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Trade in Biotechnology: Precaution and Paralysis

A critical analysis of the law regulating trade in genetically modified organisms, from a South African perspective.

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I hereby declare that I have read and understood the regulations governing the submission of LL.M dissertations including those relating to length and plagiarism, as contained in the rules of the University and that this dissertation conforms to these regulations.

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Table of Abbreviations

ALOP	**Appropriate Level of Sanitary and Phytosanitary Protection**
APHIS	**Animal Plant and Health Inspection Service**
CBD	**Convention on Biological Diversity**
CPA	**Consumer Protection Act**
DNA	**Deoxyribonucleic Acid**
EC	**European Community**
ECJ	**European Court of Justice**
EPA	**Environmental Protection Agency**
FDA	**Food and Drug Administration**
FIFRA	**Federal Insecticide, Fungicide and Rodenticide Act**
FFDCA	**Federal Food, Drug and Cosmetic Act**
GM	**Genetically Modified**
GMO's	**Genetically Modified Organisms**
ICJ	**International Court of Justice**
LMO's	**Living Modified Organisms**
NGO	**Non-Governmental Organisation**
PAJA	**Promotion of Administrative Justice Act**
PP	**Precautionary Principle**
PPA	**Plant Protection Act**
SA	**South Africa**
SAGENE	**South African Committee for Genetic Experimentation**
SADC	**Southern African Development Community**
SPS	**Sanitary and Phytosanitary**
SPS Agreement	**Sanitary and Phytosanitary Measures Agreement**
TBT	**Technical Barriers to Trade**
TSCA	**Toxic Substances Control Act**
UK	**United Kingdom**
UN	**United Nations**
USA	**United States of America**
USDA	**United States Department of Agriculture**
WFP	**World Food Program**
WHO	**World Health Organisation**
WTO	**World Trade Organisation**
WTO AB	**World Trade Organisation Appellate Body**

1. A Balancing Act

1.1 Introduction

With the dawn of Genetically Modified Organisms (GMO's),[1] humanity discovered the pathway to a future which before, only science-fiction movies had contemplated. GMO technology has made it possible to engineer plants, animals and other organisms to bear specific, desired characteristics, by manipulating the genetic structure of the organism in question, making it capable of unprecedented commercial use and humanitarian benefit in the form and manner desired by the genetic engineer.[2] GMO's can possess properties which make them cheaper and easier to produce,[3] or make them capable of specific functions – from rendering consumer products more attractive, to alleviating hunger in desperately poor areas.[4]

[1] A term which is interchangeable with 'LMO's', defined in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity , Montreal 2000 in article 3(g) as meaning 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. 'Modern biotechnology' is defined in article 3(i) as 'the application of: (a). In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b). Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'. For the purposes of this argument, GMO's do not include the genetic alteration of humans.

[2] 'These solutions continue the tradition of selection and improvement of cultivated crops and livestock developed over the centuries. However, modern biotechnology identifies desirable traits more quickly and accurately than conventional plant and livestock breeding and allows gene transfers across species, genera and families, impossible with traditional breeding.' S Zarrilli 'International trade in GMOs: legal frameworks and developing country concerns' (2004) Report for the United Nations Conference on Trade and Development at 2. Available at http://www.unctad.org/en/docs//ditctncd20041_en.pdf [Accessed 18 June 2009] ; 'For example, genes from fish that are known to survive in cold waters may be transferred to tomatoes in order to make these frost resistant, and genes from bacterium can been transferred to potatoes and corn to make these crops resistant to certain insects' N Börjeson, 'WTO, GMO and the Precautionary Principle- the conflict between trade liberalisation and environmental protection' (2007) Master-Level Thesis, Södertörn University College Department of Life Sciences Environment and Development at 35. Available at http://www.essays.se/essay/5f8da94f2c/ [Accessed 12 June 2009].

[3] 'The US, by engaging in the cultivation of eight biotech crops, increased their production by 1.8 million metric tons in one year, which in turn has lowered production costs by 1.2 billion US dollars' - *European Communities – Measures Affecting the Approval and Marketing of Biotech Products - First Submission of the United States* WT/DS292/R, WT/DS293/R and WT/DS294/R 21 April 2004 para 9; Börjeson supra (note 2) at 36.

[4] Article 11(2)(a) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) 6 ILM 363 (1967) places an obligation on states, recognizing the fundamental right of all people to be free from hunger, to take measures which will improve methods of production, conservation and distribution of food, inter alia by making full use of technical and scientific knowledge in such a way as to achieve the most efficient development and utilization of natural resources. This would include using GMO technology to eliminate hunger.

The benefits of biotechnology defy conventional barriers to the imagination - endless possibilities are presented by this ingenious science.[5]

However, there is a menace is inherent in the promise of GMO's - they are not proven to be safe to human health and biological diversity. Although clearly harmful GMO's can be identified before even considered for use, under proper testing and risk analysis,[6] a danger lies in GMO's which have not been proven to be harmful but which may still potentially cause harm in future, which is, as yet, unforeseeable. Empirical scientific evidence exists both for and against the safety of these GMO's, with no weight enough on either side to prove their safety conclusively,[7] while in all practicality, GMO's cannot be tested to prove that they pose no risk at all. It is near impossible to pre-emptively prove the effect of an altered gene in an organism, especially when taking into account the different factors which come into play in a real-life environment into which GMO's are introduced.[8] It remains scientifically uncertain as to whether GMO's pose any risk of harm.

It is arguable that GMO's which have not proven to be harmful after undergoing rigorous risk analysis and assessment clearly pose very little if no threat of harm at all. This view point is strengthened by the fact that to date, no actual reported harm has arisen from any GMO's approved for trade by competent national authorities. It is extremely difficult to justify a complete prohibition of GMO trade in light of these considerations. Due to its great many benefits, reviewed against this undeniable evidence toward the factually benign character of approved modern biotechnology, GMO's are already widely traded internationally, despite scientific

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[5] For example, GMO's will allow impoverished communities to produce enough agricultural produce to fit their own national needs as well as surplus to export, at a lower cost. New industries will emerge, such as that for biofuels, while formerly useless land will gain agricultural value through plants which are modified to prosper in any environment.

[6] For example, 'a Brazil nut protein was cloned into plants to improve the protein content of staple foods. However, the protein was recognised as the major allergen from these nuts and research with the gene did not continue. No GM soya containing a Brazil nut gene has ever been approved for commercialization and no-one has ever died from eating GM soya that contains a Brazil nut protein.' Nordlee et al 'Brazil nut gene – the truth' (1996) 334 (11) New England J Medicine 688 at 692 Available at http://www.africabio.com/biotechsa [Accessed 20 May 2009]; 'Some current consumer concerns about biotechnology' Biotech SA Report loc cit.

[7] Biotech SA Report ibid.

[8] An example of this is that Bt protein, found in some approved GMO maize crops, showed to be harmful to Monarch Butterflies in laboratory tests in which the butterflies were force-fed Bt maize. However, Monarch Butterflies do not feed on maize in nature but rather on milkweed. The only way the butterflies will eat this protein in a real life situation is if the pollen containing it from Bt maize blows onto milkweed from surrounding maize crops and the butterflies eat the pollen too. However, this situation is highly adventitious and speculative and will probably not occur in reality. It is impossible to truly assess the real-life effect of Bt maize on Monarch Butterflies. Biotech SA Report ibid.

uncertainty over the potential risks they present.[9] This is especially important towards achieving the international goal of trade liberalisation. Many states take this stance on GMO's, specifically developing countries which stand the most to benefit from biotechnology and countries strong in agricultural export. South Africa (SA) is a liberal participant in this practice, [10] being the only African country to cultivate GMO's,[11] which it has been doing since 1992.[12]

However, GMO trade has caused moral and ethical concerns of the public to be disturbed in wild disarray, based on the potential risks they pose, especially in developed, consumer-based countries.[13] While these fears cannot be taken too far so that they would arbitrarily inhibit the benefits and liberalisation of GMO trade, specifically for weaker, developing nations, the legitimate expectations and the overall safety of a community cannot be neglected.

GMO trade thus presents a novel concept for states to regulate. While potential risks need to be managed and controlled, even if wholly uncertain to realise, at the same time, commercial incentive and the benefits GMO's present need to be maximised. Law makers are thus forced to regulate biotechnology before even science itself has perfected its control. This task is exacerbated by multifarious conflicting commercial and humanitarian policy considerations which require careful balancing.[14] Furthermore, human and consumer rights obligations, such as the right to health[15] and safety,[16] require states to take measures, [17] including legislative ones,[18] to prevent rights infringement by GMO-caused harm.

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[9] 'the estimated global GM crop area in 2003 was around 67.7 million hectares, cultivated by seven million farmers in 18 countries.... Six countries accounted for 99 per cent of the global transgenic crop area... . In the same year, the global market value of GM crops was estimated to between US$ 4.5 to US$ 4.75 billion.' Zarrilli (note 2) at 3.

[10] GMO's have been found to be ideal and highly beneficial to subsistence farming in SA, more so than traditional crops, not to mention the commercial benefits of this technology to SA's economy. N Tshisela 'Farmers pick GM food seeds' The Sowetan (3 March 2009).

[11] '[SA] has approved GM maize, soybean and cotton for commercial release' while SA alone constitutes 1% of the world's total transgenic crop area. Zarrilli supra (note 2) at 8.

[12] Report of The Office of the Registrar on the South African GMO Act 15 of 1997 *The GMO Act 15 of 1997 and GMO application process* at 1. Available at http://www.agric.za [Accessed 10 March 2009].

[13] This is specifically so in the European Community (EC). C R Sunstein, *Laws off fear: beyond the Precautionary Principle* (2005) at 5.

[14] J Kinderlerer 'The regulatory system in the EU and further afield' (2004) vol.10 No.3 Journal of Commercial Biotechnonlogy 248 at 249.

[15] Article 12(1) ICESCR supra (note 4).

[16] Article 3(a) of the United Nations Guideline on Consumer Protection 1985 (as expanded in 1999).

[17] Article 2 ICESCR supra (note 4).

[18] Idem.

The Precautionary Principle (PP) [19] is seen by many states as an invaluable tool in navigating the darkness of this issue, by allowing states to prevent the import of GMO's based on the fact that scientific uncertainty exists over their safety.[20] For this reason, it has been implemented in various international treaties[21] and agreements,[22] most importantly the Cartagena Protocol on Biosafety,[23] as well as in national laws regulating trade in biotechnology. [24]

As the difficulty in regulating potential risks without preventing the benefits derived from GMO's seems insurmountable, preventing GMO trade altogether, which would enable states to completely avoid a myriad of possible liability issues should GMO's actually cause harm, seems an attractive prospect. However, it is untenable. In the first place, denying GMO trade completely would be to deny the immense possibilities and benefits presented by this technology and will have an unnecessary chilling effect on scientific development.

Moreover, prohibiting GMO's based on scientific uncertainty over their safety would constitute a de facto moratorium against GMO trade,[25] a violation of World Trade Organisation (WTO) law which flies in the face of all international efforts to achieve free trade between states. Such a measure is in direct conflict with the WTO SPS Agreement,[26] which only sanctions prohibition of goods for sanitary or phytosanitary reasons on a provisional basis, based on lack of scientific knowledge as to their safety,[27] not a permanent prohibition based on scientific uncertainty, as is allowed by the PP.

This situation presents an anomaly in international law which remains the source of a deep-rooted conflict between countries. The PP is binding international law on members to the Cartagena Protocol,[28] while the SPS Agreement is binding

[19] Defined with the most international consensus in the 1992 UN Conference on the Environment and Development (UNCED) in Rio de Janero (the Rio Declaration) 31 ILM 874 (1992) article 15.
[20] Article 10(2) of the Cartagena Protocol supra (note 1).
[21] Such asthe Convention on Biological Diversity Rio de Janero 1992.
[22] Parties are free to conclude bi- and multilateral agreements regulating the transboundary movements of LMO's, so long as the agreement is consistent with the objective of the Protocol and provides no less protection than the Protocol provides, article 14 supra (note 1).
[23] Supra (note 1).
[24] For example, EC Regulation 1946/2003.
[25] *Biotech* case (note 3).
[26] The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 1994.
[27] Article 5(7) ibid.
[28] Article 26 of the Vienna Convention on the Law of Treaties 1969 (1969) 8 ILM 679.

law on WTO member states[29] – meaning two equally binding sources of law, directly in conflict with each other, may apply to the same state regarding trade of GMO's, should the state subscribe to both treaties. If it is impossible to reconcile these two legal instruments, a state is forced to choose which set of obligations it will follow and incur the consequences of breaching the other set of obligations. Both national and international bodies have battled to resolve this matter.[30]

Undeniably, there is much need for reformation of this position. International legislation regulating trade in biotechnology currently exists in a patchwork of conflicting and overlapping obligations on states, with many gaps between these provisions through which commercial incentives and humanitarian interests can slip away. Without a solution reconciling this conflict in sight, all a state can do is to design its national laws regulating trade in GMO's in such a way that it achieves the balancing act between ensuring consumer and environmental protection, while still maintaining its WTO law obligations, which international law has failed to accomplish.

1.2 GMO Trade in SA

Trade and cultivation of GMO's in SA an ever-growing industry[31] - thus SA is particularly affected by the international legal conflict over trade in GMO's. SA is a member of the WTO, while at the same time, it is a party to the Cartagena Protocol, placing it in the impossible position of being simultaneously bound to these conflicting treaties.[32] The only way SA can avoid the harsh consequences of this difficult situation is to construct its national laws regulating trade in GMO's in such a way that the measures authorised by these laws give effect to SA's WTO law obligations, while simultaneously affording itself the protections enshrined in the

[29] Article II(2) of the Marrakesh Agreement (1994) 1867 UNTS 3.
[30] IM Sheldon 'Regulation of biotechnology: will we ever freely trade GMO's?' (2002) 29 European Review of Agricultural Economics 155 at 160.
[31] 'GMO's approved for commercial use in South Africa have been thoroughly tested for safety with regard to humans, animals and the environment. As of 2003, GMO's that are commercially available in SA include: Insect resistant maize; insect resistant cotton; herbicide tolerant cotton, maize and soybean. Genetically modified crops that have received approval for contained field trials in SA include cotton; maize; sugarcane; soybean; potato; wheat. The Council has also approved clinical trials with certain vaccines.' '[In SA] approximately R100 million is spent on biotechnology research and development annually. Over 600 biotechnology research projects exist at present....' Biotech SA Report supra (note 6).
[32] This position is similar to that of the EC in the *Biotech* case (note 3).

Protocol,[33] without invoking liability for breach of either. This task is far easier said than done, if not impossible to achieve.

In the first instance, SA has more incentive than just its international law commitments to apply the PP. The most important obligation SA's government has in relation to creating national GMO regulatory measures is upholding its Constitution,[34] which is the supreme law of the land.[35] All laws and conduct inconsistent with it are invalid and the obligations imposed by it must be fulfilled.[36] SA is founded on this very constitutional supremacy and the rule of law,[37] as well as on the advancement of human rights and freedoms.[38] This entails that the legislature, when it makes regulatory GMO legislation,[39] as well as the executive, when making decisions regarding GMO trade in SA,[40] are mandated to take into account the human rights of SA's people[41] and its unique and entrenched socio-economic obligations.[42] In specific, this includes giving effect to the right of all people to administrative action which is lawful, reasonable and procedurally fair,[43] in terms of which GMO trade is permitted or denied; the right to freedom of consciousness, belief and religion[44] of consumers regarding GMO's; as well as the right of all people to a safe and healthy environment,[45] which would be violated should permitted GMO's actually cause damage. These constitutional imperatives require SA to put the human rights of its people foremost in its considerations regarding GMO legal regulatory measures. This aim may be best served with a strict adherence to the PP, by prohibiting all GMO's which present scientific uncertainty over their safety.

However, such an application of the PP would be deeply problematic. SA cannot ignore its economic obligations under the WTO. The Constitution itself mandates SA to uphold its international law obligations when carrying out the law.[46]

[33] Supra (note 1).
[34] The Constitution of the Republic of South Africa 1996.
[35] Section 2 ibid.
[36] Idem.
[37] Section 1(c) ibid.
[38] Section 1(a) ibid.
[39] Section 8(1) ibid.
[40] Idem.
[41] Section 7(2) ibid.
[42] Chapter 2 ibid.
[43] Section 33 ibid.
[44] Section 15 ibid.
[45] Section 24 ibid.
[46] Section 39(3) ibid.

