



Università
degli Studi
di Ferrara

Department of Law

Food, Biotechnology and Agriculture

Course Information
2018

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COURSE DESCRIPTION

Introduction and unit content

This unit covers three inter-related topics: food regulation, biotechnology and agriculture

Food regulation

This unit will provide a detailed examination of the application of UK and EU food laws and standards dealing with: food safety and food hygiene; hazards, warning systems and crisis management; food labeling; genetically modified foods; the roles played by organisations such as Codex Alimentarius, WHO, WTO, The European Commission, the and consumer protection authorities. The unit will also look at the issue of food loss and waste.

Biotechnology

This unit will focus upon the intellectual property aspects of agri-biotechnology, including: patenting, plant variety rights protection, trade secrets law and geographical indications

Agriculture

This unit will focus upon those WTO Agreements which have a bearing on food regulation and biotechnology, including the Agreement on Agriculture and the Agreement on Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade. Additionally, the unit will examine international attempts to protect plant genetic resources for food and agriculture.

Lecture Schedule

Class Topic/modules

- | | |
|---|---|
| 1 | Food Security |
| | <ul style="list-style-type: none">• Definition of food security• Political responses• The right to food• Sustainable development |
| 2 | Food Loss and Waste |
| | <ul style="list-style-type: none">• Definitions• Metrics• Minimising FLW |
| 3 | Patents, Plant Breeding and Biotechnology |
| | <ul style="list-style-type: none">• WTO TRIPS Agreement• Invention and genetic engineering• Myriad Genetics litigation• Genetic modification and patenting |
| 4 | Biotechnological patenting and climate change |

- Climate change
 - Climate-ready patents
 - GM and negligence
 - GM crops in developing countries
- 5 GM Agriculture
- Food from GE agriculture-should we worry?
 - EU legislation
 - Genome editing - CRISPR
- 6 Plant Variety Rights
- The UPOV Convention, 1991 Act
 - Regional Arrangements (eg CPVR)
 - National Legislation
 - Patenting of plant breeding methods
- 7 Biopiracy Case Studies
- Plant breeding
 - Biodiversity
 - Biopiracy
 - Case studies
 - Role of patents in biopiracy
- 8 Access to Genetic Resources and Benefit Sharing
- Convention on Biological Diversity
 - International Treaty on Plant Genetic Resources for Food and Agriculture
 - The Bonn Guidelines
 - The Nagoya Protocol.
- 9 9.1 Introduction to GIs
- What are GIs
 - History of GIs
 - GIs and Trademarks
 - International Protection of GIs
 - Protection of GIs in Europe
 - Australia and USA v EU in the WTO
- 9.3 Protection of GIs in Europe
- EU trade in GIs products
 - EU legislation
 - Infringement
 - Traditional Specialities Guaranteed
 - Proposed extension of EU law to handicrafts
- 9.4 EU Agricultural Policy and GIs
- Common Agricultural Policy (CAP)
 - Regulation 1308/2013 establishing a common organisation of the markets in agricultural products
 - New World v Old World
- 10 10.1 Biosafety -The Cartagena Protocol
- Establishing the Cartagena Protocol
 - Key provisions of the Protocol

- Linkage with other instruments
- 10.2 Food Safety and the Precautionary Principle
 - Starlink Corn
 - Food Scares
 - EU-Framework Legislation Feed and Food Safety
- 10.3 Labelling of GMOs
 - EU legislation
 - European Food Safety Authority (EFSA)
 - GM labelling
- 11 SPS and TBT Agreements
 - Sanitary and Phytosanitary (SPS) Agreement
 - Technical Barriers to Trade (TBT) Agreement
- 12 Enforcement of Intellectual Property Rights in the Field of Agriculture
 - TRIPS Agreement
 - EU Draft Criminal Enforcement Directive
 - EU Civil Enforcement Directive
 - EU Customs Regulation
- 13 Exam

RESOURCES

Required text(s) and materials

Text

There is no prescribed text for this course as it ranges across three broad areas. Teaching materials are made available below.

The following texts will be quite useful: *food law*: Gabriela Steier and Kiran K Patel, *International Food Law and Policy*, Springer, 2018; Caoimhin MacMaolain, *Food Law. European, Domestic and International Frameworks*, Hart publishing, 2015; Barry Atwood, Katherine Thompson and Chris Willett, *Food Law*, 3rd Edition, Tottel Publishing, 2009; *agri-biotechnology*: Matthew Rimmer, *Intellectual property and Biotechnology: Biological Invention*, Edward Elgar, 2008; *Genetic Resources and Traditional Knowledge. Case Studies and Conflicting Interests*. Edited by Tania Bubela and Richard Gold. Edward Elgar, 2012; Charles Lawson, *Regulating Genetic Resources: Access and Benefit Sharing in International Law* (Google eBook) *agriculture*: Michael Blakeney, *Intellectual Property Rights and Food Security*, CAB International 2009; Michael Blakeney, *The Protection of Geographical Indications. Law and Practice* Cheltenham UK, Edward Elgar 2014

On-line Materials

A good deal of information is now also available on-line. Useful websites include:

International Organisations

- Convention on Biological Diversity www.cbd.int
- Food and Agricultural Organization (FAO) www.fao.int
- United States Patent And Trade Mark Office: www.uspto.gov/
- World Health Organization: www.who.org/

- World Intellectual Property Organisation: www.wipo.org/
- World Trade Organisation Intellectual Property Page: www.wto.org/wto/intellect/intellect.htm

Research Centres

- Australian Centre for Intellectual Property in Agriculture: <http://law.anu.edu.au/acipa/>
- Bancroft Library: Bioscience and Biotechnology : <http://bancroft.berkeley.edu/Biotech/>
- Cambridge University: The Intellectual Property Unit : <http://www.law.cam.ac.uk/ipunit/>
- Cardozo University: http://www.cardozo.yu.edu/ip_program/index.html
- Institute of Intellectual Property, Tokyo : <http://www.iip.or.jp/e/index.html>
- Intellectual Property Research Institute of Australia: <http://www.ipria.org/>
- Intellectual Property Society of Australia and New Zealand Inc. : <http://www.ipsanz.com.au/>
- Max Planck Institute For Foreign And International Patent, Copyright And Competition Law, <http://www.intellectprop.mpg.de/Enhanced/English/Homepage.HTM>
- Oxford Intellectual Property Research Centre, <http://www.oiprc.ox.ac.uk/>
- Queen Mary Intellectual Property Research Institute, University of London , <http://www.ccls.edu/iplaw/>
- Sheffield Institute of Biotechnological Law and Ethics , <http://www.shef.ac.uk/uni/projects/sible/sible.html>

Readings

- Abbott, Frederick M. Thomas Cottier, Francis Gurry, *The International Intellectual Property System, Commentary and Materials*, Kluwer Law International, 1999.
- **Albert, J.** 'New technologies and food labelling: the controversy over labelling of foods derived genetically modified crops', in J Albert (ed.), *Innovations in Food Labelling*, The Food and Agriculture Organization of the United Nations and Woodhead Publishing Limited, Cambridge, 2010, pp. 154–61.
- Battiste, Marie, *Protecting Indigenous Knowledge And Heritage: A Global Challenge*, Saskatoon: Purich Pub., 2000.
- **Blakeney, Michael**, *Intellectual Property Rights and Food Security*, Wallingford, Oxford CABI, 2009 This book deals with biotechnology and agriculture.
- **Blakeney, Michael**, *The Protection of Geographical Indications. Law and Practice* Cheltenham UK, Edward Elgar 2014. This book deals with EU geographical indications law.
- **Blakeney, Michael** 'Recent developments in intellectual property and power in the private sector related to food and agriculture' (2011) 36 *Food Policy* Supplement 1, 109-113.
- **Blakeney, Michael** 'Legal liabilities arising from the development, cultivation and use of GM crops (part 1)' (2010) 4 *Environmental Liability* 134-148.
- **Blakeney, Michael** 'Legal liabilities arising from the development, cultivation and use of GM crops (part 2)' (2010) 4 *Environmental Liability* 171-179.
- **Blakeney, Michael** , 'Patents and Plant Breeding: Implications for Food Security' (2011). 3(3) *Amsterdam Law Forum* 73-88. VU e-Publishing, Amsterdam.
- **Blakeney, Michael**, 'Climate change and gene patents' (2012) 1(2) *Queen Mary Journal of Intellectual Property*, 2–13.

