Thoughts on the background, vision, design and outcome of the subject of common rules on liability and redress within the Cartagena Protocol of Biodiversity

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Origin and goals

The Rio Convention on Biological Diversity was developed to protect the planet's flora and fauna from gradual extinction. Among its provisions it was decided to establish rules to regulate the transboundary movements of genetically modified organisms (GMOs). The rules were to be codified within a biosafety protocol. Initially stated to justify the protocol were environmental hazards which had to be prevented. The rules that were to emerge were to be general, uniform and binding.

The express purpose of the activist groups advocating a strict Protocol was to keep out the new GMOs from countries adhering to the Convention of Biological Diversity.

The Protocol of Biosafety project stated that its objectives were to protect the environment and especially its biodiversity from certain hazard attributed to GMOs. The wording of the Protocol finally was changed to living modified organisms or LMOs To this objective were added in succession protection of human health, protection of the right of native populations to their knowledge, and finally protection, although stated in other terms, to the sovereignty of countries regarding their right to use or not the new technology and accept or refuse GMOs in their territory.

When negotiations between Governments started in 1995, it was just before the first large scale launching of plantings of GMOs took place. The seed was being produced in 1995, and this awakened the anti-GMO groups which saw the immediacy of a threat to their positions. The Protocol was slowly and painfully negotiated in a series of meetings until it was born in 2000, but it took another three years before 50 countries ratified it and then it could be put into effect in September 2003. In the meantime, millions of hectares of GMOs were being planted in many counties around the world. By 2006 some 102 million hectares were planted that year in 22 countries. The era of modern biotechnology at arrived in full scale and was demonstrating with 10.3 million farmers (90% of them small farmers), who accepted it, that it was the fastest growing agrotechnology in history.

The Convention of Biological Diversity had enunciated the fact that biotechnology held great promises and that the sustainable utilization of biodiversity passed by developing a Biosafety Protocol that would establish a concurrence of positions on how better to utilize the new technology without causing damage to the environment and to biodiversity.

The key question before the Protocol was agreed upon was posed as follows: if GMOs are by nature risky, then why wait until the damage is done? That they should be banned outright was the prevailing rationale among the anti-GMO organizations. Then the international consensus mechanism intended to do so would be the Biosafety Protocol.

One of the instruments to achieve this objective, among others that were introduced one by one in the Protocol, was the provision of strict liability and redress. The reasoning was that by defining damage in very general terms, States and operators involved in the transboundary movement of GMOs, would be liable for real or imaginary damage to the environment and to biodiversity. Such damage could be interpreted as widely and as precisely as a plaintiff decided. And he would have on his side the Precautionary Principle that would leave all options open and which did not need scientific assurance, just simple presumption and support of a receptive environmental authority (such as Ministry of the Environment created to defend the environment and inclined to support the legal actions against the operators of GMOs).

The negotiations of the CBP were hard ones. There were those who established a position that the GMOs were not abstract entities but high quality level products derived from science that introduced high technology and which could produce a great positive impact in agriculture and food supply. This group of states, mostly but not exclusively, formed by grain exporters, claimed support from provisions in the World Trade Organization. On the other hand a majority of less developed countries backed by the European Union, tried to impose by their evident majority, a strongly worded protocol that would have made it close to impossible to allow agricultural GMOs to establish themselves in the world markets. The negotiations brought about final equilibrium positions which are reflected in the wording of the protocol. However some issues were so contentious that no agreement was reached. These points were mentioned as Articles in the Protocol but agreement on their texts were postponed. There are possible improvements in the accepted provisional situation. It is a matter for further discussions in COP MOP4.

Article 27 which deals with liability and redress was one of such articles. It has been dealt with in the Cartagena Protocol discussions and as no accord was reached it was decided to form a Commission with legal and technical experts that would study the situation and prepare the ground for a final agreed solution to be reached in the COP MOP 4 in year 2008. The Commission has been working but has yet to come to a final settlement on which texts will be brought forward for the final negotiations in Bonn in May 2008.

