 4 activities of GC include participation in a Consultation on Liability and Redress organized by the Ministry of Environment and Forests, Government of India on January 14, 2008 at New Delhi and made submissions for incorporating such components in a national liability and redress regime, which addresses India's needs and those of its people,organization of a public debate and multi- stakeholder consultationto develop civil society positions on liability and redress and put pressure on government to raise these issues at COP-MOP 4. A position paper on Liability and Redress was prepared ahead of COP-MOP 4. Post COP-MOP, the paper was further worked upon and updated to incorporate the negotiations and deliberations at this meeting.The position paper was shared electronically with all the delegates through COP-MOP 4's Virtual Display table (http://www.cbd.int/mop4/display/), and was also uploaded onto the discussion forum of the workshop "Key Issues of the Official Biosafety Negotiations this Week- NGO Strategies and Input", organized by Ecoropa, Globelaw, Washington Biotechnology Action Council and Greenpeace on May 13, 2008.

GC's side events at COP-MOP 4 include Panel Discussion on "Legal Action to Improve Biosafety in India", This discussion revolved around efforts of civil society actors in India to effect policy changes on biosafety, by engaging with the judiciary. We shared our experiences in filing public interest litigations in the Supreme Court of India to bring about a better regulatory system in India. Another activity included a discussion on liability and redress for GM crops attended by civil society organizations both from India and abroad, the discussion was especially pertinent at a time when the official Contact Group on Liability and Redress was deliberating on a legally binding international regime for liability, which a number of developed nations were trying to block.Endorsed by Anthra (India), Centre for Interdisciplinary Studies (India) and TWN, Malaysia, GC made recommendations which were submitted to the Secretariat to feed the official negotiation process as inputs from civil society. Recommendations made broadly encompassed the adoption of strict and absolute liabilities in cases were 'damages' (to be used very broadly) occurred and the right of CSO's acting in the public interest should have the right to bring a claim for damages on behalf of those directly or indirectly affected. It should also consider that the time period for the affects could be generations. Gene Campaign had also organized a special screening of its documentary film on "Adoption of Bt Cotton in Vidarbha" for the MOP participants. This Gene Campaign film depicts the process of adoption of Bt Cotton in the Vidarbha region of Maharashtra (India) and looks into the major players responsible. It has also tried to capture the socio-economic consequences as well as impact on health and environment, as observed in the field.

Immediately after the COP-MOP 4, Gene Campaign had organized a press conference in New Delhi to brief the media about the developments at the COP-MOP 4 and the role of the Indian government in the negotiations. Gene Campaign also brought to notice the fact that the Indian government had submitted false data in their report on the government's implementation of the Biosafety Protocolwith the Government attempting to show that India has fully complied with the requirements of the Protocol. The actual position, however, is that India has not attempted in any manner to give effect to some of the key obligations under the Protocol, namely incorporating provisions in the domestic regime on liability and redress, ensuring adequate public participation in decision-making on GMOs, incorporating socio-economic concerns especially trade concerns, risk assessment based on the precautionary principle, special provisions for protecting centers of origin of crops etc.

The WTO Ruling on the EU-US Trade Dispute on GM Crops

In 2003, the United States, Argentina and Canada launched a complaint against the European Union at the WTO challenging the European Union's informal moratorium on GMOs, delays in processing applications for GMO approvals and the bans introduced by some of the member states on the import and sale of GMOs.The Panel found that the EU did have a general de facto moratorium on the approval of biotech products. It held that the de facto moratorium, approval delays and the national bans fell within the scope of the WTO's Sanitary and Phytosanitary (SPS) Agreement. The Panel concluded that there had been "undue delay" for both national bans and the moratorium, a delay that cannot be justified. It found that the national bans were not based on scientific risk assessments, despite there

being sufficient scientific evidence to carry risk assessment. Contrary to claims of the US of that flexibility of countries regarding GMO's is nullified due to EU losing: countries still possess flexibility to impose moratoria on GMOs if it can be justifiable under WTO parameters. It also did not question the right for EU member states to ban individual GMOs or allow 'substantial equivalence' of GMO's to their conventional counterparts.