- **Blakeney, Michael**, 'Patenting of Plant Varieties and Plant Breeding Methods', (2012) 63(3) *Journal of Experimental Botany* 1069-1074.
- **Blakeney, Michael**, 'Geographical Indications and the International Trade in Australian Wines' (2012) 18 (1) *International Trade Law & Regulation* 70-78.
- **Caraher M and Coveney J**, 'Public health nutrition and food policy', *Public Health Nutrition*, 2003, 7(5), pp. 591-598.
- **FAO** (Food and Agriculture Organization) and **WHO** (World Health Organization), 'Hazard analysis and critical control point (HACCP) system and guidelines for its application' in FAO/WHO 1997, *Codex alimentarius: food hygiene: basic texts*, Second Edition, Rome, 1997.
- **Food Regulation Agency (UK)**, *Better regulation initiatives, United Kingdom*, www.food.gov.uk/foodindustry/regulation/betregs/ (Simplification of regulation, strategies to deliver better outcomes)
- **Food Standard Agency (UK)**, *Simplification Plan 2006/07*, London (List of initiatives to reduce the burden of UK and EU food standards, administrative and policy costs)
- **Grubb, Philip W**, *Patents for chemicals, pharmaceuticals, and biotechnology: fundamentals of global law, practice, and strategy*, Oxford: Clarendon Press, New York: Oxford University Press, 1999.
- **Grunert, KG & JM Wills**, 'A review of European research on consumer response to nutrition information on food labels', *Journal of Public Health*, vol. 15, no. 5, 2007, pp. 385–99
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- **Heasman, M.**, *UK Food Policy and Strategy For The Next 20 Years Unveiled*, Food for Good (blog), 9 January 2010, viewed 3 December 2011, <http://www.foodforgoodblog.com/food_business_ethics_by_m/2010/01/uk-food-policy-and-strategy-for-the-next-20-years-unveiled.html>.
- **Ilardi, Alfredo and Michael Blakeney**, *International Encyclopaedia of Intellectual Property Treaties*, Oxford University Press, 2004.
- **Khor, M.** *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*. London . Zed Books, 2002.
- **Krattiger, Anatole et al** (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Oxford, MIHR, 2007
- **Labelling Logic. Review of Food Labelling Law and Policy**, Canberra, AGPS, 2011.
- **McManis, C.** Ed. *Biodiversity and the Law. Intellectual Property, Biotechnology and Traditional Knowledge*. London, Sterling, VA. Earthscan 2007.
- **Malbon, J and Lawson, C.**, *Interpreting and Implementing the TRIPS Agreement. Is it Fair?* Cheltenham UK, Edward Elgar, 2008.
- **Maskus Keith E.**, *Intellectual Property Rights in the Global Economy* Washington, D.C. Institute for International Economics, 2000.
- **May, Christopher and Sell, Susan**, *A Critical International History of Intellectual Property Rights*, Lynne Rienner Publishers 2005.
- **Miletic, B.**, 'How safe is our food?', www.safetysolutions.net.au/feature_article/article.asp?item=721, 2004
- **Nolff, Markus**, *Trips, PCT, And Global Patent Procurement*, London: Kluwer Law International, 2001.
- **Oguamanam, C.** *International Law and Indigenous Knowledge. Intellectual Property, Plant Biodiversity and Traditional Medicine*, Toronto, University of Toronto Press, 2006.

- **OutBreak**, *OutBreak Food Safety Consulting*, Seattle, www.outbreakinc.com/
- **OzFoodNet**, *OzFoodNet - Enhancing surveillance for foodborne disease in Australia*, www.ozfoodnet.org.au/internet/ozfoodnet/publishing.nsf/Content/what-isozfoodnet-1, 2005.
- **Patnoad, M S**, *Food Safety Education in England: A Report from the NEHA/CIEH Sabbatical Exchange Program*, *Journal of Environmental Health*, 2001, vol. 62, no. 10, pp. 21-26.
- **Petersmann, Ernst-Ulrich and Harrison, James** eds., *Reforming the World Trading System: Legitimacy, Efficiency and Democratic Governance* Oxford University Press, 2005.
- **Rimmer, Matthew**, *Intellectual Property and Biotechnology*, London, Edward Elgar, 2008 (available as a Google book). An Australian study with an agricultural focus.
- **Smith D & Riethmuller P** *Consumer concerns about food safety in Australia and Japan*, *British Food Journal*, 2000, vol. 102, no. 11, pp. 838-855.
- **Somsen, Hans**, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents*, Cheltenham, Edward Elgar, 2007
- **USDA** (United States Department of Agriculture), *Food Safety and Inspection Service: Protecting public health through food safety and defense*, Washington DC, www.fsis.usda.gov/index.asp

Readings

1. Food Security

M. Blakeney, *Intellectual Property Rights and Food Security*, Wallingford. CAB International. 2009, ISBN 978-1-84593-560-3

1. Intellectual Property and Food Security – Policy Issues

1.1 Food Security Defined

Hunger is a profound affront to human dignity and human rights. It is a fundamental constraint to development, fuels conflict and crime, reduces productivity and shortens life span. At the World Food Summit (WFS), convened in Rome in 1996, by the Food and Agriculture Organization of the United Nations it was reported that more than 800 million people, particularly in developing countries, do not have enough food to meet their basic nutritional needs. It was estimated that some 400,000 people were killed by malnutrition daily. The 185 countries participating at the Rome Summit, vowed to achieve universal food security.

The Rome Declaration, which was issued by the 1996 Summit pledged to cut the number of hungry people in half by 2015. This goal was also included in the Millennium Declaration of the United Nations in 2000. This objective required the number of undernourished to fall at a rate of 20 million per year. However, data in 2001 indicated that the rate of decline was less than 8 million per year.¹

¹ FAO, 'Some issues relating to food security in the context of the WTO negotiations on agriculture'

FAO Geneva Round Table on Food Security in the Context of the WTO Negotiations on Agriculture,
20 July 2001, 2.

