Int Environ Agreements (2007) 7:281–300
DOI 10.1007/s10784-007-9047-1

ORIGINAL PAPER

The legal regime for application of the precautionary principle in India: future directions for the GM regulatory regime

Nupur Chowdhury · Santanu Sabhapandit

Accepted: 14 June 2007 / Published online: 20 July 2007

Abstract The precautionary principle is one of the most contentious principles in contemporary international legal developments. The very fact that it is a principle of international environmental law has been questioned by many legal scholars. However, this does not take away the fact that the precautionary principle continues to be applied widely across sectors both internationally and nationally. The nature and scope of its application has varied widely according to the context and sector within which it has been applied. The central issue which this article seeks to address is the regulatory and the policy making space that is available to the Government of India in the context of the obligations as undertaken under the Cartagena Protocol and under various other international treaties. The regulatory space would also be affected by the domestic legal developments across sectors in which the principle has been applied. India's recent decision on the large-scale commercialisation of Bt-Cotton has already created much debate regarding its appropriateness given the realities of Indian farm practices. More specifically, it has also led to a rethinking of the role and application of the precautionary principle in addressing these realities. Considering that the Indian policy on biotechnology is currently being drafted, it is important to look into the scope of applying the precautionary principle in taking any decision on genetically modified organisms (GMO) in terms of their distribution of risks, incorporating the social and equity impacts of such decisions.

Keywords Precautionary principle · GMOs · Environmental safety

N. Chowdhury (✉) · S. Sabhapandit
Resources and Global Security Division, Centre for Global Agreements, Legislation and Trade, The Energy and Resources Institute, Darbari Seth Block, Lodhi Road, New Delhi 110003, India
e-mail: nupurchow@rediffmail.com

Present Address:
N. Chowdhury
259 SFS Flats, Dr. Mukherjee Nagar, Delhi 110009, India

1 Introduction

This article seeks to introduce the historical development of the precautionary principle in the international legal arena and various aspects of the principle in its present state of interpretation. Against this background, it proceeds to focus on the more specific question of the role, interpretation and application of the principle in newer areas like genetically modified organisms (GMOs) and in this context delve into the following issues; first, the implications of the progressive development of the precautionary principle in international law and particularly in the Cartagena Protocol for India in dealing with the principle in the domestic sphere; second, the development of the precautionary principle in India's environmental jurisprudence over the last few decades; and third, the interpretation and application of the principle with respect to GMO regulation in India and how this can be improved to both protect India's interests in the face of challenges posed by application of this technology and to give more substantive meaning to the precautionary principle.

Sections 2, 3 and 4 of this article are devoted to addressing each of these research questions, respectively. The article draws important conclusions about the development of the principle in environmental jurisprudence. Any regime for the regulation of GMOs would necessarily operate within the larger framework of environmental protection.[1] In this context the article draws a trajectory of the development of the precautionary principle within environmental jurisprudence in India and the specific implications for its application in the biotechnology sector. In the conclusion the article also provides a descriptive account of country experiences in adopting biotechnology in the agricultural sector and draws broad lessons. Given that biotechnology is a new technology and in view of the limited knowledge of its impact across sectors, these country experiences form an important reservoir of information for the regulators in India.

1.1 Meaning of the precautionary principle

The precautionary principle aims to ensure that a substance or activity posing a threat to the environment is prevented from adversely affecting the environment, even if there is no conclusive scientific proof linking that particular substance or activity to the possibility of environmental damage (Cameron and Abouchar 1991). The underlying rationale governing the application of this principle is that certain human interventions may result in human health or environmental impacts that may be both negative and irreversible in nature. The precautionary principle has developed from being a distinct environmental approach to that of becoming a crucial rule of law for guiding decision makers not only in the area of environmental policy making but also for health issues. The application of this principle in the international arena has been dogged by controversies. The primary cause for this has been the economic implications of the application of this principle for trade interests, livelihood issues, etc.

At the onset, for the sake of clarity there is a need to draw a distinction between precautionary and preventive action. A policy is said to be precautionary in nature when there is a lack of scientific certainty, which prevents the establishment of a causal

[1] This is because in India the GM regulatory regime is constructed and operative within the larger legislative framework of environmental protection. The 1989 *Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms Genetically Engineered Organisms or Cells*, are made under Sections. 6, 8 and 25 of the Environmental Protection Act 1986.

relationship between the measure undertaken and its consequences on the human environment. On the other hand, a measure is said to be preventive, where there is certainty regarding the risk of harm to the environment, which may be posed by an action. Uncertainty is therefore a crucial prerequisite for the precautionary principle to be applied.

Uncertainty in this context refers to the relative lack of consensus in the scientific community (Hansson 2001). The extent of precautionary measures must, however, be based on a minimum of knowledge, i.e. on the basis of scientific results presenting a degree of consistency (Boisson de Chazournes 2002). Thus one of the inherent requirements of the application of this principle is that of constant re-evaluation of the risks. Subsequent to a decision being taken on applying the principle, there is a presumption of responsibility to regularly collect information for the alteration and (if need be) correction of those decisions, pertaining to the protection of the environment or in the sphere of public health.

Hence, action taken due to the lack of scientific information is necessarily interim or temporary in nature and the "principle thus implies that some action will be taken by someone to reduce uncertainty to levels appropriate for taking final regulatory action. Different versions of the precautionary principle take different positions on whether returning to the question is mandatory or not and wherein lies the burden of proof" (Applegate 2002, p. 17).

There has also been terminological uncertainty. It has been contended that the usage of precaution as an approach or principle would impact differently on the state parties involved in the application of precaution. Analysts like Tickner (1997) have raised issues like whether the "precautionary approach" is a relatively weaker version in terms of the specific legal obligations, which flow from it. The precautionary approach is the term used to describe more organised attempts by risk managers to evaluate the likelihood of specific risks. The precautionary principle, on the other hand, is characterised by a subjective approach to dealing with risk, which involves a search for reassurance in the face of uncertainty over a supposed risk (Conko 2003). This suggests two possible outcomes; first, the precautionary approach functions like an environmental impact assessment, where in the face of there being a risk of environmentally detrimental consequences resulting from any activity, one should undertake a risk assessment and a decision must be based on the scientific data produced. This is unlike that of the application of the precautionary principle, which involves a policy decision in the context of insufficient scientific data. Second, the precautionary approach obligates government agencies to undertake risk assessment studies so as to gather scientific data to support any policy decision taken. On the other hand, the precautionary principle requires the person undertaking to change the status quo, to provide scientific proof that the activity is environmentally safe.

Countries like the United States have, through the negotiations of various multilateral environmental agreements, taken the policy stance that the exposition of precaution should be in terms of an approach rather than a principle. It has reiteratively used the terminology of an "approach" as against "principle" to underline its disapproval of the term "precautionary principle".[2] The underlying reason is that an *approach* describes a legal technique to deal with uncertainties, scientific or otherwise while a *principle* binds the actor (legislator, administrator or judiciary) to apply these techniques. This is, however, not the case in other domestic legal jurisdictions like that of India.

