NARRATIVE REPORT ON ADVOCACY AND INTERVENTIONS FOR FOOD AND LIVELIHOOD SECURITY

December 2007 – January 2009

J-235/A, Lane W-15C, Sainik Farms, Khanpur, New Delhi – 110062 INDIA
Ph: -+ 911129556248 Fx: -+ 911129555961
Em: - mail@genecampaign.org ; web: - http://www.genecampaign.org

NARRATIVE REPORT ON ADVOCACY AND INTERVENTIONS FOR FOOD AND LIVELIHOOD SECURITY

December 2007 – January 2009

GENE CAMPAIGN
DELHI, INDIA

Developing countries must be mindful of several aspects of agriculture to ensure food and livelihood security for their people and to protect their trade interests, specially when it is mediated through multilateral agencies like the WTO. Countries also have concerns with respect to adoption of GM technology in agriculture, one of them being the impact on its trade with other countries. By adopting GM technology in agriculture, India for instance may lose in terms of its trade with countries and markets, which are opposed to GM products.

In order to preserve its export prospects, a country exporting non-GM products may either need to be totally 'GM- free' or have a stringent system for segregation of GM and non- GM crops. Segregation of GM from non- GM crops, foods and products requires vast financial and technical resources, which may be beyond a developing country's capabilities. Losing a 'GM-free' status by contamination has the potential to negatively impact the export opportunities of a country for all agricultural products.

As a case in point, adoption of GM technology in special crops like rice and soybean, which are major foreign exchange earners for India, can spell doom for Indian exports. India is now the only country in the world that produces soybean that can be certified as 100% GM free, because of this it has assured markets. Producing GM soybean would almost certainly lead to the loss of assured soya markets.

Similarly adoption of GM technology in rice would have an adverse effect on India's export market in both Basmati and non- Basmati rice. Once Basmati becomes a GM variety, not only is India likely to lose its markets in those countries (particularly Europe) that are not favorably inclined to GM food, it will also forfeit its claim to protection under the clause of Geographical Indication under the WTO regime.

Indian rice enjoys assured markets today and there is a distinct upward trend in exports of both Basmati and non- Basmati rice. In such a scenario, cultivation of

GM rice in India would jeopardize this assured market and cause revenue losses to the farmers and traders.

Need for Advocacy

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). The interplay of the two has a bearing on individual member countries' positions with respect to GMOs and the level of protection adopted, in terms of trade restrictions on GMOs. The incongruence between the two instruments came into sharp focus in the WTO decision on the trade dispute on GM foods, between the United States and the European Union (EU).

Trade in GM products is actually to be governed by the provisions of the Cartagena Protocol on Biosafety (CPB), also called the Biosafety Protocol, which governs the trans-border movement of GMOs. The Protocol provides for much flexibility in the case of GM trade, particularly for developing countries who have special sensitivities in the agriculture and food sector.

After the WTO ruling, the EU decided not to appeal the verdict, although they had the right to do so. This encouraged the US to promote the view with national governments that the EU challenge to import of GM products had been defeated in the WTO dispute settlement court =, a fully incorrect representation of the WTO ruling. The US has also engaged in widespread propaganda suggesting, (quite erroneously) , that the WTO has ruled that denying trade in GM products will amount to trade distortion and therefore actionable under the WTO.

The WTO Ruling in the dispute over the European Commission's moratorium on GMOs and the ban imposed by EU states on import and sale of GM foods and agricultural produce is of great relevance to all countries interested in trade in agricultural produce. India is one of them.

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 is grateful to ICCO for supporting the first phase of its advocacy work on

1. The EU-US ruling on GMOs and implications for India and developing countries.
2. To develop a liability regime for GMOs from the developing country perspective.
3. Advocacy on biosafety and better regulation of GMOs
4. Awareness generation and public education on policies protective of food, trade and livelihood security

Gene Campaign's advocacy strategies include a range of options, all or some of which may be used depending on the requirement. Some of the approaches we have used successfully over the years are:

- Research and analysis to understand the issues, leading to a position paper to share with civil society, which lays out advocacy positions
- Consultations with stakeholders to refine advocacy issues
- Produce simple literature in regional languages to include rural people in the campaign and advocacy exercise
- Public education and capacity building exercises to broaden understanding in civil society and increase the advocacy platform
- Dialogue with political leaders, policy makers, and opinion makers in society, relevant government departments etc.
- Participation in events, conferences, workshops etc at national and international levels.
- Organizing workshops, policy dialogues, public hearings etc.

The narrative report is given below under the following heads of advocacy interventions:

- ADVOCACY FOR BIOSAFETY AT THE COP-MOP- BONN
- THE WTO RULING ON THE EU-US TRADE DISPUTE ON GM CROPS
- CAPACITY BUILDING AND ADVOCACY ON WTO BIOTECH RULING AND RELEVANCE FOR DEVELOPING COUNTRY TRADE
- THE DRAFT NATIONAL BIOTECHNOLOGY REGULATORY BILL, 2008- RECOMMENDATIONS FOR IMPROVEMENT
- OVERVIEW OF ADVOCACY ON BIOSAFETY AND GM TRADE ISSUES
- LIABILITY AND REDRESS FOR GM CROPS: A DEVELOPING COUNTRY PERSPECTIVE- PAPER FOR DISCUSSION

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 favour of developing countries. Gene Campaign was in fact the only Indian NGO to attend COP-MOP 4, where we conducted a number of discussion and advocacy programs.

Even prior to the COP-MOP, in India, we have tried to create better awareness about the need for biosafety and have been pressing for a strong liability and redress regime for GMOs. Also the process has not ended with the COP-MOP 4; post, COP-MOP, we have been monitoring biosafety in the 'field', have made recommendations for better regulation, while continuing to create awareness.

Pre-COP-MOP Activities

In India, prior to COP-MOP 4, we had participated in a Consultation on Liability and Redress organised 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.

We had also organized a public debate and multi- stakeholder consultation, with other civil society organizations to develop civil society positions on liability and redress and put pressure on government to raise these issues at COP-MOP 4. (minutes attached as Appendix I).

As part of the strategy for COP-MOP, it was decided that Gene Campaign and other civil society groups would come together to lobby collectively on liability and redress.

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. (final draft enclosed as Appendix II).

The position paper was shared electronically with all the delegates through COP-MOP 4's Virtual Display table (http://www.cbd.int/mop4/display/), so that it could receive the widest possible dissemination and contribute to the public debate (both national and international) on this issue.

This paper was also uploaded onto the discussion forum of the workshop "Key Issues of the Official Biosafety Negotiations this Week- NGO Strategies and

Input" (http://www.planet-diversity.org/programme/workshops/workshop1/official-negotiations.html) , organized by Ecoropa, Globelaw, Washington Biotechnology Action Council and Greenpeace on May 13, 2008. Held under the aegis of the Planet Diversity World Congress on the Future of Food and Agriculture, held parallel to COP-MOP 4, it brought together delegates of the COP-MOP 4, so as to provide them with useful background for their national campaign activities as well as for lobby work with respect to the Cartagena Protocol. All this ensured that ahead of the COP-MOP 4, we had a discussion going on to develop components for a liability and redress regime in the interest of developing countries.

Gene Campaign's side-events at COP-MOP 4

(i) 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. Other Indian civil society organisations like the Centre for Interdisciplinary Studies(India) and Anthra (also from India) shared their individual experiences in the use of the law to ensure better biosafety regulations in India.

(ii) Discussion on Liability and Redress for GM Crops

We had organized a panel discussion on developing components of a liability and redress regime in the interest of developing countries. 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. We could arrive at a number of recommendations on liability and redress, endorsed by Anthra (India), Centre for Interdisciplinary Studies (India) and TWN, Malaysia, which were submitted to the Secretariat to feed the official negotiation process as inputs from civil society. These recommendations are as follows:

(i) the adoption of a strict liability regime for damage from GMOs, where liability could be imposed, without the necessity to prove fault or negligence on the part of the defendant (barring standard exceptions such as Act of God etc.);

(ii) the term "damage" to be given the widest possible interpretation and to include environmental damage, damage/ risks to human and animal health as well as socio-economic damage including loss of income, damage to food security and livelihood, and to culture and livelihoods of indigenous and local communities;

(iii) the liability for damage caused as a result of introduction of GMOs to be channeled to the agencies producing and approving the technology.

This will include public and private sector research agencies and the regulatory bodies of the state granting approval;

(iv) absolute liability to operate in the case of genetic contamination in areas that are centres of origin of crops and where maximum genetic diversity is found. This stringent provision is in accordance with principles of natural justice and intergenerational equity, which invokes safeguarding the environment and resources for coming generations;

(v) in the case of damage caused by GMOs, the time limit should take into consideration the fact that damage in biology may only appear after several generations. As such, an absolute time limit of 50 years (a period during which effects on two generations could be manifest) should be considered;

(vi) CSOs acting in the public interest should have the right to bring a claim for damages on behalf of those directly or indirectly affected.

Webcast and presentations of the liability side-event are also available on the link:
http://unfccc.meta-fusion.com/kongresse/CBD2008/templ/ply_cbd.php?id_kongresssession=995&player_mode=isdn_real

(iii) Screening of the documentary film "Adoption of Bt Cotton in Vidarbha"

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.

Post COP-MOP 4

(i) Media Briefing on the COP-MOP

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 (press release attached as Appendix III).

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 Protocol. A careful analysis by us of the Report prepared by the Ministry of Environment and Forests (enclosed as Appendix IV) reveal that it is full of half-truths, with 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

The dispute between the European Union (EU) and the United States (US) in the World Trade Organisation (WTO) over trade in GM crops (the EC- Biotech dispute) and the WTO Ruling in this regard is of much interest to developing countries like India. Given the highly politicized nature of the dispute and the complex nature of the findings, the implications of this Ruling on the inherent flexibilities available to developing countries to regulate Genetically Modified Organisms (GMOs) need to be assessed and evaluated.

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. In November 2006, the WTO's dispute panel reached a decision in this dispute. 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.

The United States has been claiming victory that with the EU losing its case and its decision standing nullified the flexibility of countries to regulate GMOs stands affected. However, a careful analysis reveals that the Ruling was nuanced, with no clear winners or losers. The Ruling did not question the EU's regulatory and policy regime on GMOs or the right of countries to introduce strict regulatory frameworks at the national level. The WTO Ruling did not find the moratorium to be illegal *per se*, suggesting that moratoria on GMOs can be justifiable under WTO parameters if delays can be justified. It also did not question the right for EU member states to ban individual GMOs. There was no decision on the question, whether GMOs are safe or not. The Panel also did not rule on whether GM products are "like" their conventional counterparts or not (substantial equivalence).

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 EU-US GM TRADE DISPUTE AND IMPLICATION FOR DEVELOPING COUNTRIES

Aggrieved by the European Communities' (EC) resistance since October 1998 in approving the growing/selling of GM crops/products under its pre-market approval procedures, three countries, viz. United States, Canada and Argentina (separately) requested consultations with the EC (as required under the Dispute Settlement Understanding of the World Trade Organisation before requesting for the establishment of a Panel[1]) in May 2003[2]. The complaining parties were also aggrieved by the ban that certain EC members had placed with respect to growing and selling of GMOs. In June 2003 these consultations took place but ultimately failed to reach any mutually satisfactory solution.

Subsequently, in August 2003 these three countries requested the establishment of Panel to examine the matter. Acting on this request the Dispute Settlement Body (DSB) established a single panel (which is possible under the DSU[3]) towards the end of August 2003. In February 2004, the composition of the Panel[4] was decided. Several countries[5] had reserved their rights to participate in the Panel proceedings as Third Parties.

The Panel proceedings began in March 2004. In February 2006, the Panel issued its interim report to the Parties. None of the Parties requested for review of the interim report. In May 2006, the Panel issued its final report to the Parties. After the adoption of the Panel's report by the DSB, it was published in November

[1] Under Article 4 of the Understanding on Rules and Procedure Governing the Settlement of Disputes (DSU).

[2] All the consultations took place bilaterally with EC i.e. US and EC, Canada and EC, and Argentina and EC. Similarly the three separates complaints were made before the Panel, but the WTO rules allows to club together similar complaints, if no disputing parties object. The Panel in the end came out with one report for all the three disputes.

[3] Article 6 and 9 of the DSU.

[4] Mr. Christian Haberli (Chairperson), Mr. Mohan Kumar and Professor Akio Shimizu (Members)

[5] Australia, Brazil, Chile, China, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Chinese Taipei, Thailand, Uruguay.

2006[6]. The challenged EC measures were found to be violating certain WTO rules enshrined in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

This paper analyses the scope and reach of the Panel decision in Section I. In Section II, the paper highlights the key findings by the Panel and important arguments and counter-arguments. It also examines the likely implications of such findings – as well as the reasoning and interpretation adopted by the Panel in reaching such findings – on developing countries' biosafety framework and related strategy. Section III presents the conclusion in a larger perspective.

I. Scope and Reach of the Panel's Decision

According to the WTO jurisprudence, any Panel decision is binding only on the Parties to the dispute and does not have any wider binding implications. Secondly, there is no practice in the WTO whereby the earlier decisions are binding on any subsequent decisions, like that is followed in certain municipal laws such as that in India. However, the Panel decision may carry persuasive value for subsequent disputes. Importantly, the Panel itself made certain clarifications[7] (as stated in the Box 1) before presenting their Conclusions and Recommendations, which are important to note in making any inference regarding the scope of the Panel decision.

[6] WT/DS291/R; WT/DS292/R; WT/DS293/R (All the three disputes are merged as one report)
[7] Para 8.2 and 8.3 of the Panel Report

BOX 1

VIII. CONCLUSIONS AND RECOMMENDATIONS

The issues before the Panel concerned the alleged failure of the European Communities to reach final decisions regarding the approval of biotech products from October 1998 to the time of establishment of the Panel on 29 August 2003, and the WTO-consistency of prohibitions imposed by certain EC member States with regard to specific biotech products after these products had been approved by the European Communities for Community-wide marketing.

In light of this, the Panel did not examine:

- Whether biotech products in general are safe or not.
- Whether the biotech products at issue in this dispute are "like" their conventional counterparts. Although this claim was made by the Complaining Parties (i.e., the United States, Canada and Argentina) in relation to some aspects of their complaints, the Panel did not find it necessary to address those aspects of the complaints.
- Whether the European Communities has a right to require the pre-marketing approval of biotech products. This was not raised by the Complaining Parties.
- Whether the European Communities' approval procedures as established by Directive 90/220, Directive 2001/18 and Regulation 258/97, which provide for a product-by-product assessment requiring scientific consideration of various potential risks, are consistent with the European Communities' obligations under the WTO agreements. This was not raised by the Complaining Parties.
- The conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products. These were not challenged by the Complaining Parties, although they did challenge the scientific basis for some of the questions and objections made by various EC member States. In light of this, the Panel, in consultation with the Parties, sought advice from a number of scientific experts.

Therefore, it is very clear that 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. Furthermore, certain Panel interpretations may not be taken as “well settled” in absence of any

appeal as well as viewing the fact that the Panel constitutes of "trade experts" and not "jurisprudence experts" as in the Appellate Body[8].

II. Key findings, interpretations, and their implications

Key Findings

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

In order to be covered under the SPS Agreement the challenged measure has to be either (1) a SPS Measure or (2) a measure relevant to the operation of SPS Measures[9]. In case of SPS measure, inter alia, the tests of Article 2.2 and Article 5.1 of the SPS Agreement would apply. In other words, SPS measures need to be based on "scientific principle" and be backed by "sufficient scientific evidence" and hence "risk assessment" is necessary. However, in the second case, Article 8 and Annex C of the SPS Agreement become relevant, which does not provide for any risk assessment.

