

Attempts to Regulate Biotechnology in International Law and the Response of Australian Law

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I. Introduction

Biotechnology is one of the fastest growing technology sectors in the developed world and is expected to continue its rapid growth. Publicly-traded biotechnology grew by 18 per cent in 2005, pushing biotechnology industry revenues over \$75 billion for the first time in the sector's thirty year history.¹ In Australia, the sector is considered vital for economic development and the maintenance of a high standard of living.²

Biotechnology in agriculture has created a new challenge for many countries to regulate agricultural products resulting from biotechnology. Governments are also facing a challenge to balance tremendous potential benefits of biotechnology with its possible unknown risks.

Regulating agricultural biotechnology and its possible risks to the environment has become of increasing interest since appearing on the agenda in 1992. Two international treaties have specific provisions with respect to the regulation of biotechnology. The *Convention on Biological Diversity*³ addressed the issue of biodiversity and the distribution of its benefits for the first time at a global level. The *Biosafety Protocol*,⁴ which was adopted in 2000 by over 130 States, regulates genetically modified

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1 Ernst & Young, *Beyond Borders: The Global Biotechnology Report* (2006) <http://www.ey.com/global/content.nsf/International/Biotechnology_Report_2006_Beyond_Borders> accessed 29 May 2006.

2 Commonwealth of Australia, *Australian Biotechnology: A National Strategy* (2000) at 9.

3 *Convention on Biological Diversity*, opened for signature 4 June 1992 [1992] 31 ILM 818 (entered into force 29 December 1993).

4 *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, opened for signature 29 January 2000 (entered into force 11 September 2003) (*'Biosafety Protocol'*).

organisms. It applies to the trans-boundary movement, transit, handling and use of all living modified organisms that may have an adverse effect, and the conservation and sustainable use of biological diversity. Prior to this, biotechnology was governed by certain general provisions of a number of international treaties relating to the environment and trade and general principles of customary international law.⁵

International law provisions relating to biotechnology in agriculture have been implemented or are in the process of implementation by a number of countries which have ratified the *Biodiversity Convention* and the *Biosafety Protocol*. International law increasingly has an important role in the regulation of agricultural biotechnology by individual States. In this area, the rapidly developing technology and science together with international law have mutual influences.

This article focuses on international attempts to regulate the production and trade in agricultural modified organisms and Australia's obligations under international law. At the same time, relevant portions of the *Biodiversity Convention* and its *Biosafety Protocol* and the relationship and the possible inconsistencies between these and the *General Agreement on Tariffs and Trade (GATT)/World Trade Organization (WTO)* will be examined.

2. The Issues

Scientific uncertainty in relation to the adverse effect of genetically modified organisms (GMOs) on the environment and public health are the main reason for calls for regulation of biotechnology in agriculture, both under international law and national legal systems. It is obvious that the use of biotechnology in agriculture has great potential benefits and may solve many problems such as food shortages and the use of pesticides.⁶ According to biotechnology companies, research institutions and certain governments, biotechnology has no significant risks, is quite safe, can increase productivity and eliminate the risk of using pesticides and chemicals in agriculture.⁷ It is argued that biotechnology has certain environmental benefits — including improved weed control, increase management options, reduction in the use of herbicides and reduction in the use of insecticides.⁸ But critics of GMOs argue that potential risks, such as the possibility of the new genes jumping over to other crops and even to humans, cannot be dismissed.⁹ According to other scientists, although the release of GMOs poses real risks to the environment, there are similar risks posed by the introduction of unmodified foreign organisms into the environment.¹⁰

Genetic engineering may go wrong, as was the case when one of its first products was introduced into the market.¹¹ In the late 1980s, a Japanese company began

5 See section 3 below.

6 See Thomas McGarity, 'International Regulation of Deliberate Release Biotechnologies' (1991) 26 *Texas International Law Journal* 423 at 426; Julia Novotny, 'Genetically Modified Organisms' (2001) 13 *Florida Journal of International Law* 231 at 231–232.

7 See *Biotechnology Australia* (2006) <<http://www.biotechnology.gov.au>> accessed 21 April 2006. Biotechnology Australia is a multi-departmental government agency established in 1999.

8 *Ibid.*

9 Ved Nanda, 'Genetically Modified Food and International Law – The Biosafety Protocol and Regulations in Europe' (2000) 28 *Denver Journal of International Law and Policy* 235 at 237.

making triptophan (an amino acid, which is a protein building-block) by using genetically engineered bacteria and selling it to the United States.¹² This resulted in thousands of people who had taken the supplement suffering from eosinophilia myalgia syndrome, which eventually caused 1,500 people to become permanently disabled and 37 deaths.¹³ Further, genetically engineered food can cause allergic reactions in a sizeable percentage of people who have an adverse reaction to some food.¹⁴ GM products may transfer allergies from foods which people know to food that they think is safe.¹⁵ For example, in March 1996, it was confirmed by researchers that an allergy from Brazil nuts had been transferred into soybeans, as a result of transferring a Brazil nut gene into soybeans.¹⁶ It is also argued that the widespread use of antibiotic resistance marker genes could contribute to the problem of antibiotic resistance: 'The gene can move from a crop into bacteria in the environment, and since bacteria readily exchange antibiotic resistance genes, move into disease-causing bacteria and make them resistant too.'¹⁷ For example, the significant risks of commercial production of genetically modified canola may include genes taking or so called 'superweeds', gene flow from herbicide tolerant genetically modified canola to weedy relatives of canola, or to cultivated genetically modified canola, and pose risk to the integrity of genetically modified crops through the spread of genetically modified crops.¹⁸

Environmental and health issues are the main reasons for intervention by both international and national legal systems in regulating the trade and the use of biotechnology. However, public opinion and political debates¹⁹ are other important factors.²⁰

Biotechnology, similar to climate change debates, provides a good example of the close interaction between science and law. The aim of science is, among other things, to invent new methods to serve society. The purpose of law, both international and national, is to protect society. It is the responsibility of a legal system to encourage or

10 Kirsten Jabara, 'The Biosafety Protocol' (2001) 8 *University of Baltimore Journal of Environmental Law* 121 at 124; see also Union of Concerned Scientists, *Risks of Genetic Engineering* (2006) <http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageID=346> accessed 21 April 2006. A United States Official stated 'Why don't those who rail against biotechnology extend their aversion to all non-organic agriculture? Has someone made an evaluation that the use of pesticides and other chemicals in non-organic food is less problematic than genetic modification? I doubt very seriously that one could prove such a thesis and I doubt anyone has tried. It is very difficult to manipulate attitudes of risk, and my concern is that if we stray from the strictest possible science-based analysis, we are entering very dangerous territory': quoted in Frank Joy, 'Genetically Modified Organisms: Colloquium Article Statement on Biotechnology: A Discussion of Four Important Issues in Biotechnology Debate' (2000) 8 *New York University of Law Environmental Law Journal* 605 at 608.