Quite distinct from the US approach, the European Union has used words like principle and approach interchangeably and does not allude any specific meaning to the variable

[2] Most recently this has been the stated position of the United States in its arguments submitted to the Panel of the *EC-Biotech* case (WT/DS291/INTERIM).

usage. It has accepted the precautionary principle as a broad policy tool, thus rendering the usage of its variable terminology as inconsequential.[3]

Despite the inclusion of the precautionary principle in international treaties, interestingly the debate amongst the academicians and within the courts of law has essentially focussed on the question whether the principle has achieved the status of the principle of customary international law.[4] There could be two possible and related explanations for this. First, the essential nature of the precautionary principle itself lends to its overarching application in environmental policymaking and it is intrinsically difficult to limit the implementation of the principle to a certain subsector. Second, given the different interpretations and nuances with which the principle has been stated in the various international agreements the courts have consciously sought to limit the fragmentation of the principle and have focused their energy on distilling a general principle of customary international law.

2 Scope of application in international law

In this section, we attempt to trace the international agreements and the jurisprudence resulting from the various international courts, tribunals and dispute settlement mechanisms in applying (and in this process interpreting) the precautionary principle. We also make a comparative study of the Agreement on the Application of Sanitary and Phytosanitary Measures (one of the covered agreements of the World Trade Organization (WTO)) and the Cartagena Protocol on Biosafety (under the Convention on Biological Diversity) in order to bring into sharp relief the potential conflict which may result in the implementation of the international obligations flowing from both these international instruments.

2.1 International agreements

Analysts like Perrez (2000) have characterised the emergence and application of the precautionary principle as reflective of a paradigm shift. While it was assumed until the late 1960s that the capacity of the environment to absorb human impacts could be precisely determined, it became increasingly clear that science is not always able to provide conclusions needed to protect the environment effectively. There was therefore a realization that scientific certainty could not be used as a determining criterion for responding to environmental hazards and that the consequences of not taking preventive measures early enough could be irreversible (Garcia 1996). The principle first emerged within the domestic legal regime of West Germany in 1968 (Von Moltke 1988). Principle 15 of the Rio Declaration remains by far the most widely quoted version of the principle.[5] It states that in case of "threats of serious or irreversible damage, lack of full scientific certainty

[3] Treaty on European Union, Title(2), Official Journal C 191, 29 July 1992.

[4] See ILA Resolution 3/2002: New Delhi Declaration of Principles of International Law Relating to Sustainable Development, in ILA, Report of the 17th Conference (n.d.) Retrieved December 10th, 2005 from http://www.cisdl.org/pdf/ILAdeclaration.pdf

[5] Rio Declaration on Environment and Development (1992). UN Conference on Environment and Development, Retrieved December 10th, 2005 from http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163

shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". It also brings in the element of proportionality by stating that measures should be applied according to the capability of the states. The first international convention to recognize the "precautionary measures that have been taken nationally and internationally" was the Vienna Convention for the Protection of the Ozone Layer in 1985.[6] The Montreal Protocol of 1987 recognized the application of precautionary measures with the ultimate objective of elimination of global emissions of ozone depleting substantces.[7] The 1984 Ministerial Declaration of the International Conference for the Protection of the North Sea also applied the precautionary principle with the specific purpose of marine conservation.[8] It called for a pre-emptive approach since the costs of remedial action of damage caused to the marine environment was considerable.[9] The 1990 Bergen Ministerial Declaration on Sustainable Development in the ECE region[10] was the first international convention to establish a direct link between sustainable development and the precautionary principle.[11] The United Nations Framework Convention on Climate Change in Article 3(3)[12] also alludes to the application of precautionary measures to address the adverse effects of climate change. It also introduces the concept of "cost effectiveness" as a factor that is to be evaluated in terms of the opportunity cost of precautionary measures applied in the present, as weighed against the future dividends from a particular development strategy or losses that might result from environmental degradation.

In the context of regional conventions, the Bamako Convention on Hazardous Waste[13] within Africa is an outstanding application of the precautionary principle.[14] Article 3(f) of the Convention appeals to the parties to take preventive action where there is a potential danger of substances "which may cause harm to humans or environment without waiting for scientific proof regarding such harm". The 1992 Maastricht Treaty is another regional treaty, which has provided for the application of the precautionary principle.[15] The former has a sectoral focus while the latter is relatively more general in nature. The Maastricht Treaty (1992), along with the subsequent amendments made to it, by the Amsterdam

[6] The Vienna Convention for the Protection of the Ozone Layer.(n.d.). Retrieved October 17th, 2006 from http://www.unep.ch/ozone/vc-text.shtml

[7] The Montreal Protocol on Substances that Deplete the Ozone Layer.(n.d.). Retrieved October 17th, 2006 from http://ozone.unep.org/pdfs/Montreal-Protocol2000.pdf

[8] Ministerial Declaration of the International Conference on the Protection of the North Sea.(n.d.). Retrieved October 12th, 2006 from http://www.intfish.net/docs/1984/nsc/nsc1.htm

[9] Scholars like Sands (2003), have argued that this could be interpreted to justify the application of the principle on economic grounds (i.e. of future costs).

[10] Bergen Ministerial Declaration on Sustainable Development in the ECE Region, in *Action for a Common Future*, Report on the Regional Conference at Ministerial Level on the Follow-up to the Report of the World Commission on Environment and Development in the ECE Region.

[11] The Bergen Declaration sought to implement an ecosystem approach to planning and regulation of human activities in the North Sea.

[12] The United Nations Framework Convention on Climate Change.(n.d.). Retrieved November 24th, 2006 from http://unfccc.int/resource/docs/convkp/conveng.pdf

[13] Bamako Convention on Hazardous Waste. (n.d.). Retrieved November 24th, 2006 from http://www.ban.org/Library/bamako_treaty.html

[14] The Bamako Convention seeks to provide for strong regulatory action in the context of transboundary movement of hazardous waste and also its production and disposal domestically.

[15] See *supra* note 4.

Treaty (1997)[16] have enlarged the scope of the original Treaty of Rome[17] (EC Treaty) to greatly internalise the application of the precautionary principle within the environmental policymaking apparatus of the European Union.

2.2 International judicial decisions

International case law on the application of the precautionary principle has been limited to primarily three forums, namely the International Court of Justice (ICJ), the International Tribunal on the Law of the Sea (ITLOS), and the Dispute Settlement Body (DSB) of the WTO.

In the case of the ICJ the application of the precautionary principle was first raised in the *Nuclear Tests* (*New Zealand vs. France*) case.[18] In this case, New Zealand had relied on the precautionary principle as a basis for its complaints against French nuclear tests. The precautionary principle was stated by New Zealand to be a widely accepted and recognized principle of international law, and therefore the burden of proof should shift to France to prove that the nuclear testing was environmentally benign or that it would not lead to any adverse impacts. France responded by commenting that the status of the principle is uncertain in international law and that even if it were to accept its application, there would not be any corresponding changes in the evidentiary burden.[19] Justice Palmer's dissenting argument stated that "the norm involved in the precautionary principle had developed rapidly and might now be a principle of customary international law relating to the environment".[20] In the *Gabcikovo-Nagymaros* case,[21] the ICJ let go of another chance to rule on the application of the principle even though the litigants (Hungary and Slovakia) invoked the principle. Sands (2003, p. 274) has termed this as the ICJ's "failure in considering conditions under which Hungary could invoke the concept of ecological necessity" in order to justify its order of suspension of the construction of the Gabcikovo-Nagymaros Barrage System on the Danube river under the treaty that it had concluded with Czechoslovakia in 1977.