At the current rate of global population increase it has been estimated that the global demand for cereals will increase by 20% between 1995 and 2020 and that net cereal imports by developing countries will have to double to meet the gap between production and demand.² Currently, the developing world is a net importer of 88 million tons of cereals a year at a cost of US\$14.5 billion and that the global demand for cereals will increase by 40% between 1995 and 2020.³ Paradoxically, a 1999 study of the International Food Policy Research Institute (IFPRI) has estimated that world food supply would continue to outpace population growth at least to 2020.⁴

Food security as defined by the 1996 World Food Summit is a situation in which all people at all times have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. However, it should be noted that there is a large number of definitions of food security⁵ and that these tend to be influenced by perceptions of the policy options by which food insecurity might be cured. Scoones⁶ traces the definition from its 1974 World Food Conference connotation of access to the availability of food⁷, through the World Bank's 1986 definition of food security in the sense of access to sustain a healthy life.⁸ Indicators of food security can be defined at different levels – for the world as a whole, for individual countries, or for households.⁹ At the national level, adequate food availability means that on average sufficient food supplies are available, from domestic production and/or imports, to meet the consumption needs of all in the country.

As can be seen from the 1996 World Food Summit definition, in the most recent discussions food security is discussed in a human rights context as concerning the individual. Its principal determinant therefore is the individual's entitlement to food – ability to produce and/or purchase food.

2. Causes of Food Insecurity

The opposite of food security is food insecurity. Food insecurity can be transitory (when it occurs in times of crisis), seasonal or chronic (when it occurs on a continuing basis). A person can be vulnerable to hunger even though he or she is not actually hungry at a given

² P. Pinstrup-Andersen, R. Pandya-Lorch and M.W. Rosegrant, *World Food Prospects: Critical Issues for the Early Twenty First Century*, Washington, DC: International Food Policy Research Institute, 1999, ch.1.

³ I. Serageldin and G.J. Poursley, *Promethean Science. Agricultural Biotechnology, the Environment and the Poor*, Washington: CGIAR, 2000, 3.

⁴ See Pinstrup-Andersen, n.3 supra.

⁵ Some 200 definitions of food security were noted by S. Maxwell and M. Buchanan-Smith, 'Household food security: a conceptual review' in S. Maxwell and T. Frankenburger, eds, *Household Food Security: Concepts, Indicators, Measurements: A Technical Review*, New York and Rome, UNICEF and UNCTAD, 1992.

⁶ I. Scoones, *Agricultural Biotechnology and Food Security: exploring the debate*, IDS Working Paper 145, January 2002.

⁷ Referring to UN, Report of the World Food Congress, New York, 5-16 November 1974.

⁸ Referring to World Bank Policy Study, *Poverty and Hunger: issues and options for food security in developing countries*, Washington DC, World Bank 1986.

⁹ FAO, 'Some issues relating to food security in the context of the WTO negotiations on agriculture'

FAO Geneva Round Table On Food Security In The Context of the WTO Negotiations On Agriculture,

20 July 2001, 2.

point in time. For example the FAO Report *The State of Food Insecurity in the World 2000*, gives the example of Benin where close to half the population is vulnerable to hunger whereas only one seventh of the population is undernourished, using the FAO estimate of under-nourishment.

There is a complex of factors which have been identified as contributing to food insecurity in developing countries. Principal among these factors is poverty. Over 1.3 billion of the world's population have incomes of less than \$US1.00 per day, while another 2 billion people are only marginally better off.¹⁰ Although the number of people living on an income of less than \$1.00 per day declined from 29% in 1987 to 26% in 1998, the number of poor people has remained unchanged because of population growth. The contribution of food imports to food security, while crucial, is limited by the foreign exchange earning capacity of developing countries. Thus, closing the food gap through commercial imports is not a realistic possibility for most countries that have poor prospects for substantial increases in foreign exchange earnings and/or already face heavy external debt burdens.

For some countries, food imports accounted for more than 50 percent of total export earnings, minus debt servicing. Food aid, which has been in the past used in some cases to meet uncovered market demands as well as to feed hungry people directly, has been on the decline and in any case is not a sustainable solution.

With 70 percent of the world's extremely poor and food insecure people living in rural areas, the role of agriculture, which is the predominant economic activity in rural areas, is crucial in the eradication of poverty and food insecurity. The rural poor depend on agriculture both for their incomes and food entitlements. More generally, in most countries with a high incidence of food insecurity, agriculture is the mainstay of the economy. It accounts for a large share of gross domestic product, employs a large proportion of the economically active population, represents a major source of foreign exchange and supplies the bulk of basic foods.

Another factor contributing to food insecurity is the lack of access to land for people in agrarian societies. The concentration of land ownership in societies like Brazil, where one percent of landowners own 46% of all farmland and where 4.5 million peasant families are landless, is mirrored in Central America where 60% of the population is landless or near landless.¹¹ In Africa the proportion is around 40%. The redistribution of land is an obvious solution to this particular problem and the FAO in its 2002 report on food insecurity has reported that in developing countries where land has been more equally redistributed there has been progress in reducing hunger.¹²

Land redistributions, such as in Zimbabwe under the Mugabe regime, have converted a situation of food self-sufficiency into food dependency. Part of the reason for this is corruption, which itself is another factor contributing to food insecurity. There have been a number of notorious instances where international aid from the World Food Programme has been diverted to non-food programmes, such as to the purchase of arms. This then leads to another cause of food insecurity, which is wars. For example, the FAO noted that at the time of the 1994 famine in Ethiopia, the Government applied 46% of the national budget to arms purchases.¹³

¹⁰ World Bank, *World Development Report 2002*, Oxford: Oxford University Press, 2002.

¹¹ UN Commission on Human Rights, 57th sess 'Economic, Social and Cultural Rights: the Right to Food', 7 February 2001.

¹² FAO, 'The State of Food Insecurity in the World 2002', <www.fao.org/docrep/005/y7352e/y352e00.htm

¹³ FAO, 'Recent Shocks to Food Security' www.fao.org/docrep/003/y1500e/y1500e04.htm,.2.

A more recently identified contributor to food insecurity is the impact of climate change. The FAO has observed that with global warming “many of today’s poorest developing countries are likely to be negatively affected in the next 50 – 100 years, with a reduction in the extent and potential productivity of cropland.”¹⁴ A 1996 FAO study estimated that the largest reduction in cereal production will occur in developing countries, averaging about 10 percent.¹⁵ Placing this in perspective, a projected 2 – 3% reduction in African cereal production for 2020 was estimated to be enough to put 10 million people at risk. Particularly vulnerable to climate change are those low to medium-income groups in flood-prone areas who may lose stored food or assets; farmers who may have their land damaged or submerged by a rise in sea-level; and fishers who may lose their catch to shifted water currents or through flooded spawning areas.

The High Level Conference on World Food Security, convened by the FAO in June 2008 noted that during the first three months of 2008, international nominal prices of all major food commodities reached their highest levels in nearly 50 years while prices in real terms were the highest in nearly 30 years.¹⁶ The High Level Conference observed that the constriction of food supplies was caused by the shift of farmers into the production of biofuels and also the impact of global warming on food supplies. The Declaration issued by the High Level Conference requested an immediate response to requests for food assistance by affected countries and in the longer term to enhance investment in agriculture.¹⁷

3. Policies for countering chronic food insecurity

The earliest policy approach to dealing with the question of food security addressed technological improvements in agriculture. The massive increases in food productivity in the 30 years between 1960 and 1990, which is described as the Green Revolution, was achieved by developing high-yielding crop varieties. The productivity of cereals was also enhanced by expanding the area of arable land and by massive increases in fertiliser and insecticide use. Publicly funded national and international agricultural research institutes played a significant role in the development of these new varieties. For example, the CGIAR¹⁸ network of international agricultural research institutes developed from the innovative developments of Norman Borlaug at CIMMYT with high-yielding dwarf

¹⁴ FAO, Committee on World Food Security, *Impact of Climate Change on Food Security and Implications For Sustainable Food Production*, Rome 12 May, 2003, FAO Doc. CFS:2003/INF.