Once the Panel reached to the conclusion that there was a general de facto moratorium in force in the EC between June 1999 and August 2003 (when the Panel was established[10]), the next question before the Panel was whether the said moratorium is a challengeable measure under the WTO rules i.e. whether it is a "SPS measure" (within the meaning of Annex A(1) read with the Article 1 of SPS Agreement) or a measure relevant to the operation of SPS measure.

After hearing the parties, the Panel concluded that the de facto general moratorium was <u>not</u> a SPS Measure but was concerned with the operation of the SPS measures. Therefore, although general moratorium can be challenged for its consistency with the SPS Agreement, the test would be that of the Article 8 and Annex C (See Box 3 for the text), which inter alia obliges members to complete the operation of SPS measures "without undue delay".

[8] Palmer, A. (2007)
[9] Palmer, 2007 (unpublished)
[10] It may be noted that the EC lifted the general moratorium before the Panel ruled on it.

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 (see below for the interpretation).

Similarly, the Panel held that challenged product-specific EC measures were also "measures relevant to the operation of SPS Measures" and found that the product-specific delays amounted to "undue delay" with in the meaning of Annex C(1)(a) and hence violative of Article 8.

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 Panel rejected the argument put forward by the EC that there was "insufficient" scientific evidence and hence the measure could be justified under Article 5.7 of the SPS Agreement. The Panel held that there was sufficient scientific evidence in order to carry risk assessment; hence such bans cannot be maintained under Article 5.7.

BOX 2

Article 2

Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, <u>is based on scientific principles and is not maintained without sufficient scientific evidence</u>, except as provided for in paragraph 7 of Article 5.

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

(emphasis added)

Key interpretations and their likely implications

Undue delay

BOX 3

Article 8

Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

ANNEX C

CONTROL, INSPECTION AND APPROVAL PROCEDURES[11]

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

...

(emphasis added)

On the question of whether there was "undue delay" in the approval procedure of EC (in maintaining the general moratorium or that related with product-specific approvals), the Panel observed, based on ordinary meaning of the terms, that according to the Article 8 read with Annex C(1)(a) first part, "the approval procedure be undertaken and completed with no unjustifiable loss of time"[12]. It found that both the "reasons of delay" and "its duration" were relevant factors in determining whether a Member has "unduly delayed" the approval of a GM product[13]. First there should be a delay and then it should be established that the delay was unjustified. In other words, if there was a delay but there was a legitimate reason or justification for such delay it would not be violating the Article 8 and Annex C of the SPS Agreement.

The Panel opined that the determination of "undue delay" had to be made on case-by-case basis taking into account the facts and circumstances of a case. It also observed that it was neither possible nor useful to attempt to define the

[11] Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

[12] Para 7.1495 of the Panel Report

[13] Para 7.1496 of the Panel Report

reasons which would render a given delay "undue" and those which would not render it "undue"[14].

Given the facts and circumstances of the present case, the Panel specifically rejected the two pleas put forward by the EC for justifying the delay in the completion of approval procedure, viz., (a) plea of awaiting legislation amendments to come into force; and (b) plea of "evolving science" and application of a "prudent and precautionary approach"[15].

Most importantly, although the Panel disapproved the "general moratorium" in the present case, it did not rule that every moratorium could be held to be causing "undue" delay in approval procedure. The following observation of the Panel makes it very clear.

> …we wish to note that our conclusion above should not be construed to mean that it would under no circumstances be justifiable, in the light of the provisions of Annex C(1)(a), first clause, to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products. We consider that there may conceivably be circumstances where this could be justifiable. For instance, if new scientific evidence comes to light which conflicts with available scientific evidence and which is directly relevant to all biotech products subject to a pre-marketing approval requirement, we think that it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence. The resulting delay in the completion of approval procedures might then be considered not "undue"[16]. (emphasis added)

Furthermore, according to the Panel, delays caused due to any new information or that caused by extreme events beyond a Member's control, such as natural disasters, civil war or an unexpected overload might be justified[17]. Furthermore, delays caused due to actions and omissions of the applicant would also not be taken as 'undue' delay by a Member[18].

Implications

In light of the above-explained interpretation of "undue delay" by the Panel, it can be said that the existing flexibility for Members to legitimately delay approval procedure for a GM product, whether or not through a general

[14] Para 7.1497 of the Panel Report
[15] Para 7.1530 of the Panel Report
[16] Para 7.1532 of the Panel Report
[17] Para 7.1500 of the Panel Report
[18] Para 7.1497 of the Panel Report

moratorium, remains intact. Moratorium per se, is not inconsistent with the WTO rules.

The Panel specifically mentions "new scientific evidence" as legitimate cause for procedural delay. For instance, it may be possible that in future disputes the scientific findings about genes by the researchers involved with a human genome project that "genes appear to operate in a complex network, and interact and overlap with one another and with other components in ways not yet fully understood[19]," could justify moratorium till the scientifically uncertainty is removed. According to the United States National Human Genome Research Institute – that organized the said human genome project – these findings will challenge scientists "to rethink some long-held views about what genes are and what they do"[20].

Therefore, it would be prudent for governments to prioritise scientific investigations pertaining to environment and health safety vis-à-vis GM products. This is particularly important because most developing countries are rich in biodiversity, including agro-biodiversity and are also centre for origin for most crops.

There may also be other developing country-centric reasons that could justify any 'delay' in their GM approval procedure, which may be explored as research assignments. For instance, whether the delay due to lack of human resources (e.g. scientific expertise) and/or physical resources (e.g. equipments, adequate lab facilities) to conduct risk assessment (or to scrutinize the trail data submitted by the applicant) be taken as a legitimate reason? Similarly, whether, in cases where risk assessment is required to take into account "relevant economic factors," the delay could be justified on the ground of absence of any agreed model, formula or scope of dependence on such factors?

There may also be inadequacy in physical and human resources in post-release measures related with GM products, such as detection and analysis of GMOs, inspection, monitoring, handling of GMO materials, quarantine, issues related to segregation, identity preservation etc. If such inadequacies were prevailing, then most of the conditions that are generally attached to the approval of GM products would not have any meaning.

Therefore, there may 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. However, developing countries would need to be cautious, because such measures could be alleged "protectionist" at the WTO forum. The WTO Members desired "the establishment

[19] Caruso, D; *A challenge to gene theory, a tougher look at biotech*, New York Times, 1st July 2007

[20] *ibid*

of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade"[21].

The "negative effect on trade", if any, however, need to be construed in larger light of the Agreement Establishing WTO, wherein the Members recognized that "their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development"[22] (emphasis added). This "objective of sustainable development" has also been recalled by the WTO Members in Decision on Trade and Environment, which is included in the WTO's legal text i.e. The Results of the Uruguay Round.

It may further be submitted that the basis of the SPS Agreement is mere an exception in form of Article XX(b) of GATT (General Agreement on Tariffs and Trade) and hence the Preamble of the Agreement Establishing WTO should carry more weight than that of the SPS Agreement. In other words, the objective of "adopting and enforcing SPS measures in order to minimize their negative effects on trade" need to be seen in the larger "objective of sustainable development" and in the event of any conflict between the two the latter should prevail.

Relevance of MEAs and precautionary principle in interpreting WTO agreements

As stated earlier the Panel found that the national safeguards measures maintained by certain EC members in form of bans were not based on risk assessment and hence violated the SPS Agreement. The plea that "relevant scientific evidence is insufficient" and hence such safeguard measures could be maintained by virtue of precautionary principle enshrined in Article 5.7 was also rejected by the Panel. The Panel was of the view that there existed sufficient scientific evidence in order to conduct risk assessment, basing this to the fact that the risk assessment was already conducted at the EC level.

The EC has argued that certain treaties like Convention on Biological Diversity (CBD) and the Biosafety Protocol (BSP) as well as general principle of law such as precautionary principle need to be taken into account while interpreting the WTO agreements including the SPS Agreement. The crux was that the precautionary principle enshrined the Biosafety Protocol, of which EU is a party

[21] Fourth Preambular paragraph of the SPS Agreement

[22] First Preambular paragraph of Marrakesh Agreement Establishing the World Trade Organisation.

would be able to justify the "bans" that certain countries had put up on GMOs, where there is "scientific uncertainty".

On the contention of EC and pursuant to Article 3.2 of the DSU (that the WTO agreements are to be interpreted in accordance with customary rules of interpretation of public international law), Panel considered Article 31 of the Vienna Convention on the Law of Treaties (See the text in Box 4), which provides for general rule of interpretation, including customary rules.

BOX 4

Article 31
General rule of interpretation

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;

(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) <u>any relevant rules of international law applicable in the relations between the parties</u>.

(emphasis added)

The Panel considered Article 31(3) (c) and agreed with EC that the treaties such as CBD and BSP would qualify as 'relevant rules of international law" and examined whether these are "applicable in the relations between the parties" in order for it to take into account for the purpose of interpretation. This gave rise

to question of what is meant by the term "the parties", which after logical deduction the Panel came to following conclusion:

> "…"party" means "a State which has consented to be bound by the treaty and for which the treaty is in force". It may be inferred from these elements that the rules of international law applicable in the relations between "the parties" are the rules of international law applicable in the relations between the States which have consented to be bound by the treaty which is being interpreted, and for which that treaty is in force. This understanding of the term "the parties" leads logically to the view that the rules of international law to be taken into account in interpreting the WTO agreements at issue in this dispute are those which are applicable in the relations between the WTO Members."[23] (Footnote deleted).

The Panel further says: "In relation to the present dispute it can thus be said that if a rule of international law is not applicable to one of the four WTO Members which are parties to the present dispute, the rule is not applicable in the relations between all WTO Members"[24] (emphasis added).

This means that the WTO Panel can take into account for the purpose of interpretation of WTO agreements, only those other rules of international law of which all the WTO members are parties. This would also mean that in interpreting any multilateral agreement of the WTO, even plurilateral agreement of the WTO would not be taken into account. Therefore, the Panel found treaties such as CBD and BSP not to be taken into account because all the Members of the WTO are not parties to these.

The Panel, however, refrained from taking any position as to what will happen in a dispute where all the parties to the dispute are parties to applicable relevant rules of international law (say for e.g. BSP) and all such parties argue that such rules of international law should be taken into account in interpreting a multilateral WTO agreement. In this regard, the Panel observed:

> "Before applying our interpretation of Article 31(3)(c) to the present case, it is important to note that the present case is not one in which relevant rules of international law are applicable in the relations between all parties to the dispute, but not between all WTO Members, and in which all parties to the dispute argue that a multilateral WTO agreement should be interpreted in the light of these other rules of international law. Therefore, we need not, and do not, take a position on whether in

[23] Para 7.68 of the Panel report
[24] Para 7.71 of the Panel report

such a situation we would be entitled to take the relevant other rules of international law into account"[25].

That means in a case where the parties to dispute are parties to CBD/BSP and all of them argue before the panel to take into account the international rules contained in CBD/BSP while interpreting SPS Agreement, the conclusion of the Panel may differ from that of the present case. In such a case it would be interesting to note how the Panel harmoniously constructs provisions of BSP and SPS Agreement so that both the agreements are implemented in mutually supportive manner, especially the resolution of SPS' "insufficient scientific evidence" vs. "scientific uncertainty" of BSP.

As far as the precautionary principle is concerned, the Panel agreed to take into account if such principle is found to be general principle of international law. The EC asserted that precautionary principle has by now become a full-fledged general principle of international law. EC informed that since World Charter of Nature (1982), where the principle was first recognized it has been subsequently incorporated into various international conventions on the protection of the environment for instance, Rio Declaration, UNCBD and UN Framework Convention on Climate Change. More so, in the field of GMOs, the Biosafety Protocol has clearly relied on the precautionary principle in the decision to restrict or prohibit imports of GMOs in face of scientific uncertainty[26].

The EC also put forward the examples of many national laws such the Australia, Switzerland and New Zealand which have recognized precautionary principle in their national GM approval systems, and also India where the Supreme Court has applied the principle as one of "the salutary principles which governs the law of environment"[27].

The US on the other hand strongly denied that precautionary principle has become a rule of law or can be taken as a general principle or norm of international law. This is because the principle does not have a single, agreed formulation. The US considers precaution as an "approach", rather than a "principle" of international law[28].

The US submitted that precaution does not fulfill any of the requirements to become a rule of customary international law for the following reasons[29]:

(i) it cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct;

[25] Para 7.72 of the Panel report
[26] Para 7.78 of the Panel report
[27] Para 7.79 of the Panel report
[28] Para 7.81 of the Panel report
[29] Para 7.82 of the Panel report

(ii) it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it; and

(iii) given that precaution cannot be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

More so, according to the US, even if a precautionary principle were considered a relevant rule of international law under Article 31(3)(c) of Vienna Convention, it could not override any part of the SPS Agreement[30].

After considering the above-said arguments of the Parties and the observation of the Appellate Body in the EC – Hormones, the Panel concluded that it is still not settled whether Precautionary Principle is a recognized principle of general or customary international law. It observed that till date there has been no authoritative decision by an international court or tribunal[31]. More so, the Panel did not found it prudent to take any position on the issue in order to dispose the impugned legal claims[32].

The Panel also considered whether other rules of international law could be considered in the interpretation of the WTO agreements even if such rules does not fall under the ambit of Article 31(3)(c) of Vienna Convention i.e. if they are not applicable in the relations between the WTO Members. This issue was examined because the EC had argued that in the US – Shrimp, the Appellate Body interpreted WTO rules by reference to treaties which were not binding on all parties to the dispute. According to the EC, the Appellate Body had invoked treaties (including CBD) in support of the arguments made by the US, even though it was not party to it[33].

The Panel observed that in order to interpret a treaty term "in accordance with the ordinary meaning", in addition to dictionaries, other relevant rules of international law may in some cases aid a treaty interpreter in establishing, or confirming, the ordinary meaning of treaty terms in the specific context in which they are used. Such rules would not be considered because they are legal rules, but rather because they may provide evidence of the ordinary meaning of terms in the same way that dictionaries do[34]. In the present dispute, the Panel, however, did not find any of the provisions of CBD or BSP to be necessary or appropriate to be relied upon for interpreting the WTO agreements at issue[35].

Implications

[30] Para 7.83 of the Panel report
[31] Para 7.88 of the Panel report
[32] Para 7.89 of the Panel report
[33] Paras 7.90 and 7.91 of the Panel report
[34] Para 7.92 of the Panel report
[35] Para 7.95 of the Panel report

In light of above-said, the WTO Panel giving a light treatment to multilateral environmental agreements (MEAs), such as CBD and BSP, is a serious concern from the perspective of international environmental jurisprudence. This is a harbinger of a serious international jurisprudential imbalance that is developing between "trade & commerce", on the one hand, and "environment and health", on the other. On would also have to examine whether the Vienna Convention aids in the harmonious construction of multilateral trade agreements and MEAs so that both are implemented in a mutually supportive manner. More so, developing countries need to be very cautious, because the said international jurisprudential imbalance tends to distort the domestic jurisprudential balance between trade and environment/health. One would also wonder as to how with such jurisprudential imbalance one can achieve the "objective of sustainable development" through a rights-based approach.

The international community needs to rethink about the enforceability of MEAs. If the concept of "World Environment Organization" is politically heavy can an international Dispute Settlement Mechanism be crafted for enforcing MEAs in order to generate jurisprudential counter-pressure, which in turn could rectify the emerging imbalance?

III Conclusions

As we saw that the scope and reach of the Panel decision is very limited, the developing countries need not bother much in considering their biosafety strategy to safeguard their environment and public health. Certain interpretations by the Panel do tend to narrow down the policy space for taking up measures like "moratorium" and "bans" with respect to import and approval of GMOs, there are windows available for them.