11 Jean Halloran & Michael Hansen, 'Why We Need Labelling of Genetically Engineered Food' (1999) 18 *Synthesis/Regeneration* at 18 <<http://www.greens.org/s-r/18/18-07.html>> accessed 21 April 2006.

12 Ibid.

13 Ibid.

14 See Dean Metcalfe, 'Introduction: What are the Issues in Addressing the Allergenic Potential of Genetically Modified Foods?' (2003) 8 *Environmental Health Perspectives* 111 at 111.

15 Ibid.

16 Ibid.

17 Ibid.

prohibit scientific innovations in order to protect society and the environment against possible risks. However, it is science, not law, which decides whether there is any risk resulting from any scientific activity. The problem in the area of biotechnology, as well as climate change, is that of scientific uncertainty.

Since 1992, a principle has developed in the field of international environmental law, which provides that 'when there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost effective measures to prevent environment degradation'.²¹ This principle, known as the precautionary principle,²² has been adopted both in international law (The *Biosafety Protocol*) and in national laws (such as Australian law with its different interpretation) in dealing with the issue of biotechnology in agriculture.²³ This reflects recognition of the fact that the development and the use of GMOs may have an adverse effect, not only on the natural environment, but also on human health. The latter, if not dealt with properly, may lead to extensive and complicated litigation in both national and international arenas.

3. Historical Background of Regulation of Agricultural Biotechnology in International Law

The legal issues of agricultural biotechnology are mainly covered by three branches of modern international law. These are international environmental law, international trade law and international intellectual property law. International environmental law regulates the development and other uses of biotechnology in agriculture. Indeed, its aim is to reduce the possible adverse effects of GMOs on the environment and

18 Sara Kiyork, 'The Gene Technology Act 2000 (Cth) and the Licensing of Australia's First Genetically Modified Crop: A Case Study in Ignoring Risks to Biodiversity' (2005) 22 *Environmental and Planning Law Journal* 174 at 177–178; see also Nicole Rogers, 'Seeds, Weeds and Greed: An Analysis of the Gene Technology Act 2000 (Cth), its Effect on Property Rights, and the Legal and Policy Dimensions of a Constitutional Challenge' (2002) 2 *Macquarie Law Journal* 1 at 3; David Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *Australasian Journal of Natural Resources Law and Policy* 129.

19 For example, the President of the United States, George W Bush, on 21 May 2003 blamed opponents of GM foods for the hunger in Africa: David Sanger, 'Bush Says Opponents of GM Food are Failing the Hungry of Africa' *Sydney Morning Herald* (23 May 2003).

20 These have given rise to considerable public concern and political and international debates. According to a poll released in April 2003, 68 per cent of more than 12,000 people in EU candidate countries reject GMO food, with more than half believing it to be positively dangerous; *The Economist* (5 April 2003). For a discussion about public attitudes to the GMOs see David Morgan, 'International Trade Rules and the Implication for Biotechnology Regulation' (2004) 8 *Asia Pacific Journal of Environmental Law* 178 at 182–184. For the public attitudes of Australian people in relation to GMOs see Commonwealth Department of Industry, Science and Resources, *Biotechnology Public Awareness Survey: Final Report* (2003) at 9–12.

21 *Rio Declaration on the Environment and Development*, (1992) UNGA, 47th sess, Annex 1, principle 15, UN Doc A/Conf.151/26.

22 For a study of the precautionary principle see David Freestone & Ellen Hey (eds), *The Precautionary Principle and International Law* (1996) and Arie Trouwborst, *Evolution and Status of Precautionary Principle in International Law* (2002).

23 See section 5(B) below.

human health. International trade law regulates trade in GMOs between nations. Finally, international law provisions also cover the important issue of intellectual property rights to GMOs. This article covers the first two of these three branches with respect to biotechnology.²⁴

International law has long provided some protection of certain aspects of the environment.²⁵ However, it was not until the 1972 UN Conference on Environment and Development (UNCED), held in Stockholm, that for the first time the protection of the environment on a comprehensive basis was considered. In this conference, following some debate, Principle 21 was accepted. It provides that:

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or areas beyond the limits of national jurisdiction.²⁶

This principle remains an accepted principle in drafting almost all international treaties relating to the environment and natural resources. It more or less confirms the sovereignty of States over their natural resources and the environment, but it also makes States responsible for activities within their jurisdiction, which may damage the environment of other countries.²⁷

Twenty years later, the principle of sovereignty over natural resources was reaffirmed in the 1991 Rio Conference.²⁸ One of the most important outcomes of the conference was the *Biodiversity Convention*.²⁹ Issues covered by the *Convention* include conservation of biodiversity, sustainable use, and most controversially in article 19, the distribution of genetic resources.

24 For a study of intellectual property rights and biotechnology see Michael Kirby, 'Ethics, Intellectual Property and Biotechnology Work in Progress and UNESCO Initiatives' (2005) (paper presented at UNESCO International Congress of Bioethics, Tehran, 26–28 March 2005); Kimberly Moore & Francesco Parisi, 'Symposium on Constructing International Intellectual Property Law: The Role of National Courts: Thinking Forum Shopping in Cyberspace' (2002) 77 *Chicago-Kent Law Review* 1325; Dianne Nicol & Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347; Steven McDaniel, 'Protecting Biotechnology Trade Secrets in University and Industrial Research' (1994) 16 *Houston Journal of International Law* 565; Charles Lawson & Catherine Pickering, 'The Conflict for Patented Genetic Materials under the Convention on Biological Diversity and the Agreement on Trade Related Aspects of Intellectual Property Rights' (2001) 12 *Australian Intellectual Property Journal* 104; Charles Lawson & Catherine Pickering, 'Controlling Access to Genetic Resources under the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) Requires an Assessment of the *Patents Act 1990* (Cth)' (2002) 13 *Australian Intellectual Property Journal* 109; Charles Lawson & Catherine Pickering, 'Patent Laws Undermine Access Provisions in the Environment Protection and Biodiversity Conservation Bill 1998 (Cth)' (1998) 15 *Environmental and Planning Law Journal* 401; Judith Jones, 'Regulating Access to Biological and Genetic Resources in Australia: A Case Study of Bioprospecting in Queensland' (1998) 5 *Australian Journal of Natural Resources Law and Policy* 89; Upendra Baxi & Clarence Dias, 'Preservation and Access to Plant Genetic Resources' (1984) 32 *International Commission of Jurists Review* 49; Harold Bordwin, 'The Legal and Political Implications of the International Undertaking on Plant Genetic Resources' (1985) 12 *Ecology Law Quarterly* 1053.