¹⁵ FAO, Global climate change and agricultural production: direct and indirect effects of changing hydrological, pedological and plant physiological processes, CFS:2003/INF/11.

¹⁶ FAO, ‘Soaring Food Prices: Facts, Perspectives, Impacts and Actions Required’, FAO doc., HLC/08/INF/, para.1.

¹⁷ http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf.

¹⁸ Consultative Group for International Agricultural Research, today comprising: [Africa Rice Center \(WARDA\)](#); [Bioversity International CIAT - Centro Internacional de Agricultura Tropical](#); [CIFOR - Center for International Forestry Research](#); [CIMMYT - Centro Internacional de Mejoramiento de Maiz y Trigo](#); [CIP - Centro Internacional de la Papa](#); [ICARDA - International Center for Agricultural Research in the Dry Areas](#); [ICRISAT - International Crops Research Institute for the Semi-Arid Tropics](#); [IFPRI - International Food Policy Research Institute](#); [IITA - International Institute of Tropical Agriculture](#); [ILRI - International Livestock Research Institute](#); [IRRI - International Rice Research Institute](#); [IWMI - International Water Management Institute](#); [World Agroforestry Centre \(ICRAF\)](#); [WorldFish Center](#).

wheat. The research at CIMMYT and at IRRI, which was responsible for similar developments in high-yielding rice varieties, was largely funded from charitable donation. Four fifths of agricultural research was then undertaken at publicly funded research institutes.

At the time of the Green Revolution there was no consideration of any role which intellectual property might play in agricultural innovation. It was largely, the development of the new biotechnology based upon genetic engineering which precipitated intellectual property into the agricultural and into the food security arena. These technological developments were underpinned by changes to the international intellectual property landscape effected by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement in Article 27.1 extended patent protection to inventions in all fields of technology. Judicial determinations in the USA¹⁹ and legislation in Europe²⁰ treated the modification of genetic material as inventions, rather than discoveries, thereby creating the possibility of the patenting of genetic material and of enabling technologies. This intrusion of intellectual property into agriculture been paralleled by a significant diminution of the role of publicly-funded research institutes in agricultural research. This is in part a function of the expense of the new biotechnology both in terms of research investment and because of the legal expense associated with the protection and enforcement of agricultural innovations. A feature of the involvement of the private sector in agricultural research has been the privatisation of the fruits of its research, whereas the public agricultural research sector has tended to eschew the process of seeking intellectual property rights in its research. The budgets of public research institutes are not even sufficient to permit them to defend their biological assets from third party appropriation.

A second Green Revolution to meet the modern challenge of increasing food insecurity will have to deal with the new economic reality of the dominant role of the private sector which seeks to commercialise its agricultural innovations. Exacerbating this problem is the fact that as food insecurity is grounded in poverty a way has to be found to secure for poor farmers the productivity benefits of the new biotechnology, while satisfying the share-holders of the life-sciences companies which are investing in this technology.

4. Sustainable Agriculture

By the 1980's it became accepted that reliance upon the chemically nurtured, high yielding crop varieties which had precipitated the Green Revolution was no longer economically or environmentally acceptable.²¹ Thus it was argued that to meet the food security needs of the next 30 years and to create wealth in poor communities, there was a need to increase agricultural productivity on the presently available land, while conserving the natural resource base.²² The CGIAR called for a second Green Revolution which combined traditional agronomic wisdom with modern agricultural science.²³

¹⁹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

²⁰ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213 , 30/07/1998 P. 0013 – 0021.

²¹ See G. Conway and J. Pretty, *Unwelcome Harvest. Agriculture and Pollution*, London: Earthscan, 1991.

²² See G. Conway, *The Doubly Green Revolution- Food for All in the Twenty-First Century*, Harmondsworth: Penguin, 1997.

²³ See I. Serageldin and G.J. Persley, *Promethean Science .Agricultural Biotechnology, the Environment and the Poor*, Washington D.C.: Consulting Group for International Agricultural

The agricultural practices of traditional farming communities were called in aid to underpin sustainable agriculture.²⁴ An important implication for food security is the contribution which traditional farmers and traditional communities have made in conserving and identifying useful biological material which are embodied in biotechnological innovations. The research and breeding activities of the international agricultural research institutes associated with the CGIAR commenced with the collection of useful germplasm from many of the countries which are now considered to be food insecure. The contribution of these source countries to new proprietary varieties or to patented genetic material has not yet been recognised by the international intellectual property regime, but as is indicated below, there is significant agitation to confer intellectual property rights upon traditional knowledge and to acknowledge the role of source countries in the patenting of biotechnological inventions. There is also agitation to graft upon intellectual property legislation the obligation for rights holders to share benefits and technology with source countries and communities.

From the civil society perspective, the intrusion of intellectual property into agriculture is to be deplored. As is indicated in subsequent chapters, allegations are made about “biopiracy” and questions are raised about market concentration and the ethics of patenting “life”. To a large extent the current debate about protecting traditional knowledge and in recognising “farmers rights” and the rights of source countries is a response to these civil society criticisms. Some parallels with the impact of intellectual property upon food security can be found in the contemporary debate on the impact of intellectual property rights upon access to essential medicines.

At the end of the 1990s there was a perception that access to the medicines needed to deal with the HIV/AIDS pandemic in developing countries was hindered by the patent provisions of the TRIPS Agreement.²⁵ A particular problem with the TRIPS Agreement was that the effect of Article 31 (f) was to permit the compulsory licensing of relevant patents to produce HIV/AIDS drugs was allowed only to countries which had a domestic pharmaceutical production capacity. Following an effective NGO campaign and as a result of pressure brought by a number of developing countries, WTO Members promulgated a Declaration on the TRIPS Agreement and Public Health at the 4th Ministerial Conference in Doha on 14 November 2001.²⁶ The Doha Public Health Declaration affirmed that the TRIPS Agreement does not and should not prevent measures to protect public health and that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.²⁷ By a decision of 6 December 2005, the General Council of the WTO inserted Art.31*bis* into TRIPS, permitting the extension of compulsory licences to overseas suppliers.

Research, 2000, 6.

²⁴ See J. Pretty, *Regenerating Agriculture. Policies and Practices for Sustainability and Self-Reliance*, London: Earthscan, 1995

²⁵ See eg Richard P. Rozek ‘The Effects of Compulsory Licensing on Innovation and Access to Health Care’, (2000) 3 *Journal of World Intellectual Property* 889 at 896; Richard P. Rozek and Renee L Rainey ‘Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy’ (2001) 4 *Journal of World Intellectual Property* 463 at 471.

²⁶ *The Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/W/2,14 November 2001.

²⁷ See eg E. Noehrenberg ‘TRIPS, the Doha Declaration and Public Health’, (2003) 6 *Journal of World Intellectual Property* 379 at 381.