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 endeavour 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.

Today it is an observable phenomenon that the trade and economic interest is setting the main law/policy framework and social sector such as environment and health are being pushed as mere exception or exemptions of the trade and economic framework. The onus lies on the social sector to invoke such exceptions and exemptions for which the proponents are required to generate evidences, which at times become a time-taking and money-consuming exercise.

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. For instance, in most countries GM technology is being viewed as necessary for addressing food insecurity by increasing agri-production. Is it based on any evidence or is mere an assumption? Developing countries need to be careful as vested interest is driving the adoption of this technology and should question every arguments / assumptions in favour of its adoption as well as conduct a logic-based cost-benefit analysis, including its socio-economic impact. The elements of the socio-economic risk assessment are still not clear. Therefore it needs to be standardized and protocol established, as an immediate strategy.

As a long-term strategy, however, developing countries need to come out of this "evidence-gathering mode" by steering establishment of a suitable global framework. Civil society has a significant role to play in this regard. Else "sustainable development" would remain a myth.

References

1. European Communities – Measures Affecting the Approval and Marketing of Biotech Products; Reports of the Panel; WT/DS291/R, WT/DS292/R, WT/DS293/R

2. Agreement on the Application of Sanitary and Phytosanitary Measures, Legal Text

3. WTO Biotech Dispute: Why developing countries wanting to regulate GM imports might support an appeal; Alice Palmer; Draft dated 20.10.06 (unpublished)

4. EC-Biotech: Overview and analysis of the Panel's interim report; The Centre for International Environmental Law, March 2006

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

Gene Campaign

1. Gene Campaign recommends that India needs to have a distinct law in place to oversee genetic manipulation and its implementation, which must harmonise with other laws and national and international agreements. The draft National Biotechnology Regulatory Bill, 2008 needs to achieve harmonization with international agreements such as the Biosafety Protocol, to which India has ratified. To do so, specific provisions need to be incorporated which deal with public awareness and participation, socio- economic concerns, liability and redress, inclusion of the precautionary principle etc. (dealt with in detail later).

2. The Bill must provide for the setting up of a statutory National Bioethics Commission.

3. It must provide for a consultative and participatory process to prioritise crops and traits for genetic improvement through biotechnology with the goal of addressing the needs of small farmers and Indian agriculture.

4. The NBRA must take a strong position on research and commercialization of GM crops for which India is a Centre of Origin (eg. Rice). Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood. Mexico, the country that is the centre of origin and diversity for corn has a clear- cut policy. It has imposed a ban on not just the cultivation of GM corn, but also research in GM corn. Mexico has taken this stance in order to safeguard the natural gene pool of corn, another major staple food of the world. Similarly, China has a ban on the cultivation of GM soybean, for which it is a centre of origin, while Peru, which is a centre of origin for potato, has imposed a ban on GM potato.

5. Like the Protection of Plant Varieties and Farmers' Rights Act, 2001 has taken a clear cut position against terminator technology; the NBRA must take a clear position forbidding the use of the Herbicide Tolerance trait. The Agbiotech TaskForce chaired by Dr. M.S. Swaminathan in its Report has also stated that no technology that will displace labour should be given preference in this country. The Herbicide Tolerance trait will not only displace women as wage labours but will also destroy food, fodder and sources of medicinal plants.

6. The law should contain provisions whereby alternatives to the GM approach could be carefully evaluated in each case before deciding on the GM route.

There should be provision for a mandatory cost and benefit analysis before deciding on a GM product.

7. The Bill should put in place protocol for vastly improved food safety tests and mechanisms for long term monitoring of human health (post GM food release).It should also have a stringent protocol to assess environmental and ecological impact.

8. The law must have sections providing for post- market surveillance and monitoring of GM products.

9. It should have a provision to deal with bio- terrorism.

10. The Bill must contain a provision requiring an annual review of all decisions on GM products to be presented to Parliament.

11. 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.

12. The draft bill should incorporate a provision, whereby producing edible vaccines or vaccines in fruits like tomatoes and melons is actively discouraged.

13. The Bill has tried to facilitate "a more uniform and consistent" approach under a single biotechnology regulatory authority, which is the National Biotechnology Regulatory Authority (NBRA). While doing so, the Bill should incorporate provisions ensuring that the Authority functions in a democratic and transparent manner and that it is answerable to the Inter- Ministerial Advisory Board and the National Biotechnology Advisory Council (NBAC). In order to achieve this, section 6 (3) should be amended with the effect that the Inter- Ministerial Advisory Board and the NBAC have the authority to intervene on product- specific decisions made by the NBRA.

14. Composition and qualifications of members of NBRA need to precisely defined:
The NBRA is the sole regulating agency on biotechnology in India; it is the body to which the data from field trials and large- scale evaluation trials are presented. The data have to be evaluated for safety and a decision taken on whether to approve or disallow a GM crop for commercial cultivation. It therefore stands to reason that the NBRA should be a technically competent body, strong on Risk Assessment and Risk Management of GM crops as also on Monitoring.

However, the draft Bill does not describe the composition, qualification and expertise required of its members. It is also silent about the qualifications required for the Chairperson of the Authority.

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.

The National Biotechnology Regulatory Authority (NBRA) should have overall responsibility for all aspects of risk assessment, risk management, risk communication leading up to decision-making about the safety of a GM crop for the environment, human and animal health and post release monitoring. It is important to ensure that there is no conflict of interest in the NBRA like there is in the present GEAC, where ICAR is a member and ICAR is also a potential applicant for several crops on which it is doing research. The rules for the NBRA should be framed in a clear and unambiguous manner so that it is not possible to stack the Agency with any particular kind of people.

15. National Biotechnology Advisory Council (NBAC) needs to have broad-based multidisciplinary membership-

Section 6(2) specifies that the National Biotechnology Advisory Council (NBAC) shall be established to provide the Authority with independent, strategic advice from various stakeholders on developments in modern biotechnology and their implications for human society. Gene Campaign recommends that the term 'stakeholder' used here should be interpreted as broadly as possible to include a broad based multidisciplinary membership.

As recommended by the UNEP, the following scientific disciplines should be represented in the Advisory Body:

Nucleic acid technology	Plant biology/botany
Molecular genetics	Veterinary science
Population genetics	Agronomy
Marine biology	Forestry
Ecology	Pathology
Taxonomy	Epidemiology
Microbiology	Process technology
Virology	Biochemistry
Zoology	Toxicology
and Entomology	

Apart from this scientific expertise, NBAC members must include social scientists, environmentalists, civil society groups, women farmers and members of farmers organisations, *adivasi* communities, representatives of *panchayati raj* institutions, specially from states where transgenic crops are tested and cultivated, and a legal expert.

12. Provisions for public participation and consultation-
The bill has just two clauses which provide an interface with the public. It is not in the nature of public participation but just merely informing the public about applications for field and clinical trials, regulatory decisions (section 9(3)(g)) and about the mandate and programs of the Authority (section 9(3)(h). There is no provision for ensuring that the public is provided with all information supplied by the applicant to the national competent authority, including the risk assessment report. There is also no provision for public consultation.

The draft legislation also totally excludes NGOs from any aspect of decision making or implementation of biotechnology. Apart from the fact that excluding the public from decision making constitutes undemocratic governance, it is also a violation of the Cartagena Protocol on Biosafety. The Biosafety Protocol, to which India is a signatory, requires that the public be consulted in decision making in matters related to GMOs. On the practical front, excluding NGOs deprives the government of a valuable and critical source of information and analysis, since civil society usually has better and quicker access to information and developments in the field of Agbiotech than government departments in India.

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. India's claim that it has 'fully' complied with the requirement under Article 23.2- whereby in accordance with its respective laws and regulations, it consults the public in the decision- making process regarding LMOs and makes the results of such decisions available to the public – is negated by the Bill (Government of India's Report on the Implementation of the Cartagena Protocol on Biosafety).

Gene Campaign submits that the regulatory process should be transparent, accountable and technically competent. Data from field trials and the rationale for decision-making should be available to the public, through websites and notices in popular newspapers, especially local language papers. 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 organise a series of public debates across the country to elicit the views of the people, to channel it into policy-making. It should also be clarified in which manner the inputs of the public will be taken on board.

13. Provisions on "risk assessment"- It appears that the draft Bill follows a standard western view on risk assessment, making liberal use of the 'science-based' approach promoted by the GM lobby and the U.S. Despite their being mentioned in the Convention on Biological diversity and the Biosafety Protocol,

nowhere does the draft Bill acknowledge the special developing country concerns like the Precautionary Principle, especially relating to the centers of origin for crop plants, socio-economic concerns relating to small farmers and consumers and the right of the public to participate in decision- making.

It is surprising that a draft legislation which seeks to regulate "research, manufacture, importation and use of products of modern biotechnology" has omitted to define "risk assessment" and outline its broad parameters. This is a contradiction to what is claimed by the Government of India that it has 'fully' established appropriate mechanisms, measures and strategies to regulate manage and control risks identified in the risk assessment provisions of the Biosafety Protocol, which is not reflected in the draft Bill.

The Bill should clearly state that risk assessment would be based on the precautionary principle, that is, the absence of scientific evidence or certainty does not preclude the decision makers from denying approval of the introduction of the GEO or product thereof if this may cause, or have a proven or theoretical potential (or based on reasonable scientific theory of hazards based on deductive, circumstantial as well as inductive evidence) to cause, harm to biological diversity, ecosystems, or human or animal health.

'Risk assessment' should be defined to mean the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio- economic impacts, which may be posed by the import, contained use, deliberate release or placing on the market of GEOs or products thereof. This includes the evaluation of secondary and long-term effects.

The steps in risk assessment identify characteristics, which may cause adverse effects, evaluate their potential consequence, assess the likelihood of occurrence and estimate the risk posed by each identified characteristic of the GMO.

The *UNEP International Technical guidelines for safety in Biotechnology* outline the following steps for identifying potential impacts and assessment of risks:

- Identify potential adverse effects on human health and/or the environment
- Estimate the likelihood of these adverse effects being realized
- Evaluate the consequences should the risks materialize
- Consider appropriate risk management strategies
- Estimate the overall potential impacts that may be beneficial to human health or the environment.

These steps should figure prominently in the NBRA Bill.

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. If the questions asked are not critical or adequate, the data collected will not be of sufficient quality to allow any meaning

full decision to be taken with respect to safety. In order to ensure this, framing the questions should be the result of a consultative process and should be jointly undertaken by the advisory NBAC and the NBRA. Until India builds up its own skills in this field, there is no harm in taking the help of experienced experts from other countries, if this is needed.

The legislation should contain elaborate questionnaires, arrived through this process, that are required for an applicant to answer

14. Inclusion of Socio- Economic Considerations

As mandated by the Biosafety Protocol, socio-economic considerations- a broad spectrum of concerns about the actual and potential consequences of biotechnology, such as impacts on farmers' incomes and welfare, cultural practices, community well being, traditional crops and varieties, rural employment, indigenous peoples, food security, trade and competition etc. should figure prominently in biosafety decision- making. This is, however, absent as could be inferred from a reading of section 11(5) (b) which says that the Products Ruling Committee could refuse to authorize the proposed undertaking where it poses as "unacceptable risk to human health, animal health or the environment". Nowhere are 'socio- economic considerations' mentioned.

This goes contrary to the requirements of the Biosafety Protocol, which India has ratified.

It is important that the Bill incorporates India's specific socio- economic concerns, which it can do so by adding in section 11(5)(b) that a proposed undertaking would be refused if it poses an unacceptable risk to human health, animal heath, environment as well as socio- economic considerations.

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. -

The Draft Bill should contain an express provision banning GM crops that could have harmful social or economic impacts for farmers and consumers, those that are frivolous and those that will displace labour and impact rural livelihoods such as Herbicide Tolerance.

15. Special Provisions to protect Centers of Origin and Diversity-

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.

The draft Bill should incorporate a provision whereby cultivation of GM rice is not allowed in India until the nature of gene flow and its impact is understood. The Cartagena Protocol on Biosafety (Preamble, 141) points out that there is special need to be particularly sensitive to the potential effects of genetically engineered organisms on such centers. The Agbiotech Task Force headed by Prof. M.S. Swaminathan has also stressed on the need to protect the centres of origin and diversity.

15. Provision on Liability and Redress

With India ratifying the Biosafety Protocol, it is committed to enacting provisions for fixing liability and ensuring redress for damage suffered as a result of LMOs. A comprehensive draft national law on biotechnology should address this. For instance, the Swiss Gene Technology Law, based on the precautionary and the polluter-pays principle, has provided a legal framework providing strict conditions for the release of GMOs and a strong liability regime. Austria's Law of Genetic Engineering, Finland's Gene Technology Act, 1995, The German Genetic Engineering Act, the Gene Technology Act, 1993 of Norway are other examples of legislation which have provided for a domestic liability and redress regime.

16. Recommendations taken from Best Practices in Regulatory Systems of other Countries

(i) . Risk Assessment

The draft Bill should incorporate the following concerns, which would find consideration in the Risk Assessment process-
biosafety, food safety, human health and socio-economic risks.
It is, however, not enough to incorporate these concerns but they should be backed by adequate institutional structure (as has been achieved by the Australian and Indonesian regulation).

There should be Joint Ministry Conference system to ensure coordination among different departments, as has been done by the Chinese regulation to deal with matters addressing major problems regarding agricultural GMOs.

The Bill should contain elaborate questionnaires that are required for an applicant to answer. The questions should relate mostly to scientific information (as seen in the Chinese and Indonesian regulations).

(ii) Risk Management

The Bill should contain specific provisions on monitoring and labeling. The agency which has got approval to carry out activities involving GMOs should be obliged to submit periodical reports every 6 months or wherever there is an event of 'biosafety harm'. An applicant should also be required to submit detailed descriptions of procedure to monitor survival of the GMO, likely adverse effects on their characteristics.

Agency getting the approval for the GMO should also have the obligation of labeling so as to reveal that the commodity contains GMO.

The Bill should include a provision for appointing monitoring inspectors having adequate powers of inspection to carry out monitoring activities (as in the Australian regulation).

c. Decision Making Process

The Australian regulation requires members of the different advisory/consultative committees to be skilled and experienced in their respective fields. There is a unique requirement that each committee contains at least one member from each of the other committees. This ensures coordination while considering different aspects of a problem. A similar approach is seen in the Chinese regulation in creating Joint Ministerial Committee. The Chinese regulation also emphasizes individual expertise of the constituent members of different authorities set up under it. India should also endeavour to achieve this.

In the Australian regulation there are provisions for public participation and access to information. There is mandatory provision for publication of notice about intentional release of GEOs involving risk. Assessment and risk management plans are available for public comments. The decision-making authority, i.e the Regulator also has the function of providing information and advice public about the regulation. The Regulator in deciding upon an application may also conduct public hearings. As also stated earlier, the Indian Bill must incorporate such provisions for ensuring better public awareness and participation.

OVERVIEW OF ADVOCACY ON BIOSAFETY AND GM TRADE ISSUES

Gene Campaign and other groups have been involved in the field of agricultural biotechnology and biosafety since the late 1990s, making a strong case for transparency and accountability in the regulatory system and to incorporate the public interest and greater common good in policy decisions. They have played a crucial role in highlighting the biosafety concerns which adoption of GM technology would entail- concerns regarding the health safety of humans and livestock, safety of the environment (possible impact on ecology and

biodiversity) and socio- economic safety. Concerns with respect to socio-economic safety include concerns regarding the likely economic and social impact on farmers, consumers, traders and different social classes and the possible ramifications on trade and economy.