If it did refuse GMO's into SA based on scientific uncertainty over their safety, SA would be violating its WTO law obligations,[47] leaving it open to liability claims.

Another relevant consideration against a strict application of the PP is that in terms of its international human rights law obligations, SA is mandated to take measures which will 'improve methods of production, conservation and distribution of food, inter alia by making full use of technical and scientific knowledge in such a way as to achieve the most efficient development and utilization of natural resources' in order to alleviate the problem of hunger.[48] Preventing GMO technology, which would achieve all these goals, would cause SA to act directly in contravention of this obligation, something it and more importantly, its poorest people, cannot afford to let happen.

The EC's strict application of the PP, without taking into account the negative trade effects such measures might have, has caused much suffering in other countries,[49] which serves as a warning to SA of things to come should it apply a similar approach. An example of this already exists close to home. Namibia has stopped imports of corn from SA on the premise that the GM nature of the corn, which it traditionally used as cattle feed in beef production, poses too much of a risk to its beef export industry to the EC, which will not accept GM corn or its products based on its strict application of the PP. Namibia perceives itself to be under an obligation to remain 'GM-Free' so as not to compromise its vital trade relations with the EC, costing SA millions in lost revenue.[50] Furthermore, SA cannot ignore its heavy economic reliance on the USA as a trading partner. It cannot simply sever GMO trade with the USA and other GMO-producing nations without suffering economic hardship.

SA's existing laws gave have attempted to address these concerns. Given the constitutional, commercial and consumer implications involved, one cannot analyse SA's GMO regulation laws in isolation. A proper analysis entails consideration of three main sources – SA's GMO Act and its amendments,[51] its Consumer Protection Act[52] and the Constitution,[53] all of which are always to be viewed in light of SA's

[47] Specifically in terms of the General Agreements on Tariffs and Trade (GATT) (1994) 1867 UNTS 190 and the SPS Agreement (note 26).
[48] Article 11(2)(a) ICESCR (note 4).
[49] Zambia, Sudan and Angola inter alia.
[50] Avialible at http://www.dti.gov.za; http://www.itac.org.za/ [Accessed 4 August 2009].
[51] Act 15 of 1997; Act 23 of 2006.
[52] 68 of 2008.

international law obligations.[54] In between the EC's has conservative approach to GMO regulation,[55] characterised by the PP and the Cartagena Protocol[56] and the liberal view of the USA,[57] which gives precedence to WTO law, SA has adopted a middle-road approach, aiming to allow trade and development of biotechnology, giving effect to its WTO law obligations, while showing protectionist views toward human safety and the environment. This approach, although in its infancy, is a step in the right direction.

Sadly, this collection of legal rules is characterised by inefficient liability and redress measures, sweeping, vague provisions and an avoidance of issues which will cause conflict in the future regarding GMO trade, specifically those concerning the rights of consumers – a situation in need of reform.

SA's position regarding legal regulation of GMO's is delicate indeed. It still has not solved the problems set out above, leaving SA vulnerable to many potential dangers. The law needs to keep ahead of biotechnology, not behind it, to avert potential disaster, commercial or humanitarian. It is not enough to leave the issue to be determined by the courts only if and when conflict arises. This would be too little, too late, leading to the endurance of much unnecessary hardship. All that is required is for SA's lawmakers to balance conflicting interests in a far-thinking way, by embracing the principles already in its very foundations – openness, democracy, human dignity, equality and freedom[58] – to create a sound legal framework regulating trade in biotechnology.

[53] And its enabling legislation, such as the Promotion of Administrative Justice Act 2000.
[54] 39(3) of the Constitution (note 34).
[55] Sheldon (note 30) at 140.
[56] Supra (note 1).
[57] Kinderlerer (note 14) at 249.
[58] Section 1 Constitution (note 34).

2. A Patchwork of Legislation

2.1 The International Legal Framework

2.1.1 The Precautionary Principle

The novel concept in law of controlling and managing risks which are uncertain to happen, before they actually realise, has been embodied in the controversial Precautionary Principle (PP), which entails 'the adoption of protective measures in situations of scientific uncertainty'.[59] '[P]recaution is used when scientific research has not yet reached a stage that allows the veil of uncertainty to be lifted',[60] being applied where there is no 'adequate theoretical or empirical basis for assigning possibilities to a possible set of outcomes' presented by the subject matter in question.[61] Three basic conditions trigger the application of protective measures under the PP: uncertainty, risk, and lack of proof of a direct causal link between the potential risk and the feared harm.[62] It thus differs from prevention, which involves stopping harmful consequences which are certain to occur.

No universal definition for the PP exists, as even this aspect of the PP is controversial. However, it has been defined with the greatest international consensus in the Rio Declaration[63] as being: '[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'[64]

This construction of the PP allows much room for interpretation. It removes scientific uncertainty as a barrier against invoking legal preventative measures but allows a broad margin in which potential risks can be graded for sanction or prohibition. This is left up to the unfettered discretion of the state, based on what it perceives to present 'serious or irreversible damage' in the absence of law or certain scientific proof defining this objectively. It confines the invocation of these measures to what is 'cost-effective' to prevent only 'environmental degradation', but this concept is undefined and impossibly wide.

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[59] A Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (2007) at 105.
[60] N de Sadeleer, *Environmental Principles: From Political Slogans to Legal Rules* (2005) at 74-75.
[61] T Christoforou 'The Precautionary Principle in European Community law and science' in J A Tickner *Precaution, Environmental science and preventive public policy* (2003) at 246.
[62] Zarrilli (note 2) at 3.
[63] The Rio Declaration (note 19).
[64] Article 15 ibid.

The principle has been questioned by many states. The sanction of preventative measures for perceived risks which are unproven to exist appears overly broad and unnecessary, if not irrationally restrictive. Resultantly, although it 'is regarded by some as having crystallised into a general principle of customary international law',[65] the PP's status as such is 'less than clear.'[66] International tribunals have declined to decide on whether the principle is binding in international law.[67]

However, undeniable merits exist in the idea of the PP. The fact that serious risks may exist despite being unproven cannot be ignored and there is no other feasible way to protect vital interests from harm caused by this than to act to prevent the potential harm pre-emptively. Thus many states have chosen to bind themselves to the PP, through subscribing to binding international law or through the implementation of national laws.

2.1.2 The Cartagena Biosafety Protocol

In terms of the Convention on Biological Diversity (CBD),[68] which was implemented to protect 'the intrinsic value of biological diversity',[69] the Cartagena Protocol on Biosafety was enacted,[70] specifically to regulate transboundary movement[71] of LMO's between states.[72]

'The focus of the protocol lies on the international trade with LMOs and not with the question of LMOs *per se.*'[73] It applies to 'any transboundary movement, transit, handling and use of all LMO's that may adversely affect biological diversity,

[65] *EC Measures Concerning Meat and Meat Products - Hormones,* WT/DS26/AB/R, and WT/DS48/AB/R AB Report 16 January 1998 para 123.
[66] A Cosbey and S Burgiel *The Cartagena Protocol on Biosafety: an analysis of results. An IISD briefing note* (2000) at 14; *EC-Hormones* (note 65) para 123.
[67] Cosbey ibid at 14; *Biotech* case (note 3) para 7.71.
[68] Supra (note 1).
[69] The CBD (note 1), in the preamble.
[70] Under article 19(3) 'which provides for Parties to consider the need for and modalities of a protocol on the safe transfer, handling and use' of LMOs 'that may have an adverse effect on biodiversity.' A Cosbey (note 19) at 3; also in terms of articles 19(4) and 8(g) aid 17 of the CBD, Preamble to the Cartagena Protocol supra (note 1).
[71] '"Transboundary movement" means the movement of a living modified organism from one Party to another Party... and extends to movement between Parties and non-Parties.' Article 3(k) of the Cartagena Protocol ibid.
[72] Article 1 ibid.
[73] G Eklöf 'Miljön på undantag – de internationella miljöavtalen och WTO' (2004) Forum Sydförlag, Stockholm, Sweden at 18; Börjeson (note 2) at 29.

taking also into account risks to human health', [74] necessarily including international trade of LMO's in its scope of application.

It requires parties to 'regulate, manage and control the risks associated with the use and release' of LMO's likely to have 'adverse environmental impacts'[75] and to ensure the 'safe transfer, handling and use' of LMO's that may be harmful.[76] The Protocol specifically incorporates the PP into the regulation of LMO trade,[77] stating 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 that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question… in order to avoid or minimise such potential adverse effects.'[78]

This article provides a wide scope for interpretation. It modifies the Rio Declaration's version of the PP,[79] extending its application to include potential threats human health as well as the environment. It also removes scientific uncertainty over the safety of LMO's as a barrier against a party taking decisions, specifically regarding their import, to prevent these potential adverse effects. Such decisions include the imposition of conditions on imports, or prohibiting LMO imports entirely. Which of these constitutes an appropriate decision under the circumstances is left to the discretion of the decision-maker. However, uncertainty, risk and lack of proof of a causal link between the harm and the LMO remain preconditions for invoking the PP.

The Protocol does limit the scope of this discretion by mandating that a party is to base its decision on a risk assessment,[80] which is to be undertaken on a case by case basis[81] in a scientifically sound manner,[82] before the first release of the GMO.[83]

The Protocol obliges exporter parties to inform the importer party, in advance,[84] of the GM nature of the goods to be imported[85] for cultivation,[86] even if

[74] Article 4 Cartagena Protocol (note 1).
[75] Article 8(g) of the Convention on Biological Diversity (note 21).
[76] Article 1 Cartagena Protocol (note 1).
[77] Article 1 and in the preamble of the Catagena Protocol ibid.
[78] Article 10(6) ibid.
[79] Principle 15 (note 19).
[80] Article 15 in accordance with annex III of the Cartagena Protocol (note 1).
[81] Annex III article 6 ibid.
[82] Article 15(1) ibid.
[83] Article 16(3) ibid.

the goods only might contain LMO's. This must be done before the 'first intentional transboundary movement of the LMO for intentional introduction into the environment of the party of import'.[87] The importing party must acknowledge this notice[88] and the goods cannot be imported until it has further consented to such in writing, after acknowledgement.[89] This 'informed consent' provision[90] does not apply to LMO's intended for use as food, feed[91] or in processing (LMO-FFP's). These only need the exporter to notify the importing party of the LMO nature of the goods[92] and are not subject to informed consent before being imported.[93] The principle exists to ensure that the importing party has full discretion to allow import or not and attempts to ensure that the decision taken is done in a fully informed manner.

However, the power of the decision-maker to determine the ultimate nature of the decision is unfettered. The Protocol specifically states that lack of scientific knowledge or consensus should not be taken to necessarily mean that either an absence or a particular level of risk exists – moreover, it does not indicate an acceptable risk[94] - when making this decision, leaving the ultimate determination of acceptable risk up to the decision maker. Furthermore, the Protocol removes the requirement that the measures to be taken should be 'cost-effective' from its version of the PP, unlike in the Rio Declaration.[95] Therefore, the Protocol allows the importing party to take any measure regarding LMO import which it deems fit to prevent or minimise potential harm, regardless of cost-efficiency, based purely on the fact that the GMO poses safety risks, despite this being scientifically uncertain, even if there is no conclusive proof that it is unsafe at all.[96]

[84] In accordance with the Advanced Informed Agreement Procedure, article 7(1) ibid.
[85] Article 8(1) ibid.
[86] Article 7 ibid.
[87] Article 7(1) ibid.
[88] Article 9(1) ibid.
[89] Article 10(2) ibid.
[90] Articles 7 – 10 ibid.
[91] 'Food' meaning goods intended for human consumption; 'feed' meaning goods intended for animal consumption.
[92] Article 11(1) of the Protocol (note 1).
[93] Article 7(2) ibid.
[94] Annex III article 4 ibid.
[95] Supra (note 19).
[96] Eklöf, supra (note 73) at 1; Börjeson supra (note 2) at 29.

2.1.3 The SPS Agreement

International trade of goods, including GMO's,[97] between WTO member states is regulated by WTO law.[98] Measures taken by a member to avoid potential harm to human, animal or plant life and health caused by goods, which directly or indirectly affects international trade, constitute sanitary and phytosanitary (SPS) measures,[99] which brings the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) into application.[100] Thus, a decision to allow GMO imports or not based on their safety falls under the scope of this agreement, which is automatically binding on all members.[101]

Members have the right to institute SPS measures so long as the measures taken are consistent with the SPS Agreement.[102] This entails, inter alia, that the measures taken are not to be more restrictive than is necessary to protect these interests[103] and specifically should not be applied in such a way that they constitute a disguised restriction on international trade.[104] The measures should be based on risk assessment,[105]which must include a review of available scientific evidence[106] and relevant economic factors.[107] Members are specifically obliged to take into account the objective of 'minimising negative trade effects' when determining the level of SPS measures to implement.[108] The agreement mandates that these measures are to be based on scientific principles[109] and should not be maintained without sufficient scientific evidence.[110]

However, an exception to this rule exists,[111] for cases where 'relevant scientific evidence is insufficient', in terms of article 5(7).[112] In such an instance, a

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[97] CropBiotech Update 'US to Strengthen biotech regulation for GMOs' (6 February 2004) Available at http://www.isaaa.org/kc/cbtnews/bcentral/cbtupdate.htm#us [Accessed 27 June 2009]; Zarrilli supra (note 2) at 10.
[98] Specifically the General Agreement on Tariffs and Trade (note 47).
[99] Annex A article 1of the SPS Agreement (note 26).
[100] Article 1(1) ibid. This does not prejudice the application of the Agreement on Technical Barriers to Trade (TBT Agreement), article 1(4) ibid.
[101] Article II(2) of the Marrakesh Agreement (1994) 1867 UNTS 3.
[102] Article 2(1) SPS Agreement (note 26).
[103] Article 2(2) ibid.
[104] Article 2(3) ibid.
[105] Article 5(1) ibid.
[106] Article 5(2) ibid.
[107] Article 5(3) ibid.
[108] Article 5(4) ibid.
[109] Article 2(2) ibid.
[110] Article 2(2) ibid.
[111] Idem.
[112] Idem.

state may adopt provisional SPS measures based on pertinent information.[113] The state then has an obligation to find additional information which is 'necessary for a more objective assessment of risk',[114] while it also is required to review these SPS measures within a reasonable period of time.[115]

In *Japan varietals*,[116] the WTO Appellate Body (AB) held that Article 5(7) of the SPS Agreement mandates the attainment of four cumulative requirements before a provisional SPS measure may be legally taken or maintained:

> 'A country may provisionally adopt an SPS measure if this measure is: (i) imposed in respect of a situation where relevant scientific evidence is insufficient; and (ii) adopted on the basis of available pertinent information. Such a measure may not be maintained unless the country that adopted it: (i) seeks to obtain the additional information necessary for a more objective assessment of risk; and (ii) reviews the measure accordingly within a reasonable period of time.'[117]

In *Apples*,[118] the AB expanded on the requirements, stating that:

> 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A[119] to the SPS Agreement.'[120]

A WTO member state may only implement SPS measures in relation to GMO's in accordance with these provisions. Therefore, as GMO's do not show a scientifically conclusive risk of harm after risk assessment, there is no basis in terms of the SPS Agreement to implement and maintain SPS measures preventing their trade. Furthermore, the fact that there is enough scientific evidence to conduct 'an adequate assessment of risks'[121] of GMO's, means that there is no insufficiency of relevant scientific evidence regarding their safety. This automatically precludes the implementation of provisional SPS measures in this instance as well, as all four cumulative requirements need to be present before provisional SPS measures can be

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[113] Ibid.
[114] Article 5(7) of the SPS Agreement (note 26).
[115] Ibid; Zarrilli (note 2) at 12; M Matthee and Vermersch. 'Are the Precautionary Principle and the international trade of genetically modified organisms reconcilable?' (2000) vol. 12 Journal of Agricultural and Environmental Ethics 60 Vol. 12 at 64.
[116] *Japan - Measures Affecting Agricultural Products (Japan Varietals)*, WT/DS76/R, 27 October 1998, and WT/DS76/AB/R, 22 February 1999.
[117] Ibid; Zarrilli (note 2) at 12.
[118] *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, 26 November 2003.
[119] Article 4.
[120] *Apples* case (note 118) at 179.
[121] Ibid.

legally implemented. Mere scientific uncertainty over the safety of GMO's is not a justification for taking an SPS measure and doing so would necessarily result in breach of the SPS Agreement.