ITLOS has also been faced with the task of determining the boundaries of the legal application of the principle. It has been relatively more forthright in addressing the issues involved in the application of the principle. In the Southern Blue Fin Tuna cases,[22] both New Zealand and Australia alleged that Japan had failed in its obligation under the United Nations Convention on the Law of the Sea (UNCLOS) 1982 with respect to the management and conservation of southern blue fin tuna. The Tribunal in its order stated that the "the parties should in the circumstances act with prudence and caution to ensure that

[16] Treaty of Amsterdam amending the Treaty of European Union, The Treaties Establishing the European Communities and Related Acts, Official Journal C 340, 10 November 1997.

[17] Treaty of Rome establishing the European Economic Community, signed on 25 March 1957. Document available from http://eur-lex.europa.eu/en/treaties/treaties_founding.htm

[18] Nuclear Tests (New Zealand vs. France) (*Interim Measures*), ICJ Reports. (1973); (*Jurisdiction*), ICJ Reports (1974).

[19] The ruling of the ICJ however did not allude to these arguments.

[20] Dissenting Opinion of Justice Palmer (Ad Hoc) ICJ CR/95/20; Also opinion of Justice Weeramantry in the same case.

[21] Gabcikovo-Nagymaros (Hungary vs. Slovakia), ICJ Reports (1997). The case involved suspension by Hungary the works on construction of the Gabcikovo-Nagymaros barrage system, for which it was responsible under a Treaty signed with Slovak Republic.

[22] Southern Bluefin Tuna Cases (Provisional Measures) (1999) ITLOS.

effective conservation measures are taken to prevent serious harm to the stock of southern bluefin tuna".[23] It further stated that "although the Tribunal cannot conclusively assess the scientific evidence presented by the parties, it finds that measures should be taken as a matter of urgency to preserve the rights of the parties and to avert further deterioration of the southern bluefin tuna.[24] The tribunal implicitly applied the precautionary principle by directing the parties to refrain from conducting experimental fishing activities.

In the MOX Plant case,[25] Ireland alleged the failure on the part of the United Kingdom in applying the precautionary approach in protecting the Irish coast from the environmentally detrimental operation of a MOX plant.[26] The UK in its defence pleaded that "Ireland had failed to supply proof that there will be either irreparable damage to the rights of Ireland or serious harm to the marine environment" and therefore there is insufficient evidence to support a case for the application of the precautionary principle. The tribunal[27] ordered the parties to cooperate and consult with each other in finding a solution. The tribunal did however, call for "prudence and caution"—which is a reflection of the "precautionary character" of the judgement.[28]

Within the Dispute Settlement Body of the WTO the precautionary principle has been alluded to in two disputes. In the *EC-Hormones* case,[29] the US and Canada brought a case against the European Community which had prohibited the import of meat treated with growth hormones. The EC defended its measures under Article 3 of the SPS Agreement[30] that allows countries to adopt domestic measures, (that may be higher than the prevalent international standards) provided that such measures are based on scientific evidence. The Panel and Appellate Body ruled that the EC failed to provide for a risk assessment that justified the imposition of stated measures.[31] The Appellate Body, however, consciously refused to rule on the international legal status of the precautionary principle. Nevertheless, it did make a preliminary observation that the acceptance of the principle as a general principle of international law is "less than clear", moreover it held that the legal nature of the principle as is applicable within the context of WTO Agreements, is an abstract question.[32] Analysts (Sindico 2005; Palmer 2006), however, interpret the drift of the ruling to conclude that the Appellate Body remains unconvinced about the legal import and its

[23] Ibid., para. 77.

[24] Ibid., para. 80.

[25] The MOX Plant Case (Ireland vs. United Kingdom), (*Interim Measures*), ICJ Reports (2001).

[26] MOX refers to mixed oxide. It is a process of re-using plutonium residues left over from nuclear fuel waste, which is then combined with uranium and used as a new fuel source. Refer to http://news.bbc.co.uk/1/hi/uk/1643435.stm (accessed 19th November 2006) for more information.

[27] The Tribunal refrained from commenting on whether circumstances had warranted the application of the principle.

[28] Para. 84 of the Provisional Order; MOX Plant Case.

[29] WT/DS26/AB/R and WT/DS48/AB/R: Appellate Body Report: EC Measures Concerning Meat and Meat Products (Hormones); 1998.

[30] Agreement on the Application of Sanitary and Phytosanitary Measures; Annex IA Marrakesh Agreement Establishing the WTO; April 1994; Retrieved on 25th November, 2006 from http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm Note that "SPS" stands for Sanitary and Phytosanitary Measures.

[31] Within the WTO Dispute Settlement Mechanism, the Panel refers to a 3/5 member ad hoc expert group which makes the first ruling and which may be approved by the DSB. Appeals based on points of law can be referred to the Appellate Body (AB) which is a permanent body consisting of seven members. Each appeal is heard by three members of the AB. The DSB has to also endorse the AB ruling prior to seeking implementation.

[32] *EC-Hormones*, supra note 32, para. 28.

application within the WTO legal regime. In the *EC-Asbestos* case,[33] though the precautionary principle was not directly discussed, the case is significant. In this case Canada challenged a French ban on asbestos and asbestos containing products. The French ban was upheld by both the Panel and the Appellate Body. Though there was no explicit mention of the precautionary principle, it was the crucial basis for the French measure and therefore the decision to uphold the French ban is supportive of the interpretation that the members have the ability to protect human health and safety and determine the level of protection necessary to achieve that purpose. Some analysts have interpreted this as supportive of the application of SPS measures in light of the precautionary principle (Srinivas 2001).

The precautionary principle is also increasingly seen as a tool for creating trade barriers. The *EC-Hormones* case had raised debate about the scope for applying the precautionary principle vis-à-vis trade. In that case, the Panel arguably did have a chance of defining the nature and extent of the application of the precautionary principle in interpreting rights and obligations under the WTO agreements—however in a significant manner it refused to comment on the international legal status of the principle. The Panel judged it inconsequential to the ruling of the case. However, it did in an 'aside' suggest that the status of the precautionary principle as a principle of general international law has yet to be firmly established. The *EC-Biotech* case,[34] however, was anticipated by international legal experts to clarify this subject of debate. They were to be disappointed, as the Panel in this case largely stuck to the position taken in the *EC-Hormones* case. The Panel did, however, come up with certain interpretative principles—which would have a significant bearing on the definition, application and operation of the precautionary principle within the WTO member countries. This deserves some reflection as it also has a significant relation to the operation of the precautionary principle within the domestic legal regimes of the member countries.