Presented below is the role that Gene Campaign and other CSOs have played in highlighting these issues, their engagement in the GM trade debate, especially in the context of the trade dispute between the European Union and the United States, over the European Commission's moratorium on approval of GMOs and the Ruling of the WTO in this regard. However, while doing so, the GM trade debate is sought to be placed in the broader context of the agricultural biotechnology and biosafety debate in India and CSO participation in it, as an illustration of what CSOs have done and can do in the future.

Trade Concerns of Developing Countries with Respect to GMOs

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.

In order to preserve their export prospects, developing countries exporting non-GM products may either need to be totally 'GM- free' or have a stringent system for segregation of GM and non- GM crops. Segregation of GM from non- GM crops, foods and products requires financial and technical resources that may be beyond developing countries. The fact that a country like the United States with vast resources at its disposal has not been able to prevent the accidental contamination of food corn with corn containing the Cry9C Bt gene, known to have allergenic potential in humans, drives home the point that contamination from trial plots and field sites assumes a strong likelihood in a developing country like India.

Losing 'GM-free' status or the slightest hint of contamination has the potential to negatively impact the export opportunities of such countries for all agricultural products. In order to avoid cumbersome documentation, traceability requirements, as well as to meet consumers' expectations, trade diversion may be resorted to by the importing country by replacing some inputs with others (which do not bear the risk of being genetically modified) or by using inputs from alternative countries, which are supposed to be 'GM-free'.

Gene Campaign has played an important role in pointing out the implications of adoption of GM technology with respect to special crops like rice and soybean, which are major foreign exchange earners for India. Green Peace, in a market

report,[36] also warns that growing GM crops could cost Indian farmers their entire European market.

India is one of the few countries in the world from where soybean can be sourced without risk of contamination and it can easily certify it to be 100% GM free. Today, all the soy that India produces is sold. Even if it were to increase its soy production several fold, all the soy would still be sold because the international market is increasingly seeking GM-free foods due to growing rejection by consumers. The Indian soy is supplied to niche markets mainly in Japan and South Korea, which are seeking assured GM- free produce and are strongly opposed to GM foods. Dr. Suman Sahai[37] 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 were to become a producer of GM soy, it would loose its special markets. Further, its GM soy would not be able to compete with huge producers like the US and its highly subsidized, low cost soy.

Gene Campaign[38] has highlighted that adoption of GM technology with respect to rice would have an adverse effect on India's export market in both Basmati and non- Basmati rice. Basmati rice is perhaps India's most easily identifiable premium product in the area of food, after Darjeeling tea. It is a high end, expensive product, comparable to Champagne wine and truffles from France, with a growing niche market among discerning international consumers. It is precisely this section of international consumers, who are willing and able to spend money on expensive foods, who are the most strongly opposed to GM crops. Gene Campaign opposed the Department of Biotechnology's (DBT) efforts to promote a genetically modified Basmati. According to Dr Suman Sahai, [39] 'tainting' Basmati with the GM label would ruin its legend and perception in the international market and that it needs to be handled in a special way.

Apart from Basmati, India also exports non- Basmati rice, largely to the European Union and West Asia as well as to Africa. The importers of Indian rice are countries where there is mounting opposition to GM foods. Indian rice enjoys assured markets today and there is a distinct upward trend in exports of both Basmati and non- Basmati rice. In such a scenario, as pointed out by Gene Campaign, cultivation of GM rice in India would jeopardize this assured market and cause revenue losses to the farmers and traders. A similar opinion has also been expressed in the Report of the Centre for Budget and Policy Studies and

---

[36] Holbach, M., L. Keenan, "No Market for GM Labelled Food in Europe," April 16, 2005, http://www.greenpeace.org/india/press/reports/eu-market-report-no-market-fo (accessed on August 23, 2007).

[37] Sahai, S., "GM or GM Free, What is India's USP?", *The Hindu*, June 4, 2004.

[38] *ibid.*

[39] Sahai, S., "Bt Basmati: Does it Make Sense?" www.genecampaign.org/Publication/Article/GMtech/BT-BASMATI.pdf.

the Stockholm Environment Institute[40], which is a comprehensive and credible, report on the state of agricultural biotechnology and biosafety in India till date. It suggests that in order to preserve its export markets for rice and other food crops, India would do well to emulate Thailand. The world's premier rice exporter, Thailand is maintaining its ban on the commercial cultivation of GM-crops, while simultaneously encouraging R&D work.

International Trade Dynamics and GMOs

The above trade concerns of developing countries like India 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). The interplay of the two has a bearing on individual member countries' positions with respect to GMOs and the level of protection adopted, in terms of trade restrictions on GMOs.

The Cartagena Protocol on Biosafety allows countries to refuse to import genetically modified organisms where there are legitimate safety concerns even when there is a lack of scientific evidence (a use of the precautionary principle). On the other hand, international trade rules like the Technical Barriers to Trade Agreement of the WTO allows the discrimination only on the basis of scientific certainty of harm. Under the Biosafety Protocol, it remains open to Parties to determine independently the level of protection of environment or human health they wish to achieve, and they may then impose such restrictions on the trade in GMOs as are appropriate to achieve the desired level of protection. However, the WTO may be used to challenge and potentially overturn trade regulations introduced by countries under the Protocol, even if they have been tailored to the needs of the country and respond to public concerns. Under the WTO's General Agreement on Tariffs and Trade (GATT) and the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), the reasons that may be used to justify restrictions on trade are strictly limited; they must be based on scientific risk assessments.

According to Issac[41], there are two significant differences between the two instruments: the first being that the WTO has a product approach, whereby trade agreements do not focus on how a good is processed or produced but rather on the end- use attributes of the good. On the other hand, the Cartagena Protocol

[40] Indira, A., M. R. Bhagavan, I. Virgin, April 2005, *Agricultural Biotechnology and Biosafety In India: Expectations, Outcomes and Lessons,* Centre for Budget and Policy Studies and Stockholm Environment Institute, p.132.

[41] Isaac, Grant E., 2003, "The WTO and the Cartagena Protocol: International Policy Coordination or Conflict? ", *Current Agriculture, Food & Resource Issues* 4: 116-123. : //www.CAFRI.org (accessed on June 14, 2007).

supports a process- based approach whereby it is the use of modern biotechnology- regardless of the impact of the end like product –that triggers regulatory oversight. Also, while WTO's underlying regulatory principle is the principle of non- discrimination, underlying the Cartagena Protocol is the principle of Advance Informed Agreement. The Cartagena Protocol essentially treats products of biotechnology as hazardous whereby the government of the importing country must be notified by the government of the exporting country of the intended transboundary movement of living products of biotechnology to allow the party of import to conduct its own risk analysis and permit parties of import to set market access bans according to any factors which they deem fit.

The incongruence between the two approaches to the international regulation of biotechnology gets reflected in domestic and regional regulatory mechanisms which impact trade. It is these inconsistencies between the two instruments that came into sharp focus in the WTO decision on the trade dispute between the United States and the European Union (EU), with the US favouring the WTO approach and the European Union going by the Cartagena Protocol.

The WTO Ruling in the EC Biotech Products case between the European Union and the United States, over the European Commission's moratorium on approval of GMOs and EU member states bans on import and sale of certain GMOs is of great interest to the rest of the world, particularly India. The US has been promoting the view that with the EU losing its case and its decision standing nullified, countries' flexibilities to regulate trade in GMOs stands affected.

CSOs across the world, which had campaigned for strong controls on GM trade under the Biosafety Protocol were concerned that the outcome of the EC-Biotech dispute could undermine biosafety regulation around the world. This is, however, not the case. A careful interpretation of the Ruling reveals that it is binding only to the parties to the dispute and post the WTO- Ruling, countries' flexibilities to choose any level of protection they deem fit remains unaffected. It is now upto these organisations to carefully consider the implications of the Ruling and generate awareness regarding it, critically assess the strategies they used to voice their concerns about the dispute and forge the way ahead.

Civil Society Organisations (CSOs) and the GM Trade Debate

Gene Campaign has played a key role in highlighting the country's trade concerns, both nationally and internationally. CSOs have made their presence felt at the international level, contributing to the democratisation of international governance. On the other hand, there is an increasing assertion and effective advocacy by them in the domestic policy and regulatory deliberation on GMOs, together with awareness generation. While still heavily reliant on state mandated legal control mechanisms and bodies, the Indian state is exhibiting frequent and ever increasing engagement with these 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.

Advocacy and Policy-Making at the National Level

According to the Report of the Centre for Budget and Policy Studies and the Stockholm Environment Institute[42], civil society groups in India have been actively engaged in the field of agricultural biotechnology and biosafety, particularly after 1999, in the context of four important issues: (i) the biosafety of GM crops (ii) the biosafety regulatory regimes and the formulation of biosafety and biotechnology policies (3) the workings of and the procedures within the biosafety regulatory authorities, and (4) the implementation of biosafety legislation, regulations and procedures. The Report states that organizations like Gene Campaign, Karnataka Rajya Raitha Sangha (KRRS) and Research Foundation for Science, Technology and Ecology (RFSTE) were the first to raise the issues of agricultural biotechnology and biosafety in India publicly. It further says that but for the vigilance of these groups and their sustained effort over the years, the environmental, health and socio economic issues (including trade) linked to the introduction of GM- crops would not have emerged into the public domain at all.

The SEI report lists in order of influence and effectiveness, the groups in India active in the arena of Agbiotechnology and biosafety, indicating their main stated activities, objectives and constituencies:

CSO	Main activities and objectives	Main constituencies catered to
Gene Campaign, New Delhi	Policy Issues. Farmers' Rights. Studies and Research. Dissemination of information and studies through articles, seminars, workshops etc. Scrutiny of regulatory and policy- making	Farmers, media, policy-makers and opinion-makers, general public

[42] *op.cit.*, p.74.

	bodies	
Research Foundation for Science, Technology and Ecology (RFSTE), New Delhi and Navadanya, Dehra Dun	Policy issues, with focus on biodiversity, intellectual property rights and international trade.	Media, policy- makers and opinion- makers
Forum for Biotechnology and Food Security, New Delhi	Analyses of issues and dissemination of information and studies through articles	Media, policy- makers and opinion- makers
M.S. Swaminathan Research Foundation (MSSRF), Chennnai	Research in sustainable agriculture and policy issues relating to sustainability	Farmers and the government
Green Foundation, Bangalore	Organic farming and indigenous knowledge	Farmers
Shetkari Sanghatana, Maharashtra	Farmers' rights and interests. Dialogue with government	Farmers and the government
Karnataka Rajya Raitha Sangha (KRRS)	Farmers' rights and interests. High profile field campaigns.	Farmers, media
Karnataka Krishi Sangha	Farmers' rights and interests. Agricultural policy.	Media, policy- makers and opinion-makers.
Federation of Farmers' Associations (FFA), Hyderabad	Promotion of agriculture as a profitable occupation	Media, policy-makers and opinion-makers. Own subscription membership. The general public.
Centre for Science and Environment, New Delhi	Protection of the environment. Policy issues. Studies and research. Dissemination of information and studies through articles, workshops and seminars	Media, and opinion-makers. Subscribers to CSE's journal *Down to Earth*.
Greenpeace India	High profile campaigns for the protection of the environment. Policy issues. Dissemination of information and studies through articles, workshops and seminars.	Media, policy-makers and opinion-makers. Own subscribing membership. The general public.

AgBioIndia	Network for information dissemination and campaigning	Media, policy-makers and opinion-makers
Foundation for Biotechnology Awareness and Education, Bangalore	Dissemination of information through articles, workshops and seminars.	Media, policy-makers and opinion-makers
All India Biotech Association, New Delhi	Exchange and dissemination of information through meetings, workshops and seminars. A scientific and industrial lobby.	Government, research funding councils and industry
Consumer Voice, New Delhi	Food safety and consumer protection	Media, policy-makers and opinion-makers

Source: the Report of the Centre for Budget and Policy Studies and the Stockholm Environment Institute,. *op.cit*

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. Main issues:

(i) Lobbying for Public Participation and Integrating Socio- Economic Considerations

Lobbying for more effective **public participation and integrating socio-economic considerations**, particularly India's trade interests, in national policy. The Biosafety Protocol, to which India is a signatory, in Article 23, requires Parties to promote and facilitate public awareness, education and participation with regard to biosafety, and also requires mandatory public consultation and disclosure of results of decisions back to the public in the decision- making process. Civil society groups all over the world have been instrumental in opening up the decision-making processes on biotechnology and biosafety to public scrutiny and challenge. Public participation addresses the democratic deficit in regulatory systems and ensures a greater plurality of voices and points of view and can accomplish many things which a state cannot.

The need for developing a sound policy framework on biotechnology which takes into account real public concerns, based on indigenous needs and a thorough needs assessment needs to be highlighted.[43] The hasty framing of a draft biotechnology policy without adequate time for public comments have been protested against by civil society, in response to which the Department of Biotechnology (DBT) organized two hearings for selected members of civil society, one at Chennai and the other at Delhi. Dr. Suman Sahai[44], the only member representing CSOs in the Expert Committee constituted by the Government of India to frame the National Biotechnology Policy (also discussed later on in the paper) has pointed out that atleast one year should be set aside for comments and public participation.

During this period, a genuine effort should be made to make the consultation process on the draft policy more inclusive and transparent. She has regretted the fact that the draft report totally excludes civil society, particularly NGOs from any aspect of decision making or implementation of biotechnology, stressing on the need for having civil society members on board in the regulatory structures and bodies.

Gene Campaign[45] has submitted that excluding the public from decision making constitutes undemocratic governance and a violation of the Cartagena Protocol on Biosafety. Excluding NGOs also deprives the government of a valuable and critical source of information and analysis, since civil society usually has better and quicker access to information and developments in the field of agricultural biotechnology than government departments in India.

Besides public participation, civil society groups have been proactive in making a case for **more liberal socio economic risk assessment parameters** (including indicators to assess impact on trade) and negotiate for their inclusion in the Biosafety Protocol. Though the Protocol admits consideration of socio- economic concerns, the scope is greatly restricted and limited to effects on biodiversity (Article 26). Even then, it can be further curtailed by a Party's international obligations, chiefly with respect to the WTO. NGOs have pointed out that Developing country policy makers need to be especially vigilant about the potential for devastating economic impacts when adopting biotechnologies. For instance, Gene Campaign[46] has highlighted that indicators need to be developed to measure the loss of organic markets by small farmers owing to the introduction of GM technology and assess their impact on incomes and livelihoods. A similar viewpoint has been expressed by La Vina and Fransen[47] when they say that where exports or domestic consumption of organic products

[43] Sahai, S., "Does India have a Policy for GM Crops?"2003

[44] Sahai, S., *Recommendations for Change in India's Biotechnology Strategy*, New Delhi: Gene Campaign

[45] *ibid*.

[46] Sahai, S., "Indicators Needed to Assess the Socio- Economic Impact of GM Crops", *Biospectrum*, March 29, 2005.

comprise a significant percentage of a country's agricultural sector, governments would be particularly wise to institute policies that take special measures to safeguard organic markets, research on which will be helpful.

We should develop possible ways of taking socio-economic considerations into account, like procedures for assessing and addressing socio-economic impacts in risk assessment and management and prior public consultation processes with respect to decisions on import, especially with respect to communities that will be directly affected by the import.

(ii) Recommendations to the Government from Gene Campaign's National Symposium

According to the Report of the Stockholm Environment Institute, perhaps the most significant CSO activity, leading to significant changes in the government's handling of agricultural biotechnology, was the result of a two-day **national symposium** organized by Gene Campaign in New Delhi in November, 2003. The symposium titled "The Relevance of GM Technology to Indian Agriculture and Food Security brought together influential 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 consensus recommendations emerged from this multi- stakeholder symposium, which were presented to the Government of India.