The WTO Ruling is binding only to the Parties to the dispute. It can be interpreted as not affecting the right of developing countries to choose the level of protection they deem fit. This is especially important because most developing countries are rich in biodiversity, including agro- biodiversity and are also centre of origin for most crops. Also, there could be many genuine reasons that could justifiably cause delay in GM approval procedures in developing countries, which cannot be said to be violative of WTO rules, particularly the SPS Agreement.

Analysis of WTO ruling on US-EU GM Trade Dispute and Implication for Developing Countries

The ruling of WTO Panel is binding to the parties if the dispute and not to other nations and although these rulings may possess weightage on subsequent decisions, they are not binding.The Panel did not rule whether GM Products are safe or not and that whether the biotech products are "like" their conventional counterparts, which could have bearing on "labeling" of GMOs. The Panel neither reviewed the WTO-consistency of the EC approval procedures for GM products nor did it ruled on the right of the Members to regulate GM products. That means the WTO Members remains free to consider possible risks of GM products before giving it approval. The right of the members in this regard remains unhindered. The flexibilities available in the WTO agreements for this purpose remain intact.

There were three types of EC measures that were challenged by the complainants before the Panel, alleging inconsistency with the WTO Rules, namely,

1. General EC moratorium on approval of biotech products
2. Various product-specific EC measures related to the approval of biotech products
3. Various EC Members' safeguard measures prohibiting the import and/or marketing of specific biotech products

The panel found that the de facto general moratorium on GMO approvals lead to "undue delay" in approval of certain GM product and hence the EC is in breach of Annex C(1)(a), and consequently it has violated Article 8 of the Agreement.As far as the third category of the challenged EC measures were concerned, the panel found that the national bans as "safeguards measures" were SPS measures within the meaning of Annex A(1) and Article 1 of the Agreement. As it was a SPS measure, the panel looked into whether it was based on risk assessment under Article 5.1 and hence stands the test of Article 2.2 of the SPS Agreement (See Box2 for the text). The Panel found that the bans were not based on risk assessment and hence violated Article 5.1 and Article 2.2 of the Agreement.

The most worrying part of the Panel report is the treatment given to CBD and BSP at the WTO forum. There seems to be some ambiguity also, which the developing countries should endeavor to get

clarified. The Vienna Convention would need to be examined in light of it providing any help for "harmonious construction" for multilateral trade agreements and environmental agreements. The growing jurisprudential imbalance between trade & environment at the international level need also to be addressed should the international community want to aspire for the objective of sustainable development. While a significant energy of the social sector is wasted in adopting the evidence-generation mode, the trade & economic policy is being steered on certain assumptions for which there may not be any evidence.

The Draft National Biotechnology Regulatory Bill, 2008- Recommendations for improvement

Gene Campaign recommends that India needs to have a distinct law in place to oversee genetic manipulation and its implementation, which must harmonize with other laws and national and international agreements.The Bill must provide for the setting up of a statutory National Bioethics Commission.

It must provide for a consultative and participatory process to prioritize crops and traits for genetic improvement through biotechnology with the goal of addressing the needs of small farmers and Indian agriculture.Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood and examples of Mexico, Peru and China should be followed and their clear cut policy of no GM interference with their key exports. The NBRA must take a clear position forbidding the use of the Herbicide Tolerance trait. There should be provision for a mandatory cost and benefit analysis before deciding on a GM product and also safety standards. The law must have sections providing for post- market surveillance and monitoring of GM products and have provision on how to deal with bio terrorism. There should be a moratorium on commercial cultivation of GM crops until the regulatory system is demonstrably improved. Research on GM crops, however, should continue. The draft bill should incorporate a provision, whereby producing edible vaccines or vaccines in fruits like tomatoes and melons is actively discouraged. The composition and qualifications of members of NBRA need to be precisely defined.Gene Campaign recommends that this Authority should be staffed by people skilled in Bio safety Assessment, Environmental Assessment and Environmental Impact Assessment. A person of the highest technical competence and integrity who has experience in the regulation of GM crops should head the body. It should also incorporate a multi-disciplinary team on council.