First, in terms of contexualising WTO law within the larger public international legal regime, the Panel examined the applicability of the Convention on Biological Diversity and the Biosafety Protocol with reference to the WTO Agreement. On this issue, the Panel, made reference to the Vienna Convention on the Law of Treaties—specifically Article 31(3)(c)—to explain that in treaty interpretation, it is only those rules of international law "which are applicable in the relations between treaties" which would be considered.[35] In this case, it goes on to draw the conclusion that since one of the parties to the dispute (i.e. the United States) is not a party to the Cartagena Protocol, this would negate its application "in the relations between all WTO Members"[36] and therefore would negate its application to the dispute.[37]

In a related issue—that of the status of the precautionary principle as a principle of general international law (as contended by the EC)—the Panel largely reiterated the decision in the *Hormones* case. It found that the debate on the nature and status of the

[33] WT/DS135/AB/R: Appellate Body Report: European Communities—Measures Affecting Asbestos and Asbestos-Containing Products, 2001.

[34] WT/DS291, WT/DS292 and WT/DS293 refers to the separate complains filed by US, Canada and Argentina respectively—which however the WTO Panel considered to be one dispute essentially. (Panel Report).

[35] Ibid., Panel Report, para. 4.543.

[36] Ibid., para. 7.74.

[37] It is interesting to note that this finding was expressly criticized in the Study Group Report on the fragmentation of international law (ILC 2006).

precautionary principle in general international law was still "ongoing".[38] Quite specifically, it reflected on the lack of any authoritative international legal decision by another court of law on its status and its rather fluid nature (in the absence of an internationally acceptable precise definition), and the scepticism of the previous Panel in the *EC-Hormones* case[39] as the underlying logic behind its conclusion. More surprisingly, the Panel went on to affirm that the precautionary principle has been incorporated in various international conventions and declarations, specifically in environmental conventions and declarations. Furthermore, it also gave the example of its application in the domestic judicial decisions pertaining to environmental law. Both these statements seem to allude to the hypothesis that the statement of the principle within the specific discipline of environmental law would impede its status or its recognition as a general principle of international law. Subsequently, the Panel moved on to make a measured statement that "since the legal status of the precautionary principle remains unsettled",[40] it would decline from commenting on the status of the principle in international law, as it was not pertinent to the dispute. This is indeed quite a perturbing conclusion, since the EC had specifically relied on the precautionary principle to defend its position and had largely relied on arguments of the international acceptability of the precautionary principle as a principle of general international law to support its contentions.

In fact the Panel, by determining the legal status of the principle to be *unsettled* did exactly what it formally denied doing, i.e. address the issue of the legal status of the principle. The Panel therefore seems to be following the position of its predecessor in the *EC-Hormones* case. It seems to draws its conclusions on the question of the status of the principle in general international law and yet quite firmly withdraws from the responsibility of being the author of such an interpretative conclusion. Second, in terms of judging the applicability of the specific measures by the member states of the EC and its compliance with their WTO commitments, the Panel laid down several interpretive rules of application and operation of Article 5(7) of the SPS Agreement.[41] First, it reiterated the four cumulative requirements of adoption and maintenance of a "provisional measure" under the SPS agreement as was elucidated by the Appellate Body in the *Japan—Agricultural Products II* case.[42] Second, it noted that the first statement of Article 5(7) referred to "a more objective assessment of risk". Hence, although the risk assessment required under this article would not meet the criteria of risk assessment contained in Annex A (4) of the SPS Agreement,[43] there would necessarily be a risk assessment, which needed to be performed prior to the application of Article 5(7). Its third, and possibly most far reaching conclusion in relation to the operation of Article 5(7) is its factual and interpretative

[38] Supra note 37, Panel Report, para. 7.88.

[39] See *supra* Note 35.

[40] Supra note 37, Panel Report, para. 7.89.

[41] Article 5(7) of the SPS Agreement; states that "[i]n 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".

[42] WT/DS76/AB/R.

[43] Annex A (4) of the SPS Agreement deals with Risk Assessment: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs".

conclusion that the measures undertaken by each of the EC member states were not justifiable under Article 5(7)—which only applies in the case of insufficiency of scientific evidence to conduct an adequate assessment. It drew this conclusion primarily on the basis of the fact that for each of the individual products in question (which were impugned by the national safeguard measure), the EC had conducted an evaluation of the potential risks to human health and the environment; i.e. a risk assessment, and had given its approval based on the results of such an evaluation. This interpretation seems to suggest several distinct underlying assumptions as to the nature and extent of the regulatory apparatus, which would control and conduct such risk assessments (as constituted under the SPS Agreement). The essential assumption is that conclusive risk assessments undertaken at the EC level would necessarily dissolve the right of the member state to undertake subsequent risk assessment exercises. In such a case, any subsequent risk assessment undertaken at the level of the member state would have to withstand judicial scrutiny at the international level. Lastly, the risk assessment of a member state would withstand judicial scrutiny only if the exercise would successfully rebut the claims of the risk assessment undertaken at the EC level.

This is an entirely new territory—that of regulatory capacities between member states and the supranational or international legal entities in which they hold membership. The Panel seems to presume regulatory authority of the EC in this context, over its members states, whereas in reality, regulatory competence in such cases is shared between the EC and the member states. This also holds true for federal constitutional states like India, where the central government shares regulatory competences with state governments on a wide range of subjects. In this context, it is rather surprising that the Panel would assume the regulatory supremacy of EC institutions over those of the member states within the context of risk assessment—especially since the legal framework provides for divergences between member states based on national exigencies to be determined by the competent national entities of the member states.[44] In such a case it would be legally untenable to make such a generalistic interpretation of regulatory capacities without reference to the constitutional documents, legislative acts and executive policies determining such competence.

2.3 The precautionary principle in the Cartagena Protocol and the SPS Agreement

The principle of precaution that provides for undertaking measures against actions involving scientific uncertainty is itself surrounded by uncertainties regarding its scope of implementation. The application of this principle in international legal instruments is widespread, and yet the legal status of this principle suffers from ambiguity.

Within the international trade regime, the SPS Agreement is the most direct exposition of the principle (see also the above discussion on Article 5(7) of the SPS Agreement). On the other hand, the Cartagena Protocol is the single most important international legal instrument, which expounds the precautionary principle within the international environmental legal regime.

The Cartagena Protocol on Biosafety stands at the juncture of the trade and environment regimes and addresses the issue of the environmental and health impacts of GMOs. It therefore prima facie allows trade restrictions on the basis of the rationale that the transboundary movement of GMOs could pose environmental risks. Thus, it is the first

[44] Safeguard measures by the EC Member States are allowed under Article 12 of Regulation 258/97 and Article 23 of Directive 2001/18. See Official Journals L 43, 14 February 1997 and L 106, 17 April 2001.

international agreement, which specifically seeks to apply the precautionary principle to a specific area of international regulation. In a temporal sense, it indicates a certain shift towards the recognition of the international legal character of the principle. However, sceptics would deride such a contention on the basis of the limited number of countries actually ratifying the Cartagena Protocol. Nevertheless, if state practice is taken to be an indication of the development of customary law, a case could be made for the slow but steady development of the precautionary principle as a principle of international law, which is being increasingly crystallized through a process of codification via treaty making.

Article 10(6) of the Cartagena Protocol states that "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism (...), in order to avoid or minimize such potential adverse effects". Similar language is also used under Article 11(8) which is applicable to decision procedures for living modified organisms intended for direct use as food or feed or for processing.