Consensus recommendations from the Symposium:

1. A distinct law should be enacted to oversee GM Technology and its implementation. This law must harmonize with other laws and national and international agreements.
2. A comprehensive biotechnology policy should be developed in consultation with all stakeholders.
3. A statutory National Bioethics Commission must be set up.
4. There should be 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.
5. Investment in public sector research should be encouraged and strengthened. Novel gene discovery in crops of relevance to India should get highest priority.
6. India must develop a policy for transgenic varieties of crops for which it is a Centre of Origin and Diversity. Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood.

[47] La Vina, Antonio and Lindsey Fransen, "Integrating Socio- Economic Considerations into Biosafety Decisions: The Challenge for Asia", http://pdf.wri.org/lavina_fransen_socioeconomics.pdf (Accessed on June 10, 2007).

7. The Herbicide Tolerance trait should be subject to rigorous cost and risk benefit analysis before being considered for adoption.
8. Alternatives to the GM approach must be carefully evaluated in each case before deciding on the GM route. A cost and risk benefit analysis must be conducted before deciding on a GM product.
9. Protocol for food safety tests must be vastly improved and mechanisms for long term monitoring of human health (post GM food release) be put in place.
10. Develop a stringent protocol to assess environmental and ecological impact.
11. There should be provisions for post- market surveillance and monitoring of GM products.
12. Have a policy to deal with bio terrorism urgently.
13. India must exercise caution in the Intellectual Property Rights (IPR) regime that it adopts. The current Protection of Plant Varieties and Farmers' Rights Act should be retained since it balances Breeders and Farmers' Rights.
14. A new statutory, independent National Biotechnology Regulatory Authority must be established.
15. Make the Genetic Engineering Approval Committee (GEAC), the apex regulatory body, more competent, transparent and accountable. Post data on research and development of GM crops and products on websites and local newspapers.
16. An annual review of all decisions on GM products must be presented to Parliament.
17. Conduct a scientifically sound study to assess attitudes and perceptions about GM technology among stakeholders in India.
18. Undertake a program of awareness about GM technology to educate the public.
19. Organize a series of public debates across the country to elicit the views of the people, to channel it into policy- making. The government should fund this exercise.
20. 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.

(iii) Submissions before the Agbiotech Task Force

Due in part to the submission of these recommendations, as well as mounting pressure from a number of influential stakeholders, the Government set up an Agbiotech Task Force in 2004 under the chairmanship of Dr. M.S. Swaminathan to submit a report on 'streamlining' the biotechnology and biosafety regulatory structures and procedures. This was accomplished after consulting a range of stakeholders, which included groups like Greenpeace India and Gene Campaign. Another Task Force was also constituted with respect to medical/ bio-medical/ pharmaceutical biotechnology (chaired by Dr. R. A. Mashelkar).

The mandates of both the Agbiotech Task force as well as the Task Force on Recombinant Pharma were to formulate a long term policy on applications of biotechnology in agriculture and pharmaceuticals and suggest modifications in the existing administrative and procedural arrangements in order to improve regulation. Both the Task Forces have found the regulatory system to be cumbersome, ambiguous and inadequate to deal with the challenges of transgenic technology in agriculture as well as pharmaceuticals, which has also been the submission of NGOs like Gene Campaign. The Agbiotech Task Force Report's basic recommendation is that the national policy should seek the 'economic well-being of farm families, food security of the nation, health security of the consumer, protection of the environment and the security of our national and international trade'. Dr. Suman Sahai has said that if the recommendations of this Task Force are upheld, no policy implementation can deviate from these goals.[48]

In submissions before the Agbiotech Task Force, Gene Campaign stressed that India's trading interests must be kept in mind when deciding on research and product development. It has highlighted here the connection between transgenic research in India and the international market, recommending that transgenic research should not be done on crops that we sell in the international market, like soybean, Basmati rice and Darjeeling tea.

(iv) Recommendations for Change in the National Biotechnology Development Strategy

It is Gene Campaign's view that the draft National Policy on Biotechnology (also discussed earlier) must take into account the socio- economic concerns in addition to science based evidence when doing risk assessment. The Precautionary Principle, especially relating to the centers of origin for crop plants, socio- economic concerns relating to small farmers and consumers and the right of the public to participate in decision making must form an integral part of the biotechnology policy, implemented with the highest levels of technical competence.

Dr. Suman Sahai[49] of Gene Campaign has pointed out the imperative for the national policy to address India's trade interests. In her view, which GM tagged crops will get hurt in the export market, what should we keep off GM and where can using the GM approach be beneficial, are questions which the policy must address. It must also provide answers to questions like what sort of liability and redress regime should we have that would protect farmers, consumers and traders and what will be our policy on GM crops for which India is a center of origin/ diversity, especially rice.

---

[48] Sahai, S., "The Agbiotech Task Force Report", *Biospectrum*, June 14, 2004.

[49] Sahai, S., "Recommendations for Change in the National Biotechnology Development Strategy", New Delhi: Gene Campaign.

Civil society groups have also criticized the considerable leeway given by the Policy to the producers of GM products with respect to the introduction of foreign genes into different kinds of crop plants. This puts at risk farmers' livelihoods, the nation's trading interests as well as the health of consumers and the environment, and should be revoked immediately. They have also criticized the reticence discernible in the policy to forbid the private sector to use GM technologies which they warn, would hurt trading interest and livelihoods.

One CSO recommendation has been for the constitution of an autonomous Trade Monitoring Body (TMB), located in the Ministry of Agriculture, to collect market intelligence with respect to GM crops and products and follow the trend of organic markets. The TMB should watch international developments to identify niche markets, monitor countries that are rejecting GM foods and feed this intelligence to concerned agencies to help guide national policy on GM crops and products. The TMB should conduct studies to identify India's comparative advantage and assess the socio- economic impact of imports of GM crops and foods.

(v) Planning Commission Task Force on Biodiversity and Genetically Modified Organisms to prepare framework for 11th Plan

A Task Force on Biodiversity and Genetically Modified Organisms was set up by the Planning Commission under the chairmanship of Dr. Suman Sahai to develop recommendations for the Eleventh Plan period. The Report of the Task Force has reiterated the concern repeatedly expressed by civil society on achieving greater transparency and public participation in regulation and decision- making. Pointing out the problems in India's existing regulation on GMOs, it has recommended a liability and redress regime and has called for a vastly improved regulatory system. The Report also recommends that until such steps are taken, commercial cultivation of GM crops should not be allowed.

The Task Force has highlighted that the GM crop research agenda must be sensitive to India's trade interest. It has also stressed the need to review the policy of promoting GM vs. Organic crops, assessing the USP of particular agriculture zones like rainfed areas, hill states and mountain ecosystems.

(vi) Gene Campaign interventions With Respect to Approval of GM Crops

Community groups have been voicing many concerns with respect to approval of GM crops in India. They have expressed worry over the lack of capacity of the regulatory institutions to play a strong and independent monitoring role, conflict of interest within government agencies, the lack of transparency and hesitation

to heed public demands for information and participation in the decision- making process. Their interventions have to some extent influenced government decision to defer approvals for field trials and subsequent commercialization of certain GM crops in India.

As mentioned earlier, Gene Campaign had successfully opposed efforts to develop a genetically engineered Basmati in India, warning that it would have a disastrous impact on the high- end market for this premium product. The government has since then abandoned this plan. Other examples of Gene Campaign's successful lobbying are stopping the release of GM mustard and GM potato since adequate biosafety tests were not done.

Initial approval for commercialisation of the genetically modified mustard developed by Aventis/ ProAgro was given by the GEAC in early 2003, based on the claims made by ProAgro regarding the safety of the crop. Gene Campaign[50] questioned the veracity of the test data for GM mustard, highlighting that the safety tests were conducted by ProAgro itself, by feeding seeds and leaves of the transgenic plant to pigeons and rabbits. The company reportedly supplied both the samples to be tested and the controls against which the samples had to be tested, making the tests a farce. Moreover, the tests were not conducted in any government laboratories which are open to scrutiny but in private institutions. Even in these privately conducted tests, there was no involvement of scientists from the national agricultural system. Equally questionable was the manner in which the field trials were done. Like in the food and feed safety tests, ProAgro had supplied the bulk of the data on field performance to the GEAC, on the basis of tests it has done itself on its own trial variety.

As a result of Gene Campaign's analysis and presentation of facts, the GEAC deferred the decision to allow cultivation of transgenic mustard in India, which would have been the first GM food crop in India.

GM Potato was projected by its promoters as offering a solution to malnourishment and susceptibility to blindness among poor children in India. Advocacy groups pointed out the dangers inherent in rushing untested GM potatoes to these children through government- run mid- day meal schemes in schools, as envisaged by the promoters. *Dr. Suman Sahai*[51] *in an article published in 2003, highlighted that at that time, the appropriate experiments had not been done to test whether this transgenic potato is stable or not in the long run. Experiments had been done only on the vegetative cycle, which means that that was no knowledge on how the variety behaves when it is sexually*

[50] Sahai, S., "ProAgro's Inferior Mustard Variety to be Released Soon", AgbioIndia Mailing List, September 24, 2002, http://www.lobbywatch.org/archive2.asp?arcid=636 (accessed on September 10, 2007).

[51] Sahai, S., "Splice of Life: GM Potato Could Come a Cropper?", *The Times of India*, June 21, 2003.

reproduced (flowering and setting seed). Also, the increase in protein in the GM potato, touted by its promoters, was negligible and would make no real difference nutritionally. Since then, there has not been much headway in the direction of approval of GM potato for commercial release.

(vii) Engagement with the Judiciary

Gene Campaign has been pointing out the inadequacy of the regulatory mechanism to control the potential environmental and health hazards due to GMOs. It has also expressed worry over the lack of attention to the socio-economic and ethical aspects of GM technology in food and agriculture; and lack of transparency and public participation in the decision-making process.

Unfortunately, the Indian government chose not to heed these legitimate public concerns, showing no sensitivity to the concerns that civil society was raising. Despite repeated representation made to the authorities, Gene Campaign faced continuous stonewalling from the government departments, leaving it with no alternative but to approach the judiciary for relief. It filed a Public Interest Litigation (PIL) in the Supreme Court of India on 7th January 2004.

The PIL challenges the constitutionality of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989 framed under the Environment (Protection) Act, 1986 and which govern the regulatory regime on GMOs in India. It alleges that they are not in consonance with the principles evolved under Article 21 (Right to Life) of the Constitution and that they have not been brought in line with the Biosafety Protocol, to which India is a signatory. The PIL points out lacunae in the Rules of 1989 and the bodies set up under it, which includes the Genetic Engineering Approval Committee (GEAC). 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.

In the light of the above, the PIL has prayed for amendment in the present Rules governing GMOs and the setting up of a High Powered Committee to formulate a National Policy on GMOs through a multi-stakeholder consultation process. It has prayed that the government must observe a moratorium on permissions/ approvals/trials concerning GMOs, especially those of a commercial nature and 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.

In 2005, a second, similar PIL was filed by Aruna Rodrigues and others, whereby the court was requested not to allow any release of GMOs into the environment by way of import, manufacture, use or any other manner unless certain specific precautions are taken. It also prayed for banning the import of any biological

organism, food or animal feed unless they have been certified and labelled to be GM free, by the exporting country and to put in place rules to ensure that it shall be compulsory for any dealer or grower selling GMOs to label them as such.

Proceedings in the two PILs are still ongoing in the Apex Court.

(viii) Using the Right to Information Act

It has been the experience of NGOs in India that the government does not readily provide information on transgenic research, field trials or biosafety, despite persistent enquiries. There is neither interface with the public nor any consultations with it. This is a clear infringement of the people's right to know and to participate in a matter that has grave implications for their life and welfare.

Since the enactment of the Right to Information Act, 2005, groups such as Gene Campaign, Greenpeace India and the Centre for Sustainable Agriculture have used this new legislation to access information from the biosafety regulatory bodies.

Gene Campaign had moved applications before the Ministry of Environment and Forests (MoEF) seeking information on the GEAC, on educational and professional qualifications required to be appointed as Member of different committees, on Bt cotton, on GM crops and on risk and cost benefit analysis of GM crops. It asked for release of data related to allergenicity and toxicity testing of Bt brinjal, which the government denied. Gene Campaign then took the matter to the Supreme Court, which ordered release of the data. The government has had to comply.

A similar request for information under the Act was later made by Greenpeace India requesting the Review Committee on Genetic Manipulation (RCGM), to make public the toxicity and allergenicity data for GE brinjal, rice, mustard and okra. There was also a request to make the minutes of the RCGM meeting public.
The Centre for Sustainable Agriculture has also used the Right to Information Act to obtain crucial information with respect to decision- making process and approvals for GE crops, biosafety data and other data which form ostensible basis for decision- making, monitoring reports, Bt cotton performance reports, compliance to laws, Public Private Partnerships in consortium projects etc. This data has been put into the public domain through a website and has aided legal challenges by putting forward compelling evidence and have also helped substantiate civil society investigations into field trials.

Participation in the International Arena

(i) Amicus Curiae Briefs in the WTO Dispute

Civil Society has been instrumental internationally in asserting the right of every country (especially, developing countries) to be able to decide their own level of protection from the risks of GM crops and food, free from pressure exerted by GM exporter countries. Three amicus Briefs have been filed by civil society. All these briefs stressed the public interest, pointed out the dangers of unimpeded trade in GMOs and emphasized on health, environmental, social and economic issues.

The WTO dispute settlement system provides the possibility for non- parties like CSOs and private individuals to file *amicus curiae* (friend of the court) briefs, whereby they can set out facts or arguments relevant to the dispute and often in the public interest. The Appellate Body is vested with the discretion to take or not take them into account while deciding the case. Though there is no guarantee that these would be taken into account, it is expected that amicus curiae briefs would help in developing balanced and just decisions in the WTO dispute settlement system by presenting relevant information and technical advice. In that sense, they are effective advocacy tools.

One such amicus brief was submitted by a coalition of CSOs from both developed and developing countries, of which Gene Campaign was a part. The members of the Coalition included Gene Watch UK, Foundation for International Environmental Law and Development (FIELD), Five Year Freeze, Royal Society for the Protection of Birds (RSPB), the Centre for Food Safety, Council of Canadians, Polaris Institute, Grupo de Reflexión Rural Argentina, Centre for Human Rights and the Environment (CEDHA), Gene Campaign (India), Forum for Biotechnology and Food Security (India), Fundación Sociedadus Sustentables, Greenpeace International, Californians for GE-Free Agriculture and International Forum on Globalisation.

The CSOs decided to submit an amicus brief because they felt that the decision on the WTO GM dispute will have far reaching implications not only in the EU, but also on other developing countries like India, where agriculture is the most important sector in the socio-economic fabric. It was pointed out that the science of GM crops and foods is uncertain and the potential for serious and irreversible risks to the environment and human health remains. Also, the ownership and control of the technology by multi-national corporations means it does not meet the needs of the poor and hungry. Thus, countries should be able to decide their own level of protection.

Another amicus brief (April 30, 2004) was submitted by a team of international scholars of science, technology and society, comprising of Lawrence Busch, Robin Grove- White, Sheila Jasanoff, David Winickoff and Brian Wynne. This brief aimed at providing information on two fundamental aspects of the dispute: interpretation of the terms 'science', 'risk assessment' and 'risk management' in

the context of evaluating agricultural biotechnologies and the relationship of risk assessment to the broader role of public deliberation and rational decision making in supporting the free flow of trade. While acknowledging that regulatory polarization in the agricultural biotechnology sector has created tensions in the world trading system, it brought into focus the fact that risk assessment of GMOs is full of complexities and therefore, requires processes of public deliberation and review and most especially in relation to the transfer of GMOs across national borders.