Although this amendment to the TRIPS Agreement resulted only after extensive negotiations, it does illustrate the possibility of changing the primary international intellectual property instrument in response to the same sort of international emergency which characterises the food security crisis. Indeed, at the same time as the 4th Ministerial Conference in Doha issued the Public Health Declaration discussed above, it issued a general declaration setting out what has been described as a development agenda for the WTO. Clause 19 of directed the TRIPS Council “to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore”. In undertaking this work, the TRIPS Council was directed to “be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.” This direction suggests a refashioning of the TRIPS Agreement to include traditional knowledge as a new category of intellectual property or to insert development perspectives in the interpretation of its provisions.

To some extent this already exists within Articles 7 and 8. Article 7 expresses as an objective of the Agreement that the protection and enforcement of intellectual property rights should contribute “to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” Arguably, the patenting of biological material of source countries, for agricultural purposes, often informed by the knowledge of traditional communities, could through the sharing of the benefits deriving from this activity become conducive to the social and economic welfare of those providers and contribute to a balancing of rights and obligations between all parties.

Article 8 of the TRIPS Agreement provides that

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

The role of Article 8 is unclear, given that measures for the protection of public health and nutrition have to be consistent with the other provisions of the Agreement, but it has singled out matters germane to food security for special treatment. The TRIPS Council is currently discussing how to “operationalise” this provision.

5. Human Rights Discourse

The human right to food has been identified directly and indirectly in over one hundred international instruments.²⁸ The first of these was the Universal Declaration on the Eradication of Hunger and Malnutrition of 1974, which stated "that every man, woman and child has the inalienable right to be free from hunger and malnutrition in order to develop fully and maintain their physical and mental faculties". The right to adequate food was also reaffirmed in the Declaration on the Rights of Disabled Persons of 1975,

²⁸ Eg see Katarina Tomasevski ed., *The Right to Food through Applicable International Law*, Dordrecht, Martinus Nijhoff Publishers, 1987.

the provisions of the Convention on the Elimination of all Forms of Discrimination against Women of 1979 and the Declaration on the Right to Development of 1986. The Declaration of the Rights of the Child of 1959 and the Convention on the Rights of the Child of 1989 recognized the right of every child to a standard of living adequate for the child's physical, mental, spiritual, moral and social development. The ILO Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries also affirmed the right to adequate food.

The *Universal Declaration of Human Rights* 1948 (UDHR), which in Article 25 recognises that everyone has the “right to a standard of living adequate for the health and well-being of himself and his family, including food”. Similarly, Article 11 of the *International Covenant on Economic, Social and Cultural Rights* 1966 (ICESCR) in Article 11 (2) details the measures state parties to the ICESCR should take once they have recognised the “fundamental right of everyone to be free from hunger”. State parties should “improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge” and “ensure an equitable distribution of world food supplies in relation to need”. The *International Covenant on Civil and Political Rights* 1966 in General Comment no 6 on Article 6 provides that “states parties are required to take positive steps to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics”. Similarly, the *Convention on the Rights of the Child* provides that “States parties are required to take appropriate measures to combat disease and malnutrition including through the provision of nutritious food and drinking water”.

The rights to adequate food and freedom of hunger are not only associated with the inherent dignity of humankind, but underpin the fulfilment of the other human rights enshrined in the UDHR, ICESCR and ICCPR.²⁹

The right to adequate food is realised when everyone, regardless of gender or age, alone or in a community with others, has “physical and economic accessibility at all times to adequate foods or means for its procurement”.³⁰ The UN Commission on Human Rights points out that adequate food does not mean merely the “minimum package of calories, proteins and other specific nutrients” but requires food being made available in “quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture”.³¹ The availability of food also has to be on a sustainable basis such that food security for both present and future generations is not undermined.

Civil society organizations have entered the human rights discourse by calling for food sovereignty” that challenges the current model of agricultural trade, which they see as cultivating an export-oriented, industrial agriculture that is displacing peasant and family agriculture. Via Campesina originally developed and introduced the concept in 1996, introducing it into the discussions at a parallel meeting held by NGOs and civil society organizations during the 1996 World Food Summit.”³² The term was refined during the World Food Summit in 2002 where representatives of civil society and farmer organizations, defined the concept of food sovereignty meaning “ the primacy of people’s and community’s rights to food and food production, over trade concerns. This entails

²⁹ See Committee on Economic, Social and Cultural Rights, *General Comment 12: The Right to Adequate Food (Article 11)*, UN ESCOR, 20th Sess., Agenda item 7, UN Doc. E/C.12/1999/5 (1999) at para. 4.

³⁰ *Ibid.*, at para. 6.

³¹ *Ibid.*

³² Via Campesina, “Priority to people’s food sovereignty”, 1 November 2001 www.peoplesfoodsovereignty.org/statements.

the support and promotion of local markets and producers over production for export and food imports.” It seeks to guarantee food security first, by favouring local production for local markets. The central idea is that small-scale, peasant agriculture should be protected for its role in ensuring food security, employment, and environmental objectives - as long as that protection does not threaten the livelihoods of other farmers in other countries. Under the logic of food sovereignty, subsidies should never be permitted to large-scale farming or the export sector.

Food sovereignty calls for equitable access to land, seeds, water, credit and other productive resources so that people can feed themselves. It implies challenging the increasing concentration of ownership of agricultural trade, processing and marketing by transnational agribusiness corporations through, for example, improving competition law at a transnational level and through the prohibition of the appropriation of knowledge through intellectual property-rights regimes.³³ Jean Ziegler, the UN Human Rights Commission’s Special Rapporteur on the right to food, suggests that food sovereignty offers an alternative vision that puts food security first and treats trade as a means to an end, rather than as an end in itself.³⁴

An unresolved problem, which is addressed in this book is the collision of the right to adequate food with other international obligations, particularly those within the WTO package of agreements, such as the Agreement on Agriculture (AoA), Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

6. Food Security, Trade and the Agreement on Agriculture

Jean Ziegler, the UN Human Rights Commission’s Special Rapporteur on the right to food, observed in his 2004 report that in the European Union, the average European dairy cow has a bigger annual income than half the world’s people, and it is estimated that 70 per cent of subsidies go to 20 per cent of Europe’s largest farms.³⁵ He noted that despite preaching the benefits of free trade in agriculture, the European Union, the United States of America, Japan and other industrialized countries still heavily protect their agriculture in order to ensure the production of basic staple foods.³⁶

Domestic subsidies encourage over-production, which in turn increases supplies on world markets and depresses world prices. These low prices make it harder for producers in developing countries to compete in their home markets, as well as in international markets, thus reducing incentives for production and retarding the development of the agricultural sector. Export subsidies have a similar effect in depressing world prices. Developing countries would appear to have an interest in the reduction of both domestic support and export subsidies in the developed countries.

The WTO was established as part of the trade liberalisation programme which was inaugurated at the time of the promulgation of the General Agreement on Tariffs and

³³ Commission on Human Rights, The right to food. Report submitted by the Special Rapporteur on the right to food, Jean Ziegler, in accordance with Commission on Human Rights resolution 2003/25, E/CN.4/2004/10, 9 February 2004, para. 31.

³⁴ Ibid., para. 32.

³⁵ Commission on Human Rights, *The right to food*. Report submitted by the Special Rapporteur on the right to food, Jean Ziegler, in accordance with Commission on Human Rights resolution 2003/25, E/CN.4/2004/10, 9 February 2004, para. 38.

³⁶ Ibid.