As the Convention of Biological Diversity was a meeting of environmental representatives, many countries had not yet had time to accumulate experience with the issues at stake, and therefore many binding agreements were made at the time of the formation of the Cartagena Biosafety Protocol (CBP) without full information on the benefit/risk balance of GMOs. In cases where disputation on fundamental positions prevented an agreement, undefined language or a decision to kick the subject of the discussion forward to future MOPs, was the compromise not to compromise, at least at the time. The learning curve on the risk of GMOs has moved forward and perceived risks

of present agricultural GMOs, now widely grown and used around the world, have not materialized. Therefore, a softening of radical positions in doubtful quarters may allow a better climate for a moderate type of overview of risk perceptions of GMOs. But since persisting radical positions against GMOs are based mostly on ideological, commercial, and political premises, rather than on scientifically agreed and proven facts, it is deemed very improbable that uniform views on strict binding legislation may be adopted within the context of the CBP.

In the case of Article 27 the problematic issues at MOP4 are not simply of agreement on legal terms. It is neither whether a set of recommendations for the development, modification or use of existing legal instruments privy to each State or binding strict uniform legislation is accepted. If the latter should be the outcome, it is not clearly seen how the differences in outlook among different countries on the use and importance of GMOs, balanced by their corresponding perceptions of risk, could be compromised in a single set of rules under Article 27 of the Protocol.

If the final decision on wording agreement is left to Environmental Ministers, the positions of the Developmental Ministries could be left out of consideration. It has been the experience of previous CBP meetings that some countries have been represented by delegations of persons with a primary environmental leaning and with limited experience on GMOs, to the exclusion of those in their countries who are favorable to the use of GMOs. After all, the CBP is a derivative of the Convention of Biodiversity and it did not originate in either commercial or developmental or scientific settings. In certain countries the composition of their delegations reflects the primeval rooting of the CBP. In other countries balanced delegations are attempted, taking simultaneously into consideration concerns on the environment and on development. Some of these national delegations have done their home work and come to the CBP meetings with clear and firm uniform state positions and defend them. In other countries their delegations are mixed, have no agreement among themselves and are unable to participate in the debate. Because of the nature of the internal debate it is impossible that any state may have consensus on the positions. Therefore, a state position must be based on higher considerations that take into account not only environmental issues but primarily the political, environmental and economic design of the country.

Legislation

International rules establishing civil and state liability are being discussed at present within the CBP.

As the European Union is a leader of the groups of states that have a hard negotiating position on the environment and biodiversity and tend to look with antagonism to the GMOs, we will start with a quick overview of how they have patterned their pown position and legal strategies on liability and redress.

A liability regime for environmental harm arising from the use of genetically modified organisms (GMOs) has been introduced in the EU. It is the Environmental Liability Directive (ELD - 2004/35which was promised during the negotiation of the Deliberate Release Directive (2001/18 - Recital 16). As a consequence of using a GM organism if environmental damage takes place, the operator (company or person) responsible should be liable and would have to pay the costs of remediation.

The Environmental Liability Directive (ELD) in Europe has a number of provisions on which member states can and do exercise discretions.

National legislations in European counries could have inadvertent or intentional overlaps with EU legislation to allow each State its own interpretation in specific cases.

NGOs for conservation of the environment strive to have State legislation more stringent than common legislation and never less than it.

Liability may originate in an authorized release of GMOs in the environment. The likelihood of liability arising for deliberate release in the environment of lawfully authorized GMOs is almost nil. An operator who follows rules and maintains precautions that he may have been instructed to carry, could not be liable for any damage to the environment. The State regulator who has authorized the use of the specific event has released the operator from damage suits of law being effective.

Transfer of responsibility to the owner of the patent is unlikely to be accepted by the owner of the patent unless it can be proven that he is guilty of retaining information that might have provoked the damage. In any case the regulating agency in the country where the event has been registered, and the damage is reported may carry some residual responsibility.

The State from which the GMO was shipped is deemed by some advocates of strict liability as being totally or partially responsible for damages due to GMOs originating in it. However, if the originating state is a non-Party to the CBP it may decline accepting responsibility under the CBP. It could be sued under international rules that might apply, if such rules are accepted by the non-Party state.