The Protocol also invokes the precautionary approach contained in Principle 15 of the Rio Declaration. However, there are some differences in the language used in the Protocol and the Declaration, which might lead to interpretative distinctions. For instance:

1. The threshold for undertaking preventive measures under the Declaration is "threats of serious or irreversible damage to the environment". In contrast, under the Protocol it is the "potential adverse effects on the conservation and sustainable use of biological diversity" that triggers an action under the principle.
2. The precautionary principle in the Declaration is directed at preventing damage to the environment as a whole. In the Protocol, however, the concern is conservation and sustainable use of biological diversity.
3. The precautionary principle as defined in the Declaration refers to cost-effective measures. On the other hand, the Protocol refers to the taking of a 'decision' in order to avoid or minimize potential adverse effects.
4. While under the Declaration a lack of *full scientific certainty* is the threshold for undertaking precautionary measures, under the Protocol it is the lack of *scientific certainty* due to insufficient relevant scientific information or knowledge. What constitutes full scientific certainty and what amount of information a country considers as sufficient is subject to interpretation.

Though broadly compatible, Principle 15 arguably sets a stricter standard for precautionary actions than the Protocol language (Gupta 2000). The precautionary principle is also increasingly seen as a tool for creating trade barriers. The *EC-Hormones* case has raised debate about the scope for applying the precautionary principle vis-à-vis trade.

Article 5(7) of the SPS Agreement is essentially an enabling provision, which allows member countries to take sanitary and phytosanitary measures in the case of insufficient scientific evidence on the basis of available pertinent information. Pertinent information in this case, also includes information received from international organizations as well as sanitary and phytosanitary measures applied by other members. However, members undertaking such measures are also under the obligation to obtain additional information that is necessary for a more objective assessment of risk and thereafter review the sanitary

or phytosanitary measure in question, based on the additional information, within a reasonable period of time.

Both under the Cartagena Protocol and the SPS Agreement, the rationale for undertaking a precautionary measure is insufficient scientific information. In other words, both instruments rely on the scientific risk assessment of an action. However, there is one key difference in the formulation of the precautionary principle under these two instruments. The SPS Agreement allows only temporary precautionary measures. It requires the member countries to undertake measures to review its precautionary decision within a reasonable period of time. However, in the Protocol there is no such requirement.[45] Yet, it is important to note that the absence of such a requirement in the Protocol can be seen as providing more flexibility to the countries to take more restrictive decisions.

3 Judicial application of the Precautionary Principle in India

This section discusses certain landmark judgements that have been made by the Supreme Court of India, and in which the precautionary principle has been applied. This has contributed to the jurisprudence and has considerably influenced policy making within key sectors. Procedurally speaking, the application of the precautionary principle has been interpreted to formalise a structure of responsibilities and liabilities of governmental agencies and also that of individual rights and duties.

In October 1991, in response to a petition filed by Bittu Sahgal and Nergis Irani, secretaries of the Danahu Taluka Environmental Welfare Association, the Supreme Court passed a landmark judgement[46] asking the National Environmental Engineering Institute to undertake a study and offer recommendations for the preservation of Dahanu's[47] green status. The case involved the clearance, given by the State of Maharashtra and Union of India, to a proposal of the Bombay Suburban Electricity Supply Company Limited (BSES) for the construction of a thermal power plant over an area of approximately 800 ha in Dahanu, Maharashtra. The Supreme Court upheld the decision by the state of Maharashtra but directed BSES to install a Flue Gas Desulphurisation plant and to use gas rather than coal. The order also required the establishment of the special environmental authority comprising scientists and other experts to monitor and protect Dahanu. The Dahanu Taluka Environment Protection Authority was to be chaired by a retired High Court judge. This authority was also obliged to implement the 'polluter pays principle' and the 'precautionary principle' to pre-empt any environmentally damaging activities from taking place.

It was however only in 1996, that the Supreme Court in *Vellore Citizens Welfare Forum versus Union of India*[48] deliberated extensively on building a rationale for the application of the precautionary principle in India. The result of the deliberations has been listed below.

While deliberating on the meaning of the precautionary principle in the context of municipal law, Justice Kuldip Singh expressed the opinion that, first, environmental measures by the state government and the statutory authorities must anticipate, prevent and attack the cause of environmental degradation and, second, when there are threats of

[45] However, it does not automatically follow that the Protocol allows a country to take a precautionary measure ad infinitum.

[46] 1991(1) SCALE 472.

[47] A pristine ecologically fragile coastal region in the state of Maharashtra, India.

[48] AIR 1996 SC 2715.

serious and irreversible damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. The Court also put forward arguments for legitimising the application of the principle. It categorically stated that the precautionary principle and polluter pays principle are part of the environmental law of the country. Support for the precautionary principle was derived from Articles 21, 47, 48A, and 51A (g)[49] of the Constitution of India. Furthermore, various statutes, such as the Water Act 1974 and the Environment Protection Act 1986 implicitly incorporate the concept of the precautionary principle. The above-mentioned constitutional and statutory provisions are supportive of the fact that the precautionary principle is part of the environmental law of the country. The Court also recognized the precautionary principle as part of customary international law and therefore part of domestic laws.

The court further applied the concept of the reversal of burden of proof, thereby shifting the onus to the person, proposing to alter the status quo, to show that the proposed action is environmentally benign. After laying down the rationale and the legal basis for the application of this principle in India, the Supreme Court then went on to further elaborate on the judicial and administrative processes that would have to be put into place prior to the operationalization of the principle.

In *A.P. Pollution Control Board versus Prof. M. V. Nayudu (Retd.)*,[50] the Supreme Court further developed the framework of substantive duties that the application of the principle entailed. It reiterated the reversal of the burden of proof doctrine as elaborated in the *Vellore* judgement. It further held that the person on whom the onus of proof has been put is to discharge this burden by showing the absence of a "reasonable ecological or medical concern". That is the required standard of proof. Therefore in the face of insufficient evidence to alleviate concern about the level of uncertainty, the presumption should operate in favour of environmental protection.

The court further held that the precautionary principle suggests that where there is an identifiable risk of serious or irreversible harm, it may be appropriate to place the burden of proof on the person or entity proposing that the activity is potentially harmful to the environment. If the environmental risk being run by regulatory inaction is in some way "uncertain but non-negligible risk", the burden of proof is to be placed on those attempting to alter the status quo. The absence of a reasonable ecological or medical concern is the required standard of proof. If insufficient evidence is presented by them to alleviate the concern about the level of uncertainty, then the presumption should operate in favour of environmental protection. The required standard is that the risk of harm to the environment or to human health is to be decided in the public interest, according to a 'reasonable persons' test.[51]

The court strongly emphasized the need to include technical personnel well versed with environmental laws in the appellate authorities/tribunals constituted under environmental enactments. The court recognized the fact that in the absence of such experts there is nobody in the appellate authorities to help the judges in technical matters. Such defects in the constitution of these bodies can certainly undermine the very purpose of those legislations. The court pointed out that appellate authorities and tribunals set up under the Water Act;[52] the Air Act[53] and under the 1989 Hazardous Wastes (Management and Handling)

[49] The Constitution of India. Text available at http://lawmin.nic.in/coi.htm

[50] AIR 1999 SC 812.

[51] It is a legal fiction in common law where the court looks at how the given activity will affect an average person. For a general definition see Black's Law Dictionary (West Publication Co.).