The fact that there is practically no scope for public participation and consultation under this newly drafted Bill is contradictory to India's position at the Biosafety Protocol negotiations.Gene Campaign submits that the regulatory process should be transparent, accountable and technically competent.A risk benefit analysis should be conducted in public after the safety data are in and before any approvals are given. Clear-cut channels should be created for the public to participate in the decision-making and to voice concerns. Gene Campaign suggests that the government should organize a series of public debates across the country to elicit the views of the people, to channel it into policy-making.

The term "Risk Assessment" is not defined originally by the state but follows the definition used by US and hence needs to be re-addressed. The key to the efficacy of any risk assessment process is the nature of questions asked. Well-framed questions will yield exhaustive and pertinent data on which correct

decisions can be taken.The legislation should contain elaborate questionnaires, arrived through this process, that are required for an applicant to answer.

NBRA also needs to include socio-economic factors in its bio-safety protocol as required by the Biosafety Protocol. Moreover, under section 2, socio- economic considerations should be defined to include "the direct or indirect effects to the economy, trade, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, release, contained use or placing on the market of GEOs or products thereof.

OVERVIEW OF ADVOCACY ON BIOSAFETY AND GM TRADE ISSUES

The main concerns of a developing country like India, with respect to GMOs arises from the fact that while very few developing countries export GMOs, many are exporters of conventional agricultural products. By adopting GM technology, such countries may suffer losses in terms of their trade with countries and markets, which are opposed to GM technology

Products like soybean and basmati rice that are GM free have become huge earners for India and losing the GM free status will lead to loss of market. Dr. Suman Sahai of Gene Campaign has pointed out that under these circumstances, resolutely remaining a non- GM producer of soybean best serves the interest of Indian farmers. If India turned to GM crops it could not only lose market but will also be unable to compete with countries like US who are mass producers of cheap soy; even the basmati rice would lose its patents acquired of geographic indications.

Role of CSO's: The Indian state is exhibiting frequent and ever increasing engagement with the non-state, independent actors. Participation of NGOs and the public is vital owing to the need to tailor national approaches to regulation to address the specific circumstances of individual countries or regions. The impacts and risks associated with GMOs are likely to be specific to different local and regional situations, which only NGOs with their local level constituencies can address.The role played by Indian CSOs in the context of the GM trade debate and in highlighting the trade concerns of India in advocacy and policy- making may be studied from a national and international perspective.

Gene Campaign and other advocacy groups have led a sustained campaign for transparency, full disclosure, serious monitoring and inclusion through a number of activities such as research and dissemination of information, advocacy at policy level (questions in parliament, engaging parliamentarians, through membership of different Committees etc.), awareness generation, public debates, legal challenges, activist action, capacity building (local, national and regional levels) and networking with like- minded NGOs. CSOs must play a role in advocacy and policy making with respect to adoption of GM technology and its fallout on trade.

Liability and Redress for GM Crops: A Developing Country Perspective a Position Paper for Discussion

Gene Campaign, which has been working on developing components of a liability law for India, had organized a panel discussion on developing components for a liability regime, on the sides of COP-MOP 4, in which civil society groups from India, and other Asian countries had participated. Some key

consensus recommendations had emerged from the discussions which have been submitted to the Secretariat of the Meeting of Parties as inputs from civil society.