Trade (GATT). A key factor constraining agriculture in developing countries has been the high levels of subsidies and protection provided to agriculture in the developed world. The objective of the Agreement on Agriculture (AoA), one of the agreements annexed as a membership obligation for the WTO is to establish “a fair and market-oriented agricultural trading system” through “reductions in agricultural support and protection”. The expectation is that this would result in “correcting and preventing restrictions and distortions in world agricultural markets”. Intellectual property considerations have had a limited role to play in the negotiations on the AoA. The main subject which has been discussed is the role which geographical indications for agricultural products can play in improving market access for developing countries.

The focus of the WTO Agreement on Agriculture (AoA) is not food security. Its objective is to establish “a fair and market-oriented agricultural trading system” through “reductions in agricultural support and protection”. The expectation is that this would result in “correcting and preventing restrictions and distortions in world agricultural markets”. The most direct form of trade distortion is the escalating use of export subsidies (subsidy “wars”) to dispose of surpluses on world agricultural markets.

Food security has been identified as a “non-trade concern” to be taken into account in the reform of agricultural trade.³⁷ A number of submissions have emphasised that in developing countries, where the majority of the population depends on agriculture for their livelihood, physical access to food can be ensured only through a minimum level of self-sufficiency.³⁸ The findings by the FAO on the interrelationship between the promotion of economic growth, reduction of poverty, the enhancement of food security and the development of agricultural capacity were cited in these submissions.³⁹ Thus, for example, India submitted that the particular vulnerability of agriculture in developing countries justified the extension of special provisions to the developing country members for ensuring their food and livelihood security concerns, such as exempting product specific support given to low income and resource poor farmers from AMS calculations.

The requirement in Art. 20 of the AoA that WTO Members in their reform of the Agreement, shall have regard to non-trade concerns, special and differential treatment to developing country members and the principles of equity and fairness was reformulated in the Doha Ministerial Declaration to take account of the needs and interests of the developing countries, particularly the vulnerability of the least-developed countries and the importance of the objective of sustainable development. In the work programme decided in March 2002, non-trade concerns, including food security, and “special and differential treatment” were to be an integral part of the negotiations.

A particularly difficult issue in the context of food security is the impact of the AoA on food aid. The AoA makes a distinction between domestic support measures, which have at best a minimal distorting effect upon trade ‘Green Box’ Measures (Annex 2 of the

³⁷ WTO Agreement on Agriculture, Art. 20.

³⁸ Eg. Submission to the Special Session of the WTO Committee on Agriculture by Barbados, Burundi, Cyprus, Czech Republic, Dominica, Estonia, the European Communities, Fiji, Iceland, Israel, Japan, Korea, Latvia, Liechtenstein, Madagascar, Malta, Mauritania, Mauritius, Mongolia, Norway, Poland, Romania, Saint Lucia, Slovak Republic, Slovenia, Switzerland, and Trinidad and Tobago. WTO doc., G/AG/NG/W/36/Rev.1; Submission by India, WTO doc., G/AG/NG/W/102, 15 January 2001; Proposal by Nigeria, WTO doc. G/AG/NG/W/130, 14 February 2001.

³⁹ Eg FAO Symposium on Agriculture, Trade and Food Security: Issues and Options in the forthcoming WTO Negotiations from the Perspective of Developing Countries, Geneva, 23-24 September 1999.

AoA) and trade-distorting support ‘Amber Box’ Measures (Art. 6 AoA). Public stockpiling for food security purposes and domestic food aid for people in need is exempted as Green Box Measures, provided that the public authority buys at market prices.⁴⁰

Article 9 provides for the general reduction of export subsidy commitments. Excluded from this reduction is food aid although Article 10 provides that subsidised food aid, should not be used as a means of circumventing commitments to reduce and eliminate subsidised agricultural production.⁴¹

Given the obviously deleterious impact which the AoA restrictions upon food aid might have a *Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed Countries and Net Food-Importing Developing Countries* was adopted as part of the Uruguay Round of the GATT. This *Decision* of the Trade Ministers agreed on a set of measures, including financial support, to ensure that adequate food imports on reasonable terms could be maintained during any structural dislocations caused by the agricultural reform process. To date, the *Decision* has not been implemented despite the fact that food aid has dropped to very low levels. Implementation has been hampered by several factors which include, the requirement of undisputed proof of the need for assistance and the variety of instruments called under the *Decision* to respond to such needs, without precise specification of the respective responsibilities of all concerned. As the FAO explained “more basically, however the *Decision* addresses a transitional problem whereas the food security problem in the countries concerned is long-term and complex and encompasses broader development issues that go beyond just trade.”⁴²

Article 20 of the AoA envisages that further negotiations would be undertaken to continue trade liberalization and that food security would be included in these negotiations. The Doha Ministerial Declaration in para. 13 identified special and differential treatment for developing countries as “an integral part of all elements of the negotiations and shall be embodied in the schedules of concessions and commitments ...to enable developing countries to effectively take account of their development needs, including food security and rural development.” This commitment was reaffirmed in para 4 of the Ministerial Declaration issued in Hong Kong on 18 December 2005. In para. 6 of that Declaration it was proposed that a “safe box” for bona fide food aid would be provided “to ensure that there is no unintended impediment to dealing with emergency situations.” It was proposed that the disciplines on food aid would be completed by 30 April 2006 “as part of the modalities, including appropriate provision in favour of least-developed and net food-importing developing countries as provided for in paragraph 4 of the Marrakesh Decision.”

7. The Right to Food and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT)

⁴⁰ Aoa Annex 2, paras 3 and 4.

⁴¹ See M.G. Nesta, ‘Food Security and International Trade Law, An Appraisal of the World Trade Organization Approach’ (2001) 35 *Journal of World Trade* 449-468, 451.

⁴² FAO, ‘Issues at stake relating to agricultural development, trade and food security’, FAO Special Programme for Food Security Website (www.fao.orgs/spfs/lifdc).

Among the arguments in favour of the application of recombinant DNA technology in the areas of food and agricultural production, concern its capacity to increase food security through higher yielding and disease resistant crops.⁴³ Opponents of these applications point to the environmental and public health implications of this technology.⁴⁴ Overlaying and incorporating all this is enormous consumer concern about genetically modified organisms (GMOs), especially where they occur in food or are used in food production. These consumer concerns range generally across issues concerned with health, environmental protection and ethics. The WTO has responded to these concerns through the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). These Agreements define rules for setting national standards and regulations relating to sanitary and phytosanitary measures as well as technical requirements for food safety and quality so that such regulations do not unduly restrict trade.

The SPS Agreement is essentially concerned that measures for the protection of human, animal or plant life or health are “not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members ... or a disguised restriction on international trade”.⁴⁵ The SPS agreement permits an assessment of risks, relying upon scientific principles, where they have been established or within the context of the precautionary principle, where the science is evolving. This principle, which is embodied within Art. 5.7 of the Agreement provides that 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.” This principle was explored by the WTO panel and Appellate Body in the US/EU Beef Hormone dispute, which concerned an evaluation of whether an EU ban on trade in beef from any source containing artificially administered growth hormones violated the SPS Agreement.⁴⁶

The SPS Agreement probably has an indirect relationship to the right to food. The fifth recital to the SPS Agreement recognises “that developing country Members may encounter special difficulties in complying with sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories”. Thus where developing countries are dependent upon overseas agricultural markets to generate revenues to underpin domestic production or for the procurement of food supplies, the rigorous application of sanitary and phytosanitary measures to exports from developing countries can undermine food security. The Beef Hormones case indicated that there had to be a rational relationship between the protective measure and the risk assessment. The EC rules were considered not sufficiently specific as they dealt

⁴³ See, eg, Ives, Bedford & Maredia, “The Agricultural Biotechnology for Sustainable Productivity Project: A New Model in Collaborative Development” in Ives & Bedford (eds), *Agricultural Biotechnology in International Development* (1998)1, 2; Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical & Social Issues*, esp ch 4, <http://www.nuffield.org/bioethics/publication/modifiedcrops/index.html>.