[52] Water (Prevention and Control of Pollution) Act, 1974. Available at http://indiacode.nic.in/

[53] Air (Prevention and Control of Pollution) Act, 1981. Available at http://indiacode.nic.in/

Rules should include not only judicial but also technical personnel well versed in environmental laws. Moreover, the appellate bodies are not to be restricted by the Wednesbury limitation.[54] The principle of good governance was also mentioned, suggesting that the application of the principle is one of the measures of good governance. This is an accepted principle of international and domestic law, and comprises the rule of law, effective state institutions, transparency and accountability in public affairs (UNDP 1997). The court in a follow-up case reiterated this ruling that the principle of good governance includes the need for the state to take the necessary "legislative, administrative and other actions" to implement the duty of prevention of environmental harm.[55] The court in this case recognized that the provision of adequate judicial and scientific input was a crucial prerequisite for the establishment of environmental courts, authorities and tribunals.

For many commentators, "the true test of the effectiveness" of any legal principle is the Court's willingness to recognize it as a basis for striking down decisions in judicial review cases (Gullett 2002; see also Leelakrishnan 1992). This relates to the justiciabilty of the precautionary principle, which in effect means that the courts would recognize the precautionary principle as a basis for striking down administrative decisions. The question, which then arises, is whether the case law relating to the precautionary principle in India supports the hypothesis that the precautionary principle would be justiciable in India.

A quick perusal of various Indian judgments related to the precautionary principle suggests the following:

- It is mandatory for any administrative body, which is involved in environmental decision making to take decisions on the basis of the principle.
- The application of the principle by the administration requires the inclusion of not only judicial but also technical officers.
- The fact that the appellate bodies are not to be restricted by the Wednesbury principle also strongly suggests that the decisions of the administrative bodies would be open to challenge on a relatively lower threshold than unreasonability of an extreme degree.
- There are two aspects to its justiciability. First, the principle can become a basis for a judicial review on procedural issues. Thus, the non-inclusion of technical personnel within administrative bodies (and therefore the implicit failure to implement the precautionary principle) could provide a basis for striking down decisions of administrative bodies involved in environmental governance by the Court. Second, substantively, the precautionary principle could provide a basis for calling administrative decisions into question. Hence, a decision may be challenged on the ground that it has failed to take into cognisance certain scientific evidence.
- It would, however, be difficult to prove arbitrariness or unreasonableness from the fact that the court has failed to take account of certain scientific evidence. Traditionally, the Court has looked at decision-making within administrative bodies as part of the discretionary powers of these bodies and consequently followed a policy of strict judicial non-interference.

[54] The Wednesbury principle means that only an administrative decision that is unreasonable to an extreme degree can be brought under the legitimate scope of judicial review. The principle is generally considered as a reason for courts not to interfere in administrative body decisions. Non-applicability of the principle would imply that courts will be less hesitant in interfering in such decisions.

[55] Research Foundation for Science Technology and Natural Resources Policy v. Union of India and Another, WP 657/1995; http://www.keralapcb.org/laec/New%20Folder/HWM%20-%20Supreme%20-Court%20Order.pdf accessed on 20th October 2006.

In addition to the recognition that it has received at the judicial level, the precautionary principle has been adopted as a guiding principle in India's National Environmental Policy[56] for realising its objective of sustainable development. The precautionary principle has been adopted as one of the tools of strategic intervention by the government at the Central, State and local level. The National Conservation Strategy[57] also incorporates this principle, though indirectly, in emphasising environmental impact assessments and cost-benefit analyses of all development projects right from the planning stage. It calls for the incorporation of environmental safeguards and protection measures at all stages of the policy cycle, site selection, technology selection and implementation of developmental projects across sectors. For the agricultural sector, the draft Biotechnology Strategy 2005[58] calls for a precautionary approach in the application of biotechnology.

4 The Precautionary Principle and GMO regulation in India

In this section, the nature, scope and extent of application of the precautionary principle is discussed with respect to the specific policy area of GMO regulation. The regulatory apparatus in this area is still at a nascent stage. Hence, this is an opportune time to discuss and debate the various policy options available to the government to regulate agrobiodiversity.

The contours of the application of the precautionary principle in general and under the Cartagena Protocol in particular are still evolving. The application of the principle by the EU in imposing the alleged moratorium on GMO imports could be seen as one extreme. Obviously, this brings the precautionary principle in direct conflict with interests of those involved in the trade of GMOs. Although the Protocol allows countries to come to a decision on imports of GMOs on the basis of the principle, whether this is justifiable under the SPS provisions is an issue yet to be resolved.

Irrespective of the developments at the international stage, India should first identify its own concerns and use every scope within the developing circumference of the precautionary principle to address them. The ongoing concerns about the safety issues of GMOs at the international level is also shared by India (Gupta 2002). The extremities of conflicting opinions are also equally present within India. The country is the centre of origin of a number of food crops like rice and millet. It is also the centre of diversity for food crops like wheat and maize and non-food crops like cotton and oilseeds (mustard, sunflower, etc). Furthermore, India is one of the 12 megadiverse countries in the world with two of the 25 biodiversity hotspots (that of the eastern Himalayas and the western ghats). These characteristics also make India one of those countries of the South that are most vulnerable to genetic contamination and thereby the destruction of native species. The other issues of farmers' rights, and the socio-economic implications of new scientific developments in the agricultural sector also contribute to the relevance and urgency of a cost-benefit analysis of such developments.

[56] National Environmental Policy 2006; http://www.envfor.nic.in/nep/nep2006.html accessed on 17th October 2006.

[57] National Conservation Strategy and policy statement on environment and development (1992); http://envfor.nic.in/divisions/csurv/csps.doc accessed on 17th November 2006.

[58] National Biotechnology Development Strategy (Draft) 2005; http://dbtindia.nic.in/biotechstrategy.htm accessed on 17th November 2006.

As the Cartagena Protocol is the primary instrument dealing with the transboundary movement of GMOs, the determination of the scope of the application of the precautionary principle necessarily involves interpretation of its provisions. As mentioned above, the Protocol provides a lower threshold for the application of the principle. Under the Protocol, potential adverse effects of the intended activity on the conservation and sustainable use of biological diversity justifies a decision on the basis of the principle. It also allows the Parties to reach a decision on imports on the basis of socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity.[59] Whether such a decision can be taken as a precautionary measure is a relevant issue that needs further inspection.

The capacity of a developing country to handle GMOs has to be seen in two stages. First, before taking a decision: how effective are the legal regimes in these countries to stop illegal introduction of GMOs into their environment, and, second, after taking a decision, how effectively can these countries ensure compliance of such decisions.

Several nations have discovered that GM seeds have been illegally sold to farmers without their consent—sometimes GM seeds have deliberately been marketed as conventional seed, often conventional seed supplies contain suspiciously high levels of GM contamination and, finally, GM seeds provided as food aid have been accidentally planted by farmers. Furthermore, empirical evidence from various countries have established the genuine risk of contamination even in the case of field trials, which are generally done in isolation.