Agenda 21 addresses the issue of biodiversity.³⁰ According to Chapter 16 of *Agenda 21*, entitled 'Environmentally Sound Management of Biotechnology', the Agenda's goal is to foster international principles for the environmental management of biotechnology and to promote sustainable applications of biotechnology.³¹ Chapter 14 of the *Agenda* provides for the sharing of research and plant genetic resources among nations.³²

Although only two international treaties, the *Biodiversity Convention* and its *Biosafety Protocol*, have specific provisions in relation to biotechnology, general provisions of certain other international treaties relating to the environment and trade are relevant to the issue of developing and using biotechnology. These include the *Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment*,³³ the *Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters*,³⁴ and *WTO Agreements*. Also certain non-binding international instruments, such as the United Nations General Assembly Resolution establishing the Commission on Sustainable Development³⁵ and the *1982 World Charter for Nature*,³⁶ have general provisions relating to the international protection of the environment and may be relevant to certain aspects of biotechnology development. In addition, international customary law principles relating to the protection of the environment may govern certain aspects of the use and trade in GMOs.³⁷ Of most direct relevance, however, is the *Biosafety Protocol* concluded in February 2000 by 130 countries. To date, 132 countries have acceded to the *Protocol*.

25 The earliest treaties relating to the protection of certain aspects of the environment go back to the early years of the 20th century. See for example: *Convention Destinée à Assurer la Conservation des Diverses Espèces Animales Vivant à l'État Sauvage en Afrique qui sont Utiles à l'Homme ou Inoffensives*, IV IPE 1607 (entered into force 19 May 1900); *Convention for the Protection of Birds Useful to Agriculture*, opened for signature 19 March 1902, IV IPE 1615 (entered into force 20 April 1908); and *Convention between the United States of America, the United Kingdom of Great Britain and Northern Ireland, and Russia, for the Preservation and Protection of Fur Seals*, opened for signature 7 July 1911, VIII IPE 3682 (entered into force 15 December 1911).

26 *Agenda 21* (UNCED, 1992), chapter 16, UN Doc A/CONF.151/26/Rev.1.

27 For further discussion about the issues of sovereignty and the protection of the environment see: Susan Bragdon, 'National Sovereignty on the Global Environmental Responsibility: Can the Tension be Reconciled for the Conservation of Biological Diversity?' (1992) 33 *Harvard International Law Journal* 381.

28 United Nations Conference on Environment and Development, also known as the Earth Summit, was a major conference held in *Rio de Janeiro* from 3–14 June, 1992.

29 Above n3.

30 *Agenda 21* above n26, was a non-binding instrument, which was concluded at the Rio Conference in 1991.

31 Id at chapter 16.

32 Id at para 14.57(d).

33 *Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment*, open for signature 21 June 1993 (not yet entered into force).

34 *Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters*, opened for signature 25 June 1998 (entered into force 30 October 2001).

35 *Institutional Arrangements to Follow up the United Nations Conference on Environment and Development* UNGA Res, 47th session, UN DocA/RES/47/191.

36 *World Charter for Nature*, UNGA Res 37/7 (28 October 1982).

4. 1992 Convention on Biological Diversity

The global *Convention on Biological Diversity* (or *Biodiversity Convention*), which had been under negotiation since 1988, was concluded in 1992 and entered into force on 29 December 1993.³⁸ It has, to date, 187 parties and therefore is one of the most widely ratified international treaties.

The issue of biotechnology caused considerable difficulties during the negotiation of the *Biodiversity Convention*.³⁹ This was the first time biotechnology had been addressed at a global level. Before the adoption of the *Biodiversity Convention*, international law provisions in this area were limited to governing the introduction of alien species into regions.⁴⁰

Article 19 of the *Biodiversity Convention* makes provisions with respect to the distribution of benefits resulting from the use of biotechnology techniques.⁴¹ This article is the only section of the *Biodiversity Convention* that is solely concerned with the issue of biotechnology and the distribution of its benefits. Article 19 puts obligations on State parties to transfer biotechnology. These provisions are inconsistent with patent rights and are the basis for the United States' objection to the article.⁴² The biotechnology provisions of the *Convention* have also been criticised for being very general and do not touch on many important legal issues of biotechnology.⁴³ And the sharing of benefits, provided for in article 19 of the *Convention*, is subject to private arrangements between the parties, without any specific guidelines provided by the *Convention*.⁴⁴

Although some of the above criticisms of the provisions of the *Biodiversity Convention* relating to biotechnology are important, the *Convention* was a very significant step forward in regulating international legal issues relating to biotechnology. The treaty provides certain general provisions relating to biotechnology and establishes the ground for a more detailed protocol. The extensive conflict during the negotiation of the treaty and its conclusion was inevitable. Biotechnology is a recent phenomenon resulting from modern technological advances. There are very important economic issues that can affect many industries. Scientific predictions about the possible adverse effects of using biotechnology are not certain. Therefore it was sensible for the *Convention* to hint at certain general legal issues and leave the details to a later complementary treaty. Certain provisions of the *Convention* on the issue of biotechnology are important. Apart from article 19, which

37 For a study of international customary law and the environment see Patricia Birnie & Alan Boyle, *International Law and the Environment*, (2nd ed, 2002) at 104–111; John Lee, 'The Underlying Legal Theory to Support a Well-Defined Human to a Healthy Environment as a Principle of Customary Law' (2000) 25 *Columbia Journal of Environmental Law* 283; Joshua Eaton, 'The Nigerian Tragedy, Environmental Regulation of Transnational Corporations, and the Human Right to a Healthy Environment' (1997) 15 *Boston University International Law Journal* 261; Anthea Roberts, 'Traditional and Modern Approaches to Customary International Law: A Reconciliation' (2001) 95 *American Journal International Law* 757; Geoffrey Palmer, 'New Ways to Make International Environmental Law' (1992) 86 *American Journal International Law* 259.

38 See Fiona McConnell, *The Biodiversity Convention: A Negotiation History: A Personal Account of Negotiation: The United Nations Convention on Biological Diversity, and After* (1996).

39 Philippe Sands, *Principles of International Environmental Law* (2nd ed, 2003) at 478.

40 Ibid.

is entirely concerned with biotechnology, articles 8, 15 and 16, have provided further regulations concerning biotechnology.⁴⁵ Article 8(g) of the *Convention* requires a State party to 'establish or maintain means to regulate, manage or control the risks associated with use and release of modified organisms resulting from the biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.'

Article 14 also obliges a State party to 'introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects.'

Taking into account that the *Convention* does not permit reservations⁴⁶ and the large number of States that are parties, the existing provisions, embodied in the *Convention*, are of considerable significance.