2.2 A Fundamental Conflict : The Cartagena Protocol v WTO Legal Framework

There is a fundamental problem in the dual application of WTO law and the Cartagena Protocol to regulation of GMO trade. It is impossible for any state to comply with one set of these legal rules without disregarding the other, as the two are fundamentally in conflict. Should a state subscribe to both, it faces a real problem, whereby it is liable for breach of one set of obligations merely due to it following its other set of legal obligations in the sphere of GMO trade. This leaves the state forced to carefully decide which one it will apply and which it will abandon, causing it to lose vital protections provided by the abandoned agreement in the process.

> '[T]here are four aspects of the Protocol that might give rise to some overlaps and tensions with WTO law: (a) the scope for legitimate government action without conclusive scientific evidence; (b) risk assessment and risk management; (c) the socio-economic factors which may be taken into account in the decision-making process; and (d) documentation requirements.'[122]

2.2.1 The Scope for Legitimate Government Action Without Conclusive Scientific Evidence

The greatest area of conflict between these two legal instruments centres on the PP, which is applied in the Protocol[123] but disregarded in WTO law entirely. Both the Protocol and the SPS Agreement allow for precautionary measures to be taken where there is 'insufficient information to carry out a risk assessment'.[124] In terms of the PP under the Protocol, [125] importing countries can also ban GMO imports because of lack of scientific certainty after risk analysis. However, under the SPS Agreement, if there is enough scientific evidence to conduct proper risk assessment, inconclusiveness of scientific evidence, or scientific uncertainty, 'related to the

[122] Zarrilli (note 3) at 10 – 11.
[123] Article 10(6) of the Protocol (note 1).
[124] Idem; article 5(7) of the SPS Agreement (note 26); Zarrilli (note 3) at 13.
[125] Article 10(6) of the Protocol (note 1).

actual or potential impact of GMOs'[126] remaining after such assessment , is not a sufficient reason for taking precautionary measures.[127]

> 'The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The two concepts are decidedly not interchangeable.'[128]

Although '[a]ccording to the Protocol, the insufficiency of scientific evidence would lead to scientific uncertainty, which, in turn, would justify a precautionary approach.',[129] this argument is not congruent with the meaning of article 5(7) of the SPS Agreement. In accordance with the AB's interpretation,[130] 'insufficient scientific evidence' can only exist if the evidence in question is not enough for a proper risk assessment to be undertaken.[131] It is distinctly different from scientific uncertainty,[132] which is a conclusion drawn from the risk assessment process. Ergo, in the case of insufficient scientific evidence, no risk analysis can take place, hence no conclusion, including scientific uncertainty, can be drawn at all. However, if 'scientific uncertainty' was meant to imply that no proper risk analysis could take place due to insufficient scientific evidence, leading to scientific uncertainty, then the concept intended by the phrase 'scientific uncertainty' would be equivalent to the meaning of 'insufficient scientific evidence'. It is highly unlikely that this latter position reflects the true state of affairs. If this was so, the drafters of the Protocol would have included only the concept of 'scientific insufficiency or lack of scientific knowledge' in article 10(6) and not included 'scientific uncertainty' in the provision as well. As they did, it is clear that scientific uncertainty represents a distinct concept from 'insufficiency of scientific evidence' and the two cannot be considered as equivalent. To the extent that the Protocol implies this concept of scientific uncertainty as a justification for taking measures to prevent potential harm, despite being legally justified under the Protocol, it cannot be based on insufficient scientific knowledge and therefore is not sanctioned as valid justification for implementing provisional SPS measures under the SPS Agreement.

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[126] Zarilli (note 3) at 13.
[127] Article 5(7) of the SPS Agreement (note 26); Zarilli ibid at 13.
[128] *Japan* case (note 112) at 184.
[129] Ibid at 13.
[130] Supra (note 118).
[131] Ibid.
[132] Supra (note 120).

A further conflict between the two legal instruments is that in terms of the Protocol, the importing country is not obliged to seek necessary information to reach scientific certainty[133] on whether the GMO does in fact pose such risks, or more importantly, on whether they are likely to realise at all. Thus, the ban on GMO trade 'may last until the importing country decides that it has arrived at scientific certainty about the effects of the products on biodiversity and human health',[134] which is unlikely to happen at all if the state has no incentive to ever reach a conclusion on the safety of GMO's. 'This in turn can easily amount to 'a trade-restrictive measure'[135] which 'may be in force without time limits.'[136]

Such a trade-restrictive measure directly contravenes the objective and provisions of the SPS Agreement, which mandates that precautionary measures should not be taken in such a way that this result ensues.[137] The Appropriate Level Of SPS Protection (ALOP) under the SPS Agreement is left to the free discretion of the member implementing the measure. However, this discretion must take into account the goal of minimizing negative trade effects.[138] The SPS Agreement institutes a proportionality requirement with regard to the measures taken, in that members must make sure that the measures implemented 'are not more trade-restrictive than required to achieve the [ALOP], taking into account technical and economic feasibility'.[139] Equally effective and reasonably available measures which achieve the ALOP in the least restrictive way are the only measures which may be legally implemented. Arbitrary or unjustifiable distinctions in the ALOP which a member deems appropriate in different situations must be avoided, 'if such distinctions result in discrimination or disguised restriction on international trade.'[140] When determining ALOP, a member must also take into account relevant economic factors, including 'the relative cost-effectiveness of alternate approaches to limiting the risks'.[141] The Protocol does not contain this very important anti-trade restriction requirement, nor does it impose any consideration of cost-effectiveness in its

[133] Zarilli (note 3) at 12.
[134] Idem.
[135] Idem.
[136] Idem.
[137] Article 2(3) of the SPS Agreement (note 26).
[138] Article 5(4) ibid.
[139] Article 5(6) ibid.
[140] Article 5(5) ibid.
[141] Article 5(3) ibid.

measures.[142]Thus, decisions taken under the Protocol which may be legal in terms of its provisions, but which do not take these trade and proportionality requirements into account, will not satisfy the requirements of the SPS Agreement.

The Cartagena Protocol does provide a form of recourse to the exporting party, however, in that it may request the importing party to review its decision to pre-emptively ban LMO's from import, if circumstances change which would alter the risk assessment upon which the ban is based, or if relevant scientific or other knowledge becomes available. The importing party is then obliged to respond to the exporting party's request within 90 days, in writing, giving reasons for its decision.[143] However, these provisions do not apply to LMO-FFP's, which means that decisions to prevent their import cannot be requested to be reviewed. This leaves the exporters of these items unjustifiably without recourse against the importer, even if circumstances change to alter the risk assessment of these goods. The provision also does not ensure that the importer will actually review its decision but in effect, merely mandates the importer to give reasons for its decision.

In contrast, the SPS Agreement applies to all LMO's and specifically requires states to seek further information to gain at least a more objective assessment of the risk after the measures are out in place.[144] The importing party, not the exporting party, bears the burden of finding this additional information. Also, the importing party is obliged to actually review the measures put in place within a reasonable period of time, [145] not just to consider its decision in hindsight and furnish the exporting party with reasons. These measures are only provisional, [146] unlike the measures sanctioned by the Protocol, which may be permanent.

2.2.2 Risk Assessment and Risk Management

Risk assessment is the basis for reaching decisions to prevent potential harm posed by LMOs under both the Protocol[147] and the SPS Agreement in general,[148] with the exception that provisional SPS measures can be implemented without risk

[142] Article 10(6) of the Protocol (note 1); Zarrilli (note 3) at 13.
[143] Article 12(2) and (3) of the Protocol (note 1).
[144] Article 5(7) of the SPS Agreement (note 26).
[145] Ibid.
[146] Ibid.
[147] Article 15(1) of the Protocol (note 1).
[148] Article 5(1) of the SPS Agreement (note 26) as set out in article 4 of Annex A.

assessment if the criteria of article 5(7) are met – a situation which is not legally permissible under the Protocol.

Under the SPS Agreement, the importing party usually carries out and bears the costs of risk assessment, although this is not specified. It mandates members to take into account specific factors when conducting a risk assessment.[149] This includes relevant economic factors,[150] something the Protocol does not mandate at all.

However, in terms of the Protocol,[151] the onus to carry out risk assessment is either on the importing party itself, or on the exporting party should the importing party request it to do so.[152] The information upon which the risk assessment is based comes largely from the information furnished by the exporting party. Also, where the importing party carries out the risk assessment, it may recover the cost involved from the exporting party.[153] In the case of LMO-FFP's, risk assessment information must mandatorily be referred to the Biosafety Clearing-House by a Party that takes a final decision regarding their domestic use, which may be subject to transboundary movement. These provisions are very different from the SPS Agreement, if not in conflict with it, making them difficult for a state who subscribes to both sets of legal rules to apply both these provisions fully.

2.2.3 The Socio-Economic Factors Which May Be Taken Into Account in the Decision-Making Process

Under the Protocol, the importing party may take into account 'socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities' when making its decision but is not mandated to do so.[154] This is not an obligation, however. It may also be interpreted as the Protocol allowing 'trade-restrictive measures justified by the fact that imports of LMOs might lead to a loss of cultural traditions, knowledge and practices,

[149] Article 5(2) and (3) ibid.
[150] Article 5(3) ibid.
[151] Risk assessment is set out in annex III.
[152] Article 15(2) ibid.
[153] Article 15(3)ibid.
[154] Article 26 of the Protocol (note 1).

particularly among indigenous and local communities',[155] a position not shared by WTO law.

Trade restrictions justified only by the fact that that cheap imports would undermine the traditional livelihoods of a certain minority population was rejected by the GATT Panel,[156] a decision which underlines the WTO's strong position against trade restrictions in general. The SPS Agreement gives precedence to the objective of minimizing negative trade effects,[157] obliging members to avoid arbitrary and unjustifiable distinctions in its ALOPs which result in discrimination or a disguised restriction on trade.[158] Unlike the Protocol, it is very unlikely that a trade restrictive measure will be justified by socio-economic factors in terms of the SPS Agreement. It does mandate that socio-economic considerations must be taken into account when undergoing risk assessment of risks posed at animal or plant life or health[159] but this is not the case for assessment of risks to human health.

However, it does mandate that when taking SPS measures, the special needs of developing countries should be taken into account,[160] something not mentioned in the Protocol. Due to the potential devastating socio-economic effects of pre-emptive action by developed states on these countries, this is a serious flaw in the construction of the Protocol which needs to be addressed.

2.2.4 Documentation Requirements

The Cartagena Protocol also regulates the handling, transport, packaging and identification requirements for LMO's[161]. However, on an expansion of this requirement at the first meeting of the parties, with regard to FFP-LMO's, Governments were encouraged 'to require information on the name of the organism and the transformation event or unique identifier code'.[162]

> 'Compliance with this requirement is more cumbersome than simply indicating in the accompanying documentation that the shipment "may contain LMOs", since it implies the establishment of strict systems of identification and segregation.'[163]

[155] Zarrilli (note 3) at 14.
[156] *Japanese Measures on Imports of Leather*, GATT Panel Report BISD 31S/94, 2 March 1984, p. 44
[157] Article 5(4) of the SPS Agreement (note 26).
[158] Article 5(5) ibid.
[159] Article 5(3) of the SPS Agreement (note 26).
[160] Article 10(1) ibid.
[161] Article 18 of the Protocol (note 1).
[162] Zarrilli (note 3) at 15.
[163] Ibid .

This provision presents another area of potential conflict with WTO law, in that it may constitute a violation of the principle of non-discrimination.[164]

2.2.4.1 Substantial Equivalence

In WTO law, the TBT Agreement regulates documentation and labelling requirements. Article 2(1) reiterates the GATT's principle of non-discrimination,[165] stating that imported products and 'like' or substantially equivalent products of domestic origin or originating in any other country must be treated the same way. In relation to GMO's, this means that

> 'the issue to consider is whether a genetically engineered product that sufficiently resembles a conventional product in outward characteristics would be considered substantially equivalent to the conventional product. If this were the case, the two products would therefore be regarded as equally safe and should be treated in the same way.'[166]

The end use which a product is put to determines the likeness of that product to other products which are put to the same use.[167] This is an objective analysis, based largely on a consideration of the product from the consumer's perspective,[168] in that the goods are directly substitutable or competitive with each other.[169] This is generally determined by asking the question: if there was a small but significant price increase of the conventional product, would the consumer substitute it with the product in question? If the answer is yes, the products are substantially equivalent.[170]

Objectively, it is highly probable that in such an instance, a GMO product which for outwardly is the same as conventional products will be substituted for the conventional product by consumers, rendering approved imported GMO's substantially equivalent to other imported products put to the same end use. Should these two products then not be treated the same way, despite being substantially equivalent, a member would be in violation of its WTO obligations.[171] As LMO-FFP's are subjected to rigorous risk assessment measures before being approved for

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[164] As contained in Articles I and III of the GATT (note 47).
[165] Idem; Zarrilli (note 3) at 13.
[166] Zarrilli ibid at 13 – 15.
[167] *Spain Tariff Treatment of Unroasted Coffee* BISD S25/49 11 June 1981 at para 4.7 and 4.9.
[168] *Korea – Measures affecting Imports of Fresh, Chilled and Frozen Beef* Report of the Appellate Body AB-2000-8 WT/DS161/AB/R WT/DS169/AB/R 11 December 2000.
[169] *Chile – Taxes on Alcoholic Beverages* AB-1999-6 WT/DS87/AB/R WT/DS110/AB/R 13 December 1999 at para 48.
[170] *Chile – Taxes on Alcoholic Beverages* Reports of the Panel WT/DS87/R, WT/DS110/R, 15 June 1999 at para 8(1).
[171] In terms of the GATT (note 47) article III(4) and article 2(1) of the Agreement on Technical Barriers to Trade 1994 (TBT Agreement).

import, legally they have satisfied all requirements necessary to be deemed as substantially equivalent to other conventional domestic products. Therefore the expanded labelling requirements for LMO-FFP's as contemplated by the first meeting of the parties, which may negatively impact on their trade in competition with conventional products, would indeed constitute an unnecessary trade restriction on them, as there is no need to subject approved imported products with such discriminatory measures.

2.3 Which Law Applies?

Given these vast discrepancies in the legal instruments above, the ultimate question to be answered is which set of legal rules is to be applied?

In the first place, only the instruments to which a state is a party is binding on that state.[172] The primary problem to be resolved is which law applies to a state which is a party to both sets of treaties. The Vienna Convention[173] states that 'when a treaty specifies that it is subject to, or that it is not to be considered as incompatible with another treaty, the provisions of that other treaty prevails'.[174] This is taken to mean that 'in the event of an incompatibility between two successive agreements relating to the same subject matter, the requirements of the later agreement prevail, if nothing else is stated in the agreements'.[175] In the instance that in a dispute 'parties to the later treaty do not include all the parties to the earlier one, the treaty to which both States are parties to prevails and governs the mutual rights and obligations of the States'.[176]

The Cartagena Protocol was the later treaty entered into, being effective in 2000, while the relevant WTO law came into force in 1995. Therefore, in following with the Vienna Convention's mandates, the Protocol should prevail unless it contains provisions to the contrary.

The Protocol's preamble states that 'trade and environmental agreements should be mutually supportive with a view to achieving sustainable development'

[172] Articles 34, 35 and 36 of the Vienna Convention supra (note 28).
[173] Supra (note 28).
[174] Article 30(2) ibid.
[175] S Safrin 2002. 'Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements' (2002) Vol. 96, Nr. 3. The American Journal of International Law 610 at 613.
[176] Article 30(4) of the Vienna Convention (note 28).

This can be interpreted to mean that the Protocol 'stands in parallel with other international agreements, including the WTO agreements'.[177]

However, the Protocol's preamble is confusing on the issue of precedence of concurrent treaties at best. The preamble goes further to say that 'this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements', a strong suggestion in favour of the WTO Agreements having precedence over the Protocol's provisions in times of conflict between the two. 'Such a clause is commonly referred to as "a savings clause" because, in effect, it saves provisions of the earlier agreement [the WTO Agreements in this instance] that would otherwise be overcome by incompatible provisions of a latter agreement'.[178] 'The Protocol includes a clear savings clause in its preamble'.[179]

However, the preamble continues to contradict this provision by saying that 'the above recital is not intended to subordinate this Protocol to other international agreements'. Article 14(1) of the Protocol reiterates this sentiment, setting out that Parties may enter into bilateral, regional and multilateral agreements regulating transboundary movement of LMO's under the Protocol's objectives 'provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol' – in effect, preventing the Protocol's subordination by subsequent instruments.