⁴⁴ See eg, K. Barrett & G. Flora, *Genetic Engineering and The Precautionary Principle: Information for Extension*, Minnesota, Science & Environmental Health Network, 2000, ch 2.

⁴⁵ SPS Agreement, Art 2.3.

⁴⁶ *EC – Measures Concerning Meat & Meat Products (Hormones)*, Panel Reports: Case WT/DS26/R/USA, 18 August 1997 & Case WT/DS48/R/CAN, 18 August 1997; Appellate Body Report: WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998.

with the carcinogenic effects of the hormones in question in general. “They do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from the cattle to which the hormones had been administered for growth promotion purposes.”⁴⁷

Food safety scares, such as those associated with BSE and Avian Flu can generate strong political agitation for sanitary and phytosanitary measures. This was recognized in the Beef Hormones case where the Appellate Body noted that “responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible, e.g., life-terminating, damage to human health are concerned”.⁴⁸

8. The Right to Food and the WTO Agreement on Technical Barriers to Trade (TBT)

To a considerable extent the TBT Agreement reflects the obligations found in the SPS Agreement. Thus the general obligations under the TBT Agreement are to ensure that technical barriers (which are comprised of technical regulations, standards and conformity assessment procedures) are subject to national treatment and MFN obligations⁴⁹ and that they do not create “unnecessary obstacles to international trade”.⁵⁰ There are, however, some important differences, including the scope of the Agreement and the latitude which it gives for members to justify measures apparently outside the obligations contained in the Agreement.

The TBT Agreement applies to: technical regulations, standards and conformity assessment procedures. Each of these types of measures is defined in Annex 1.⁵¹ A “technical regulation” is defined in paragraph 1 as:

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

A “standard” is defined in paragraph 2 as:

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Finally, a “conformity assessment procedure” is defined in paragraph 3 as:

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

The particular application of the TBT Agreement to the field of biotechnology area is in relation to labelling or marking requirements. Such requirements explicitly fall within the definitions of technical regulation and standard, the main difference between the two is that the former are mandatory requirements whereas the latter are not. Whether

⁴⁷ Ibid., para 200.

⁴⁸ Ibid., para.124.

⁴⁹ TBT Agreement, Art 2.1 (technical regulations); Art 4 & Annex 3, para D (standards); Arts 5.1.1, 7, 8 & 9 (conformity assessment procedures).

⁵⁰ Ibid., Art 2.2 (technical regulations); Art 4 & Annex 3, para E (standards); Arts 5.1.2, 7, 8 & 9 (conformity assessment procedures).

⁵¹ Ibid., Art 1.2.

mandatory or recommended, the issue of labelling, especially eco-labelling, has been a hotly contested one within the WTO. Traditionally, the issue of eco-labelling, in general, has been one of the bones of contention between the developed and developing countries.⁵² As with the SPS agreement these the imposition of labelling requirements can imperil access to the agricultural market for developing countries.

9. The Right to Food and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

One of the most significant recent developments in the field of food security is the application of recombinant biotechnology to agriculture and the concomitant intrusion of intellectual property rights into agriculture. The provision of the TRIPS Agreement which is most relevant to food security is Article 27, which defines patentable subject matter and which obliges WTO Members to provide protection for plant varieties. Article 27.1 obliges the protection of inventions in all fields of technology, which includes agriculture. This provision also requires that “patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology and whether products are imported or locally produced.”

The patenting of genetic material and the conferral of plant variety rights has enabled the proprietisation of both of plant material and research tools. Developing countries face two sets of difficulties in this area. On the one hand, most of them, particularly the LDCs, lack the scientific capability to innovate and patent new materials - and are not even in a position to fully catalogue the natural resources of bio-materials that they currently possess. They also do not have appropriate legislation in this area. On the other hand, there is a growing concentration of transnational corporations in bio-tech industries, notably in the seed sector. This concentration or lack of competition (reinforced by global patentability) enables these industries to exact monopoly rents from farmers worldwide. In addition, aside from the issue of costs, many countries feel it is unsafe to rely entirely on external sources for an input as important as seeds. The market dominance of these private corporations also has an important influence upon the sort of agricultural research which is undertaken. For example, the observation is made that biotechnological research will be diverted away from Southern food priorities.⁵³

The mandatory obligation imposed by TRIPS for WTO members to protect plant varieties has resulted in most countries adopting laws based on the 1991 iteration of the UPOV Convention. This latest version of the Convention may be contrasted with the earlier versions because it does not guarantee the right of farmers to save, exchange and replant seed. It is suggested that these restrictions on the rights of farmers risks exacerbating the crisis of hunger and malnutrition and would be a “violation of international norms”.⁵⁴

The TRIPS Agreement states as a basic principle that “Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect vital

⁵² See Surya Subedi, “Balancing International Trade with Environmental Protection: International Legal Aspects of Eco-Labels” (1999) 25 *Brooklyn Journal of International Law* 373.

⁵³ See J.P Alston, G. Pardey and J. Rosenboom.. ‘Financing Agricultural Research: International Investment Patterns and Policy Perspectives’ (1998) 26 *World Development* 1045.

⁵⁴ S. Edwardson, ‘Reconciling TRIPS and the Right to Food’ in T. Cottier, J. Pauwelyn and E.B. Bonanomi, *Human Rights and International Trade*, Oxford, OUP, 2005, 383 at 386-87.

health and nutrition...provided that such measures are consistent with the provisions of this Agreement”. A matter yet to be tested is the extent to which countries can rely upon this provision to exclude from protection, proprietary rights which may have a bearing on food security. For example, the exclusion from patent protection of inventions which might have a bearing on food security would conflict with the obligation in Article 27.1 of TRIPS to provide patent protection in all fields of technology.

Because of the internal difficulties within the TRIPS Agreement to resolve the tension between intellectual property rights and the right to food, resort is had to principles of human rights law. The UDHR does not expressly refer to intellectual property rights, but Article 27.2 states that “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” This is complemented by the proclamation in Article 17.1 of a general right of property. This Article states that “[e]veryone has the right to own property” and 17.2 states that “[n]o one shall be arbitrarily deprived of his property.” The implication of Article 17.2 is that states do have a right to regulate the property rights of individuals, but that they must do so according to the rule of law.