It is precisely this conundrum which will make it very unlikely that any international action on assignment of liability and request for redress that may prosper in cases of actual damage that can be well defined and whose responsibility can be laid squarely on a cause linked to a GMO.

Bird Life International’s insistence that the ELD include GMO effects on preservation of bird habitats and their biodiversity is an example of a fixation on GMOs being at the root of any potential environmental damage.

Definition of damage

The definition of biodiversity damage (Art 2 (1)(a) of ELD is as follows: *"any effects that undermine the maintenance and long term viability of the relevant protected biodiversity"* according to the view of the NGO conservationist view. Let us make a dissection of this statement.

What is the meaning of "relevant"? In the view of some what is relevant may not be what others think it is. Such an undefined concept results in objections to plain relevance being accepted. What is meant by undermine? It may mean several things, such as a long term processes working to destroy or disrupt. It surely includes a timing mechanism which is not compatible with a clear cut short term and immediate effect that can be precisely evaluated. Causes that undermine biodiversity are long term processes, underground by nature, sometimes concealed and which may make themselves felt at an unknown time after they start their action, ending in producing the effect. What is protected biodiversity? This means that there is a very cautious separation of some types of biodiversity. Unprotected biodiversity is perhaps separated because it can not be defined or is such a type of biodiversity which is of no particular interest, but the question is to whom and under what definitions and circumstances?

For damage to occur it must be identifiable in an objective manner. It can be observed, has to be proven that it is adverse, and must be quantified in physical measures and in economic terms.

Damage under the CPB is meant to the conservation and to the sustainable utilization of the biodiversity. When introducing the word sustainable some different interpretations are possible, but we will not go into this at this time and just leave it for thought.

The time scale on which damage is to be observed must be defined within the possible activity of a current national authority. This authority is the one responsible for assessing damage.

The presence of a GM transgenic event in a population for which it was not intended, does not constitute by itself damage. This is a key consideration underlying the whole discussion on liability and redress, and which tends to be overlooked.

Damage can be classified as actual, predictable and unpredictable.

Actual damage must be clearly and unambiguously ascertained and is quantifiable[1].

[1] Quantification is to render the logical quantity of a term explicit; measuring is applying a unit of measure to find the number of times it fits in a given dimension of space, volume or weight. In the case of estimation of damage I submit that the term quantification of damage covers the concept better than that of measurement of damage.

Predictable damage surges as a logical effect of a given cause based on previous experience with a high degree of probability. The probability used is a matter of legal decision but must be based on scientific evidence.

Unpredictable damage is a harmful effect manifesting itself at very low frequencies because of its subjection to low likelihood of a conjunction of components that trigger the construction of a causal factor. A low probability of coincidental components of a causal situation or factor coming together in time and place, results in either low or even absence of a harmful effect. In this last case unpredictability may be confused with improbability, which is a different concept and term, one that can be limited within statistical boundaries. Unpredictable damage as a concept does not correspond to improbable damage. As a social construction, unpredictable damage is the basis of the precautionary principle. Although not rooted on hard science or experience, a precautionary principle built to avoid real or imaginary damage, serves the purpose of agglutinating like-minded visions of opponents of GMOs willing to defer as a last resource to the use of the unpredictable damage concept when some of the others fail them.

The unpredictable effect of a given technology manifesting itself at a later time, must be considered here. Several cases have been presented in the literature, such as effects on non target insects or horizontal transfer of resistance to antibiotics to soil and digestive tract bacteria. Each of these cases when it occurs ceases to be unpredictable and becomes an actual case which must be evaluated as to its effects and harm. When the effect has not appeared it may be considered predictable and requires study if there is a likelihood that it might occur. Most predictable cases have been evaluated for risk and have had an appropriate risk management solution. There are other cases that are in the process of evaluation. Each GMO event has to be examined on its own merits and its risk probability and likely effect must be evaluated independently of other cases before the GMO is liberated in the environment. Risk is thus minimized. But this is not to say that there is a probability, no matter how low, that an occurrence of damage may appear. There is no zero risk. The process of risk evaluation reduces itself to a judicious analysis of risk and its evaluation of likely effects on biodiversity, the environment and human health.