'[T]here are many roads for the interpreters of paragraph 30(2) [of the Vienna Convention] and these clauses [of the Protocol] to take.'[180] It can be concluded that although the Protocol's provisions may indicate an intention that the WTO Agreements should retain precedence in situations of conflict between certain provisions, the fact that the Protocol's preamble and its provisions indicate a clear intention not to render the Protocol subordinate to any other agreements, coupled with the fact that the Protocol is the most recent of the legal instruments, means that the provisions of the Protocol should prevail over the WTO agreements in times of conflict.

However, in practice, this is not always the case. WTO law cannot simply be ignored by a member state lest it face severe sanctions for doing so. Although the

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[177] A H Qureshi, 'The Cartagena Protocol on Biosafety and the WTO: Co-existence or Incoherence?' (2000) Vol. 49, Nr. 4. The International and Comparative Law Quarterly 852 at 854.
[178] Safrin (note 174) at 613.
[179] Ibid at 618.
[180] Börjeson (note 2) at 32-33.

former outcome is legally justifiable, it is not practically workable. Thus, little guidance is given on which law to apply, leaving the choice ultimately up to the state in question, despite the fact that any choice made will necessarily violate the set of legal rules abandoned.

Where a state is a member to only one or none of these legal rules, the situation as to which law applies must be ascertained on a case by case basis. The only instance in which an obligation may be imposed on a state when it has not bound itself to upholding an obligation in a treaty is if the obligation constitutes customary international law and if the aggrieved state has a direct legal interest in the matter,[181] in the form of either national harm due to the breach, or where the harm involved constituted a breach of an obligation erga omnes.[182]

Thus, a state wishing to rely on the invocation of the PP when it or the state against which it wishes to use the justification is not party to any binding legal instrument incorporating the PP, is to prove that the PP constitutes customary international law. This will only be the case if it can be proved that the PP is a settled practice (usus); and that there is acceptance of the obligation to be bound by the rule by states in general (opinio juris).[183] States bear a general obligation to ensure activities within their jurisdiction and control do not harm the territories of other states.[184] However, this does not necessarily mean that the PP is binding international law. [185]

Usus is evidenced by formal implementation of the rule in practice, existing when states abide by the rule as they subjectively believe that they are compelled to.[186] The incorporation of the PP into the CBD and the Protocol provide evidence of such,[187] as well its prominence in the Rio Declaration.[188] However, frequency or even habitual character of the principle is not enough in itself.[189]

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[181] *South West Africa, Second Phase* 1966 ICJ Reports 6; J Dugard *International Law: A South African Perspective* (2005) at 460.
[182] *Barcelona Traction, Light and Power Company Limited*1970 ICJ Reports 3; An obligation erga omnes is an obligation all states bear based on the nature and importance of upholding the obligation in the international community. All states have a direct legal interest in matters of the breach of such obligations due to their nature. Dugard ibid at 44.
[183] Dugard ibid at 28 – 34.
[184] *Trial Smelter Arbitration* (1938-1941) 3 RIAA at 1965-6; *Legality of the Threat or Use of Nuclear Weapons* 1996 ICJ Reports226 at para 29; Rio Declaration supra (note 10) article 2.
[185] Dugard (note 180) at 29 – 34.
[186] Ibid at 33.
[187] Cosbey (note 66) at 14.
[188] Principle 15.
[189] *North Sea Continental Shelf Cases* 1969 ICJ Reports 3 at 44.

A state will face great difficulty proving opinio juris exists for the PP as many states, including the USA, criticise it and do not consider it as binding. Based on this weakness, the PP's existence as customary law is greatly criticised.[190] 'The precaution's status as a principle of general or customary international law [is] "less than clear."'[191]

However, as there is no international consensus on the PP's binding force, the opinio juris requirement is absent, thus it must be concluded that the PP cannot constitute customary international law.

[190] For example Sunstein supra (note 13).
[191] Cosbey (note 66) at 14; *EC-Hormones* (note 65) para 123.

3. The GMO Policy Wars

3.1 Comparative Synthesis of Biosafety Law

3.1.1 The EC

Being a member of both the WTO and the Protocol, the EC is placed in the very problematic position of trying to uphold a dual set of conflicting obligations. In following with the theoretical legal point of view as to which of these obligations takes precedence, along with its own policy considerations, the EC has chosen to afford the Protocol prominence in its legal regulation of GMO trade.

3.1.1.1 The Precautionary Principle in the EC

The PP bears great importance in the sphere of EC law. It was introduced as a founding principle of the European Community's environmental policy in the Treaty of Maastricht,[192] which later became Article 174(2) of the EC Treaty.[193] The ECJ extended the scope of the PP, holding that it is to be applied to 'ensure a high level of protection of health, consumer safety and the environment in all the Community's spheres of activity.'[194] The EC Treaty[195] also mandates that the Community should contribute 'to achieve a high consumer protection level'.[196] Thus the laws in place strive to completely eliminate all risks to the consumer.

3.1.1.2 The Position of the ECJ

The ECJ has defined the PP in EC law as being: 'where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become apparent'.[197]

On an invocation of this extended version of the PP, The ECJ upheld[198] a ban by the European Commission on the export of beef and bovine products based on a 'probable link between a disease affecting cattle in the UK and a fatal disease[199] for

[192] Article 130r(2).
[193] Alemanno (note 59) at 111.
[194] T-144/00, T-76/00, T-83/00, T-84/00,T-85/00,T-132/00 and T-141/00 *Artegodan a.o. v. Commission* [2002] ECR 4945, at 183;
[195] Article 3(p).
[196] Alemanno (note 59) at 111, note 116.
[197] Alemanno ibid at 117.
[198] Case 180/96 *UK v Commission* [1996] ECR 3903.
[199] bovine spongiform encephalopathy ('BSE'), or 'mad cow disease', *UK v Commission* ibid at para 7.

which no known cure yet exists',[200]despite there being no scientific certainty on whether the products actually caused the disease.[201]

The UK contested the Commission's decision, alleging that it was 'an unlawful impediment to free movement of goods within the Community', constituting 'a misuse of powers'. It further contended, inter alia, that the measure was discriminatory; that it infringed the principle of proportionality; and that the action was unlawful because it infringed the principle of legal certainty.[202]

The ECJ held that in order to assess the legality of the Commission's invocation of the PP, it would have to balance all the interests involved.[203] It held that even though in the UK, 'damage to commercial and social interests is likely to result from maintaining the export ban in force for the time being and that a part of such damage would not easily be reparable if the main action were to be upheld',[204] that 'cannot outweigh the serious harm to public health which is liable to be caused by suspension of the contested decision, and which could not be remedied if the main action were subsequently dismissed.'[205] As the ban had 'a legitimate aim - the protection of health - and, as a containment measure prior to eradication measures, it was essential to the achievement of that aim', the measures taken were proportional.[206] Thus the ECJ held that the ban was not a 'manifestly inappropriate measure' in view of the 'seriousness of the risk and the urgency of the situation'[207] given the 'paramount importance to be accorded to the protection of health.'[208]

According to the ECJ, so long as on a balance of considerations, the measures taken to prevent harm, even when there is only a risk of it occurring, are done to achieve a highly important aim, such as protection of health, the action taken is legal, provided the measures taken are proportional to the achievement of the aim in question. This enquiry is to be undertaken based on the potential severity of the risk posed and its nature.

However, the court did not set parameters to the content of proportionality in this instance. If the risk is uncertain, so is its severity – hence the determination of

[200] *UK v Commission* ibid at 61; Alemanno (note 59) at 116.
[201] *UK v Commission* ibid at 20.
[202] Ibid at 49.
[203] Ibid at 89.
[204] Ibid at 91.
[205] Ibid, at 92.
[206] Ibid at 73.
[207] Alemanno (note 59) at 117.
[208] *UK v Commission* (note 197) at 93.

what conduct is proportional under the circumstances is solely up to the decision-maker, which may easily lead to an abuse of powers.

3.1.1.3 EC Biosafety Laws

With the rise of biotechnology, the EC saw it as necessary to create new legislation to deal with the issue of GMO's and the potential risks they pose.[209] It instituted strict legislation to control all aspects of GMO trade from 1990, which is constantly being refined.[210] The legislation is complex and its provisions are often unclear and confusing to interpret and apply, a wide-spread criticism levelled against it.[211]

EC Regulation 1946/2003 makes the Cartagena Protocol legally binding in on a regional level in the EC.[212] The European Food Safety Authority (EFSA) was created to deal with matters pertaining administrative and executive issues surrounding risks involved in foodstuffs.[213]

The framework currently in place includes EC Directive 2001/18 and its predecessor EC Directive 90/220, which regulate deliberate release of GMOs into the environment for experimental purposes, as well as the placing of products that consist of or contain GMOs in the market, with the aim of protecting human health and the environment. A 'case-by-case evaluation of potential risks to human health and the environment'[214] is mandated by the directive as a prerequisite to GMOs or any product containing GMOs being placed on the market or released into the environment, based on which the item is either allowed to be released or not. The scope of the Directive is aimed at the release and marketing of GMO's within the territory of the EC. The onus lies on the applicant to 'demonstrate the "safety" or "lack of harm" of each individual product.[215] The product is deemed to be dangerous until the interested manufacturer carries out the necessary scientific work and demonstrates its safety.'[216]

On paper, this is a very comprehensive system. However, the level of risk presented by a GMO which the Directive deems to be low enough to sanction the

[209] Kinderlerer (note 14) at 225; Zarrilli (note 2) at 252.
[210] Zarrilli (note 2) at 5.
[211] Kinderlerer (note 14) at 252.
[212] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms; Kinderlerer ibid at 254.
[213] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002.
[214] Zarrilli (note 2) at 5.
[215] Idem.
[216] Idem.

release of the GMO into the market is set at the GMO posing 'no risk' to human health or the environment. Already, the first problem with the EC legislation is apparent. It is impossible to prove that GMO's pose no risk to human health and the environment because there is no scientific certainty in the matter. By imposing a level of 'no risk', the EC has not only created an impossible criterion to meet, for the applicant and for the item itself[217] but has circumvented its own flexibility provisions for analysis of GMO's on a case by case basis, instituting a de facto ban on all GMO's by virtue of the fact that by their very nature, GMO's cannot be proven to pose a level of 'no risk'. This in itself has seen extremely few GMO's or products containing GMO's actually being sanctioned for release in the EC, most of these only very recently being approved for release in the EC.[218] A conception of the PP which invokes a blanket ban on GMO imports would be overly broad and intrusive and has an unnecessarily harsh stifling effect on trade and technology.

However, among the positive aspects of the Directive is that it introduces 'a mandatory post-marketing monitoring system of GMOs and traceability at all stages of their being placed on the market.'[219] It is also very consumer-sensitive in nature, requiring the authorities who allow or disallow GMO's to directly inform and consult the general public during the authorization procedure, as well as mandating a labelling system for GMO foods and their products.

The EC went even so far as to pass regulatory legislation on novel foods and novel food ingredients which includes products derived from GMOs but which no longer containing any GM material[220] in Regulation 258/97, which has now been vastly modified by Regulation 1829/2003,16. The latter Regulation still provides for such novel foods, even when they no longer contain GM material and also 'provides for Community procedures for the authorization and supervision of GM food and feed, and includes specific provisions for their labelling'.[221] This measure is seen by many as overly-stringent as products which no longer contain GM material in all reality fall outside the scope of GMO regulation.

[217] Most items, not just GMOs, can never said to be entirely risk-free.
[218] Kinderlerer (note 14) at 224.
[219] Zarrilli (note 2) at 5.
[220] '...such as food products like paste or ketchup derived from a GMO tomato' ibid at 6.
[221] Ibid at 5.

3.1.2 The USA

3.1.2.1 GMO Trade in the USA

The USA is one of the greatest proponents of biotechnology, making up 63 per cent of global total transgenic crop area.[222] It is not a member of the Cartagena Protocol and does not formally accept the legal validity of the PP.

The USA sees its existing regulatory system for products produced by traditional genetic manipulation techniques[223] as adequate to cover GMO's too. This is premised on the idea that GMO's are not significantly different from organisms modified in the ordinary agricultural sense[224] and therefore do not merit special treatment.[225] This in turn means that the federal institutions of the USA already in existence 'that were responsible for regulatory oversight of certain product categories or for certain product uses are also responsible for evaluating products developed using genetic engineering'.[226] These include the Food and Drug Administration (FDA), which is responsible for food and feed safety; the Department of Agriculture (USDA); the Animal and Plant Health Inspection Service (APHIS), which is responsible for assessing the environmental safety of GM crops; and the Environmental Protection Agency (EPA) which is responsible for development and release for GM plants with pest control properties.[227] GMO trade is sanctioned by these authorities granting permits for experimental use; licences for commercialisation; registration of the product, which expires after five years; and for LMO-FFP's, a petition for established or exemption from tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FDDCA).[228]

However, the USA authorities did recognise that there were aspects of certain microbial products which did need extra regulation which the federal government would have to provide outside of the already-existing 1986 Coordinated Framework for Biotechnology, which was put in place as a 'comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products'.[229] New regulations were promulgated under existing laws to deal with GMO's, especially as

[222] Ibid at 3.
[223] Office of Science and Technology Policy, Coordinated Framework for Biotechnology, Federal Register Report 51 pp 23302 – 23350, 26th June 1986 in Zarilli (note 2) at 7.
[224] Zarrilli (note 2) at 7.
[225] Supra (note 222); Kinderlerer (note 14) at 252.
[226] Zarrilli (note 2) at 7.
[227] Ibid.
[228] Sheldon (note 30) at 7.
[229] Kinderlerer (note 14) at 252.

new products have been developed. These include The Plant Protection Act (PPA), the FFDCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA).[230]

3.1.2.2 Precautionary Action in the USA

Despite not formally accepting the PP as binding international law, USA has not abandoned pre-emptive precaution in their approach to GMO's. Consumers in the USA are increasingly resistant to GMO's[231] and there has been growing public demand for appropriate labelling of GMOs and their products.[232] The USDA has made a declaration to the effect that its biotechnology regulations for GMOs will be subject to improvements, making them stronger and more comprehensive.[233] The USA still cannot circumvent the process of assessment and management of risks which may or may not materialise.

> 'Currently, companies creating new transgenic plants must submit an application to the USDA and the new GM crops must undergo field tests to ensure that they do not pose a threat to agriculture or other plants. The updated rules are likely to be broader in scope, and will encompass threats to the environment and public health. The USDA will prepare an environmental impact statement to evaluate biotechnology regulations and several possible regulation changes. This will also include a multi-tiered, risk-based permitting system to replace the current permit/notification system, as well as a more flexible process for monitoring.'[234]

Should this pre-release risk analysis be implemented and the safety of a GMO's be severely questionable after assessment, it is doubtful that US Authorities will actually sanction its release. It is therefore arguable that effectively, the USA does in fact apply a weak version of the PP to GMO trade. However, the USA accepts a higher level of risk than the EC before taking pre-emptive action, interpreting the results of a risk assessment which does not prove the GMO to be harmful as meaning that it poses no relevant risk, as opposed to its safety being scientific uncertain.

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[230] Zarrilli (note 2) at 7.
[231] Ibid.
[232] 'In May 2004, a major US producer of GM products announced that it would not try to market the GM wheat it had developed in recognition that the business opportunities for the product were not very attractive.' ibid.
[233] Ibid.
[234] *US to Strengthen Biotech Regulation for GMOs*, *Crop Biotech Update*, 6 February 2004. Available at: http://www.isaaa.org/kc/cbtnews/bcentral/cbtupdate.htm#us [Accessed 15 August 2009]; Zarilli (note 2) at 7-8.

Overall, the approach of the USA is not to focus on preventing GMO trade due to the uncertain risks it presents, but rather to regulate it after import for these reasons. This measure is by far less restrictive on trade than the EC's approach and encourages trade liberalisation.