Australia has signed and ratified the *Biodiversity Convention*⁴⁷ and has been a WTO member since 1 January 1995.

A. Implementation of the Convention in Australia

Australia's international obligations under the *Biodiversity Convention* have been implemented in the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ('*EPBC Act*'). Policies have been developed pursuant to legislative provisions for protection of biological diversity in Australia such as the National Strategy on the Conservation of Australia's Biological Diversity.⁴⁸ In 2002, the *Diversity Convention* adopted the *Bonn Guidelines*⁴⁹ which provide for best practice guidelines for national legislation. All Australian State governments and the Commonwealth government have agreed to a nationally consistent approach to implement the *Bonn Guidelines*.⁵⁰

41 Article 19 of the *Convention on Biological Diversity* provides:

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms...
3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular, those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights...
4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above....'

The Act intends, among other things, to assist in the cooperative implementation of Australia's international environmental responsibilities.⁵¹ The Act attempts to provide an extensive regime for the conservation of biodiversity. The Act includes provisions dealing with identifying and monitoring biodiversity and making bioregional plans,⁵² protected areas, such as Commonwealth reserves⁵³ and access to biological resources on Commonwealth areas.⁵⁴ Article 301 of the Act provides for regulations for the control of access to biological resources in Commonwealth areas. Further, since 1 December 2005, new regulations came into force in order to manage the sustainable access and equitable distribution of benefits resulting from genetic resources.⁵⁵

The Act covers six matters of national environmental significance as triggers for the Commonwealth assessment and approval regime. These matters are world heritage properties, Ramsar wetlands, nationally threatened species and ecological communities, migratory species, Commonwealth marine areas and nuclear actions (including uranium mining). None of those areas are specifically related to genetically modified organisms. However, the Act introduces a number of initiatives in the area of ecologically sustainable development.

B. EPBC Act and GMOs

The environmental impact assessment provisions of the Act did not extend to any dealing with GMOs which may cause a risk of harm to the environment or human health. It is argued that the environmental impact assessment of the Act should be extended to provisions of the *Gene Technology Act* in order to protect Australia's biodiversity.⁵⁶ The failure to extend the environmental impact assessment of the Act

42 Klaus Bosselmann, 'Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity' (1996) 7 *Colorado Journal of International Environmental Law and Policy* 111 at 115. The provisions of the *Biodiversity Convention* in articles 8, 16 & 19 were amongst the main reasons for the US not signing the treaty initially and not yet ratifying it after it was signed by the Clinton administration in June 1993. Article 8(g) of the Convention obliges State parties 'to regulate living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.' The objection of the US to these provisions was that biotechnology is unfairly singled out while many other activities could have an impact on the environment and health: See David Bell, 'The 1992 Convention on Biological Diversity' (1993) 26 *George Washington Journal of International Law and Economics* 479 at 525–26. The US further argued that the biotechnology industry was already adequately regulated under US domestic law (*ibid*). The US also objected to the provisions of article 19(2) which was considered to be being inconsistent with patent and intellectual property rights (*ibid*).

43 For example see Alan Boyle, 'The Rio Convention on Biological Diversity' in Michael Bowman & Catherine Redgwell (eds), *International Law and the Conservation of Biological Diversity* (1996) at 33; Lakshman Guruswamy, 'The Convention on Biological Diversity: A Polemic' in Lakshman Guruswamy & Jeffery McNeely (eds), *Protection of Global Biodiversity: Converging Strategies* (1998) at 351; David Downes, 'New Diplomacy for the Biodiversity Trade, Biotechnology, and Intellectual property in the Convention on Biological Diversity' (1993) 4 *Towro Journal of Transnational Law* 1; Ashish Kothar, 'Beyond the Biodiversity Convention: A View From India' in Vincence Sanchez & Calestous Juma (eds), *Biodiplomacy: Genetic Resources and International Relations* (1994) at 67.

44 See Sean Murphy, 'Biotechnology and International Law' (2001) 42 *Harvard International Law Journal* 47 at 73; Amanda Hubbard, 'Comment: The Convention on Biological Diversity's Fifth Anniversary: A General Overview of the Convention – Where Has It Been and Where Is It Going?' 10 *Tulane Environmental Law Journal* 415 at 426.

to the *Gene Technology Act* and failure to insert those provisions into the *Gene Technology Act* may represent a breach of provisions of articles 8 and 14 of the *Biodiversity Convention*.

5. The 2000 Biosafety Protocol

The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* was adopted by over one hundred and thirty countries on 29 January 2000, pursuant to article 19(3) of the *Biodiversity Convention*.⁵⁷ The *Protocol* intends to establish an international legal framework to protect biological diversity from the potential risks posed by 'living modified organisms'. The *Protocol* applies 'to the trans-boundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.⁵⁸ The *Protocol* has forty articles and three annexes. The *Biosafety Protocol* is 'a historic attempt to reconcile economic and trade policies with environmental concerns'.⁵⁹

A. The Advanced Informed Agreement Procedure (AIA)

Under the *Protocol*, the trans-boundary movement of genetically modified organisms is subject to an international regulatory regime. The *Protocol* establishes a requirement that exporters must obtain permission in advance from importing countries before the first shipment of a particular 'living modified organism' for release into the

45 See William Lesser, *Sustainable Use of Genetic Resources under the Convention on Biological Diversity: Exploring Access and Benefit Sharing Issues* (1998).

46 Article 37 of the *Convention on Biological Diversity* provides: 'No reservation may be made to this Convention.' However, some developed states made declarations on signing the Convention. The EU made a declaration emphasizing the importance of technology transfer and biotechnology to ensure conservation and sustainable use of biological diversity and the importance of observing intellectual property rights: see Patricia Birnie & Alan Boyle, *Basic Documents on International Law and the Environment* (1995) at 390.

47 Australia signed the *Convention on Biological Diversity* on 5 June 1992 and ratified it on 18 June 1993.

48 Department of Environment and Heritage, *National Strategy on the Convention of Australia's Biological Diversity* <<http://www.deh.gov.au/biodiversity/publications/strategy/index.html>> accessed 21 April 2006.

49 UN Environment Programme, *Access to Genetic Resources and Benefit Sharing – Bonn Guidelines* <<http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp>> accessed 21 April 2006.

50 Department of Environment and Heritage, *National Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* <<http://www.deh.gov.au/biodiversity/publications/access/nca/index.html>> accessed 21 April 2006.

51 *Environmental Protection and Biodiversity Conservation Act 1999* (Cth), s 3(1)(e).

52 *Id* at s 3(1)(e), pt 12.

53 *Id* at s 3(1)(e), pt 14, div 4.

54 *Id* at ss 3(1)(e), 302; for a commentary on the Act, see Helen Mould, 'The Proposed Environment Protection and Biodiversity Conservation Act' (1999) 16 *Environmental and Planning Law Journal* 290.