Damage to the environment and to biodiversity can be also defined as ‘short termed’ or ‘long termed’ depending on the time considered necessary for recuperation of the effects of such damage to the previous condition. Implicit in long term damage is the consideration of its pervasiveness, extension and resilience to remedial measures. To be regarded as meaningful, these definitions must be subject to the test of science, absent empirism.

Economic damage claims including loss of income and loss of competitivity must be carefully scrutinized to characterize the nature of such losses. Loss of income may come from actual quantifiable and measurable damage beginning at a certain date in the past and carried on until a point in time when remediation may start. Loss of competitivity may be interpreted as arising from reduction of value of crops and possibly outright loss

of markets. This would be the case, for example, for organic crops, where failure of certification could occur on account of the presence of OGMs mixtures being higher than a regulated threshold limit.

The case of organic crops is one of the most important to consider because the organic producers associations are some of the most vociferous opponents of the planting of GMOs, alleging economic losses due to contamination. With proper legislation and policing, conventional, organic and GMO crops can coexist. The USA is the largest producer of both organic and GMO crops and can do both with proper regulations.

Threats to biodiversity.

New plant GMOs have been considered as particularly dangerous to biodiversity. Their threat has not been defined on a case by case basis but on a wholesale manner. It is their mode of development by the manipulation of DNA which is suspect. Other breeding schemes which involve interspecific or intervarietal crosses and mutation breeding have not have opposition even if the results of DNA alteration in the final breeding product involves massive rearrangement of genetic materials. For example breeding a wild rice into cultivated rice may introduce whole chromosomal segments with hundreds of genes which were eliminated by human selection thousands of years ago and which might not work the way it is needed today by modern agriculture. This would require in classical breeding several generations of backcrossing and careful elimination of undesirable genes which is not always possible. On the other hand introducing one single gene in a small DNA construction added to the 44,000 genes of rice would cause the minimal possible effect as compared to more disruptive breeding methods.

The main threat to biodiversity being often mentioned is the loss of biodiversity. Somehow, it is thought, the introduction of GMOs will reduce biodiversity. Let us look at this proposition objectively.

If a new crop variety is introduced in a given area and local farmers find it attractive they will buy seed or acquire in other ways and they will grow it. This has been going on for as long as there is agriculture. Higher potential yields, market preference, resistance to pest and diseases, ease of cultivation and harvest, drought tolerance, earliness, post harvest handling, are among the many factors that determine variety preference. New varieties of crops are being introduced regardless of whether they are developed by genetic engineering or by conventional breeding. As a relatively low number of improved varieties replace land races in a process which has been proceeding for a long time, it causes genetic erosion within the original biodiversity of the species. This is unavoidable unless stagnancy in yields and increased vulnerability with time of old varieties to pests and diseases is predicated. Maintenance of biodiversity will have to rely on ex-situ collection of variability in germplasm banks supplemented by some in-situ preservation areas. Attempts to freeze the cropping situation of traditional farming communities with their old own varieties is doomed to failure. And this is regardless of whether GMOs or conventional improved varieties or hybrids are used. As population pressure, market forces, and the sheer demand of food security increase, agricultural

productivity will be a necessity. Native and traditional farming communities are no longer isolated, as roads, highways and markets are built in their neighborhood.

Will GMOs be any different than traditional varieties in modifying the local crop biodiversity? Since GMOs are simply improved commercial varieties or hybrids bred by conventional breeding systems, onto which a gene construction has been added or suppressed, that gene construction which may have one additional marker gene and promoter and expression additional DNA components represents a tiny fraction of the new DNA brought in by a new variety or hybrid. Two extra genes out of 55,000 genes in the case of maize would not modify the previously existing gene pool and contribute to its loss of biodiversity. If anything, they would contribute to its increase. The contribution of the thousands of new genes carried by an improved variety, other than the GM gene, are many orders of magnitude more important in modifying the frequencies of genes and alleles of those genes in the free breeding populations of native crops which they may be brought in contact.