3.2 The Biotech Panel Dispute

The policy conflict between the USA and the EC over the application of the PP in GMO trade cumulated in a controversial international trade dispute,[235] cumulating in 'the lengthiest report in WTO history'.[236] The complainants, the USA, Canada and Argentina, disputed the EC's strong application of the PP with regard to GMO's in its regional laws, alleging that the EC had effectively placed a de facto moratorium on GMO's and products containing them, as a consequence of '(1) the operation and application by the EC of its regime for approval of biotech products, and (2) certain measures adopted and maintained by EC member states prohibiting or restricting the marketing of biotech products'.[237] This de facto moratorium against GMO's was alleged to be a consequence of the EC's indefinite suspension of decisions to approve GMO imports, under invocation of the PP, in effect banning GMO imports indefinitely. The de facto ban was enhanced by the fact that seven EC member states[238] declared that they would not authorize the placing of GMOs on the market until it was shown that these have no adverse effects on the environment and human health at all,[239] with six member states completely prohibiting the importation or marketing of certain biotech products.[240]

The complainants' main allegations were that the EC was in breach of its obligations under WTO law, specifically the SPS Agreement, through instituting this de facto moratorium on GMO trade,[241] as based on the application of the EC's laws regulating assessment of risk and authorisation of GMO's for import and marketing – at the heart of which, was the EC's strict application of the PP. The USA further specified that, with respect to the general and product-specific moratoria, they did

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[235] *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* WT/DS291/R, WT/DS292/R and WT/DS293/R 29 September 2006.;
[236] Spreij M 'The SPS Agreement and Biosafety' (2007) 65 FAO Legal Papers Online at 15. Available at http:// www.fao.org/legal/prs-ol/paper-e.htm [Accessed 4 September 2009].
[237] Ibid at para 37.
[238] Austria, Belgium, Finland, Germany, the Netherlands, Spain and Sweden
[239] *Biotech* case (note 233) at para 440.
[240] Ibid at para 36.
[241] A de facto moratorium is a factual ban or restriction on trade. This would also be a direct violation of the GATT Article XI(1).

not request the Panel 'to make findings on the WTO-consistency of the EC approval legislation *per se* but on the suspension of applications for/granting of approval of biotech products under the EC approval system'.[242] Sixteen states gave third party submissions to the Panel,[243] while amicus curiae submissions were also allowed.

In the first instance, the Panel had to decide on the law applicable to the dispute. Although 'WTO agreements should be interpreted and applied by reference to relevant rules of international law outside of the WTO context',[244] this does not necessitate the binding force of such international law to which all the parties to the dispute are not members. The Panel held that 'if a rule of international law is not applicable to one of the four WTO Members which are parties to the present dispute, the rule is not applicable in the relations between all WTO members'.[245] Resultantly, as the USA was not party to the Cartagena Protocol, the Protocol was found not to apply in this instance, leaving the dispute to be settled only in relation to WTO law.

The EC, obviously put at an automatic disadvantage by this position, argued that the PP was customary international law and therefore it was binding in the matter, allowing the EC to still rely on the founding principle of its GMO laws. However, the Panel held that as there is still much debate over whether the PP exists as customary international law, its status as such is at most, unclear. The Panel chose to 'refrain from expressing a view in this matter',[246] leaving the status of the PP in international law decidedly uncertain and leaving the EC in a very precarious position. If the binding force of the Protocol on the EC was taken into account, which, as discussed above, on an argument constructed from the provisions of the Vienna Convention, probably would have had precedence over the EC's WTO law obligations, it probably would've been successful in defeating the complainants' allegations against it. However, this is refuted by the fact that not all parties to the dispute are members of the Protocol.[247] Thus the Panel decided on the WTO laws being the only instruments applicable, leaving the EC to defend its actions made under its laws, which are set out in accordance with the Protocol's obligations, by WTO law standards, which are fundamentally in conflict with the Protocol's provisions ab initio.

[242] First Submission of the United States 2004 supra (note 3) at para 50; Börjeson supra (note 2) at 44.
[243] *Biotech* case (note 233) at para 2.
[244] Ibid at para 328.
[245] Ibid at para 334.
[246] Ibid at para 340.
[247] Supra (note 176).

In applying WTO law to the matter, the Panel held that in order for an SPS measure to exist, to which the SPS Agreement applies, three essential elements of the action must be present: its purpose must be to impose pre-marketing requirements for GMO's, including 'procedures to check and ensure that GMOs released into the environment do not pose a risk to human health or the environment as well as that novel foods do not present a danger';[248] taken in terms of law;[249] and its nature must be that it is capable of affecting international trade, [250] directly or indirectly.[251] The Panel held that the EC's actions under Directives 90/220 and 2001/18, as well as Regulation 258/97, 'are SPS measures', fulfilling all of these requirements. It held that these measures ' may, directly or indirectly, affect international trade[252] within the meaning of the SPS agreement and, as such, are subject to the provisions of the SPS agreement',[253] despite the EC's contention to the contrary.

The Panel held that on the facts,[254] 'the European Communities applied a general de facto moratorium on the approval of biotech products between June 1999 and August 2003'.[255] It held further that this moratorium was

> 'generally applicable, i.e., to all applications for approval which were pending between June 1999 and August 2003 under Directives 90/220 and/or 2001/18 or under Regulation 258/97 and that this moratorium was applied *de facto*, i.e., without having been adopted through a formal EC's rule- or decision-making process and more particularly, that the final approval of applications was prevented by the five member states Denmark, France, Greece, Italy and/or Luxembourg and/or the Commission through their actions and/or omissions.'[256]

The Panel concluded that the EC had 'breached its obligations under Annex C(1)(a), first clause, of the SPS agreement and consequently also under Article 8[257]

[248] Ibid at para 425
[249] Ibid at para 424.
[250] Ibid at para 426
[251] Ibid at para 355
[252] As GMO's cannot be imported without prior approval due to these measure and as the procedures per se 'may themselves have a direct or indirect effect on international trade because their completion takes time, or because they impose information and documentation requirements on applicants' Ibid at para 426.
[253] Ibid at para 427.
[254] 'during the relevant time period (October 1998 to August 2003) both member states and the Commission had the ability and opportunity to prevent or delay the approval of applications, and that during the relevant time period no applications were approved either. This despite the fact that a large number of applications were pending and that many of these had received one or more favourable scientific assessments' Ibid at para 612.
[255] Ibid at para 616.
[256] Ibid at para 613.
[257] Which ensures that the obligations of Annex C are applied in approval procedures.

of the SPS agreement', being an obligation not to arbitrarily impair trade by causing undue delay in their approval procedure and treating these products less favourably than domestic like products,[258] which was not justified due to mere scientific uncertainty.[259] Thus the breach 'must be presumed to have nullified or impaired benefits accruing to the [USA] under the agreement'. The Dispute Settlement Body requested the EC 'to bring the relevant product-specific measures into conformity with its obligations under the SPS agreement'.[260]

3.3 A Middle Road

The outcome of this decision cannot truly be said to be fair under the circumstances. Instead of deciding on the matter properly, the Panel glossed over the obligations held by the EC under the Protocol, discounting them completely, despite the fact that these were the founding principles of the EC's GMO laws. Such a decision left the Panel's ultimate conclusion obvious from the start, in light of the fact that the Protocol and the WTO Agreements are in conflict with regard to mandating the measures taken in relation to the risks posed by trade in GMO's. Although it is true that the EC still held obligations under its WTO agreements, simplistically applying only WTO law in the case did not give effect to the binding nature that the Protocol holds in international law, a position which is erroneous. Even if the Protocol could not be used as all parties to the dispute were not members to it, it still should have been taken into account as binding authority on the EC when reviewing the EC's actions which decidedly would've influenced the position of the EC in the dispute. It is unfortunate that the Panel missed this valuable opportunity to attempt to harmonize the conflict of laws in this situation.

The Panel's decision cannot be so heavily criticised, however, as the conflicting laws regulating trade in GMO's most likely cannot be reconciled. It had to pick a route to come to the fairest decision, which in the circumstances, it did. However the methods taken to reach this decision cannot be said to be sound in principle as the Protocol cannot simply be ignored. To mitigate the effect of this

[258] Annex C(1)(a) of the SPS Agreement (note 26).
[259] As set out above, the SPS Agreement only takes into account lack of scientific certainty as justification for implementing pre-emptive trade-restrictive sanitary or phytosanitary measures, unlike the PP which allows pre-emptive action even on the grounds of mere scientific uncertainty.
[260] *Biotech* case (note 233) at para 1073.

finding, the Panel was correct in only reviewing the actions taken by the EC under its legislation and not attacking the legislation itself. [261]

However, although the PP may have given the EC an avenue of justification of these actions if it were permitted to rely on it, the de facto moratorium would still have breached WTO law. The Panel was correct in finding that an absolute ban on GMO trade constituted an unacceptable restriction on international trade.

The solution to this blunder of legal rules is far from clear. International trade should not be arbitrarily restricted, while health and safety measures should not be undermined.

> 'social, cultural and ethical attitudes to the technology have driven the dispute from the outset. Any process that seeks to marginalize such concerns... or... rule in favour of one side over the other runs the risk of deepening distrust in a way that, as the EU institutions have already witnessed, threatens the very goal of advancing world trade, as the WTO itself becomes the point of resistance.'[262]

Börjeson[263] opines that 'if we have one rule saying that trade liberalization is to prevail and another saying that taking a precautionary approach is more important than de-regulating trade, subsequently a third rule which is independent of the other two is needed to decide which one is to govern the issue' in each circumstance.[264] Perhaps a third international law instrument is needed which reconciles these conflicting provisions and gives a clear light to guide the issue of regulating trade in GMO's, especially on an international level.

However, as idealistic as this solution is, it is not practical. With the immense policy differences between states regarding GMO's and an even more deep-set conflict over the PP, international consensus on a set of rules incorporating every state's most important considerations is extremely unlikely.

A legal regulatory solution for trade in GMO consumer products is undoubtedly needed,[265] perhaps a legislative reform which at least incorporates trade-impact considerations into the Protocol, or includes scientific uncertainty as justification for the invocation of SPS measures under the SPS Agreement, would be the answer.

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[261] First Submission of the United States 2004 supra (note 3) at 50; Börjeson supra (note 2) at 44.
[262] B Lee 'GM resistant: Europe and the WTO Panel Dispute on biotech products' The Centre for Business Relationships, Accountability, Sustainability and Society at 12. Available at http://www.brass.cf.ac.uk/uploads/GMdispute.Pdf [Accessed 4 September 2009].
[263] Börjeson (note 2) at 65.
[264] Idem.
[265] Sunstein (note 13) at 5.

However, until and if this happens, the best a state can do is to analyse all the areas of conflict surrounding GMO regulation, in light of its individual international law obligations, in order to formulate its domestic GMO legislation in such a way that solves the problems the international law community cannot. What is needed is a flexible, middle-road approach, which manages and controls risks before they realise while still not stifling GMO trade.

4. Gaps in the Patchwork

4.1 The Precautionary Principle in Practice – a Conflict of Interests

The application of the PP has been widely criticised due to its severe socio-economic effects in relation to trade in GMO's. The problem mainly stems from the fact that no mandate exists to take into account minimizing negative trade effects or the position of developing countries when taking these measures under the Protocol, leading to much international unrest.

4.1.1 Domestic Dissention

Even on a national level, within the EC, the failure of authorities to take into account the negative economic impacts of their actions when invoking the PP in relation to GMO trade has caused dissention. An example of this recently occurred in Germany,[266] when an Augsburg district court in Bavaria ordered a local honey supplier to stop selling, or even giving away, his honey, leaving the honey to be put through a waste incineration facility,[267] after tests on samples of the honey reflected that up to 7 per cent of the pollen collected by his bees was adventitiously from GM plants in the Bavarian State Research Centre for Agriculture.[268] A €10,000 loss of profit resulted due to this forced destruction of honey on account of the PP's strict application by the judicial authority in this instance.[269] The matter is pending appeal in the highest court in Germany for consideration.[270]

The court's decision appears to be arbitrary and disproportionate. Had the court been mandated to take into account the socio-economic consequences of its actions, it is likely that at least a less restrictive measure would've been taken, saving the supplier much unnecessary expense.

4.1.2 Economic Manipulation

For developing countries, the PP is not just a bone of contention between states based on principles but rather, it presents the basis for potential humanitarian and economic crises.

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[266] U Buse 'Montesanto's uphill battle in Germany' (14 March 2009). Available at Spiegel Online via Checkbiotech http://www.spiegelonline.com [Accessed 2 May 2009].
[267] Ibid.
[268] MON801, a common GMO cultivated inter alia in SA.
[269] Buse (note 266).
[270] Ibid.

For most developing countries, agricultural export to developed countries, in specific, the EC, is a vital source of revenue. A developing country, with a weak economy and filled with some of the poorest people in the world, is not in a position to bargain over the correct approach to GMO regulation with its wealthy and powerful trading partners.

> '[Developing] countries find themselves in a particularly difficult situation: in order to preserve their export opportunities, especially towards markets that are sceptical about bioengineered products, they may need to be "GM- free". This means not only that they should not be exporters of GMOs, but also that they should not be producers of GMOs for domestic consumption and not even importers of GMOs.'[271]

This absolute avoidance of GMO's[272] is, inter alia, an indirect result of the application of the EC's GMO laws. Resultantly, the EC's GMO laws have a practical extraterritorial effect in developing countries. This is deeply problematic, specifically because of the immense value of using GMO's for food aid and in sustainable farming, which allows poor farmers to produce more yield from GM crops at a lower cost than traditional crops, even in desolate and impoverished conditions.[273]

4.1.3 The PP as a Humanitarian Crisis

In 2002, due to severe food shortages in Zambia,[274] the USA donated thousands of tons of maize to it.[275] Zambian scientists and economists subsequently visited American maize farms and silos, conducting research as to the type of maize crop grown there, concluding that the American corn sent to Zambia most probably contained GMOs. The Zambian government subsequently refused[276] the maize donation, stating that due to the 'inconclusiveness of studies on the health risks of genetically modified foods',[277] the PP dictated that the maize should be rejected. The USA offered to mill the maize so that contamination could not take place but Zambia did not accept.

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[271] Zarrilli (note 2) at 8.
[272] Ibid.
[273] Tshisela (note 10).
[274] In 2002.
[275] J Bohannon 'Zambia Rejects GM Corn on Scientists' Advice' (2002) Sciene at 1153. Available at www.bioutexas.edu/courses/stuart/zambiareject.pdf [Accessed 24 April 2009]; Sunstein, (note 13) at 31.
[276] Bohannon ibid at 298.
[277] Sunstein (note 13) at 31.

It cannot be denied that there are potential risks involved in GMOs or that States have human rights obligations embodied in many international covenants,[278] which bind them to protect their citizens from potential harm caused by GMO's by putting in place laws and taking steps which ensure their protection.[279] The Zambian government may have taken its own such obligations into account in applying the PP. But was its fear for its citizens' health justified or irrational, especially in the face of the long term, safe use of such crops in other nations?[280] More pointedly, was its fear of potentially violating human rights obligations through sanctioning the use of GMO's justified to the extent that it could refuse the food aid and in so doing, violate the human rights of its people in an immediate and more severe way by depriving them of feasibly the only readily available food source and ensuring for many of them certain death?

This seems blatantly unlikely. It is obvious that the certain threat of death due to starvation is infinitely worse than the unproven, unidentified and potentially non-existent risks of GM maize,[281] especially in a humanitarian crisis such as that which Zambia was facing in the wake of mass starvation. In fact, states have an obligation to use science and technology to alleviate hunger.[282] Deliberations over contingent and potentially phantom dangers hiding in the only actual source of salvation in such an instance seems absurd.

Furthermore, certain Zambian government officials expressed concern that the donated GM maize crops would be planted on Zambian soil and that therefore their seeds might contaminate Zambia's export maize intended for sale in the EC, as a reason for rejecting the food aid. The extremely strict approach[283] of the PP which is applied in the EC necessitated that Zambia remain GM-free or face a de facto ban on export to the EC.[284] The fourth-world state of Zambia[285] would face almost certain economic collapse in its agricultural sector due to the severance of its

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[278] For example, in the International Covenant on Social, Economic and Cultural Rights (1966) (note 4).
[279] Ibid.
[280] First Submission by the United States in the *Biotech* case (note 3) at 1.
[281] J Mackenzie 'French Agency says Montesanto GM Maize Safe: Report' The Financial Times Ltd 2009(14 March 2009).
[282] Article 11(1)(a) of the ICESCR (note 4).
[283] Kinderlerer (note 14) at 248 – 257.
[284] J Chaffin 'European Ban on Modified Maize Upheld' The Peninsula (9 March2009).
[285] As recognised by the United Nations Development Programme, defined in C W Kegley Jnr, *World Politics;Trade and Tranformation* (2007) at 590.

financial lifeblood in being denied trade with the EC, its main trading partner,[286] a situation it could not allow to take place.