55 *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth), Part 8A.

56 Anne Lin Jin Tsui, 'Australian Regulation of Gene Technology: Impacts on Biodiversity' (2004) 1 *Macquarie Journal of International and Comparative Environmental Law* 95 at 106.

57 Above n4.

58 *Biosafety Protocol*, above n4.

environment.⁶⁰ Therefore, advanced notice and permission are not necessary in relation to the export of agricultural products, which are for food and processing purposes. Some other types of GMOs are excluded from the scope of the AIA: most pharmaceuticals for humans that are addressed by other relevant international agreements and organizations;⁶¹ GMOs in transit to a third party;⁶² GMOs destined for contained use;⁶³ and GMOs which a meeting of the parties has declared as being safe.⁶⁴

Although GMOs that are used for food, feed and processing are not subject to the AIA procedure, they are subject to other regulations in the *Protocol* with a less rigorous regulatory regime. Article 11 of the *Protocol* requires that 'a party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to trans-boundary movement for direct use as food or feed, or for processing sale, within fifteen days of making that decision, inform the parties through the Biosafety Clearing House'.⁶⁵ Parties are obliged to make available to the Biosafety Clearing House copies of their national laws which regulate the import of LMOs intended for direct use as food or feed, or for processing.⁶⁶

B. The Application of the Precautionary Principle

The *Protocol* applies the precautionary principle.⁶⁷ The precautionary principle is used in international environmental law where there is scientific uncertainty. Principle 15 of the *Rio Declaration* states:

Where 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.

59 Nanda, above n9 at 236.

60 *Biosafety Protocol*, above n4, arts 7–16, 25–26 (entered into force 11 September 2003).

61 *Biosafety Protocol*, above n4, art 5.

62 *Id* at art 6.

63 *Ibid*.

64 *Id* at art 7(4).

65 *Id* at arts 11(1), 20(1). The Biosafety Clearing House is established to: (a) facilitate the exchange of scientific, technical, environmental and legal information of, and experience with, living modified organisms; and (b) assist parties to implement the Protocol, taking into account the special needs of developing country parties, in particular the least developed and small island developing states among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity. The Liaison Group of Technical Experts on the Biosafety Clearing House met in Montreal on 10–11 April 2003 to provide input on relevant technical issues which will be considered by the first meeting of the conference of parties to the *Convention on Biological Diversity* serving as the meeting of the parties to *The Biosafety Protocol*. The liaison made a number of recommendations including requirement for establishment of national components for participating in the Biosafety Clearing House by State parties. It also made recommendations in relation to data structure and management issues and training needs: *Liaison Group of Technical Experts on the Biosafety Clearing-House*, UN Doc UNEP/CBD/BC/LG-MTE/1/2 (2003).

66 *Biosafety Protocol*, above n4, art 11(5).

67 Above n23.

The definition and the application of the precautionary principle are not clear under international law. The meaning of the principle is evolving, but it can be argued that State practice supports that the principle generally reflects a tenet of customary international law.⁶⁸ The principle has now been recognised as a customary principle within the context of the European Union (EU).⁶⁹

During the *Biosafety Protocol* negotiations, there was a gap between the position of the EU and the Miami group (including Australia) in relation to the extent of inclusion of the precautionary principle into the provisions of the *Protocol*. While the Miami Group made minimal reference to the precautionary principle, the EU advocated a stronger version of the precautionary principle in the *Protocol*.⁷⁰

The *Protocol* provides a procedure, based on the precautionary principle, by which parties to the *Protocol* decide how to regulate the import of GMOs. According to article 11 of the *Protocol*:

[L]ack of scientific certainty, due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a leaving modified organism on the conservation and sustainable use of biological diversity, shall not prevent a party from taking a decision, as appropriate, with regard to the import of the living modified organism in question ...

This means that the *Protocol* expands on the precautionary principle and relies extensively on this principle. Therefore, the burden of proof in relation to the safety of technology is on the producers of the technology. This is a shift from the traditional approach in international law where the burden of proof used to lie with the person or State opposing an activity likely to prove of risk to that environment. These precautionary measures to indicate the importance of regulating the export, import and use of GMOs. This is based on the fact that, in dealing with the issue of GMOs, the health of humans is involved and requires extra precautionary measures be taken. Therefore, these provisions of the *Protocol* may establish international and national principles, which, in the future, may create legal responsibility for companies and scientists who are involved with the production of GMOs. The *Protocol*, however, does not establish a liability regime for adverse health effects caused in an importing country resulting from an imported GMO product.⁷¹

The inclusion of an expanded version of the precautionary principle in the provisions of the *Protocol* was considered as the first use of the principle in an international environmental instrument.⁷² However, according to another commentator, the inclusion of the precautionary principle in the *Biosafety Protocol* was

68 Philippe Sands, *Principles of International Environmental Law* (2nd ed, 2003) at 279: 'There is certainly sufficient evidence of state practice to support the conclusion that the principle, as elaborated in Principle 15 of the Rio Declaration and various international conventions, has now received sufficiently broad support to allow a strong argument to be made that it reflects a principle of customary law'.

69 Ibid.

70 International Centre for Trade and Sustainable Development, 'Biosafety Protocol Negotiations to Resume in January' (1999) 3 *Bridges* 7 at 11.

71 Jabara, above n10 at 137.

used by the EU and NGOs during the negotiations to conclude the *Protocol* as a 'stalking horse for surreptitious, undemocratic social change'.⁷³

Obviously, the *Biosafety Protocol* uses a strong version of the precautionary principle in regulating the use and trade in genetically modified organisms. However, it is clear that the exact limit of the principle is not clearly defined in international law. Nonetheless, the position of the *Protocol* in applying a strong interpretation of the precautionary principle is a forward step in relation to protection of the global environment and human health.

C. The Biosafety Protocol and the GATT/WTO

The provisions of the *Biosafety Protocol* permit member States to impose restrictions on the import and export of certain biotechnology products. This may be inconsistent with certain provisions of the GATT.⁷⁴ The *Protocol's* provisions may also be inconsistent with WTO agreements including the *Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement)*⁷⁵ and the *Agreement on Technical Barriers to Trade*.⁷⁶ The provisions of the two WTO agreements are inconsistent with the approach of the *Biosafety Protocol* in accepting the precautionary principle. Under the *SPS Agreement* 'members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence'.⁷⁷

According to some, there is no major inconsistency between the provisions of the *Biosafety Protocol* and the GATT/WTO agreements.⁷⁸ The *Agreement on Technical Barriers to Trade* provides that technical regulations and standards, including packing, marking and labelling requirements, shall not create unnecessary obstacles to international trade.⁷⁹ Although the preamble of the *Biosafety Protocol* provides that 'this protocol shall not be interpreted as implying a change in the rights and obligations of a party

72 Heike Baumüller, 'The Cartagena Protocol on Biosafety—Environmental Perspectives' (2001) 18 *Environmental and Planning Law Journal* 46 at 51; International Centre for Trade and Sustainable Development 'Victory for the Environment': The Cartagena Protocol is Based on the Precautionary Principle' (2000) 4 *Bridges* 1 at 17.