The third amicus brief (June 1, 2004) was submitted by a group of CSOs, mainly from the developed countries, including Centre of International Environmental Law, Friends of the Earth- United States, Defenders of Wildlife, Institute for Agriculture and Free Trade and Organic Consumers Association- United States. This brief presented considerable scientific evidence as to the extent of the uncertainty involved in evaluating the risks of GMOs to human, animal, and plant life and health so much so that it impedes any adequate consideration of those risks. This situation fulfils the condition of 'insufficient scientific evidence' provided for in Article 5.7 of the SPS Agreement, which can be used by Member Countries to assert their right to establish the level of protection they deem adequate.

Though the amicus briefs were not able to exert much influence in the decision (with the WTO Panel stating that it did not consider it necessary to take them into account), nevertheless, the amicus submissions served a broader purpose. They brought CSOs from all over the world on a common platform and raised considerable awareness. CSOs not only represent the interests and perspectives of their country and of the broader society at the international level. They also serve to transmit information and arguments back to their respective constituencies, governments and fellow members of civil society, building capacity for more informed participation in the future.

(ii) Participation in the Biosafety Protocol

Civil society groups since the early 1990s have worked very hard to develop international and national rules on production and trade in GMOs and GM products. The framing of international rules for trade in GMOs, is mandated in the Convention of Biological Diversity (CBD) under Article 19(3).The Cartagena Protocol on Biosafety, adopted in January 2000 and which came into force in September 2003, is a significant outcome of these global efforts and testifies to the right of countries to control the movement of GMOs and GM products across their borders.

CSOs have tried to participate in an effective way in the Conference of the Parties to the CBD serving as the meeting of the Parties to the Protocol (COP-MOP), both in official negotiation discussions and in parallel events held

simultaneously. They have tried to contribute through elaboration of positions and strategies, effective interventions, identification of main issues of discussion and the organization of side events, mobilization and awareness-raising campaigns. The positive thing about the COP-MOP as against WTO meetings is that CSOs are allowed to sit and hear in; they can also interact and make suggestions, which give NGOs a chance informally to put across their view points.

At the first Meeting of Parties to the Protocol held at Kuala Lumpur, Malaysia in 2004, a coalition of NGOs, including Gene Campaign initiated debate that led to some decision on certain pertinent issues in the Cartagena Protocol which the Miami Group (United States, Canada, Argentina and Mexico) were keen to suppress. Some of these issues were identifying shipments of LMOs, dealing with Parties that do not comply with the provisions of the Protocol and liability and compensation in cases of damage due to trans- boundary movement of LMOs,. There were also discussions and deliberations on Advance Informed Agreement (AIA) and labeling of GMOs, prompted by civil society. They initiated debate over the *adhoc* grant given to the GM soybean oil import; because although it was given as a special case and not under US pressure, formally the AIA has been exhausted for that. NGOs also highlighted the need for exhaustive labeling on containers of GMOs and that labeling should have detailed scientific information about what is contained so as to anticipate the quarter from which risk may come, meaning from which quarter one should be concerned about biosafety.

Gene Campaign and Consumers International (Asia- Pacific) pointed out at Kuala Lumpur that the ongoing discussions on the Convention of Biological Diversity and the Biosafety Protocol dealing with the impact of GM crops on the biodiversity of the world were ignoring the central concern of developing countries: that of the social and economic impacts of GM technology. The freedom to use socio- economic considerations such as the impact of trade is limited by the condition that such an action must be consistent with the country's other international obligations, particularly with regard to international trade. Gene Campaign has pointed out that an understanding of the socio-economic impact of trade in GM crops needs to be developed urgently by initiating brainstorming discussions involving all stakeholders. The specific socio-economic concerns need to be identified; how are these to be handled in the Protocol; and whether these could be built into the Biosafety Framework, etc.

The Way Ahead

Gene Campaign works at the national and international level towards a policy on GMOs, which keeps India's concerns about health and environmental safety as well as its trade interests at heart. It has also been relentlessly engaged in research on GM policy issues, generating awareness, conducting public debates and building capacity among the public for informed choices.

There is a need for increased and more effective civil society intervention using instruments such as the Right to Information Act to build awareness, feed legal challenges, take on regulators and strengthen advocacy. For such efforts to yield results, it is imperative that the information on GMOs be demystified and translated into regional languages. There is a need for awareness generation and capacity building among a variety of stakeholders to enable public participation and informed choice. Advocacy groups also need to network more effectively, building coalitions not only with like- minded CSOs but also strategic alliances with diverse groups, to achieve their objectives.

Liability and Redress for GM Crops: A Developing Country Perspective

A Position Paper for Discussion

Gene Campaign

The Parties to the Convention on Biological Diversity, in recognition of the unique risks that genetically engineered organisms pose to the conservation and sustainable use of biodiversity, adopted the Cartagena Protocol on Biosafety in 2000. The Protocol sets out the first international legal framework for the cross-border movement of GMOs (it uses the term LMOs (living modified organisms) to denote genetically engineered organisms), on the basis of the precautionary principle. The principle holds that when society is weighing risks caused by human activities (such as the introduction of new technologies), lack of scientific certainty shall not be used as an excuse for not taking preventive action to protect human health and the environment.

The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology or genetic engineering. Genetic engineering is a radical new technology, in which genes are spliced from one organism and inserted into another. Although genetic modification has always been a part of evolution within species, this new technology is significantly different from what takes place in nature in that it breaks down the species barrier and introduces novel combination of genes. The risk posed by GMOs is entirely of a novel kind. Being capable of self-replicating, once released into the environment, GMOs and microorganisms are capable of multiplying and spreading through the food chain and ecosystem. They can transfer the modified genes to the other organisms, which can reproduce and spread modified genes further, thereby resulting in a kind of genetic pollution. Thus, while damage to the environment resulting from an oil spill could be rectified, it is impossible to recall a genetically engineered organism once it is introduced into the environment. Also, unlike chemistry, the results appear very late in biology. It is not easy to predict the long-term consequences of gene transfer into wild species. It is also possible that the true impact becomes clear only after several years of full scale commercial growing. The Protocol recognizes that GMOs may have biodiversity, human health, and socio-economic impacts, and that these impacts should be risk assessed or taken into account when making decisions on GMOs.

The Protocol, signed by 147 countries as of 2008, was adopted after years of contentious negotiations and entered into force in September 2003. Its ratification was achieved through the efforts of developing country delegations, organized as "the Like-Minded Group." On the opposing side, the country delegations that did not want a legally binding protocol and were hostile to the very idea of biosafety, was "the Miami Group." This small but powerful group was led by the United States and included Argentina, Chile, and Uruguay. None of the Miami Group members have signed the Protocol.

One of the most important components of a global biosafety regime, as envisaged under the Protocol, is international rules and procedures on liability and redress in case of damage resulting from the products of modern biotechnology. Article 27 of the Protocol provides that "the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years".

The twin issues of liability and redress have been the most contentious issues since the Protocol was conceived in the 1990s, leading to an impasse in the enforcement of the Protocol. In fact, the inclusion of substantive liability and redress provisions in the Biosafety Protocol was seen as critical to its success, and during the negotiations that led to the final version of the Protocol, many delegates supported the NGO campaign, 'No Liability, No Protocol' and later, 'No Liability, No Biosafety'.[52] The Like-Minded Group and the Miami Group were deadlocked on this particular area until the Like-Minded Group agreed to postpone the discussion and return to the issue after the Protocol came into force. Article 27 thus states that at the first MOP (Meeting of the Parties), work would begin toward establishing a mechanism for liability and redress and this work should conclude in four years. The first MOP took place in 2004, so a liability and redress regime should have been agreed upon by the time of the 4th MOP held in Bonn in May, 2008. But, unfortunately, such has not been the case.

[52] Cook, Kate, 2002, "Liability: 'No Liability, No Protocol' ", in Bail, Christoph, Robert Falkner and Helen Marquard, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?*, London: The Royal Institute of International Affairs.

At the first MOP, held in Kuala Lumpur in February 2004, the Parties, in paragraph 1 of decision BS-1/8, decided to establish an Open- ended Ad Hoc Working Group of Legal and Technical Experts to carry out the process pursuant to Article 27 of the Protocol. Since that time, the Working Group have met five times under the co- chairmanship of Mr. Rene Lefeber (Netherlands) and Ms. Jimena Nieto (Columbia), the last meeting being held in March, 2008 at Cartagena, Columbia. The Working Group has been striving hard, including through a Group of Friends of the Co-Chairs, to reach an agreement on certain core elements of international rules and procedures for liability and redress, in readiness for the fourth meeting of the Parties to the Protocol (COP-MOP 4) held in Bonn, Germany from May 12-16, 2008.

In spite of the efforts of the Friends of the Co-Chairs, the negotiators left Cartagena with no agreement to bring to Bonn. During the MOP 4 at Bonn, Malaysia led the developing country efforts supported by the Phillipines, Columbia and other Latin American and African countries to press for a legally binding regime. To add strength to their case, the developing countries formed a block of 80 countries called the Like Minded Group of which India was a member.

Countries like Japan, Brazil and Peru offered stiff resistance to this proposal. Ultimately, a compromise could be worked out with an agreement to continue discussions in early 2009 and come up with a legally binding instrument on mutually agreed terms before COP-MOP 5, scheduled to be held in Nagoya, Japan in October 2010. The conclusion of the Bonn meeting without reaching an agreement may be viewed "as a failure, since undoubtedly, the message that the (Bonn) MOP sends the biotech industry is that they will enjoy at least for this period, impunity in their actions"[53].

Gene Campaign, which has been working on developing components of a liability law for India, had organised 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.

This paper seeks to provide the context, existing opinions and elaborate Gene Campaign's position as well as the consensus recommendations for some of the outstanding substantive issues, within the ambit of liability and redress.

[53] Ruiz-Marrero, Carmelo, "The Biosafety Protocol and the Future of Biosafety", Americas Policy Program, Centre for International Policy, 25 September 2008.

Legally Binding, GMO Specific Liability Regime

As already stated, negotiations at the Contact Group on Liability and Redress at MOP 4 mainly revolved around the choice of an instrument for liability and redress. The delegates debated the following options: non- legally binding guidelines; a legally binding regime; and a two-step approach consisting of developing one or more non- binding instruments, evaluating the effects of the instruments, and then considering developing one or more legally binding instruments. Some delegates opposed a legally binding regime, underscoring the lack of time and the complexity of such a regime.

On the other hand, with the objective of avoiding a legally binding regime, a global industry coalition composed of BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto and Syngenta proposed a voluntary compensation scheme in lieu of a binding instrument. Referred to as the 'compact', it is a contract, a voluntary commitment among Members active in plant biotechnology who choose to sign the instrument and who qualify for Membership. These entities agree that if their bio-technology derived products cause actual damage to biological diversity, the responsible member will provide recourse for that damage, under the terms and conditions of the contract.

The industry position all along has been that there is no evidence that any unique hazard exists in the development of GM because of the novel gene construct. Such claims however fall short of the truth. Reports and articles reveal that only about 1% of the genetic transfer yields the desired result in comparison to 99% normal offspring from natural sexual breeding. The incorporation of foreign DNA alters the organism in constantly unpredictable ways. Most, if not all commercially approved transgenic lines are genetically unstable and non-uniform. Thus, the claim that no liability is required as there is no evidence of damage is not only dubious, but also, complacent.

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. It is a fact of biology that pollen will follow and with that genes will flow. The interests of justice and equity also demands that there exists a clear binding framework for compensation to the injured party should harm occur. It is also unacceptable for an international legally binding instrument to be dependent on a voluntary private scheme floated by industry. This is completely contrary to fundamental principles of good governance and transparency. Also, 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.

Gene Campaign thus advocates:

- A legally binding, GMO specific liability regime based on the precautionary principle, where liability can be imposed on the basis of possible effects of introduction of GM crops for which strict scientific proof is not yet available.
- 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.

Primary Civil Liability with Residual State Liability

States setting up a liability and redress regime need to consider whether to opt for a state liability regime or a civil (or private) liability regime or a combination of both.

The concept of state liability denotes the liability of a state for damage suffered by another state. It is based on the premise that every state is responsible for the actions of its nationals and that every state has the function of protecting the interests of its nationals. Thus, here, the legal relationship is between the state where the damage originated and the state where damage was sustained. The concept of state liability in the environmental field is not well developed. The 1972 Convention on International Liability for Damage Caused by Space Objects is one of the only examples of an international treaty on state liability, which addresses damage caused in one state by space objects launched in another state.[54]

On the other hand, civil liability refers to the liability of a private entity (an individual or a company) for damage suffered by another private entity, where claims are brought before a national court by the private entity that suffered the damage. However, it is possible for a government authority to be the claimant or the defendant if it is in the same factual position as a private entity (for example, if it is the owner of a property that was damaged or the operator of a facility that caused the damage).

Gene Campaign takes the position that liability and redress should be channelled to the same agency that is responsible for causing the damage. While the primary

[54] Peiry, Katharina Kummer, 2005, "State Liability and Civil Laibility: Two Fundamentally Different Concepts", Paper No.3, *Biosafety Prtocol Process on Liability and Redress: Food for Thought on Key Issues*, Switzerland: Kummer EcoConsult.

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 authorised 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.

Gene Campaign advocates:

- A regime providing for primary civil liability of private parties and residual liability of the state, in recognition of the duty of care owed by both.

- A liability regime equipped to address situations where-
    1. Stipulated conditions not complied with- private party being held liable.
    2. Loss or damage occurs despite compliance with precautions- liability of both technology provider as well as regulatory agencies.

Damages- Functional and Geographical scope

Owing to the specificities associated with GMOs and uncertainties concerning the magnitude of possible damages to the environment and the extent to which they may occur over a long period of time, the term 'damage' needs to be given the widest interpretation. This need also arises from the fact that unlike other damages to the environment which could be rectified, it is not possible to 'recall' a genetically engineered organism once it is introduced into the environment.

A liability and redress regime should also be able to address the question of damages to areas which are not the object of real property rights, such as common/ community lands and the community should have the statutory right to seek reparation for the damage caused which may have consequences for their traditional livelihood, socio- cultural life, indigenous knowledge systems etc. To address this, apart from damage in areas under national sovereignty, the regime should also cover damage in areas beyond any national jurisdiction- that is, common lands. The precautionary principle needs also to be applied to the introduction of GMOs in the high seas.

Gene Campaign advocates:

- 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.

Definition and Valuation of Damage

Because of the peculiar nature of LMOs/GMOs and the limited knowledge and experience with such products, many countries have felt the need for focused attention in defining, valuing and classification of such damage. Countries have recognized that the concept of damage deserves top priority by the Ad Hoc Group, considering that everything else flows from it. It has been pointed out that with regard to damages, the liability and redress regime needs to build upon existing principles in the field of civil liability and take into account the specificities of modern biotechnology. According to Cullet, this implies providing a definition of damages which includes damages to the environment, to human health, to property and to socio-economic interests. Environmental damage is central to a liability and redress regime for GMOs, given that the Biosafety Protocol is an environmental law treaty. However, while defining environmental damage and damage to biodiversity, the specific context of biotechnology needs to be kept in mind. As recognized in Article 26 of the Protocol, socio- economic aspects constitute an important concern of Member States and in fact some of the main impacts of the introduction of GMOs in agriculture may turn out to be the socio- economic aspects related to livelihood concerns. These impacts need to be recognized in a comprehensive definition of damages in the context of GMOs. Similarly, risks to human health which also fall within the scope of the Protocol need to be considered as a number of GMOs end up directly or indirectly in the food chain.