It was estimated by the WHO that 2.9 million people were vulnerable to starve to death due to this refusal by the Zambian government to accept American food aid and even a 'conservative scenario' would see 35000 people in the country dying from starvation if no alternative food aid was found.[287] Sunstein rightly questions whether this refusal to accept the corn was truly precautionary in nature.[288] The question is resonant.

A similar situation occurred in Zimbabwe in 2002, when the Zimbabwean Government agreed to allow GMO food aid into the country, 'provided it was milled immediately upon arrival to avoid any possible contamination of local varieties',[289] after initially rejecting the food aid due to its GMO nature and the threat such GMOs posed to Zimbabwe's beef exports to the EC and to local maize varieties.[290] Similarly, Uganda has allowed GMO imports under the provision that they be used only for 'consumption and not for cultivation'.[291] Other African states have followed suit. 'Sudan has requested that GM food aid be certified "GM free" [although the Sudanese Government has put in place an interim waiver on the GM food restrictions until January 2005] and Angola will accept GM food aid only on condition that the whole GM grain is first milled.'[292] The fact that the Sudanese government has temporarily waived the restriction on GMO food aid, despite the massive negative trade implications of this action, underlines how truly desperate the need for food aid is in the country.

Preventing possible damage to EC consumers from GMO foods which more than likely will pose no risk of harm at all, on the basis that it cannot be proved that a

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[286] *Zambia: History, Geography, Government and Culture* available at www.infoplease.com; *Zambia: Altapedia.Online* available at www.altapedia.com [Accessed 14 April 2009].
[287] Sunstein (note 13) at 31 – 32.
[288] Ibid at 32.
[289] *Bridges Trade Biores* (11 July 2002) available at http://www.ictsd.org/biores/02-07-11/inbrief.htm. [Accessed 14 April 2009].
[290] Ibid.
[291] 'Uganda gives cautious approval to GM food' Science and Development Network (2 March 2004). Available at http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1257&language=1 [Accessed 14 April 2009].
[292] 'Food rations to be halved in Angola amid funding crisis and GM ban' World Food Programme, In Brief (2 April 2004). Available at www.wfp.org/newsroom/in_brief/Africa/angola/angola-040402.html [Accessed 14 April 2009]

level of 'no risk' exists in these products, is causing actual and far more severe harm to the people of countries like Sudan who are literally starving to death.

'The international policy conflict over GMOs is fragmenting international markets, thereby decreasing economies of scale'.[293] This has forced developing countries to follow laws put in place by their trading partners based on the principles of their trading partners and not on their own principles and needs. There is an increasing level of urgency to address the harsh extra-territorial effect of the EC's GMO laws on African countries, based on the severe economic effects this has caused.

> 'Some trade diverting effects [in developing countries] are allegedly already taking place because of company practices to replace some inputs with others (which do not bear the risk of being genetically modified) or to use inputs coming from alternative countries, which are supposed to be "GM-free", to avoid cumbersome documentation and traceability requirements, as well as to meet consumers' expectations.'[294]

In 2004, representative groups from 15 African countries 'representing farmer, consumer and environmental organizations' protested to the World Food Programme (WFP)[295] over the WFP and USAID's pressure on Sudan and Angola to change their decision to restrict GM food aid. Their contention was that non-GM food aid was readily available and should be sent instead of GM food aid. The submission was heavily influenced by the economic pressure put on these private parties to remain 'GM-free'. However, it is by far more costly and difficult for the WFP to supply conventional food aid or milled food aid than GMO food aid. The WFP contended that the Government of Angola's mandatory milling requirements for GMO food aid implicated 'substantial extra costs' and would 'cause shipment delays of up to two months.' It would 'further aggravate an already serious funding situation where the WFP has received only 24 per cent of the funds it asked for under its current operation in the country. As a consequence, WFP is to halve the food rations given to the majority of the 1.9 million people it assists in Angola.'[296]

[293] Zarrilli (note 2) at 5.
[294] Ibid at 9.
[295] 'African countries 'forced' to accept GM food aid' Mail&Guardianonline, (5 May 2004) Available at http://www.mailandguardian.com [Accessed 18 May 2009]; Zarrilli (note 2) at 9.
[296] Zarrilli ibid.

Is it truly that the PP, or merely its application,[297] would disregard human rights in the interest of preventing unknown and very possibly imaginary risks to such an extent that its price is tolled in human lives? No doubt the EC's application of the PP in its own laws has factually infringed the principle of sovereignty of state, imposing de facto trade sanctions against GMO's on countries who do not abide by its dictates. The strong arm of the EC's application of the PP[298] has forced all states which depend on the its trade to follow the same practices with regard to GM foodstuffs as it does, regardless of whether this approach is in line with the principles of the country in question and moreover, regardless of whether the application of the PP in such a way is correct, or if the principle is correct at all.

4.1.4 Regional Reaction

The EC's GMO laws' ripple effect on African countries has even triggered a large-scale regional reaction. The Southern African Development Community (SADC) addressed the problem in 2003 in the form of approving the recommendations on Biotechnology and Biosafety created by the SADC Advisory Committee. The measure, although intended to be for the interim, was greatly innovative in addressing these sensitive areas of economic and humanitarian conflict.

> 'The recommendations are divided into four main sections: Handling Food Aid; Policy and Regulations; Capacity Building; and Public Awareness and Participation. Under "Handling Food Aid", donors providing GM food aid should comply with the Prior Informed Consent principle and with the notification requirements in accordance with Article 8 of the Biosafety Protocol. Food aid consignments containing GM grain should be milled or sterilized prior to distribution to beneficiary populations. The sourcing of food aid should be within the region, and the region should develop and adopt a harmonized transit in a safe and expeditious manner. GM food aid in transit should be clearly identified and labelled in accordance with national legislation. In the absence of such a system, it is recommended that countries make use of the requirements under the African Union model law on biosafety.'[299]

As part of this incentive and in accordance with the goal of achieving international harmonisation of laws to reduce conflict situations, SADC countries are encouraged 'to develop national biotechnology policies and strategies to exploit the

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[297] Sunstein (note 13) at 4.
[298] Kinderlerer (note 14) at 5.
[299] SADC Advisory Committee Recommendations on Biotechnology and Biosafety Avialable at http://www.sadc.int/fanr.php?lang=english&path=fanr/agrres&page=sadc_biotechnology_gmo [Accessed 27 July 2009]; Zarrilli (note 2) at 9.

benefits of biotechnology, to establish national biosafety regulatory systems and to sign and ratify the Biosafety Protocol and the Convention on Biological Diversity'.[300]

Based on these recommendations, SADC passed guidelines in respect of the management of GM food aid by developing SADC countries, which give full effect to the Advisory Committee's Recommendations.[301] The recommendations advise that the preoccupation of health and environmental risks, as well as the threat to trade relations posed by GMO's 'must be balanced with Governments' responsibility to improve the quantity and quality of agricultural and food production made available for domestic uses: agro-biotechnology may prove an effective tool to address food shortage and malnutrition.'[302]

The guidelines are, no doubt, a step in the right direction. This is especially so when considering the immediate problems these African countries face from the effect EC's GMO laws as they are, providing a loophole way to stay 'GM Free' for all trade purposes, while allowing food aid to reach the starving populace and save millions of lives in the process. However, the guidelines are only satisfactory as interim relief. Although harmony of national laws regarding GMO's on an international scale will reduce conflict in the area of GMO trade, uniformity of the strict application of the PP toward GMO's as sanctioned by the EC will not solve the root of the problem and in the long run, will only exacerbate the economic and humanitarian suffering of the general public in developing countries. The guidelines tolerate and make adaptations to fit the EC's strict application of the PP in GMO law and in so doing, as illustrated by the example of the WFP in Angola, will make food aid measures slower, more expensive and less in quantity due to these cost restrictions, meaning a great number of people in need will not receive food aid at all under these new legislative mandates.

4.2 An Enlightened PP

The PP cannot be abandoned due to the vital role it serves. Despite the negative effects of the PP in practice, a total lack of it would leave states helpless to prevent grave and irreparable harm caused by the realisation of formerly uncertain risks.

[300] Zarrilli (note 2) at 9.
[301] 'SADC sets guidelines for GM food' Zambezi Times Online (14 May 2004) Available at http://zambezitimes.com ; Zarrilli (note 2) at 9.
[302] Zarrilli ibid at 8-10.

Some manner of pre-emptive precaution is undoubtedly needed where the danger of scientifically uncertain risks occurs, as is the case with GMO's.

However, the legal sanction of taking precautionary measures to prevent the harm caused by scientifically uncertain risks needs stricter regulation, so as not to cause the harsh socio-economic suffering the strict application of the PP has caused in the past. Rather, an evolved manner of regulating uncertain risks in GMO trade is needed. The onus lies on the stronger trading partners of weaker developing countries to develop the application of the PP with regard to GMO trade for the sake of developing nations and improve this current position.

If the decision-maker is also mandated to take into account the impact these measures will have on international trade and socio-economic conditions, specifically in developing countries, coupled with a duty to seek certainty over the risks and review the measures within a reasonable time, the negative effects of taking pre-emptive precautionary measures will be greatly mitigated, while overall, the risk evaluation process will become more broad-based and objective. Lowering the level of risk acceptable from only allowing GMOs posing 'no risk' to be traded, to a level of 'highly unlikely for risk to materialise' or 'reasonably low risk' instead will also help this cause. This forms an 'enlightened' pre-emptive approach to risks - one which merges the obligations of the SPS Agreement with the Protections of the Protocol, putting legal parameters in place so that this discretion is not left to be arbitrary and overly broad, amounting to an application of the PP in such a strict manner that any risk at all is grounds for a blanket ban on GMO trade

Ideally, this should constitute a legally binding obligation on the decision-maker, giving a source of recourse to states injured due to breach of this obligation. However, to the extent that all that all that is required is for the decision-maker to apply his mind to these factors, a failure of which would at least need to be justified even if only on an administrative level, such a position would still lessen the hash extra-territorial effect of these laws, encouraging developing countries to more openly accept GMO food aid which is at least certified to be low in risk and meet their international human rights law obligations without fear of violating their economic relationships at the same time.

5. Closing the Gaps

5.1 The South African Solution

Subscribing to both the WTO and the Protocol, SA finds itself torn between upholding conflicting international law obligations regarding GMO trade. SA has chosen to construct its national laws somewhere in between the two. This enlightened approach towards merging these obligations is to be congratulated. However, it is incomplete and certainly not without problems, succeeding more in avoiding issues of conflict between these dual obligations rather than actually harmonizing them. SA's problems in this regard are more complex than most countries, as it not only has to comply with its international law obligations to avoid liability but it also cannot contravene its own constitutional obligations in the process, lest it undermine its very own foundations.[303]

Three main sources need to be considered in order to fully analyse the sufficiency of SA's legal regulatory system for GMO trade in terms of its many obligations, being GMO legislation, the Constitution and Consumer Protection legislation.

5.2 GMO Legislation in SA

When GMO's were first permitted for use in SA in 1992, no legal framework existed to regulate their use, movement and release. Instead, a committee[304] was established 'to advise government, industry and the public on the safety of GMO's'.[305] It was 'responsible for the evaluation of risk assessments, i.e. food, feed and environmental impact assessments, of all applications requesting authorisation to conduct activities with GMO's'.[306] These were to be carried out via permits issued under an amendment to the Agricultural Pest Act No. 36 of 1983. This position was in line with WTO law's principle of non-discrimination,[307] treating GMO's as substantially equivalent to other modified organisms, placing them under the ambit of existing legislation.

[303] Section 1 of the Constitution of SA 1996.
[304] SAGENE
[305] Supra (note 12) at 1.
[306] Ibid.
[307] Article ii and III of the GATT (note 47); Article 2(1) of the TBT Agreement.

This position has now changed. The Genetically Modified Organisms Act No. 15 of 1997 came into force in December 1999, with Regulations,[308] specifically applying to the genetic modification of organisms[309] and their development, production, release and use, including gene therapy[310] but excluding, inter alia, human gene therapy.[311] The Act shows that SA has recognised a difference inherent in GMO products and thus saw the need to implement specific legislation for their regulation. In 2007, the Genetically Modified Organisms Amendment Act 23 of 2006 came into force, incorporating the Protocol[312] and thus the PP[313] as binding law in SA.[314] Although its incorporation leaned SA's legislative structure in favour of the Protocol, the actual provisions of the Amendment Act do not exclude SA's WTO law obligations, aiming to merge the two sets of obligations in SA national legislation.

The Regulations mandate that besides complying with its own provisions, an applicant applying for a permit to trade GMO's must also comply with the provisions of all other laws regulating the importation and exportation of GMO's.[315] This necessarily includes the application of both the Protocol and the WTO agreements.

The Amendment Act incorporates a duty on the Council to take into account scientifically based risk assessments[316] and proposed risk management measures,[317] in considering applications to permit GMO's and related activities into SA, giving effect to the obligation common to both the SPS Agreement and the Protocol regarding risk assessment.[318] Furthermore, while the GMO Act makes provision for the applicant to submit a risk assessment of the GMO to the Council, based on its environmental impacts,[319] the Amendment Act stretches this duty further, incorporating SA's SPS Agreement obligations[320] into its provisions as well, by requiring the applicant to also base this on its socio-economic effects.[321]

[308] Regulation (576) No. 1420, 26 November 1999.
[309] Including viruses and bacteriophages.
[310] Section 2(1) of the Genetically Modified Organisms Act No 15 0f 1997.
[311] Ibid.
[312] Annexed to the Act.
[313] In article 10(6) of the Protocol (note 1).
[314] Section 231(4) of the Constitution (note 34).
[315] Regulation 2(3) (note 303).
[316] Section 59(c)(i) of the GMO Amendment Act.
[317] Section 5(c)(ii) ibid.
[318] Article 15(1) of the Protocol (note 1); Article 5(1) of the SPS Agreement (note 26).
[319] Section 5(a) of the GMO Act. (note 305)
[320] Article 5(3) of the SPS Agreement (note 26).
[321] Section 5(a) of the Genetically Modified Organisms Amendment Act 23 of 2006.

The amendment was implemented on the basis that SA 'cannot afford to lag behind developed nations on genetically modified foods' as it 'cannot afford not to have its own home-grown biotechnology... that can produce traits and products that are suited to our environment and our diseases',[322] leading SA's government to reject activist calls for stricter controls on biotechnology and rather, to make the admittance process for GMO's more flexible. SA's GMO legislation therefore encourages GMO trade, yet it still maintains the protective measures of the PP. The only real question remaining is whether these two can ever actually be married in this way.

5.2.1 The Application Process

The current position is that GMO trade must be carried out via permits issued under the Act,[323] granted by the Directorate Genetic Resources Management. A 'Registrar, two regulatory bodies, i.e. the Advisory Committee[324] and Executive Council, and inspectors',[325] also carry out administrative functions with regard to GMO permits and the actual use of GMO's under the Act. The process by which GMO's are approved for trade and use involves an application to the Registrar, who is responsible for issuing the permits.[326] He then refers the application to the Executive Council,[327] which is the highest decision-making body in the process, consisting of ministers from 6 governmental departments.[328] It is the body which ultimately decides what measures to take and whether to permit the GMO or not.[329] The Act makes provision for a party who is aggrieved by a decision of the Council to appeal the matter to the Minister of Agriculture and Land Affairs, who will have the final say in the matter. The Council bases its decision on the advice[330] of the Advisory Committee.[331]

> 'Members of the Advisory Committee are appointed by the Minister for Agriculture and consist of ten scientists who are experts in fields related to GMO's. This Committee evaluates risk assessments, which are submitted

[322] Ben Durham, director in the Department of Science and Technology 2006, in his parliamentary address to the Department of Agriculture regarding acceptance of the GMO Amendment Act. 'South African Government Seeks Law to Extend Support of GMOs' Reuters (20 Jan 2006. Available at http://www.genet-info.org./ [Accessed 4 August 2009].
[323] Regulation 2(1) (note 303).
[324] Section 10 of the GMO Act (note 310).
[325] Supra (note 12) at 1.
[326] Section 9(a) of the GMO Act (note 310).
[327] Established under section 3 of the GMO Act ibid.
[328] Section 3(2) ibid.
[329] Section 5(g) ibid.
[330] Section 5(g) ibid.
[331] Established under section 10(1) of the GMO Act ibid.