73 Andrew Thomson, 'The Dangers of Secret Treaty-Making: The Biosafety Protocol as a Case Study' (2000) *Review* 21 at 22.

74 *General Agreement on Tariffs and Trade*, opened for signature 30 October 1947, 55 UNTS 194 (entered into force). The GATT has been amended a number of times, most importantly as part of the Uruguay Round in 1994. The GATT calls for non-discrimination between foreign and domestic goods (article 3) and prohibits on quantitative restrictions on imports or exports (article 11).

75 *Agreement on the Application of Sanitary and Phytosanitary Measures* (15 April, 1994), Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A, Legal Instruments—Results of the Uruguay Round, vol 27 <http://www.wto.org/english/docs_e/legal_e/15-sps.pdf> ('*The SPS Agreement*').

76 *Agreement on Technical Barriers to Trade* (1994) (WTO Agreement, Annex 1A, Legal Instrument—Results of the Uruguay Round, vol 1).

77 *The SPS Agreement*, above n75, art 2(2).

78 See generally Sabrina Safrin, 'Treaties in Collision? The *Biosafety Protocol* and the World Trade Organization Agreements' (2002) 96 *American Journal of International Law* 606.

79 *The SPS Agreement*, above n75, art 2(2).

under any existing international agreement',⁸⁰ it fails to settle the question of its relation with the GATT/WTO agreements. In particular, the preamble, immediately after the passage, states that 'the above recital is not intended to subordinate this protocol to other international agreements.' However, the provisions of the *Protocol* do not make clear how conflicts between GATT and the *Protocol*⁸¹ should be resolved.

Already, disputes have erupted between the US and the EU over the export and the import of GM foods. The EU had a four-year freeze on import arrivals from biotechnology products.⁸² This persuaded some members of the US Congress to press the Bush Administration to take necessary action with the WTO.⁸³ In 2003, the US, Argentina and Canada took legal action against the EU moratorium before the WTO and against the labelling requirements of the genetically modified food being enforced in the EU countries. They argued that the EU ban is breaching the provisions of the *SPS Agreement*. Under the *SPS Agreement*, parties may prohibit imports due to safety concerns only if there are scientifically justified reasons and without discriminating against trading partners. However, the EU member States base their argument on the precautionary language in the *SPS Agreement* which provides for precautionary provisional measures to be implemented where scientific evidence is insufficient.⁸⁴

In February 2006, the WTO panel handed down its interim report condemning the EU moratorium on genetically modified organisms.⁸⁵ The interim ruling was considered a victory for the agricultural biotechnology industries which were battling opposition to their products from European governments.⁸⁶ However, the verdict does not object to the labelling requirements of genetically modified food.

The Australian federal Agriculture Minister has spoken out against countries with moratoria on GM foods and declared his opposition to such bans.⁸⁷ Within Europe, dispute erupted following an Italian ban on GM foods derived from maize.⁸⁸ A

80 *Biosafety Protocol*, above n4, preamble.

81 The *travaux préparatoires* of the *Biosafety Protocol* shows that the participating parties were divided into three camps on the issue of the relationship between the Protocol and the other international treaties. The Miami Group (Argentina, Australia, Canada, Chile, the United States and Uruguay) firmly held that the Protocol should expressly provide that it did not alter a party's existing international rights and obligations: *Extraordinary Meeting of Conference of Parties*, 1st mtg, Annex III at 17, para 7(a), UN Doc UNEP/CBD/ExCOP/1/3 (2000). A group of other states, including the European Union, took the position that the Protocol should be silent on the issue of its relations with other international trade conventions: *Extraordinary Meeting of Conference of Parties*, 1st mtg, Annex II at 15, 16, para 3, UN Doc UNEP/CBD/ExCOP/1/3 (2000). Some other States, including most developing countries, took a middle position to include a clause similar to article 22 of the *Convention on Biological Diversity*. Article 22 of the Convention provides 'the provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.' 'The chairman of the Biosafety working group (the negotiating body for *The Biosafety Protocol*) ultimately included this approach in his suggested compromise treaty text, which he produced during the final days of the penultimate round of negotiations on the Protocol in Cartagena': Safrin, above n78 at 615.

82 For a legal analysis of this dispute, see Charles Smitherman, 'World Trade Organization Adjudication of European Union–United States Dispute over the Moratorium on the Introduction of New Genetically Modified Foods to the European Common Market: A Hypothetical Opinion of the Dispute Panel' (2002) 30 *Georgia Journal of International and Comparative Law* 475.

83 'Court Rejects Italian GM Ban', *Chemistry and Industry* (17 March 2003) at 7.

preliminary opinion issued by a judge of the European Court of Justice in March 2003 indicated that the Italian ban may be endorsed by the court provided that new evidence proving risks to human health or the environment can be provided.⁸⁹

D. Australia and the Biosafety Protocol⁹⁰

The *Biosafety Protocol* is still to be signed by Australia. Nevertheless, Australia was actively involved during the negotiations which led, in 2000, to the adoption of the *Protocol's* text. When the negotiations on the *Biosafety Protocol* began in 1995, Australia, along with a number of agricultural exporting nations including Argentina, Canada, Chile, Uruguay and the US, was part of the Miami group. That group was an informal caucus of agriculture exporting nations. It was evident that Australia and the US held the line against the position of the EU nations, developing countries and NGO allies, but later both Australia and the US capitulated to the EU.⁹¹

The government of Australia has not indicated any timetable for considering the possibility of acceding to the *Biosafety Protocol*.⁹² In its official position in relation to signing the *Biosafety Protocol*, the government has expressed concerns about the operation of the *Protocol*; uncertainty about the methods of implementation of the *Protocol* by parties and 'whether they will do so in a way which respects all of their international obligations, including those under the World Trade Organization', and uncertainty about meeting rules under the *Protocol*.⁹³ Further, the Australian Government believes that the *Biosafety Protocol* does not help in managing GMO imports because the Office of the Gene Technology Regulator, along with a robust regulatory framework, is able to effectively manage GMO imports.⁹⁴

The Chairman of the Parliamentary Joint Standing Committee on Treaties argued that the *Biosafety Protocol* 'is a terrible treaty. Far from arguing about whether or not to sign it, the Australian Government ought to be busy organising a campaign to destroy it.'⁹⁵ He further asserts that the 'argument against the global green NGO movement is very much a David and Goliath struggle'.⁹⁶

The official reasons provided by the Australian Government for *not* signing the *Protocol* do not all seem genuine. Such objections could be applied to any international treaty. Uncertainty may exist in relation to the implementation of most multilateral treaties. Furthermore, concerns may arise in relation to the operation of any international treaty. It is therefore hard to come to a conclusion why Australia, in spite

84 *The SPS Agreement*, above n75, art 5.7 provides: 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.'