Closely related to the definition of damage, is the issue of valuation of damage. Where damage is not directly linked to property rights or where damage cannot be easily measures in financial terms such as in the case of loss of biodiversity, compensation cannot be conceived only in monetary terms. Where no direct economic loss is registered, the restoration of the environment is one solution. In case where damage is irreversible, other solutions must be devised, for example,

creation of a similar environment in a different location or a criminal sanction. The Lugano Convention is noteworthy with regard to the definition of damage it proposes which includes not only impairment of the environment- limited to the costs of measures of reinstatement actually to be undertaken- but also the costs of preventive measures and any loss or damage caused by preventive measures.

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.

Gene Campaign advocates:

- Definition of damage to include:

(a) Damage to human health including:

(i) Loss of life or personal injury or disease together with medical costs including costs of diagnosis and treatment and associated costs;

(ii) Impairment of health;

(iii) Loss of income;

(iv) Public health measures;

(b) Damage to or impaired use of or loss of property;

(c) Loss of income /directly/indirectly/derived from an economic interest in any use of the environment/ biological diversity, incurred as result of impairment of the environment/biological diversity/ taking into account savings and costs;

(d) Loss of income, loss of or damage to cultural, social and spiritual values, loss of or reduction of food security, damage to agricultural biodiversity, loss of competitiveness or other economic loss or other loss or damage to indigenous or local communities.

(e) Damage to the environment and biological diversity, including:

(i) The costs of reasonable measures of reinstatement or remediation of the impaired environment/biological diversity, /where possible/, measured by the costs of measures actually taken or to be undertaken, including introduction of original components;

(ii) Where reinstatement or remediation to the original state is not possible, the value of the impairment of the environment, taking into account any impact on the environment, and the introduction of equivalent components at the same location, for the same use, or on another location for other types of use, and

(iii) The costs of response measures, including any loss or damage caused by such measures; and

(iv) The costs of preventive measures, including any loss or damage caused by such measures

(v) The costs of any interim measures; and

(vi) Any other damage to or impairment of the environment, taking into account any impact on the environment.

- Unlike other damages, in biology, damage takes much time to surface and be visible in actual terms. Thus, for the plaintiff, absolute proof of damage would be difficult to come up with, as it occurs over a considerable length of time. Evidence of gene introgression should be constituted sufficient on its own to establish damage.

Liability of Non- Parties

Gene Campaign advocates:
National rules on liability and redress should also cover damage resulting from the transboundary movements of LMOs from non-Parties, in accordance with Article 24 of the Cartagena Protocol and COP/MOP decisions BS-I/11 and III/6.

Channelling of Liability

In the handling, transport and use of LMOs, there are often a number of persons involved. In the event of damage, the applicable legal rules determine which of these persons are liable. National and international civil liability rules use different ways to attribute liability. Options include:

- Channelling liability for the entire transaction to one particular operator in the chain (for examples, the producer, or the person arranging the transboundary movement)
- Channelling liability to each operator for the particular stage of the transaction for which he or she is responsible
- Holding all persons involved in the transaction jointly and severally liable; this means that the victim will be able to bring a claim against any or all of them for the entire damage.[55] The notion of channeling comes into play when the standard of liability is not fault based. In those instances, liability is normally channeled in accordance with the polluter- pays principle. According to the submission of the European Union, all the activities must internalize all the costs, and the industries and activities connected with the use of LMOs are not an exception of such a principle. Accordingly, it has been submitted that the primary liability for damage resulting from the transboundary movement of LMOs should rest with person or persons responsible for the carrying out of an action related to the transboundary movement of LMOs that may be directly or indirectly at the origin of the damage.

[55] Peiry, Katharina Kummer, 2005, "Channelling Liability to Persons Having Control Over an Activity Provides the Necessary Legal Certainty", Paper No.9, *Biosafety Protocol Process on Liability and Redress: Food for Thought on Key Issues*, Switzerland: Kummer EcoConsult.

While the polluter pays principle should prevail, the State, under whose jurisdiction or control activities involving LMOs are carried out, cannot escape totality from the liability. Principle 21 of the Stockholm Declaration and Principle 2 of the Rio Declaration both recognise the general duty of States for transboundary harm. This obligation means that States must take measures to prevent the occurrence of transboundary environmental harm and where harm does occur, to redress the consequent damage. Even if private individuals cause the environmental injury in their personal capacity, States still have the obligation to prevent the harm by taking appropriate measures by exercising due diligence to prevent private individuals from causing environmental harm.

One issue being debated in this context is channeling the liability to the person who is in the best position to prevent damage or one who is most financially liquid. Another issue is whether liability should be channeled to a single person or multiple persons. While it has been admitted that the channeling to multiple persons will result in the need for multiple coverage for liabilities arising out of a single accident, require a bigger share of the capacity of the relevant securities market and hence, increase the costs of covering such liabilities, nevertheless, channeling to multiple persons enhance the options for claimants to recover damage.

Gene Campaign advocates:

- Application of Polluter pays principle.
- Liability to be channelled jointly or severally to the following persons, except in the case of agriculture or forestry:
    - The developer
    - The producer
    - The notifier
    - The exporter
    - The importer
    - The owner of the installation
    - The carrier
    - The supplier, provided he knows the nature of the LMOs and the risks associated thereto
    - The provider of the technology
    - The governmental agencies that deal with the LMOs e.g. customs etc.
    - The operator
- The definition of operator to include
    - Any person who has the operational control;

- Any person who is in the best position to control the risks and prevent the damage;
- Any person who operates the activity from which the LMOs are discharged;
- Any person who does not comply with the provisions implementing the Biosafety protocol;
- Any entity who has the responsibility to put in place the provisions for implementing the protocol;
- Any person to whom intentional, reckless or negligent acts or omissions can be attributed.

- If the definition of operator is taken to mean any person or entity which has the control of the LMO at the time of the incident causing damage it could result in end users such as farmers being held responsible. Thus, there should be a provision expressly exempting end- users from any liability.
- In case of agriculture and forestry, when harm is caused by bringing LMOs into the market for use as aids to agriculture or forestry, the following operators shall be responsible:
  - The producer who first placed these organisms on the market;
  - In case of imported LMOs, the producer who first placed them in the market abroad and the importer are jointly and severally liable.
  - The owner of a company or installation that imports such organisms is jointly and severally liable with the producer; and
  - The persons who have handled such organisms improperly or have otherwise contributed to the worsening of the harm (Here also, end users should be expressly exempted from liability).
- When LMOs are released unintentionally during transport, the transporter should be responsible for taking immediate measures, but the owner or the sender will pay the cost of measures taken.
- The states are often involved in promoting biotechnological innovations. Thus, state liability for the acts that are not prohibited by the international law.
- The Residual state liability shall apply in the cases where it is either impossible to identify the perpetrator who had caused damage or where all other options had been exhausted. Also in cases where the financial securities of the primary liable person are not sufficient to cover liabilities

Limitations on Patent Liability

An important question which states need to address, while drawing up a framework for liability and redress, is the question of patent liability. Patent

liability is relevant in the context of the debate for two broad reasons.[56] First, while there is no recognized legal connection between the granting of a patent on a GMO and the biosafety procedures leading to its commercialization, the link exists in practice and needs to be recognized. Second, while the liability of persons illegally using a patented invention has generally been separate from biosafety considerations, this is, for instance, not the case in the context of GM seeds where there is a potential clash of liabilities between the liability of the entity commericalising the seed and the liability of the farmers found in possession of GM seeds without having purchased it from a licensed dealer.

Since most GMOs are protected by patent or other intellectual property rights, the case of Monsanto v P. Schmeiser[57] deserves special attention in the context of patent liability arising from contamination (as opposed to breach of contact between the farmer and the patent holder). In this case, Percy Schmeiser was held liable by the Canadian Supreme Court for having acquired the patented GM canola involuntarily. In other words, the simple presence of the GM seed on his land without his knowledge or consent, was found to be an infringement of Monsanto's patent.

The Schmeiser case highlights the need for liability regimes to address the relationship between intellectual property rights and property rights such as land rights as well as the relationship with other rights such as the fundamental right to food. Indeed, if the Schmeiser precedent were to be adopted in other jurisdictions, it would have far reaching consequences for farmers the world over, as well as to issues related to land management generally. For instance, a land user will be both responsible for the unwanted intrusion on the land and for the damage that occurred as a result of the unwanted intrusion/contamination against the will of the land user.

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.

Gene Campaign advocates:

[56] Cullet, P., "Domestic Policy Options: International Trends in Liability and Redress", Asian Biotechnology and Development Review, July 2007, Vol.9 No.3, pp.1-18.

[57] (2004) SCC 34, Judgement by the Canadian Supreme Court.

- The framer should have legal protection against unauthorized transgression or trespass by an unwanted alien crop/ gene.

- In a situation where owing to contamination, the farmer has saved seeds of the GM crop, the Farmer's Right to save, replant or sell seeds cannot be made subject to any claim by the GM crop owner.

- The scope of the provision for innocent infringement under the Protection of Plant Varieties and Farmers' Rights Act, 2001 require to be extended. Under this provision, farmers are guarded against legal actions arising from the infringement of rights granted under the Act.

- No liability should be attached for unintentional damages caused by a farmer who has chosen to grow GM crops. A farmer's decision to grow GM crops can hardly be attributed to an intention to cause damage and it is unlikely that he would even have the knowledge of any such possible damage.

Standards for Liability

International as well as national legal regimes generally provide for three standards of liability, which are:

- Fault-based liability, which requires that the damage be caused through a wilful or negligent act of the liable person. Fault is determined on the basis of whether or not the person to whom the damage is attributed observed the prescribed duty of care in carrying out the activity.
- Strict liability, which applies regardless of whether or not the person to whom the damage is attributed is at fault. The claimant is only required to prove the damage and the causal link, but not a failure to observe the duty of care. This means *prima facie* liability, but the actor can avail of a limited set of defenses such as act of God, act of war or civil unrest, and intervention by third parties.

- Absolute liability- This standard of liability only requires the establishment of a causal link between an act or omission and the damage, and does not allow for defences.

Thus, the rules of both strict and absolute liability make the defendant liable for accidental harm caused, without any intention and negligence on his part. The rationale behind these higher standards of liability is that the activities coming within their fold are those entailing extraordinary risk to others, either in the seriousness or the frequency of the harm threatened.

The rule of strict liability, as laid down in Rylands v Fletcher[58], provides for three conditions for its application. Firstly, the defendant should have brought or collected on his land some dangerous thing, that is, a thing likely to do mischief if it escapes. The liability exists whether the land is or not owned by the defendant. The second condition for the rule to apply is that the thing causing the damage must escape to the area outside the occupation and control of the defendant. And thirdly, there must be non- natural use of the land, with the concept of non- natural use being flexible. This rule of strict liability for damage may best be summed up in the words of Blackburn, J.: "The rule of law is that the person who, for his own purpose, brings on his land and collects and keeps there anything likely to do mischief if it escapes, must keep it at his own risk; and if he does not do so is prima facie answerable for all the damage which is the natural consequence of its escape". As already mentioned, this rule allows for some exceptions or defences.

In most national legal regimes, strict liability for environmental damage applies to activities generally recognized as hazardous with high potential of causing severe damage to the environment and human health, such as marine transport of crude oil, transport and management of toxic chemicals and wastes, and nuclear activities. There is a growing respectable scientific concern that GMOs are intrinsically hazardous. Even if the incidence of any harm occurring may be low, the magnitude of the harm, once it takes place, could be incredibly great, with long term and short term impacts on other crops and species, ecosystems, human and animal health and socio- economic effects. The potential costs arising out of harm caused by genetically modified organisms (GMOs), in a worst case scenario, could easily run into millions. The movement of these GMOs, through trade, to parts of the world with knowledge that these countries lack the capacity to assess the technology and its products adequately and put in place measures to deal with them safely, makes the transboundary activity ultra hazardous as well[59]. Also going by the conditions laid down in Rylands v Fletcher, damage due to GMOs fulfils these requisites, in the sense that GMOs are dangerous things likely to do mischief on escape, and the damage escapes to the area outside the control of the defendant. Also, use of GMOs could be interpreted as non- natural use of the land.

The majority of nations that have implemented GMO liability legislation have recognized the pitfalls of a fault- based system. Reports submitted on national laws[60] show that, to a large extent, the basic standard to apply to LMO-related

[58] (1868) LR 3 HL 330

[59] Nijar, G.S., 2000, "Laibility and Redress for GMO Harm: The Starlink Case Study", Third World Network, Doc. TWN/Biosafety/2000/E

[60] Intergovernmental Committee for the Cartagena Protocol on Biosafety, 2002, "Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms", UNEP/CBD/ICCP/3/3

activities is strict liability, where liability is engaged regardless of fault. In the Danish Act on Environmental Damage, all the activities identified in the list of the Act are subject to strict liability. The German Genetic Engineering Act focuses on the sheer risk posed by LMOs whether or not the person responsible for the genetic engineering operation is at fault. Section 23 of the Norwegian Act lays down strict liability "for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of LMOs into the environment".

It has been pointed out that a strict liability regime should be implemented when the need to protect the public and provide effective compensation outweights the need to establish the moral culpability of the defendant.[61] It has been recognized that with the rapidly changing nature of biotechnology, it is difficult to define a socially optimal duty of care and assess when that duty has been breached. When a strict liability system is in place, the search for a socially optimal duty is unnecessary. A strict liability system is especially appropriate in a situation where a party derives an economic benefit from the risk it creates (which is the case with trade in GMOs).

Similarly submissions[62] have been made in favour of a strict liability regime for GMOs because it is iniquitous to expect that resource poor farmers who plant Bt cotton for instance, and who suffer some sort of damage, should have to prove the causal connection between the act of planting GM cotton and the resultant damage that has arisen from such planting. It is believed that the interest of the public is best by a strict liability approach.

The Space Objects Liability Convention imposes strict or absolute liability. Three reasons have been advanced to justify the imposition of strict or absolute liability in the context of the Space Objects Convention, which resonates well with the challenges posed by GMOs. First, scientific causation is difficult to establish given the nature of the technology and its relative short history. Second, there is secrecy attached to the space exploration programmes. Accessing information to establish fault would be unusually difficult. Third, the person who benefits from the activity should bear the cost.

In recognition of the intrinsically hazardous nature of GMOs, Gene Campaign supports the adoption of a strict liability regime for damage due to GMOs. In addition to strict liability, Gene Campaign believes in the need for adopting absolute liability zero tolerance legislation for contamination in centers of origin and genetic diversity.

---

[61] Migus, M., 2004, *GMO Statutory Liability Regimes: An International Review*, Toronto: Canadian Institute for Environmental Law and Policy.

[62] African Centre for Biosafety, South Africa, 2005, South Africa Civil Society Submissions and Contributions to the Open- Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress on the "Annex" to the Working Group's Report (May 2005).

The Cartagena Protocol points out that centers of origin and centers of genetic diversity are of crucial importance to the future security of humankind (Preamble, 141) The Protocol signals the need for special care in the conservation of such locations and the need to be particularly sensitive to the potential effects of LMOs on such centers. This is of special concern for countries that are themselves centers of origin and diversity of crop plants.