> with every application, to determine the potential impact of the proposed activity on the environment, human and animal health'[332]

The committee makes a recommendation to the Executive Council, detailing on whether the GMO or activity involving it should be allowed or not,[333] including which risk management procedures should be applied,[334] from which it is easier for the Council to distinguish whether the risk is scientifically certain; if there is insufficient scientific evidence over it; or whether it is scientifically uncertain – a crucial distinction upon which to base its decision, when taking into account SA's conflicting international law obligations.

The public is notified through major newspapers of any proposed admittance of GMO's and in this way, the public is consulted for comment in this process, which the Council considers on evaluation of the application. 'This promotes credibility and transparency in the regulatory process.'[335]

5.2.2 An Inherent Conflict

Despite SA's laudable efforts to achieve this harmonization, it falls short of its aim in many respects, the most significant of all being the fundamental incongruence of the PP with WTO law obligations.

Based on this legislation, in principle, SA's government can legally rely on the PP to block GMO's from trade in SA, by denying permits to GMO exporters under the GMO Act, purely because scientific uncertainty exists with regard to the risks posed by GMO's on human health and biodiversity.

However, the GMO Act states that one of its founding principles is to ensure that activities involving GMO's are carried out in a way which limits potential harmful consequences caused by GMO's to the environment, human and animal health, a position which has not been changed by the amendment.[336] The wording of this principle is in accordance with the definition of an SPS measure should such an action affect trade,[337] leaving a door open to the decision-maker to invoke SPS measures if it sees fit in relation to allowing GMO imports or not. Furthermore, the legislation has to be interpreted to take into account SA's international law

[332] Report of the Department of Agriculture (note 12) at 1.
[333] Section 11(1)(b) of the GMO Act.
[334] Section 10(1)(a) of the GMO Act.
[335] Supra (note 12) at 1-2.
[336] Ibid at 1; Preamble of the GMO Act (note 310).
[337] Annex A article 1 of the SPS Agreement (note 26).

obligations in so far as is reasonable,[338] meaning that the invocation of SPS measures under the act necessarily need to comply with the SPS Agreement. The provisions of the SPS Agreement, as set out above, do not permit prohibition of GMO's on grounds of scientific uncertainty, accepting only insufficient scientific evidence as justification for prevention of import of GMO's.[339]

In effect, SA's national law permits an application of both SPS measures and the PP when making a decision to allow GMO imports on paper. In practicality, however, as SPS measures are permitted under the Protocol's version of the PP, which caters for instances of lack of scientific knowledge as well as scientific uncertainty[340] but the PP is not permitted in terms of the SPS Agreement, which only allows for insufficient scientific information,[341] only SPS measures may be invoked by the authority, leaving the PP without any practical force or effect. Thus mere lip service is paid to the PP under the current position, meaning scientific uncertainty is not a justification for preventing GMO imports despite sanction for this in the Amendment Act. Should SA rely on its national laws in invoking the PP in this way, it will not be a defence for failing to uphold its obligations under the SPS Agreement.[342]

5.2.3 Considerations for the Decision

Instead of addressing the conflict inherent in the considerations to be taken into account when making a decision to prevent GMO import or not, SA legislation is specifically silent on the exact principles to take into account when making the decision. It incorporates the Protocol as an annex to the Amendment Act, implying that the principles mandated by it upon which a decision regarding the import of GMO's is to be based automatically apply in SA. However, the main flaw with this is that it ignores the considerations mandated by the SPS Agreement, most specifically that the decision should be taken in the interest of minimizing negative trade aspects;[343] that the measures taken are not more trade-restrictive than is necessary;[344]that cost-effective, less restrictive alternative measures to limit the risk

[338] Section 233 of the Constitution (note 34).
[339] Article 5(7) of the SPS Agreement (note 26).
[340] Article 10(6) of the Protocol (note 1).
[341] Article 5(7) of the SPS Agreement (note 26).
[342] Article 46(1) of the Vienna Convention (note 28).
[343] Article 5(4) of the SPS Agreemnet (note 26).
[344] Article 5(6) ibid.

need to be considered;[345] and that the interests of developing countries need to be taken into account.[346] Despite mandating an enquiry into environmental effects[347] and socio-economic effects in general[348] by the Council in making its decision, putting SA in a less threatening position to developing countries than the EC, the legislature did not go so far as to incorporate a duty on the council to take into account socio-economic impacts which the GMO may have on the community living within the vicinity of its introduction when making its decision, merely granting the Council the discretion to do so.[349]

As the Protocol and the SPS Agreement are in conflict on this matter, in the interests of legal certainty, this needs to be amended.

5.3 Biosafety Law and the Constitution

As the supreme law of the country,[350] no law or action can be carried out legally in SA unless it is done in line with the Constitution.[351] Furthermore, the state bears an obligation to protect, promote and fulfil the entrenched rights[352] contained in the Bill of Rights.[353]

5.3.1 The Right to a Safe and Healthy Environment

The potential threats GMO's pose to biodiversity and human health threatens the constitutional right of all people to a safe and healthy environment.[354] Despite SA not being mandated to take action to prevent this harm if its realisation is only scientifically uncertain under international law, it has a constitutional mandate to do so. It cannot ignore this obligation without facing liability claims within its own territory.

The inaction of the state to prevent potential harm constitutes a limitation of this right as it is failing to protect the right, especially should harm actually realise. A constitutional right may only be limited if it satisfies the requirements of the

[345] Article 5(3) ibid.
[346] Articel 10(1) ibid.
[347] Section 5(a) of the GMO Act. (note 310)
[348] Section 5(a) of the GMO Amendment Act (note 321).
[349] Regulation 9 (note 308).
[350] Section 2 of the Constitution (note 34).
[351] Ibid.
[352] Section 7(2) ibid.
[353] Ch 2 ibid.
[354] Section 24 ibid.

limitations clause,[355] in that it is only limited in terms of a law of general application, to the extent that the limitation is reasonable and justifiable in an open and democratic society, based on human dignity, equality and freedom, taking into account all relevant factors, including: (a) the nature of the right; (b) the importance of the purpose of limitation; (c) the nature and extent of the limitation ; (d) the relation between the limitation and its purpose; and (e) a less restrictive means to achieve the purpose.[356]

The action would be legitimately taken in terms of the GMO Act. However the nature of the right to a safe and healthy environment is that it is extremely vital to all life, making limitation of this right almost completely impermissible in an open and democratic society based on human dignity, equality and freedom. Despite this, the importance of complying with international law obligations,[357] including SA's obligation to use biotechnology to alleviate hunger and poverty,[358] as well as the importance of fostering scientific and commercial incentive for GMO trade and development, mean that to a degree, the right in question needs to be limited lest these other important goals be neglected. Allowing trade of GMO's most certainly will serve this purpose, while the right in question is only potentially threatened by allowing GMO trade as GMO's are not certain to cause harm. However, there most definitely is a less restrictive means to achieve the purpose in question than just allowing an unqualified sanction of GMO trade.

Such a less restrictive measure would include putting proper risk management and safeguard measures in place after the GMO's are introduced into SA, which would mitigate if not avoid any potential adverse effects they may have in future. Traceability of GMOs would also aid to achieve this purpose. 'Traceability is meant to facilitate a withdrawal of food and feed from the market if any unexpected adverse effects were to arise.'[359] Should harm nevertheless ensue, the government may avoid liability if it puts proper liability and redress measures in place to ensure that injured parties are compensated for their loss due to this government action. Failing these steps, the government will fail to uphold this right should GMO-caused harm ensue, leaving its constitutional standards completely disregarded.

[355] Section 36ibid.
[356] Section 36(1) ibid.
[357] In terms of the SPS Agreement (note 26).
[358] Article 11(2)(a) of the International Covenant on Economic, Social and Cultural Rights (note 4).
[359] This entails the tracking of the movement of GM products through the production and distribution line, Zarrilli (note 2) at 6.

5.3.2 Fair Administrative Action

The decision taken by the Council for or against permitting GMO trade in terms of the GMO Act constitutes administrative action[360] for the purposes of section 33 of the Constitution – 'the right to administrative action that is lawful, reasonable and procedurally fair' and the right to written reasons.[361] This in turn brings the Promotion of Administrative Justice Act (PAJA)[362] into application, which was enacted to give effect to section 33.

Administrative action which materially and adversely affects the rights or legitimate expectations of any person must be procedurally fair,[363] while what fair administrative procedure is depends on the circumstances of each case.[364] The Council's decision must not only meet the requirements set out for it in the Protocol under the PP, or those set out by the WTO SPS Agreement, but must also pass the muster of procedural fairness in order for SA to avoid incurring liability for breaching its obligations.

Under the reasonableness requirement, a decision by the Council may be reviewed by the Judiciary, inter alia, if the action was taken for a reason not authorised by the empowering provision;[365] for an ulterior purpose or motive;[366] because irrelevant considerations were taken into account or relevant considerations were not considered;[367] because of the unauthorised or unwarranted dictates of another person or body;[368] in bad faith;[369] or arbitrarily or capriciously.[370]

The purpose for the decision is to prevent adverse effects from harming plant, animal or human life and health.[371] However, perimeters need to be set to restrict the discretion to take measures to achieve this purpose so that it does not lead to abuse. Although SA's legislation imports the considerations of the Protocol into its measures and does not mandate vital considerations like the effect of the decision on

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[360] Inter alia, administrative action includes the exercise of a public power or performing a public function under legislation, section 1(a)(ii) of The Promotion of Administrative Justice Act no. 3 of 2000.
[361] Section 33 of the Constitution (note 34).
[362] Ibid.
[363] Section 3(1) (note 360).
[364] Section 3(2) ibid.
[365] Section 6(e)(i) ibid.
[366] Section 6(e)(ii) ibid.
[367] Section 6(e)(iii) ibid.
[368] Section 6(e)(iv) ibid.
[369] Section 6(e)(v) ibid.
[370] Section 6(e)(vi) ibid.
[371] Article 10(6) of the Protocol (note 1); Article 5(1) of the SPS Agreement (note 26).

international trade as in the SPS Agreement,[372] SA is still legally bound to take these considerations into account under international law. If the decision-maker does not take them into account, the decision-maker will not have taken relevant considerations into account which may render the decision unreasonable and in breach of section 33.

Furthermore, should the Council bend to the pressure put on it by its trading partners, as other African states have done, the Council's decision may be based on ulterior motives or become arbitrary, violating the right further.

Checks and balances need to be put in place to restrict the decision-making process in such a way that it complies with all of SA's international law obligations and takes into account all truly relevant factors involved in taking such measures, economic as well as sanitary, protecting the right of exporters to fair administrative action .

5.4 Recommendations

5.4.1 Checks and Balances

The Act needs to set firm parameters of considerations which are imperative to be taken into account in the decision-making process. The considerations mandated by the SPS Agreement need to be imported into national legislation along with those of the Protocol, most specifically with regard to taking into account the measure's effect on international trade with a view to minimizing negative trade effects.[373] It should specifically consider the impact of its decision on developing countries,[374] so as not to cause such harsh effects on the developing world as the measures taken by the EC have done. Even if this acts only as an administrative mandate, it will lessen the negative effects of such decisions in general.

It is specifically important that the proportionality requirement, as set out in the SPS Agreement, is mandated in SA law that the measure taken must not be more restrictive on trade than is necessary.[375] By allowing itself the protection of the PP, SA will be able to uphold its human rights obligations to some extent. However, so as not to violate its trade obligations in the process, the legislation needs to ensure that there is an obligation on the decision-maker to seek legal certainty on the issue

[372] Articles 5(2) - (7).
[373] Article 5(4) of the SPS Agreement (note 26).
[374] Article 10(1) ibid
[375] Article 5(6) ibid.

after taking the measure,[376] so as not to effect an unnecessary blanket ban on GMO trade, with a mandatory review of the measure within a reasonable time.[377]

5.4.2 Liability and Redress Measures

In order to mitigate its liability for breaching the right of its people to a safe and healthy environment should permitted GMO's actually cause harm, it is necessary for the legislature to create proper liability and redress measures.

The existing legislation does do this to some extent. Section 17(1) of the GMO Act places an obligation on the user of the GMO to ensure that appropriate measures are taken to avoid an adverse impact on the environment which may arise from its use. 'User' implies 'a person who conducts an activity with a genetically modified organism'.[378] This is a broad definition, including anyone from consumers to farmers.

If the user does not take such measures, he is guilty of an offence[379] for which he is liable to pay a fine or face imprisonment of not more than two years.[380] Section 17(2) states that 'liability for damage caused by the use or release of a genetically modified organism shall be borne by the user concerned'. This is without qualification in the Act, a particularly harsh provision. It entails a deviation from the fault principle normative to the law of delict in SA law, creating an instance of strict liability, meaning the end user will be liable to pay for the damage caused by the GMO even if there is no fault[381] on his part.[382]

The only proviso on this exists when harm is caused by the GMO while in the possession of an inspector as set out in section 15(4),[383] whereby the user concerned will not be held liable for any damage unless he foresaw or should have foreseen such damage would occur and could or should have prevented the damage but failed to take reasonable action to prevent it. This imports an element of negligence into the

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[376] Article 5(7) ibid.
[377] Idem.
[378] Section 1(m) of the GMO Amendment Act (note 321).
[379] Section 21(1) of the GMO Act (note 310).
[380] Section 21(2)(a) of the GMO Act ibid. On a second offence of this nature, imprisonment cannot exceed four years, section 21(2)(b).
[381] Fault being either intention or negligence in this instance.
[382] JC Van der Walt and JR Midgely *Delict* (1997) at 22.
[383] Under a warrant issued under section 15(5), an inspector may conduct an investigation and enter any place he suspects a violation of the Act has taken place, to see if the provisions of the Act have been complied with by the user and may, inter alia, take samples of the substance or GMO in question.

otherwise strict liability created by the provision, mirroring the reasonable person test for negligence used in delict.[384]

As it stands, without any qualification to the contrary, should any harm at all be caused by a GMO, the last person to use it will be liable for the damage, without the possibility of justification, except in the instance that an inspector possessed the GMO when it was released and caused harm, in which the user will only be liable if he was also negligent. Undeniably, this position is may have very heavy consequences as the cost of damage may be extremely high. It does not serve the interests of the state or the wronged parties to institute a claim for damages against a poor end user, who in any event cannot pay the amount of damages due to financial insufficiency.

Under the current legislative system, should harm ensue from a GMO in the possession of a consumer, who did not know the GMO status of the item as there is no mandatory labelling requirements for GMO's in SA law, the consumer in question will be guilty of a criminal offence under the GMO Act for failing to take measures to prevent damage to the environment and the consumer will also be liable to pay the full cost of damages for the harm, even if it is exorbitant and far reaching in nature, without the safety of a compensation fund. This is despite the fact that there was no fault on the part of the consumer. This situation is untenable and most certainly does not meet the ends of justice, for anyone involved.

The creation of a compensation fund by a state for the purpose of compensating environmental harm caused by GMO's is highly useful given the important nature of the environmental interest which needs redress despite financial insufficiency.[385] Certain International Conventions place a duty on states to create such a fund, while also putting ceiling amounts on the quantum of damages which can be claimed.[386] SA would be wise to voluntarily institute the mechanism of a

[384] As set out in Kruger v Coetzee 1966 2 SA 428 (A) 430, a person is negligent if a reasonable person in the same position as the wrongdoer would forsee that his conduct could cause harm and would've taken steps to prevent this harm, but the wrongdoer did not.

[385] This was done on an international level in the 1992 International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage. The Vienna Convention on Civil Liability for Nuclear Damage (1963) and the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy provide for the state to compensate the shortfall which the offender cannot pay.