An opposite argument may be brought forward to present a case for damage. That would be that the trait introduced by the new transgene might have a selective advantage when incorporated in a context of old traditional landraces and varieties and of wild plant relatives. One such case would be resistance to insects brought about by a *Bt* gene. If such a gene would be accidentally or unwillingly dispersed in a population, it would be advantageous to plants, rather than detrimental as it would increase the number of plants that would cease to be host to insects on which it acts. A similar situation would occur if a potato transgene for resistance to potato blight or to nematodes would be introduced into a locally adapted and accepted variety of potatoes. By transfer of the new gene to other varieties and native species, mean population resistance to the parasites would increase. Rather than harm, evident benefits would occur, and the final result would be that rather than a reduction of genetic variability, an increase of variability benefiting the farmers and the species diversity would have occurred.

The transfer of DNA from a GMO could occur in various forms to native varieties and other plant populations:

a) DNA transfer by pollen to cultivated varieties of the species and wild species of the same genus or related genera.

b) DNA transfer between species by means of horizontal transfer to microorganisms which would infect plants and transfer such DNA to higher plants.

There are unknowns about the medium and long term effects of GMOs which are claimed by their opponents. Such effects on the biological diversity have been the subject of research in the past and the reality is that very few black spots of knowledge are now left. Concerns on medium and long term effects must be specifically stated if research to find about them is to be realized. Otherwise, persistence of speculations will motivate the use of the precautionary principle as a pretext to stop the progress of agriculture based on GMOs.

Environmental and agronomic impacts of the presence of GMOs on local and indigenous communities have been again been signaled as of concern. They would have to be defined in more concrete ways than the simple ones that “changes in the agricultural systems of native communities are harmful to their stability, well being, traditions and food security”. Dependency on seed supply other than their own reserve from harvest to harvest is being singled out as the most worrisome for local and indigenous communities. Dependency from sources outside of their community is not obligatory as farmers are free to make their own choices as to which varieties they wish to plant or whether thay want to buy seed or save their own. On the other hand there is trade in seeds outside of farming communities. Potato seeds for example are now grown in several disease free areas and moved and traded across long distances within Peru. Seed of improved varieties of maize developed by state agricultural research stations are bought and sold through public and private channels. Seeds of cotton and rice, being industrial crops and requiring processing are not usually saved by farmers. Agricultural credit requires that evidence is provided that certified or high quality seed is being purchased with credit funds. The progress of modern agriculture has changed seed trade and seed use in ways that could not have been conceived a generation ago. The use of corn, cotton and sorghum hybrid seeds among field crops, and of asparagus, tomato and onion hybrid seeds has had strong penetration in Peru. Non hybrid seeds of improved varieties of other field, forage and vegetable crops sold through commercial channels are now the norm in Peru. Very few farmers save seed of most non native crops any longer. These are the crops most likely to be the first to be improved through genetic engineering. Of the 20 most important crops of economic value in Peru, which is a center of origin or of secondary variation of many crops, fully 18 are not native to the country. Potatoes and beans are the exception.

Plant GMOs are now considered not more risky to human health than their equivalent ones obtained by conventional genetic procedures. So the mode of origin should not be discriminatory in their separate treatment. This is supported by FAO, the National Academies of Science of the United States, UK, Germany, Brazil, China, Australia, the Academy of Medicine of France, the World Health Organization, the Commission of Codex Alimentarius, and hundreds of scientific organizations. There are no credible scientific publications that prove the alternative point of view.

Starting from this premise, it is felt that it is not warranted today, sixteen years after the first discussions on risk of GMOs were presented at the Convention of Biodiversity, that a state of mind that still considers GMOs as particularly risky as a group can be maintained today.

Experience with GM crops

When the first results were published of transgenic crops in the early 1970s a furor started among biological scientists who perceived that maybe inadvertently they had opened a Pandora box. The famous Asilomar, California Conference convened by a group of concerned scientists in mid 1974 ended with a call for a voluntary moratorium on certain recombinant DNA experiments, especially on virus. They agreed that the new

technology created extraordinary opportunities for medicine, agriculture and industry. Nevertheless, there were concerns that this research might engender unforeseen and damaging consequences for human health and the Earth's ecosystems. Nobel Laureate James Watson, who participated in the Conference, admitted later that he regretted that the views he held at that time had helped delay the full acceptance of genetic engineering for some twenty years.