Gene Campaign believes that a legally binding liability regime is required to address the issues raised by cell technology that intervene in cell architecture, genetic composition and balance and that can create radical new proteins and compounds with unpredictable, possibly harmful effects on life forms.Considering the fact that introduction of GMOs into the environment raises novel issues, Gene Campaign advocates the adoption of a liability regime which can cover the specificities of modern biotechnology, while borrowing from already existing liability regimes for damage to the environment etc. Also, international rules and procedures need to be complemented by a domestic liability regime which is context- specific; taking into account the ground realities present in a country like India.

Gene Campaign takes the position that liability and redress should be channeled to the same agency that is responsible for causing the damage. While the primary liability would be that of the Biotech Corporation or industry directly responsible for the introduction of the GMO into the environment, the regulatory agency or the government granting permission for the same cannot escape from the liability net. The Government and its authorized agencies owe a duty of care to take adequate preventive measures before allowing any activity likely to cause harm to the environment, and thus, cannot evade liability.

With regard to functional scope, 'damage' should be given the broadest possible interpretation, including damage resulting from the transport, transit, handling and/or use of LMOs and products resulting from transboundary movements of LMOs and products, including unintentional and illegal transboundary movements and in the case of preventive measures, damage threatened to be so caused. With regard to geographical scope, it should extend to damage in Parties, non- Parties and areas beyond national jurisdiction.Further, the definition of damage needs to determine whether plaintiffs must wait for actual damage to become visible or whether an evidence of gene introgression is sufficient.

The channeling of liability should hold all the people and organization in the chain jointly and severely liable: this include all agencies from developer to the operator.

In the Indian agricultural setting, there is a high likelihood of contamination of non- GM crops by GM crops, which put the Indian farmer in a very vulnerable position. Here, individual plots of agricultural land are not separated by fence, but are simply demarcated with the help of heaped ploughed soil. Thus, Gene Campaign advocates the introduction of specific legal provisions and rights to farmers, which would protect them against innocent infringement. Also, the international regime must set minimum standards to deal squarely with the limits of patent protection.

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the current uncertainties concerning the magnitude of the possible damages and the extent to which they may occur over a long period of time and the imposition of absolute standard of liability with no exceptions in case of any kind of geneflow no matter even, 0.01% in centers of origin and genetic diversity.

Gene Campaign is in favour of the approach taken under the Basel Convention, where the person who may bring claims is not specified. By implication, the right to bring claims rests with any person who suffers damage; this would cover individuals, entities, the State itself under the provisions of the Protocol as well as under general rules of international law on State responsibility. Also, 'interest' of the affected party should be given a broad interpretation to include public interest or *actiopopularis* as well, thus giving a right to non- governmental organizations.

In the case of damage caused by LMOs, the time limit should take into consideration the fact that the harmful effects may only manifest themselves after a long period. Damages due to the biological activity of LMOs, or due to the fact that the organisms themselves are living and may reproduce, may only appear after several generations from the (unintentional or intentional) release of the LMO. A maximum of 30 years counted from the time of the act having caused the damage.

A liability and redress regime for GMOs should expressly stipulate obligations, on the part of the liable persons to provide the injured party with information about the characteristics and adverse effects of LMOs as well as steps involved in the genetic engineering operations or a release.In India, the Consumer Protection Act of 1986 guarantees to the consumer the right of informed choice, acknowledging that people must have the right to full knowledge about anything they consume. However, there exist serious bottlenecks in the implementation of this right in the case of GM products. In recognition of the right to information of consumers, farmers and others, Gene Campaign supports the incorporation of stringent provisions in a liability and redress regime to achieve the same.

In conclusion, Gene Campaign supports the development of an India- specific liability and redress regime, based on the above components, as well as the incorporation of these principles in an international regime. The precautionary principle should form the legal basis for addressing the uncertainties linked to this still relatively novel technology, whose dangers are yet to be proven. The adoption of a strong liability and redress regime, based on the precautionary principle and which adequately addresses existing regulatory gaps, would help India reconcile the aim of promoting biotechnology with the need to avoid adverse impacts on the environment.