Here, it may be mentioned that the Indian region is one of the world's eight centres of crop plant origin and diversity. At least 166 food/crop species and 320 wild relatives of crops have originated here. Gene flow and contamination in these centres of origin and genetic diversity could lead to irrepressible loss of traditional plant varieties and agricultural diversity, having grave consequences for food security. Hence, there is need for imposition of absolute liability without exceptions in these regions. This rule was evolved in the Indian legal system in M.C. Mehta v Union of India[63]by the Supreme Court of India as part of Indian law in preference to the rule of strict liability laid down in Rylands v Fletcher. It expressly declared that the new rule was not subject to any of the exceptions under the rule in Rylands v Fletcher. The Court observed that " this rule (Rylands v Fletcher evolved in the 19th century at a time when all these developments of science and technology had not taken plave…We have to evolve new principles and lay down new norms which would adequately deal with the new problems which arise in a highly industrialized economy". The Apex Court laid down a new "no- fault" absolute liability standard which provided that where an enterprise is engaged in a hazardous or inherently dangerous activity and harm results to anyone on account of an accident in the operation, the enterprise is strictly and absolutely liable to compensate all those who are affected by the accident. Such liability is not subject to any of the exceptions which operate vis-à-vis the tortuous principle of strict liability. Such an enterprise owes an absolute and non- delegable duty to the community to ensure that no harm results to anyone and if any harm results, the enterprise must be absolutely liable to compensate for such harm.

Gene Campaign thus advocates

(i) A no- fault, strict liability regime for any undesirable geneflow or geneflow to untargeted species, because of the current uncertainties concerning the magnitude of the possible damages and the extent to which they may occur over a long period of time.

(ii) Imposition of absolute standard of liability with no exceptions in case of any kind of geneflow no matter even, 0.01% in centres of origin and genetic diversity.

[63] AIR 1987 SC 1086

Exemptions from Liability

The concept of liability is based on the notion that a person or entity that has control over an activity is responsible for damage caused by that activity. This applies to both fault- based and strict liability. The law recognizes some defences, which a defendant is allowed to take in civil liability proceedings. By proving certain events that are beyond the control or influence of anyone, the defendant may avoid his liability. However, no such defences can be pleaded in case of absolute liability.

Liability and redress regimes differ according to the number and the scope of the defences allowed. The main defences allowed generally include the following:

- Natural phenomenon of exceptional, inevitable, unforeseeable and irresistible character (also referred to as Acts of God or *force majeure*)
- Armed conflict, civil war, insurrection and similar events
- Act or omission of a third person

Other defenses that can be found in international and national liability and redress regimes or drafts of such regimes include:

- Compliance with a compulsory measure imposed by a public authority
- Permission of an activity by means of a generally applicable law or in a specific authorization issued to the operator
- The state-of-the-art defence for activities that were not considered harmful according to the state of scientific and technical knowledge at the time they were carried out.

Gene Campaign advocates:

- No exemption in case of absolute liability, which is the standard for contamination in centres of origin.
- In case of strict liability, the exemptions should be:

(a) Act of God/ *force majeure*
(b) Act of war or civil unrest
(c) Intervention by a third party (including intentional wrongful acts or omissions of the third party
(d) Compliance with compulsory measures imposed by a competent national authority
(e) Permission of an activity by means of an applicable law or a specific authorization issued to the operator
(f) The 'state-of-the-art' in relation to activities that were not considered harmful according to the state of scientific and technical knowledge at the time they were carried out.

- However, in cases d, e, and f, the discharge shall be partial and the state shall take the residual liability.
- In case the damage occurs due to third party intervention, the third party should be held liable.

Causation and Burden of Proof

Causation, also referred to as the 'causal link', is the link that the law establishes between an event, action or omission and specific damage: only if causation is demonstrated will the person responsible for the action be held liable for the damage. This is one of the basic requirements for liability- whether fault- based, strict or absolute, to be attributed to a person or to another legal entity.

In law, the defendant is held liable for the wrongful act only if it is the proximate, direct or immediate cause of injury (*causa causans*) and not merely a *causa sine qua non* (cause without any other cause). The court employs the test of reasonable foresight or probability, as per which if the consequences of a wrongful act could have been foreseen by a reasonable man, they are not too remote. There is also the test of directness, according to which a person is liable for all the direct consequences of his wrongful act, whether he could have foreseen them or not; because consequences which directly follow a wrongful act are not too remote.

It would be difficult to apply the generally followed legal tests to establish causation in the context of GMOS/LMOs, because of the complexities of their interactions with the receiving environment and the possible timescales involved. The question of causality is one which has been widely discussed in the context of environmental damage. Various questions regarding the difficulties which can surface concerning the identification of the link between the source of the contamination of the environment and the felt impacts have been debated. The problem first surfaced in the context of the environmental contamination by sources which are either distant in space or time from the impacts. Examples

include the case of damage caused in a radiological emergency which can take years to or decades to become apparent, and the case of lon- range air pollution where the source may be hundreds of miles away from the impact and may also be in a different country. These issues are quite similar in case of GMOs also, where source may be distant in space or time from the impact. Then again, in case of GMOs, damage may be too diffused to be traceable, although having the potential to be significant, long term or wide spread. The existing tests would fail to establish causation in a case, where for instance, the increase in usage of herbicide in a GM Herbicide Tolerant crop damages the crop in the neighbouring field. In such a case, shall the damage be attributed to the GM nature of the crop or the activity of over usage of herbicide associated with such farming.

A solution for this problem lie in case law itself; in Scott v Shepherd[64], it was held that it is not necessary that the event which is immediately connected with the consequences is proximate and that farther from it is too remote.

Various countries have tried to overcome this difficulty in establishing causation in case of LMOs/GMOs by adopting the approach of reversal or reduction of the burden of proof in that causation is presumed until the defendant can demonstrate otherwise. The Austrian Law on Genetic Engineering as well as the German Genetic Engineering Act has adopted this approach. When the damage is caused by LMOs, it is presumed to have been caused by such properties of these organisms as a result from genetic engineering operations. Yet such presumption would be invalid if the damage is likely to have been caused by other properties of these organisms.

Gene Campaign advocates:

- Determination of causation in case of LMO related damage should not be subject to the usual standards adopted in law, as it is both difficult and different.

- Causation shall be presumed to have been caused by introduced/ modified traits of LMOs/ GMOs, unless proved to have been caused by some other properties of these organisms.

- Taking into account the specificities of GMOs, the burden of proof should be reversed from the plaintiff to the defendant (which the law holds 'justified' in special circumstances.

[64] 17 W. Bl.892.

Standing/ Right to Bring Claims

The subjects of the right to make claims are different for interstate claims based on international law, on the one hand, and claims based on civil liability, on the other. As for interstate claims based on international law, a State has the right to make claims on its own behalf that may include claims on behalf of its nationals and in special cases, on behalf of a group of States or the international community as a whole (Articles 42 to 48 of the 2001 ILC Articles on the Responsibility of States for Internationally Wrongful Acts (cited in the Submission of the European Union at the Meeting of the Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Montreal, 18-20 October 2004, UNEP/CBD/BS/TEG-L&R/1/INF/1. As for claims based on civil liability, the right to make claims is governed by the applicable domestic law on procedural matters. Generally, in most legal systems, persons or other entities wishing to bring a claim must demonstrate that they have an interest as recognized by the applicable law. Usually, the interest of a party is recognized if the person or entity is directly and materially impacted by the alleged damage.

One issue which has been widely debated in the context of the GMO liability and redress debate is whether or not a non- governmental organization (NGO) has the right to sue and seek remediation for natural resource damages. An NGO acting in the general interest (*actio popularis*) serves a fundamental civil purpose, fulfilling capacities for which the government is incapable. They are the vessel through which the affected parties' concerns are communicated.

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 *actio popularis* as well, thus giving a right to non- governmental organizations.

Gene Campaign advocates:

1. An interested party is any person directly or indirectly affected by or engaging in the transboundary movement of GM organisms. A person advocating on behalf of those directly or indirectly affected, such as an NGO, is also an interested party.
2. Depending upon the type of damage, standing to bring claims should rest with the following

(a) Traditional damage- affected person, dependents, or any other person acting on behalf or in the interest of that person
(b) Damage to biodiversity, environment, public health, health of animals: Affected state, interested groups acting in vindication of common interest, interested groups acting in public interest
(c) Damage to human health: affected state, injured person, interested groups acting in vindication of common interest, interested groups acting in public interest.
(d) Socio- economic damage: affected communities, injured person, interested groups acting in vindication of common interest, interested groups acting in public interest, state acting in interest of communities.

Limitation in Time

The limitation of liability in time is a common feature of liability and redress regimes to reduce the risk of liability of the person to whom liability has been channeled and to avoid legal proceedings where the evidence has become unreliable. Time limits are generally of two kinds: absolute time limit, within which an action may be brought and relative time limit, during which a victim should be allowed to bring a claim after the identification of the damage and the person liable.

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. The Swiss Gene Technology Act provides for an absolute time limit of 30 years and a relative time limit of three years. Similar provisions exist in the

Danish Act on Enviornmental damage, which includes two time- period limitations:

(i) Five years from the day of knowledge (or should have had knowledge) of the damage, the tort feasor, and his location'

(ii) A maximum of 30 years counted from the time of the act having caused the damage.

Gene Campaign advocates:

- Considering the difficulty in estimating the exact timeline of potential damages and the fact that long-term damages cannot be ruled out, an absolute time limit of 50 years (a period during which effects on two generations could be manifest).

- A relative time line of atleast 10 years, considering the fact that an affected party (for instance, a community or a farmer) in a developing country like India may be ill- equipped to institute a claim in short time frame.

Financial Safeguard/ Insurance

An important issue under strict liability is the extent to which it should be possible for GMO developers to transfer their risks to others by means of liability insurance. The main argument in favour of insurance is that it ensures victims of actually receiving compensation, whereas, strict liability on its own could lead to situations in which the liable firm proves to have inadequate financial resources to meet the claim.

Considering the nature and scope of possible damage that may result from release of certain LMOs, Egypt (UNEP/CBD/BS/TEG-L&R/1/INF/1) in its submissions before the Technical Group of Experts has pointed out that it will not be either fair or realistic to set a ceiling for the compensation. Thus, this would require establishing a system of compulsory insurance, rather than a voluntary fund, to cover such liability.

Compulsory insurance have been mandated by the Convention on Civil Liability for Oil Pollution Damage, 1969 and the Basel Protocol on Liability and Compensation Resulting from the Transboundary Movement of Hazardous Wastes and their Disposal. Elaborate rules exist under these international conventions for States to ensure that the person/s potentially liable take out the compulsory insurance and provide adequate evidence of the insurance or other cover.

In order to guarantee adequate compensation for victims of damage, some countries also require the operator to maintain compulsory insurance. In Australia, the Gene Technology Regulator may impose a license condition on a person dealing with a LMO requiring them to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing. Under the German Genetic Engineering Act, operators are obliged to provide for guarantee for any damage or injury that may be caused by genetic engineering operations. Similarly, the Swiss Gene Technology Act requires the proprietors to guarantee their liability through insurance or in another form.

In India, we have the Public Liability Insurance Act, 1991, which provides for mandatory insurance for the purpose of providing an immediate relief to the persons affected by accidents occurring while handling any hazardous substance. The Act covers every industry, public or private, which handles hazardous substances. The Act defines a 'hazardous substance' as one which, by reason of its chemical or physio- chemical properties or handling, is liable to cause harm to human beings, other living creatures, property or the environment. 'Handling' in relation to any hazardous substance, includes the manufacture, processing, treatment, packaging, storage, transportation, use, collection, destruction, conversion etc. of such hazardous substance. Thus, GMOs/LMOs may be construed as falling within the ambit of this Act, thus, requiring their handling to be compulsorily insured.

Many have suggested that compulsory insurance on its own is not sufficient, claiming that when a risk manifests itself as a loss, insurance can only pay indemnity in the form of money, and therefore, the only risks that qualify as insurable are those that are generally accepted, and about which there is consensus as to the value of a damaged entity and the way a loss can be

compensated.[65] Crucially, if the liability instrument should demand compulsory insurance, this requirement will only bind the liable party, and the insurance company may still limit or decline to provide cover.

In the circumstances, it has been felt that issues of coverage of liability should go beyond merely requiring compulsory insurance by the identified liable person. Arguments have been advanced in favour of an international indemnification fund, established with contributions from the biotechnology industry, and other actors benefiting from the international commerce involving GMOs, as well as those countries that have approved activities (imports, exports, release) in relation to GMOs. However, since the contributions by the State come from public spending budgets, their contributions should only be used in circumstances where the liable person is unable to meet its obligations. An example can be taken from the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 (also referred to as the HNS Convention), which provides for the creation of an international indemnification fund.

Gene Campaign advocates

1. Commercial insurance should be compulsory for all parties involved in the transboundary movement of GM organisms.

2. Creation of an international indemnification fund to secure compensation for damage that may be caused by LMOs/GMOs.

Access to Information/ Right to Know

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. Both the Austrian Law on Genetic Engineering and the German Genetic Engineering Act contain such provisions, safeguarding the right to information of the injured party, subject to the rules of confidentiality.

[65] African Centre for Biosafety, South Africa, 2005, South Africa Civil Society Submissions and Contributions to the Open- Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress on the "Annex" to the Working Group's Report (May 2005).

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 exists 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.

Gene Campaign advocates:

- Proper labeling, which confers the consumer the right of choice to accept or reject a product.
- Farmers opting to cultivate GM crops should be provided with full information about the possible effects by those responsible for introducing them.
- Traders, dealers etc. who stock or sell GM seeds must also be provided with complete information, so as to prevent contamination.
- Above all, specific legal provisions must be introduced to ensure public participation in the decision making process for the introduction of GM crops/ food.

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 uncertainities 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.

References

African Centre for Biosafety, South Africa, 2005, South Africa Civil Society Submissions and Contributions to the Open- Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress on the "Annex" to the Working Group's Report (May 2005).

Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, "Liability and Redress under the Cartagena Protocol on Biosafety", May 16, 2008, UNEP/CBD/BS/COP-MOP/4/L.18.

Cook, Kate, 2002, "Liability: 'No Liability, No Protocol' ", in Bail, Christoph, Robert Falkner and Helen Marquard, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?*, London: The Royal Institute of International Affairs.

Cullet, P., "Domestic Policy Options: International Trends in Liability and Redress", Asian Biotechnology and Development Review, July 2007, Vol.9 No.3, pp.1-18.

GreenPeace Briefing, "Overview of the Current Text under Negotiation on Liability and Redress under the Cartagena Protocol on Biosafety", May 2008.

Intergovernmental Committee for the Cartagena Protocol on Biosafety, 2002, "Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms", UNEP/CBD/ICCP/3/3

International Institute for Sustainable Development, "Summary of the Fourth Meeting of the Parties to the Cartagena Protocol on Biosafety 12-16 May 2008", *Earth Negotiations Bulletin*, Vol. 9 No. 441, May 19, 2008.

Migus, M., 2004, *GMO Statutory Liability Regimes: An International Review*, Toronto: Canadian Institute for Environmental Law and Policy.

Nijar, G.S., 2000, "Laibility and Redress for GMO Harm: The Starlink Case Study", Third World Network, Doc. TWN/Biosafety/2000/E

Peiry, Katharina Kummer, 2005, "Channelling Liability to Persons Having Control Over an Activity Provides the Necessary Legal Certainty", Paper No.9, *Biosafety Protocol Process on Liability and Redress: Food for Thought on Key Issues*, Switzerland: Kummer EcoConsult.

Peiry, Katharina Kummer, 2005, "State Liability and Civil Laibility: Two Fundamentally Different Concepts", Paper No.3, *Biosafety Prtocol Process on Liability and Redress: Food for Thought on Key Issues*, Switzerland: Kummer EcoConsult.

Ruiz-Marrero, Carmelo, "The Biosafety Protocol and the Future of Biosafety", Americas Policy Program, Centre for International Policy, 25 September 2008.