Paul Berg, Nobel Laureate in Chemistry 1980, wrote recently: *"Thirty years ago, nations were engaged in debates about whether recombinant DNA research, also referred to as gene splicing and genetic engineering, was too dangerous to be allowed to continue. Fears of creating new kinds of plagues or of altering human evolution or of irreversibly altering the environment were only some of the concerns that were rampant. Lingering doubts and concerns still persist about the use of that technology in the development of genetically modified plants and animals used as food. Notably, some nations have enacted legislation that prohibits genetically-modified plants and animals from entering into their food supply. Paradoxically, no such embargo exists for the drugs and therapies that have revolutionized the treatment of serious diseases although many of them were created with the same technologies"*.

GM crops have shown that the presumed risks that they were thought to represent have so far, not materialized. Therefore, it is being proposed by some scientists and experts that in order to help the development of agriculture, especially in less developed countries with low agricultural productivity, GM crops engineered with plant genes should be immediately deregulated. Other GM crops with genes from other sources should have their risk assessment speeded up. Massive regulatory manuals containing hundreds of pages of regulation requirements should be simplified in order not to delay the approval of GMOs that have promise and have a very low potential risk factor. A regulator of one of the exporting countries alluded once to the filter of about 15 kilos of pages of regulations that the registration of a new plant transgenic event had to go through. The current transgenic events which are presently grown in varieties and hybdrid throughout the world have been subjected to examinations which no other crops, organic or conventional have ever experienced. Their safety is thus amply certified by these tests and by the test of time – 13 years of wide scale production in seed fields and commercial production.

Simplification of risk evaluation without compromise on its quality, should go hand in hand with a realistic and promotional regulatory system for GMOs. Both should be part of a policy that establishes clear considerations on what is to be rated as damage, and within which boundaries of risk tolerance is willing the policy of the country to operate. A 100% absence of risk does not exist in any technology or activity. Minimization of risk should be the target, not the exclusion of risk.

Who is liable?

The 'operator' is considered to be the person or company who controls the activity which led to injury. He is to be liable for costs of remediation. In the UK under ELD this is likely to be interpreted to be the farmer for GM crops and doctors or veterinary surgeons who use GM drugs such as vaccines (live GM vaccines are already available or under development).

If strict liability were to be applied it would not be necessary to prove that someone is at fault for being charged for remediation of damages to biodiversity arising from the use of released or contained GMOs.

I would like to comment the following two cases of liability as seen under ELD in Europe. States can introduce (they are not obliged to) two types of legal defenses on behalf of the operator:

a) **the 'permit defense'** applies when an operator who has been carrying out certain activities perceived as dangerous (and specifically listed in the ELD), would be allowed to avoid costs of remediation if a permit had been given for the activity. In this situation, either there would be no remediation, or the state would pay. The operator exemption – companies or individuals – is allowed due to the fact that they have complied with required laws and the state has considered the activity 'safe'. There is an obvious conflict between perception of danger and permit being accorded to carry on with the planting of GMOs. It is clear that as long as the perception of danger predominates the issuance of permits will be limited.

b) **the 'state of the art' defense** – where scientific knowledge at the time of the authorization did not anticipate that harm would arise. Groups opposed to GMOs claim that if this defense be allowed, it could lead to a purposeful reduction of research into possible adverse effects, as collusion of researchers with companies could arise to limit the scientific knowledge available. However, it would be in the interest of states to clear through research as soon as possible all or at least most of the possible or imaginary threats from their list. Permits for the planting and use of GMOs until now have been issued under scientific scrutiny of all possible known harm to environment, biodiversity, humans and domestic animals, to the satisfaction of the regulating agencies. Under 'state of the art', harm has not been proven scientifically for any GMO. In the single case of StarLink corn, it was retired from the market because its owner, Aventis, had not registered it as fit for human use, only for animals, and not because of any harm to humans having been found possible. The concerns expressed by the regulatory agency motivated Aventis to ask only for permission to use the GMO for animals thus hastening its introduction into the market, rather than continuing research which could have alleviated the concerns and permitted its use also by humans. That decision proved fateful, because Aventis decided to move forward commercially based on a state of the art decision, and had to accept losses due to adventitious mixtures in corn destined for human consumption.