In Thailand for instance, GM papaya seeds were found to be growing in farmer's fields even when the law forbids the public sale of GM seeds.[60] Similar incidents of contamination have been reported in Hawaii. In yet another significant study (Warwick and Meziani 2002) of agronomic, economic and legal impacts of the introduction of GM soya, maize and oil seed rape in the USA and Canada, widespread contamination of non-GM crops was found to have occurred in these regions within a short span of time, causing major disruption at all levels of the agricultural industry, including seed resources, crop production, food processing and bulk commodity trading, that resulted in cases of patent infringement, compensation and liability claims for non-performance. Furthermore, the inevitability of transgenic contamination has been so widely acknowledged that eminent scientists from different parts of the globe have reached the conclusion that there could be no co-existence of GM and non-GM agriculture. Incidents of GMO contamination have taken place not only in countries like Thailand, Brazil and Paraguay, but also the cases with StarLink and ProdiGene in the US (Taylor and Tick 2003) point to the fact that the capacity to strictly implement the law is a far more important issue than just having a law in place. In the developing country context the feasibility of strict implementation of the safety measures should form a major part of decision making vis-à-vis introduction of GMOs.

The introduction of GMOs to Indian Agriculture started with the approval of commercial cultivation of Bt-Cotton in 2002. The Genetic Engineering Approval Committee (GEAC) approved commercial cultivation of Bt-Cotton in six Indian states. This approval was preceded by a statutory process of field level and large scale trials that took around 6 years. However, the evaluation of this crop in terms of its performance has met widespread controversy. Contrary to claims by the government and Mahyco,[61] research carried

[59] Article 26 of the Cartagena Protocol on Biosafety.

[60] http://www.grain.org/research/contamination.cfm?id=167 accessed on 17th October 2006.

[61] Licencee company for the introduction of Bt-Cotton.

out by a number of environmental organisations and independent researchers provide evidence of failure of Bt-Cotton crops, leading to economic distress to the farmers (Shiva and Jafri undated). Furthermore, there have been reports of widespread proliferation of several illegal variants of Bt-Cotton in different parts of the country. A study carried out by Gene Campaign[62] about the performance of Bt-Cotton has clearly pointed out that given that cotton fields in India are awash with a mixture of Bt-Cotton variants, it is virtually impossible to know the performance of individual varieties (Sahai and Rehman undated). In the case of Navbharat 151, an illegal variety, the Genetic Engineering Approval Committee (GEAC) became aware of its existence only after Monsanto's complaints in 2001. In October 2001, Mahyco Monsanto Biotech (MMB) discovered commercial cultivation of Bt-Cotton over 10,000 acres in Gujarat, traced the sale of the seeds to Navbharat Seeds Pvt Ltd., and demanded punitive action against the company. According to MMB, the company had been selling a Bt-Cotton variant, Navbharat 151, for 3 years. The GEAC ordered that the cotton be procured at a suitable price. But before this order could be implemented, the cotton had reached the market and seeds had been sold to numerous farmers and probably, even re-sown. Legal action was brought against the Navbharat Company. But irrespective of the outcome of such action, the incident revealed the limited capacity of the government to prevent the diffusion into the market of illegal Bt seeds with still limited knowledge of its ecological, environmental and health impacts (Krishnakumar 2003).

There have been numerous reports of cultivation of illegal varieties in certain areas in the states of Gujarat, Punjab, Madhya Pradesh, Andhra Pradesh and Karnataka. Despite the legal requirements of constituting State Biotechnology Co-ordination Committees and District Level Committees that have the responsibility to carry out monitoring exercises, the government is yet to take any action (Sahai 2002). Other country experiences in dealing with GMOs also point towards large infrastructural requirements. In the absence of proper monitoring and segregation facilities the whole regulatory process becomes futile. The illegal varieties are being grown without paying any heed to the steps that are required to be followed in cultivating GMOs. Their potential for contamination is well-known and they may well create a situation when there would be no option but to accept GMOs. To prevent such a situation, can a country resort to the precautionary principle to ensure due capacity building until GMOs are allowed to enter its territory? The Cartagena Protocol allows the principle to be applied when there are potential adverse effects on the conservation and sustainable use of biological diversity.

The implementation issue also brings to the fore some other concerns like the contamination of seeds and its effect on seed traders, the effects of contamination on organic farmers and its economic implications on domestic and export markets for India. In the culturally diverse Indian society, socio-religious issues involved with GMOs become even more acute when there is obvious potential for contamination. Other issues like consumer choice, farmers' rights over seeds and food sovereignty have also informed the present discussions on GMOs. The market practices in India are largely different from those of the developed countries where segregation of GM food or seeds from others might be possible. The costs of infrastructural requirements for adopting such practices is attached to the introduction of GMOs into the country's environment and has to be accounted for before taking any decision on GMOs. Whether a country is ready to bear such costs or if it is practically possible to maintain such strict requirements are relevant questions that must be considered at the decision making level.

[62] A New Delhi based NGO.

If we were to revisit the two regulatory parameters that have been stated above in the context of GMOs, it would not be drastic to suggest that the Indian regulatory regime is still struggling to put into place a sufficiently efficient mechanism for addressing the host of issues that are inherent to GMOs. In terms of the precautionary principle, the framework of institutional responsibilities and substantive duties that have been elucidated by the Courts in the application of the principle is instructive. On the other hand, there is also a need to broaden the scope of the application of precaution beyond its conventional domain, given the plethora of issues that GMOs give rise to. For instance, the socio-economic considerations for decision making might go beyond facts based on (natural) science. While it still remains open whether legislation can single handedly provide answers to all these demands, at the policy level the recommendations made by the Task Force on Application of Biotechnology in Agriculture under the Chairmanship of Prof. M. S. Swaminathan must be considered (Swaminathan 2004). The Task Force called for providing direction to research and development in relation to priorities, based on social, economic, ecological, ethical and equity issues and promoting environmental sustainability through natural resource conservation and enhancement. Furthermore, the Task Force holds the view that a transgenic approach should be considered as complementary and resorted to when other options to achieve the desired objectives are either not available or not feasible. Biotechnology applications, which do not involve transgenics such as bio-pesticides, biofertilizers and bio-remediation agents, should be accorded high priority.

5 Conclusion

There is clearly a lack of coherence in the manner in which the precautionary principle has been applied within international agreements and domestic state practice. Lack of coherence *per se* is, however, not a new issue within the field of international law. Nevertheless there is a clear and impending danger of a conflict of laws between international legal regimes (the international trade and environment regimes in this case), which could in effect impinge on the state's regulatory autonomy or limit the domestic policy space to the detriment of the environment and health of the population in states.

In this specific case, the recent panel ruling in the *EC-Biotech* case could generate a pre-emptive effect on further national measures in this area. This would of course give rise to a situation where the obligations on the states (which are party to both the Biosafety Protocol and the WTO) would be clearly in conflict. More crucially this is a policy area which is of grave importance to developing countries like India (where there exist competitive demands on limited resources), primarily because the environmental, health and socio-economic dimensions of a policy in this area is sure to have a long-term impact (and in many cases potentially irreversible) on the population. In this context therefore India should adopt a two-pronged approach to this issue. First, it should use options of negotiation provided under Article 31, Doha Declaration for resolving potential conflict between trade and environment. It can use the Committee on Trade and Environment within the WTO, as a forum for negotiating a more coherent and substantial linkage between the international trade and international environmental regimes (and the Biosafety Protocol and the WTO in particular). Second, it should also undertake a thorough re-examination of domestic priorities and policies in this area, so as to develop *sui generis* interpretative doctrines, principles and mechanisms through which the precautionary principle might be best applied to suit domestic needs and priorities.