85 International Academy of Life Sciences, *WTO Condemns EU Moratorium on GMOs* <http://www.lifesciencesblog.com/2006/03/wto-condemns_eu_moratorium_on.html> accessed 18 September 2006.

86 Jennifer Thomson, 'Use Biotechnology to Feed the Poor', *The Australian* (7 August 2006) at 14.

87 Above n82.

88 *Agra Europe* (14 March 2003) at 3.

89 *Ibid.*

of participation in the work of the Intergovernmental Committee for the *Cartagena Protocol* (ICCP),⁹⁷ has not acceded to the *Protocol*. It seems that the fact that Australia is an important agricultural producer and a user, developer, importer and exporter of biotechnology products may explain its caution in joining a very comprehensive international treaty, which puts significant international obligations on individual States with respect to regulating the use and trade in GM products. Further, as the Australian Government may have genuine concern that provisions of the *Biosafety Protocol* may have adverse effects on regulations on free trade in agricultural products which are based on provisions of the WTO/GATT and associated agreements. This is particularly evident from the Australian Government's position during the negotiations. Australia argued that the provisions of the *Protocol* should be consistent with other international obligations of the parties and should achieve 'its environmental objective without unnecessarily disrupting trade.'⁹⁸

Whether or not Australia accedes, the *Protocol* will significantly impact on Australia as an important agricultural producer and as a user and exporter of GMOs. A large number of countries are parties to the *Protocol* and they will implement the provisions of the *Protocol* into their domestic law. Certainly this will have an impact on those Australian companies which export or import GM products to those countries. Article 24(1) of the *Protocol* provides that 'trans-boundary movements between parties and non parties shall be consistent with the objective of this Protocol.' Obviously, international treaties do not create obligations for third parties⁹⁹ which are not parties to a convention but they may have effects on trade relations between parties and those

90 In the United States, Genetically Modified Organisms are subject to a fragmented regulatory system involving the following agencies: United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). For the position of the United States see Heather Ellison, 'Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?' (2002) 10 *Penn State Environmental Law Review* 345; Julie Teel, 'Regulating Genetically Modified Products and Processes: An Overview of Approaches' (2000) 8 *New York University Environmental Law Review* 649; John Barton, 'Biotechnology, the Environment, and International Agriculture Trade' (1996) 9 *Georgia International Environmental Law Review* 95; Gregory Jaffe, 'Inadequacies in the Federal Regulation of Biotechnology' (1987) 11 *Harvard Environmental Law Review* 491; Judith Beach, 'No "Killer Tomatoes:" Easing Federal Regulation of Genetically Engineered Plants' (1998) 53 *Food and Drug Law Journal* 181. For the position of the European Union law and practice see Nanda, above n9; Kara-Anne Yaren, 'Trade and Genetically Modified Foods: Frankenfears: A Call for Consistency' (2001) 1 *Asper Review of International Business and Trade Law* 149; and Mary Lynne Kupchella, 'Agricultural Biotechnology: Why It Can Save the Environment and Developing Nations, but May Never Get a Chance' (2001) 25 *William and Mary Environmental Law and Policy Review* 721; Brian Cain, *Legal Aspects of Gene Technology* (2003).

91 Thomson, above n73 at 21.

92 The position of the Australian government can be found on the Australian Department of Foreign Affairs' home page: DFAT, *Cartagena Protocol on Biosafety* <<http://www.dfat.gov.au/environment/bsp/>> accessed 12 April 2006.

93 *Ibid.*

94 *Ibid.*

95 Thomson, above n73 at 23.

96 *Ibid.*

97 ICCP was convened after the adoption of *The Biosafety Protocol* to prepare for the Protocol's coming into force.

98 See DFAT, above n92.

which are not parties to a treaty. Further, the *Protocol* may, in the future, create some kind of standard practice among States and establish principles of customary international law.

The Australian Government and certain industries and business groups, such as the National Farmers' Federation, are opposing the signing of the *Biosafety Protocol*. There is no obligation in international law to compel a nation to enter into an international treaty. However, the area of biotechnology, similar to climate change, requires strong international cooperation to protect the global environment against possible environmental risks. While nearly two thirds of the world's nations have signed and ratified an international treaty which provides for protection of the global environment, Australia should seriously consider signing and ratifying the *Biosafety Protocol* too.

6. The Gene Technology Act 2001 (Cth)

The Australian *Gene Technology Act* is not particularly a piece of legislation in response to the *Biosafety Protocol* nor is it intended to implement Australia's international obligations. Indeed the legislation is an Australian national response to regulate the use of and trade in GMOs. In connection with biotechnology, the *Gene Technology Act 2001 (Cth)*¹⁰⁰ covers the legal issues relating to GMOs including research, production, propagation, commercial release, import, transport and disposal.¹⁰¹ The aim of the Act is to protect the health and safety of people and the environment through the identification of the risks posed by, or resulting from, gene technology.¹⁰² The Act intends to manage the risks by regulating certain dealings with GMOs.¹⁰³ The Act makes provisions in relation to live and viable GMOs.¹⁰⁴ The Act states that it covers the legal issues relating to GMOs which are not subject to an existing regulatory regime.¹⁰⁵ This means an extensive body of laws and regulations relating to food, medicine, research, agricultural chemical, customs, quarantine and import and export law, plus the *Gene Technology Act 2001 (Cth)*, regulates gene technology in Australia. The regulatory system is obviously extensive because Australia is a major agricultural producer and needs to regulate what is directly relevant to research and the use of GMOs. The regulatory system is fragmented because the area is new and time is needed for a unified regulatory system to emerge. The Act, like the *Biosafety Protocol*, applies the precautionary approach. According to section 56 of the Act, the Gene Technology Regulator¹⁰⁶ must not issue a GMO license unless satisfied that any

99 See *Vienna Convention on the Law of Treaties*, opened for signatures 23 May 1969 (entered into force 27 January 1980), art 34.

100 The Act has already been amended by *Gene Technology (Consequential Amendments) Act 2000 (Cth)* and the *Gene Technology (License Charges) Act 2000 (Cth)*.

101 Detail of the regulatory scheme is in the *Gene Technology Regulations 2001 (Cth)*.

102 *Gene Technology Act 2000 (Cth)*, s 3.