Anti - GMO activist groups are interested in eliminating the two types of defenses and having courts exercise discretion in accepting the state of the arts defense.

Some Parties are pressing for liability against presumed damages to social, cultural, spiritual and traditional values of native communities, as well as to their food security, that they be accepted and introduced as binding in Article 27 of the CBP. Since these damages are subjective and variable from country to country and within a wide range of economic and social policies, it would not be possible to come to a uniform agreement on the applicability of such harm, even within a single State.

Harm due to transboundary movement of a GMO may be the subject of a claim to the owner of a patent or patents of the GMO and down the line of the commercial seed delivery chain, to any and all members of that chain. If the owner licensed the patent to a seed company or sold the variety containing the GMO to a general distributor in the receiving country, and the distributor in turn sold it to dealers and they to farmers, there would be a potential chain of responsibilities that might be subject to liability claims. There might also be incorporated residual responsibility for the State (or Region) and Federal (or Central) Governments when governmental responsibilities are shared, by allowing the shipment and the entry of the GMO into the receiving state. In this last case, however, GMOs must have been previously authorized by the receiving State before a legal transboundary movement has taken place.

The case of the system of transgenic cotton seed distribution in India is a case in point for distributed responsibility. There are at least 13 Indian seed companies that have been licensed to incorporate *Bt* genes by patent owners onto their respective own cotton hybrids. To avoid farmers keeping seed, GM cotton in India is sold as hybrid seed. Hybrid cotton preceded GM cotton in India and was widely accepted by farmers in spite of the fact that seed is more expensive and they could not conserve seed. Acceptance of GMO and cotton hybrid seed has motivated a growth of 192% in GM cotton area from 2005 to 2006, thus reaching 3.8 million hectares. As expected, activist groups are trying to find any possible venue to lay law suits in order to obstruct the consolidation and further growth of this extraordinary technological revolution.

An operator could claim that he has complied with all regulations in the case of a claim that harm has occurred on account of transboundary movement of a GMO either directly or indirectly.

Redress under Article 27.

The concept that he who causes damage should repair it or pay is an accepted basic principle**.**

Redress or compensation includes all such actions both legal and physical destined to repair or restore or rehabilitate a positively determined deteriorated state of the environment or of biological diversity that can be justly attributed to the effect of GMOs.

Both the nature of the harm, its quantification in physical, biological, social and economic terms and the cost of the required measures to bring back the deteriorated state to a former state, must have been estimated.

A uniform set of rules under Article 27 is inconvenient and not likely be accepted by all Parties to the Protocol, not only because the concept of damage is far from being agreed upon, but also because the practicality and realism of applying the compensation judgments under different juridical systems and internal economic and social political policies of the Parties, does not hold true.

The acceptance of a uniform set of rules would signify that all Parties would have to be bound to them without further recourse from day one of acceptance without ratification by Congress or the Executive branch of Government. This would also mean acceptance of a **supra-national type of legislation,** which because of its nature as a treaty, could not be modified by either the executive or legislative power of any of the Parties to the treaty, or in other words to the Cartagena Protocol of Biosafety. This is a very serious consideration. Imagine that due to the state of the art and scientific advances new views could become accepted and changes needed to be introduced into an approved Article 27 at the country level. It would be an almost impossible task to obtain consensus for a change. It has taken from 1995 to 2008 to discuss establishing common rules for liability and redress and no agreement is in sight. Imagine for a moment that finally agreement is reached. How long would it take to disassemble the articles of such an agreement and modify it to please the various views of the various Parties.