In the domestic sphere legislation at its present state can be analysed from two perspectives, first, for bringing cost-effective measures for preventing environmental damage and second, inclusion of socio-economic concerns in the decision making process. In the case of GMOs, a number of issues within this policy area would require considerable amount of data collection and analysis even to form a preliminary understanding of the determinant factors associated with it and ways and means to address them. The experience in dealing with Bt-Cotton clearly implies the strict requirement of monitoring facilities and their absence in the present state of legislation and its implementation. Whether the benefits of introducing this new technology and products thereof can outweigh the costs of establishing and maintaining facilities for the implementation of the law is a moot question and the precautionary principle should be applied if cost-effective measures are not feasible. There is a need to look at agricultural biotechnology not as a scientific issue only, but in congruence with all other sectors that it affects and the costs associated therewith. Following the Cartagena Protocol, the Indian regulatory system need not confine itself to scientific questions only. Given the ground realities of Indian agriculture, domestic trade practices and infrastructural capabilities full consideration should be given to all possible socio-economic issues before taking any decision in allowing GMOs into our environment. The precautionary principle allows for flexibility and diverse application attuned to the relevant context. Indian GMO policy should best use the space for flexibility granted by the precautionary principle to address all the concerns associated with this new technology.

References

Annual report of the Secretary General on the work of the organisation (52nd session). 1997. Retrieved October 17, 2006 from http://www.un.org/Docs/SG/Report97/97con.htm.

Applegate, J. S. (2002). The taming of the precautionary principle. *William & Mary Environmental Law and Policy Review, 27*, 13–78.

Boisson de Chazournes, L. (2002). The precautionary principle. In F. Perrez (Ed.), *Precaution from Rio to Johannesburg* (pp. 10–13). Geneva: GEN & SADC.

Cameron, J., & Abouchar, J. (1991). The precautionary principle: A fundamental principle of law and policy for the protection of the global environment. *Boston College International Comparative Law Review, 14*(1), 1–27.

Conko, G. (2003). Safety risk and the precautionary principle: Rethinking precautionary approaches to the regulation of transgenic plants. *Transgenic Research, 12*(6), 639–647.

Garcia, M. S. (1996). Stock-recriutment relationships and the precautionary approach to the management of tropical shrimp fisheries. *Marine and Freshwater Research, 47*(1), 43–58.

Gullett, W. (2002). The precautionary principle in Australia: Policy, law and potential precautionary EIAs. *Risk: Health Safety and Environment, 11*(2), 93–124.

Gupta, A. (2000). Creating a global biosafety regime. *International Journal of Biotechnology, 2*(1–3), 205–230.

Gupta, A. (2002). Ensuring 'safe use' of biotechnology: Key challenges. *Economic and Political Weekly, July 6*, 2762–2769.

Hansson, O. S. (2001). Applying the precautionary principle to persistent and bioaccumulating substanced. *Policy Forum, News*. Retrieved November 20, 2005 from http://www.infra.kth.se/~cr/NewS/NewS_SOH_pp.doc.

International Law Commission. (2006). Fragmentation of international law: Difficulties arising from the diversification and expansion of international law, *Report of the Study Group of International Law Commission*. Retrieved 14th June 2006 from http://www.helsinki.fi/eci/Publications/MKFragmentation.pdf.

Krishnakumar, A. (2003). A lesson from the field, *Frontline* June 6. Retrieved October 18, 2006 from http://www.hinduonnet.com/fline/fl2011/stories/20030606005912300.htm.

Leelakrishnan, P. (1992). *Law and environment*. India: Eastern Book Company.

National Biotechnology Development Strategy (Draft). (2005). Retrieved October 25, 2006 from http://dbtindia.nic.in/biotechstrategy.htm.

National Conservation Strategy and Policy Statement on Environment and Development. (1992). Retrieved October 25, 2006 from http://www.envfor.nic.in/divisions/csurv/csps.pdf.

National Environmental Policy. (2006). Retrieved October 25, 2006 from http://envfor.nic.in/nep/nep2006e.pdf.

Palmer, A. (2006). *The WTO GMO dispute: Implications for developing countries and the need for appeal; Report prepared for GeneWatch UK, the RSPB, Forum for Biotechnology and Food Security and the GM Freeze*. Retrieved December 25, 2006 from http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/WTO_Biotech_case_dcsummaryfinal_1.pdf.

Perrez, F. X. (2000). *Cooperative sovereignty: From independence to interdependence in the structure of international environmental law*. Dordrecht: Kluwer.

Rio Declaration on Environment and Development. (1992). Retrieved 14th June 2006 from http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163.

Sahai, S.(2002).*The economics of Bt-Cotton*. Retrieved on 12th October, 2006 from http://www.sanctuaryasia.com/features/detailfeaturescategory.php?id=224&catid=28.

Sahai, S. & Rehman, S. (Undated). *Bt-Cotton performance 2003–2004: Field swamped with illegal variants*. Retrieved 12 October, 2006 from http://www.genecampaign.org/Publication/Article/BT%20Cotton/Btcotton_Performance_2003_04.pdf.

Sands, P. (2003). *Principles of international environmental law*. Cambridge UK: Cambridge University Press.

Shiva, V. & Jafri, A. H. (undated). *Failure of the GMOs in India.* Retrieved October 15, 2006 from http://www.navdanya.org/articles.

Sindico, F. (2005). *The GMO dispute before the WTO: Legal implications for the trade and environment debate. The Fondazione Eni Enrico Mattei Note di Lavoro Series Index*. Retrieved August 20, 2006 from http://www.feem.it/Feem/Pub/Publications/WPapers/default.htm.

Srinivas, K. (2001). Risks, ethics and biotechnology, *Viewpoints, Discussion Forum of Science, Technology and Innovation. Centre for International Development, Harvard University*. Retrieved October 15, 2006 from http://www.cid.harvard.edu/cidbiotech/comments/comments132.htm.

Swaminathan, M. S. (2004). *Report of the task force on application of Agricultural Biotechnology*. Ministry of Agriculure, Government of India. Retrieved December 25, 2006 from http://www.agricoop.nic.in/TaskForce/tf.htm.

Taylor, M. R. & Tick, J. S. (2003). *Post-market oversight of biotech food—is the system prepared? A report commissioned by the Pew initiative on food and biotechnolgy and prepared by resources for the future*. Retrieved October 12, 2006 from http://www.rff.org/rff/Publications/Reports.cfm.

Tickner, J. (1997). The precautionary principle. *The Networker, The Newsletter of the Science and Environmental Health Net, 2*(4).

UNDP. (1997). Governance for sustainable human development. *UNDP policy document* Retrieved October 15, 2006 from http://magnet.undp.org/policy/chapter1.htm.

Von Moltke, K. (1988). The Vorsorgeprinzip in West German environmental policy. Twelfth Report of Royal Commission on Environmental Pollution, CM 310. HMSO: UK.

Warwick, H., & Meziani, G. (2002). *Seeds of doubt: North American farmers' experiences of GM crops*. Bristol: Soil Association.