103 *Ibid.*

104 *Id* at s 10.

105 *Id* at ss 10, 4(b) and 15.

106 The Regulator means the Gene Technology Regulator appointed under *Gene Technology Act 2000 (Cth)*, s 118.

risks posed by the dealings proposed to be authorised by the license are manageable in such a way as to protect the health and safety of people and the environment.¹⁰⁷ The Act refers to the 'health and safety of people and the environment' in a number of sections.¹⁰⁸ The Act establishes the Gene Technology Advisory Committee, the Community Consultative Committee and the Gene Technology Ethics Committee from which the Regulator may request technical and expert advice.¹⁰⁹

There is also a national regulatory scheme in Australia, established in 2001, to regulate the use of and trade in GMOs. The scheme is implemented through a national cooperative scheme of State and Commonwealth legislation and an intergovernmental gene technology agreement.¹¹⁰

The Regulator has issued the first license under the Act to trial a genetically modified crop. The license was issued to allow Cotton Seed Distribution to carry out a limited release of two types of genetically modified insecticide- and herbicide-resistant cotton on a 122 hectare site in Queensland.¹¹¹ At the same time, the Regulator rejected an application for the commercial release of two types of GM cotton because of the possibility that they might become a weed problem.¹¹²

Finally, in April 2003 the Regulator declared that GM canola was no more dangerous than conventional canola crops.¹¹³ This cleared the way for Australia to have its first commercial genetically modified crops. On 25 July 2003 the Regulator granted a license for the first commercial GM canola.¹¹⁴ But scientific uncertainty remains. In April 2006, the Australian Government announced funding for eight major studies to be conducted to clarify the implications of introducing GM technology and to decide the future role of GM crops.¹¹⁵

During the last few years, since the Act came into force, some commentators have praised the Act for not only its response to the community's concerns in relation to the impact of GMOs on health, safety, ethics and the environment, but also for its attempt to involve the community in the development of a regulatory regime dealing with GMOs.¹¹⁶ It has been said that the Act establishes a new era in the regulation of gene technology.¹¹⁷

107 *Gene Technology Act 2000* (Cth), s 56(1).

108 For example see *Gene Technology Act 2000* (Cth), ss 3, 49, 51, 58, 65, 66, 70, 71, 74, 75 and 185.

109 *Gene Technology Act 2000* (Cth), pt 8.

110 For an analysis of States and Commonwealth regulatory national system in response to releases of Genetically Modified Organisms see Karinne Ludlow, 'Cultivating Chaos: State Responses to Releases of Genetically Modified Organisms' (2004) 9 *Deakin Law Review* 1.

111 (2002) 1 *National Environmental Law Review* at 13: The Regulator announced the issue of the license on 19 January 2002.

112 John Ashe, 'Recent Development' (2002) 4 *National Environmental Law Review* 6 at 10. The rejection was announced on 24 September 2002.

113 'All-Clear Given for GM Canola Seeds', *Sydney Morning Herald* (2 April 2003).

114 Stephanie Peatling, 'GM Canola Ruled Safe, But Seeds of Doubt Remain', *Sydney Morning Herald* (26–27 July 2003) at 9.

115 *The Weekend Australian* (29–30 April 2006) at 6.

116 Geraldine Chin, 'The Role of Public Participation in the Genetically Modified Organisms Debate' (2000) 17 *Environmental and Planning Law Journal* 519 at 527.

117 Belinda Bennett & Greg Williams, 'Gene Technology Regulation: The Australian Approach' (2001) 1 *Biotechnology Law and Policy Reporter* 29 at 31.

There is no doubt that the *Gene Technology Act* is a comprehensive piece of legislation, covering a large number of issues relating to the development and use of GMOs in Australia. The Act is the result of a comprehensive study in the last few years and facilitates cooperation between the federal government and States and Territories of Australia. Whether the Act is successful in achieving its objectives remains to be seen. The Act came into force in 2000 and the Office of Gene Technology Regulation¹¹⁸ was officially launched on 21 June 2001. It will take several years at least to see whether the Act can efficiently protect the health of people and the environment with respect to this new technological area so subject to scientific uncertainties.

7. Conclusion

Complications resulting from the development and use of genetically modified foods in agriculture in relation to the health and safety of people and the environment have generated government action at both the international and national levels. These issues, exacerbated by scientific uncertainty, have given rise to international and national legal disputes. Since the issue of genetic engineering in agricultural products is still fairly new, its legal boundaries at both the international and domestic levels are not well defined.

Attempts have been made by States to regulate the use of biotechnology. The *Biodiversity Convention* and its *Biosafety Protocol* are two international instruments which have made provision for regulating biotechnology in agriculture and other areas.

The *Biosafety Protocol* has been signed by a large number of States and is in force. It attempts to regulate the use of biotechnology and adopts, rightly, the precautionary principle. It may take several years after the commencement of the *Protocol* to establish well-accepted rules and principles of international law in the area of biotechnology in agriculture. However, the large number of participants in concluding the *Protocol* and its important task — the protection of the environment and public health — has already influenced international law. The *Protocol* is one of the few international treaties which may have provisions inconsistent with the concept of free trade embodied in GATT/WTO associated agreements. Perhaps, in the face of inconsistency, the *Protocol* provisions will prevail, because any risk and damage to human health resulting from GMOs may lead to extensive and expensive litigation in international and national legal systems based on other principles of international and domestic law.

Australia has enacted law to implement terms of the *Biodiversity Convention*. The *Environment Protection and Biodiversity Conservation Act 1999* (Cth) has provisions in relation to access to biological resources. The biosafety legislation deals with a large number of legal issues in relation to GMOs, including research, production, commercial release and importation. However, whether or not the Act is successful remains to be seen. Nonetheless it is a significant attempt by the Australian Government to regulate GMOs within Australia's national borders.

118 The Office of Gene Technology Regulation is a Commonwealth regulatory agency under the *Gene Technology Act 2001* (Cth), which is located within the Health and Aged Care portfolio.

The emerging international legal framework relating to biotechnology in agriculture and other areas needs the support of States, international organizations, national institutions and individuals to establish efficient rules to deal with legal issues resulting from the development and use of biotechnology. The issue is one of the most important and sensitive areas of international law, because the health and safety of people and the risk of widespread and irreversible damage to the environment are involved. It is unfortunate that Australia, which has a good record of participation in international organizations and international cooperation, has failed to join the rest of international community in regulating agricultural biotechnology.

The precautionary principle applied in the *Biosafety Protocol* should be adopted as a standard clause in both international instruments and national laws and policies, while waiting for science and technology to provide a clear answer with respect to the safety and the risks of GMOs. A proper international legal framework and a more consistent national legal approach by States will contribute to the safe and sound development of biotechnology in agriculture and other areas.