The proposals of establishment of specific added compensations and other punishments for damage done in the centers of biodiversity will scare away from them research and testing, excluding the States who adopt such extra precautionary approaches and legislation from the main stream of technological advances. For example if research on GM sugar cane were to be especially treated as dangerous for the sugar cane diversity in southeast Asia, research and utilization on GM sugar cane would move away to Brasil, Peru, Australia and other countries with high yields or areas, thus benefiting the competitivity of those countries in the world markets.

The responsibility of proof of the charges should be laid squarely on the claimant. If it were not so, the accumulation of law suits with claims without the need of clear evidence, would have a severe limitation on the possibility of GMOs being established in a given region or country, a circumstance well known to activist groups against GMOs.

Charging the operator with the responsibility of attestation is likely to be tried as a strategy by anti-GMO groups. The reality to be considered is that litigation may start theoretically at a large number of places of origin, including farmers. Conditions may vary from one farmer’s place to another, and the causes of a certain effect may be many, which may or may not have to do with the GMO itself. For example, a viral or fungous disease could affect plants in a very humid year in one place and not in another, and its effect could we wrongly assigned to the fact that the variety has a transgenic event

included, which has nothing to do with the transgene but could be a consequence of the genotype of the variety. A single GM event could be installed in many different varieties, each of which will respond differently to a biotic or abiotic stress to which the GM event is neutral. Therefore claims based on the GMO should be treated independently and it is the responsibility of the claimant to present his evidence.

It must be clearly defined that responsibility for general varietal performance is something clearly different from responsibility for the specific GM trait and the first one is not contemplated under the CBP. For example, let us take the case of the variety of potatoes which is called 'Revolucion' which as an improved variety of potatoes developed and grown in Peru. Recently a transgenic event was genetically engineered into this variety by the International Potato Center in Peru and which confers it resistance to the 'Andean moth' pest. Save for this added resistance, the agronomic performance and quality of the original variety Revolucion should not have changed. If any claim to damages is laid down, it would have to be attested as to why the claimant believes that this genetically modified variety has a behavior that has produced or will produce an adverse change in the environment and in biodiversity different from the same non-GM version of the variety. The CBP would not apply in this example within Peru because there is no transboundary movement. It would apply if the same transgenic potato variety Revolucion were to be used in another country where it is now being used as a non transgenic variety, for example in Bolivia.

National legislation should be developed, if non existent or insufficiently explicit, to include the situations of liability and redress. This situation should take into consideration the peculiar political and economic circumstances of each State, not only its condition of being megadiverse, biodiverse or not.

It is well to establish at the outset that in many countries extensive introductions of new crops have taken place over the centuries and their agricultural realities are based not only on native crops but on introduced ones, which in some cases are basic to their economies. For example, in the case of Peru, of the 20 most important crops in economic and food consumption terms, 18 are not native, while at the same time Peru is a center of biodiversity for many other crops. Whether some of the native crops will be soon or eventually genetically modified by local research is a matter of consideration of cost/benefit analysis in each case. It will have to consider potential future market size and its development cost and income on global terms, not only in country terms. With an increasing outlook on exports, added market value for some crops may require that genetic engineering solutions become indispensable, while not in other cases.

Strict liability and redress considerations based on a uniform type of legislation under Art. 27, may constrain the freedom of operation and reduce export options of countries which are now active exporters of agricultural products with high market value.

Strict liability which considers the operator (improperly named by some "exploiter") as the subject or responsibility would, if applied, become a burden on him, which might have the intended effect of discouraging private operators from dealing with GMOs. If

this is the strategy of some anti - OGM groups in sponsoring hard strict liability and preventing the establishment of important links in the chain of commercialization of GMOs, this would be one of their preferred strategies.

Guidelines or compulsory general rules under Article 27?

Strict liability has been shown as not being acceptable to some countries. Therefore no consensus is foreseen on Article 27. Mild liability is not the answer either. The solution is that each state should establish its own internal civil legislation which could be based on a set of “recommended guidelines”. The elaboration of guidelines should be the practical way out of the jungle of opposite and extremely detailed but impractical luxuriance of legalisms that are subject to so many views and interpretations that no agreement is likely to occur.