[386] The Vienna Convention on Civil Liability for Nuclear Damage (1963) does this by setting a minimum liability amount with no ceiling while the1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy sets a ceiling amount on damages. Ceiling amounts are better in the instance of GMO damage.

compensation fund in this instance. SA law already has compensation funds in place, such as the Road Accident Fund[387] and the Compensation for Occupational Injuries and Diseases Fund,[388] around which it can structure a fund for GMO-caused damage, perhaps funded in part by a portion of the tariff attached to GMO imports.

Furthermore, the Act does not actually define what the 'harm' caused by GMO's entails. 'Environmental harm' lacks clear and concise international definition.[389] There is no significance to compensation if there is no actual concept of what must be paid for and how much this should be.[390] Environmental damage may be continuous, contingent and unending, especially when one considers the inter-connectivity of ecosystems. Putting a price on this type of damage presents an enormous problem to the judiciary. Boundaries need to be put in place by the legislature itself in order to define this concept which it intended to regulate with his provision, short of which, patrimonial and non-patrimonial damage[391] will have to be ascertained using the traditional methods entrenched in the law of delict but this remains difficult.

A better provision existed in the Consumer Protection Bill under clause 61(1), which placed liability for damage caused by GMO's, which did not fall under the ambit of the GMO Act, on the producer or importer, distributor or retailer of the GMO's, irrespective of whether there was any negligence on the part of this person. The 'harm' contemplated was also given parameters, being limited only to a number of instances[392] including patrimonial loss.[393] However, this provision was removed from the bill and does not appear in the final Act, based on the premise that it would cause confusion with regard to GMO regulation which is better left under the GMO Act's provisions. This is somewhat true to the extent that limiting the clause's application to only GMO's not under the regulation of the GMO Act leaves extremely few cases to which the clause applies and therefore is not very helpful with regard to liability and redress measures caused by GMO's.

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[387] Section 2(1) of the Road Accident Fund Act No. 56 of 1996.
[388] Section 15(1) of the Compensation for Occupational Injuries and Diseases Act No. 130 of 1993.
[389] M Bowman and A E Boyle et al. *Environmental Damage in International and Comparative law* (2002) at 1 state that there is no certain answer to what constitutes 'environmental harm'.
[390] Ibid.
[391] Such could emanate from damage to the environment in the form of a loss to humanity and the world of its biodiversity.
[392] Section 61(5) of the Consumer Protection Act No. 68 of 2008.
[393] Pure economic loss is also included in this concept, s 61(5)(d) ibid.

However, it is obvious that placing the burden of strict liability for harm caused by the GMO on the supplier of the product is a far more beneficial measure than the current position. The supplier, usually a juristic person of substantial wealth, hence in a better position to compensate for the damage, is in a better position to know of the dangers posed by the GMO (or, in fact, that the product is a GMO at all given the absence of mandatory labelling provisions) and to resultantly take steps to prevent the harm form occurring. Such a burden will also increase incentive on suppliers to uphold high quality consumer standards of safety. For policy reasons based on fairness and justice, strict liability is justified in such an instance and the public at large will be better served by this position.

Legislative reform in this regard is most certainly needed before the flaws in the current position are uncovered in immense and unnecessary litigation.

5.5 Biosafety Law and Consumer Protection Law

5.5.1 The Consumer Protection Act

In April 2009, The Consumer Protection Act (CPA)[394] came into force in SA. It will only gain full effect of all of its provisions 24 months after its enactment,[395] but its growing prominence cannot be ignored. It gives effect to the UN guidelines on Consumer Protection,[396] with a uniquely South African slant. The eight principles for consumer rights embodied in the Act,[397] surrounding which the Act's provisions are structured, deviate from the UN guidelines in order to make them in line with the human rights objectives of SA's Constitution.

The Act applies to every transaction occurring in SA, [398] save certain exemptions[399] and applies irrespective of whether the supplier of the goods has its business outside of the RSA,[400] is the state,[401] or supplies goods under a license via public regulation,[402] such as under the GMO Act, leaving GMO's and their products subject to the requirements of the Act.

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[394] No 68 of 2008.
[395] Transitional Provisions provide for this in Shedule 2 of the Consumer Protection Act ibid.
[396] United Nations Guidelines for Consumer Protection 1985 (expanded in 1999) (note 16).
[397] Chapter 2 (note 392).
[398] Section 5(1)(a) ibid.
[399] Most notably, sale of goods to the state or to juristic persons with an annual turnover above a certain threshold amount as determined by the Minister, section 5(2)(a) and (b) ibid; however, certain provisions still apply to the goods involved in these transactions, section 5(5) ibid.
[400] Section 5(7)(a) ibid.
[401] Section 5(7)(c) ibid.
[402] Section 5(7)(d) ibid.

5.5.2 To Label or Not to Label

In terms of the CPA, consumers have the right to choose.[403] This entails being free to select products based on their own beliefs and convictions without restriction. Coupled with this right, consumers also have the right to disclosure of information,[404] through which the exercise of the right to choose is given effect. Furthermore, consumers in SA have the right to fair value, good quality and safety,[405] which cannot be compromised by an unqualified sanction of potentially harmful products.

Despite SA's WTO law obligations relating to the principle of non-discrimination,[406] even if GMO's pass government approval under the Act, it is not fair on consumers to introduce them simply as other conventional products. Should GMO products be against the ethical or religious beliefs of a consumer and the consumer is unknowingly subjected to these products, not only is the consumer's right to freedom of choice under the CPA breached, but indirectly, it would violate the consumer's constitutionally entrenched human right to freedom of belief, consciousness and religion.[407]

The problem could be solved with the implementation of a labelling requirement for all GMO's and their products, leaving the choice whether to consume these products or not up to the discretion of the consumer. However, SA's attempts to do this have been unsuccessful to date. At the end of 2008, the adoption of the Consumer Protection Bill was postponed due to a seemingly irreconcilable bone of contention amongst Parliament regarding the compulsory labelling of consumer products containing GMO's, as provided for in the Bill.[408] The bill originally stated that:

> 'any person who produces, supplies, imports or packages any prescribed goods must display on or in association with the packaging of those goods a notice in the prescribed manner and form that discloses the presence of any genetically modified ingredients or components of those goods in accordance with applicable regulations.'[409]

[403] Part C of Chapter 2 ibid.
[404] Part D ibid.
[405] Part H ibid.
[406] GATT article I and III (note 47); TBT Agreement Article 2(1).
[407] Section 15 of the Bill of Rights in the Constitution (note 34).
[408] D Pressly 'Delay Hits Consumer Protection Bill' Business Report (20 October 2008).
[409] Clause 24(6) of the Consumer Protection Bill D Draft.

This would have instituted a mandatory labelling requirement on all GMO products in SA. However, the clause was removed from the final version of the CPA, an action which resulted in the Act finally being adopted.

The position in SA due to this legislative omission regarding GMO labelling now, is that a voluntary option is given to suppliers to label the GMO status of an item or not. This sharp turn away from the principles of the Act is a direct steering toward the current position held by the USA regarding labelling of these products.[410] This means that SA consumers eat a variety of GMO products unknowingly, with no recourse against this practice.

This provision was removed from the first draft of the bill 'after concerns raised by the Department of Agriculture around the cost of the labelling and the technical expertise required to regulate safety issues'[411] but the clause was reinstated after the Department of Trade and Industry argued that technical aspects of GMO safety were addressed in the GMO Act and '[n]o substantial cost implications were expected and the Bill did not prescribe how the labelling must be done.'[412] The final exclusion of the clause from the Act was based on the Department of Agriculture's cost argument in the end, a sad decision wholly incongruent with the purport and objectives if the CPA as a whole, one which has been largely criticised by the general public and NGO's alike.[413]

It cannot be ignored that labelling requirements on GMO products may constitute a violation of the WTO principle of non-discrimination. It is likely that SA's decision to ultimately remove this clause from the CPA was based on this consideration. It is unacceptable that this occurs at the expense of violating its consumer and human rights obligations. Even in terms of WTO law, in so far as labelling requirements are a measure put in place to protect health and safety, they will constitute a valid exception to the to the principle of non-discrimination in the form of an SPS measure, so long as the requirements of the SPS Agreement are met.

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[410] A Baker 'The Consumer Protection Bill and Labelling o f Genetically Modified Organisms' News – Commercial Aspects of IP (23 October 2008) at 1. Available at www.adamsandadams.co.za. [Accessed 10 August 2009].

[411] Parliamentary Monitoring Group Report 'Consumer Protection Bill [B19C-2008]:Departmental briefing & National Radioactive Waste Disposal Institute Bill: Department of Minerals and Energy briefing & adoption' at 4. Available at http://www.pmg.org [Accessed 10 August 2009].

[412] Ibid.

[413] C Treherne 'Safeage submission re Consumer Protection Bill' Available at http://www.Safeage.org. [Accessed 10 August 2009]; W Jasson da Costa 'Religious groups worried about GM foods' The Mercury, SA (19 January 2006). Available at http://www.int.iol.co.za/index.php [Accessed 10 August 2009].

However, to the extent that the labelling requirements only give effect to the consumer's right to choose, they will not qualify as SPS measures and may well be a violate the principle. This latter position is not acceptable. Consumer rights cannot simply be ignored and with a global movement towards their legal recognition,[414]an exception to this rule which would accommodate labelling requirements is definitely needed.

That being said, it is not difficult to perceive that a consumer's choice regarding GMO products will undoubtedly be premised upon what the consumer perceives to be safe. As GMO's are still uncertain to cause harm, it is possible to justify labelling requirements on GMO products on the fact that they warn the consumer of potential harm inherent in the GMO, which is uncertain to occur. In this way, labelling requirements still qualify as SPS measures. If the SPS Agreement is complied with, the negative impact of such measures on trade will be mitigated, while the state in question will be legally justified in its actions. To this effect, other WTO member states in a similar position have chosen to implement labelling requirements, the EC,[415] Japan, Australia and New Zealand among them.[416]

The EC's labelling requirements are particularly extensive. It implements mandatory labelling requirements for 'foods that are delivered as such to the final consumer or mass caterers in the Community',[417] which either consist of or contain GMO's; or which are produced from GMOs.[418] These products must be labelled irrespective of whether the DNA or protein resulting from genetic modification of the organism exists at all in the final product, meaning '[t]he process or production method of the GM food or feed is now a relevant factor.'[419] A threshold requirement exists, as '[t]he presence of GM material in conventional food does not have to be labelled if it is below 0.9 per cent and if it can be shown to be adventitious and technically unavoidable'.[420] EC countries have implemented the rule as meaning a

[414] United Nations Guidelines for Consumer Protection (note 16).
[415] EC. Regulation 1829/2003,16.
[416] Zarrilli (note 2) at 5.
[417] Idem.
[418] Ibid at 6.
[419] Zarilli (note 2) at 5-6.
[420] Ibid at 6.

GMO content of more than 0.9 per cent in each ingredient of a product.[421] A traceability system for GMO's was also implemented.[422]

The EC's labelling requirements have stirred up much controversy. The strict nature of these labelling provisions has proved to be too expensive for companies to comply with, which resultantly impacts international trade negatively.[423] This does not comply with the SPS Agreement's mandate that the measure taken should not be more trade-restrictive than is necessary, taking into account technical and economic feasibility.[424] There are cost-effective alternatives to limiting the risk[425] that have not been considered by the EC. Furthermore, it did not attempt to minimize negative effects on trade[426] of its measures, aggravating them instead.

It is likely that the EC's version of GMO labelling measures violate WTO law. However, this does not have to be the case in SA. It is possible to implement mandatory labelling requirements which comply with the SPS Agreement's obligations. If mandatory labelling was instituted which was reasonable and practical, this would not cause too much of a burden on suppliers while still giving effect to the consumer's right to choose. Such would include all GMO-foods and foods with at least a significant percentage of GMO's in its overall ingredients to be mandatorily labelled as 'containing GMO's', while items which the supplier knows or reasonably believes to contain GMO's falling under this percentage are to be mandatorily labelled with the catch-all phrase 'may contain GMO's', with a justification to the effect that a GMO content which was unforeseen, adventitious or technically impossible to detect is exempt from labelling. Items which no longer show any traces of GMO's should not be subject to labelling – this position is overly stringent and illogical. This would cut out the costs involved in such testing for suppliers, while still giving enough notice of the GMO content of foods to consumers for them to make informed choices, an overall least restrictive means to achieve the same purpose of giving heed to consumer rights. 'With labelling, informed

[421] M Milavec 'Traceability Measures' Report of the Department of plant physiology and biotechnology ,National institute of biology at 1. Available at www.coextra.eu.traceability.HR.en.html [Accessed 15 May 2009].
[422] EC Regulation 1830/200317
[423] Baker (note 402) at 2.
[424] Article 5(6) of the SPS Agreement (note 26).
[425] Article 5(3) ibid.
[426] Article 5(4) ibid.

consumers can maximize their utility, relative prices will reflect their choices, and the gains from trade will be maximized.'[427]

[427] Sheldon (note 30) at 24.

6. Conclusion

With the international legal regime as it is, despite the theoretically authoritative sanction of the Cartagena Protocol to prohibit GMO imports in terms of the PP, it is difficult to see how a party which is also a member of the WTO will ever be able invoke this principle without breaching its obligations in terms of WTO law. This is a highly detrimental position for states to be in. Despite the potential negative effects of a strict invocation of the PP, it remains a highly necessary mechanism by which a state can protect its vital interests in cases where risks remain scientifically uncertain to occur, as in the case of GMO's. This instance cannot be ignored, as the SPS Agreement does, due to the fact that a very real possibility exists that future harm might actually arise from GMO's which have been proven to be scientifically uncertain in terms of their safety. Should this harm actually arise and the state in question did not invoke precautionary measures to prevent the harm before it realised, it will be liable to its own nationals for this damaged caused, which it otherwise had the power to mitigate or prevent.

In SA, this is especially the case. The state is mandated to protect, promote and fulfil the constitutionally entrenched right to a safe and healthy environment of all its people. The fact that the SPS Agreement does not sanction taking precautionary action in the interests of health and safety, based merely on scientifically uncertain risks, does not preclude SA's government from this obligation, leaving it liable for harm caused by GMO's it did not prevent from import, despite it knowing that scientifically uncertain risks were inherent in the GMO's in question.

There is certainly a need for reformation of the international position. The SPS Agreement should sanction some form of provisional SPS measures in the case of scientifically uncertain risks, to accommodate all states and their obligations. The negative effects of this can be mitigated by all the factors which the SPS Agreement already mandates in relation to taking provisional SPS measures, most specifically by aiming to mitigate the negative trade effects of the measure; ensuring that the measure is not a disguised restriction on trade; taking into account the effects of the measure on developing countries; and most importantly, mandating that the state search for certainty on the issue and necessarily review the measure within a reasonable period of time.

Similarly, the Cartagena Protocol needs to be amended to reflect these considerations. Especially, it should mandate an enquiry into the effects that the precautionary measures it sanctions have on international trade and especially on developing countries. Even for countries which do not bear obligations in terms of WTO law, it is not tolerable that the effects of measures taken in terms of the Protocol, however vital to protect biodiversity, health and safety, impact so negatively on other countries, biotechnology and international trade without even an obligation to consider these goals or take a less restrictive measure.

Until this is resolved on an international level, SA can only amend its own position with regard to GMO trade in this way. National legislation should mandate checks and balances to the decision to allow GMO trade or not, including an obligatory enquiry into the trade and socio-economic effects of the measures taken, making sure that the measures are temporary and that an obligation to seek certainty on the risks, as well as mandatory review of the measures after a reasonable period of time, take place.

Even with these improvements, however, SA is not safe from incurring liability for breach of its WTO obligations should it actually invoke the PP and prohibit GMO imports. Therefore, SA is well advised to rather make its risk assessment measures before allowing GMO imports and its risk management measures after import more comprehensive, than to invoke the PP and prevent GMO imports based on scientific uncertainty. This position would be improved by implementing post-import monitoring of GMO's and a responsible liability and redress framework should GMO's actually cause harm. This situation is not ideal but its practical effect is to ensure that SA allows vibrant GMO trade while still protecting the rights of its people as much as possible, under constitutionally-sanctioned action.

Change is undoubtedly needed in all levels of legislation regulating trade in biotechnology. Given the vital humanitarian and commercial concerns involved, as trade in GMO's becomes ever expanding, this anomaly in the legal framework regulating their trade is untenable. Law, science and ethics need to unite on this issue, keeping abreast with the modern world, while the global question of whether we can afford to trade in GMO's moves rather to a consideration of whether we can afford not to.

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