A question which is raised by these provisions is whether the right of property forms part of the norms of international law. States through practices and treaties routinely recognize the property rights of their citizens as well as those of other states and their nationals. Schermers argues that most property rights cannot be included in the category of fundamental human rights as the latter are “human rights of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement.”⁵⁵ It was is for this kind of reason that the European Commission of Human Rights concluded that the grant under Dutch law of a compulsory licence in a patented drug was not an interference in the patent holder’s rights under Article 1 of Protocol 1 of the European Convention of Human Rights. The “compulsory licence was lawful and pursued a legitimate aim of encouraging technological and economic development.”⁵⁶

The tension between intellectual property rights and human rights was first significantly debated in the lead-up to the Doha Ministerial Conference of the WTO at the end of 2001. A report of the United Nations Sub-Commission on Human Rights noted that:

[A]ctual or potential conflicts exist between the implementation of the TRIPS Agreement and the realisation of economic, social and cultural rights in relation to ... impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting of genetically modified organisms, “bio-piracy” and the reduction of communities’ (especially indigenous communities’) control over their own genetic and natural resources and cultural values...⁵⁷

⁵⁵ H. G. Schermers, “The international protection of the right of property”, in F. Matscher and H. Petzold (eds.), *Protecting Human Rights: The European Dimension*, Carl Heymanns Verlag KG, Köln, 1988 565 at 579.

⁵⁶ Application 12633/87 *Smith Kline and French Laboratories Ltd v The Netherlands*, (1990) 66 European Commission of Human Rights, *Decisions and Reports*, 70, 80.

⁵⁷ *Intellectual property rights and human rights*, Sub-Commission on Human Rights Res. 2000/7, UN ESCOR, Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg., UN Doc. E/CN.4/Sub.2/Res/2000/7 (2000).

The UN Sub-Commission declared that “the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights”.⁵⁸ To this end, the Sub-Commission requested “all Governments and national, regional and international economic policy forums to take international human rights obligations and principles fully into account in international economic policy formulation”.⁵⁹

10. Political Initiatives eg World Food Summit

The First World Food Conference held in Rome in 1974 promulgated the *Universal Declaration on the Eradication of Hunger and Malnutrition* which stated that “it is a fundamental responsibility of governments to work together for higher food production and more equitable and efficient distribution of food between countries and within countries”. Subsequent world food conferences reaffirmed states’ commitments to eliminate hunger and malnutrition. The most significant of these meetings was the 1996 World Food Summit which promulgated a *Plan of Action* which contained seven commitments related to food security.⁶⁰ A key commitment was the fourth which identified the commitment of governments to ensure that “trade policies are conducive to food security”. Within this commitment the first objective of signatory governments is to provide financial and technical assistance and to encourage the transfer of technology to developing countries so that they are in a position to take advantage of new market opportunities. A second objective within this commitment is “to meet essential food import needs in all countries, considering world price and supply fluctuations and taking especially into account food consumption levels of vulnerable groups in developing countries”, which obliges exporting countries to reduce food subsidies and to avoid market disruptions.

The third objective committed signatories to support the reform process under the Uruguay Round, particularly in relation to Article 20 of the Agreement on Agriculture

⁵⁸ Sub-Commission on Human Rights, *Intellectual property rights and human rights* Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg., UN Doc. E/CN.4/Sub.2/Res/2000/7 (2000), para 2.

⁵⁹ *Ibid.*, para 4.

⁶⁰

1. We will ensure an enabling political, social and economic environment designed to create the best conditions for the eradication of poverty and for durable peace.
2. We will implement policies aimed at eradicating poverty and improving economic access by all to sufficient, nutritionally adequate and safe food.
3. We will pursue participatory and sustainable food, agriculture, fisheries, forestry and rural development policies and practices, which are essential to adequate food supplies at the household, national, regional and global levels.
4. We will strive to ensure that food, agricultural trade and overall trade policies are conducive to fostering food security for all through a fair market-orientated world trade system.
5. We will endeavour to prevent natural disasters and man-made emergencies and to meet transitory and emergency food requirements in ways that encourage development and a capacity to satisfy future needs.
6. We will promote use of public and private investments to foster human resources, sustainable food and rural development.
7. We will implement, monitor and follow-up this plan of action at all levels in cooperation with the international community.

under which WTO Members committed themselves to supporting the reform process agreed in the Uruguay Round and to promoted the food security of developing countries by facilitating their access to markets.

As part of the *Plan of Action* a process was initiated to define the content of the right to food and the relevant state obligations. The FAO and the United Nations High Commissioner for Human Rights have undertaken three expert consultations to clarify the content of the right to food. The first two of these in 1997 and 1998 formulated General Comment no. 12 which was adopted by the Committee on Economic, Social and Cultural Rights (CESCR). This General Comment provides an interpretation of the right to food which is utilised by the CESCR in its implementation of the ICESCR. A code of conduct is being formulated to provide a precise definition to states' obligations in relation to the guarantee of the right to food under the ICESCR.

The third consultation in 2001 addressed the connection between hunger and poverty and recommended that States review existing impediments to full implementation of the right to adequate food, develop a legislative agenda to strengthen implementation and repeal incompatible laws.

A key development was the Doha Ministerial Conference of the WTO in November 2001, which prioritised a development agenda for the organization. The Declaration issued by the Trade Ministers acknowledged the need for a differential treatment for developing countries to meet their needs in food security and rural development.

In June 2002 the World Food Summit: Five Years Later was held to review the progress which had been made since 1996. The participating states renewed their commitment to halve the number of hungry in the world no later than 2015 and called on all parties (governments, international organizations, civil society organizations and the private sector) to reinforce their efforts so as to act as an international alliance against hunger to achieve the WFS targets no later than 2015. The commitment to halve the number of hungry people by 2015 was endorsed also by the Millennium Summit on Poverty.

An International Code of Conduct on the Human Right to Adequate Food was drafted in 1997 by the NGO community as a follow-up to the World Food Summit. It was intended to “provide a guide for the conduct of the international community, states and all relevant actors in civil society to better focus their policies and action on those persons and groups vulnerable to hunger” and “to provide guidance for legislation at both national and international levels.”⁶¹ Article 4 of the Code defined the right to adequate food as meaning that “every man, woman and child alone and in community with others must have physical and economic access at all times to adequate food or by using a resource base appropriate for its procurement in ways consistent with human dignity.” The realization of this right requires: “a) the availability of food, free from adverse substances and culturally acceptable, in a quantity and quality which will satisfy the nutritional and dietary needs of individuals; and b) the accessibility of such food in ways that do not interfere with the enjoyment of other human rights and that is sustainable.”

Article 5 called upon States “to take joint and separate action to advance the respect and observance of human rights including the right to adequate food.” The obligations of States at the national level were defined in Article 6 to “protect everyone under their jurisdiction from having their access to food being undermined by a third party.” This obligation was defined to include “the State's responsibility to ensure that private entities or individuals, including transnational corporations over which they exercise jurisdiction, do not deprive individuals of their access to adequate food.” This obligation could be

⁶¹ International Code of Conduct on the Human Right to Adequate Food, Preamble.

considered to be in tension with the right of individuals to exercise their intellectual property rights.

The Committee on World Food Security of the FAO, noting the broad subscription to the Draft Code within the NGO addressed the question of the way in which the Code could best be pursued.⁶² At the World Food Summit: *five years later*, the decision was taken to establish within FAO an Intergovernmental Working Group (IGWG) to elaborate a set of voluntary guidelines to support the progressive realization of the right to adequate food.⁶³ In response to the serious challenges to world food security caused by the dramatic escalation of food prices at the beginning of 2008 the UN system developed a Comprehensive Framework for Action (CFA). At a meeting in Berne on 28 and 29 April 2008, the Secretary General of the UN established a High Level Task Force (HLTF) on the Global Food Security Crisis under his chairmanship, with FAO Director General as Vice Chairman, and bringing together the Heads of the United Nations specialized agencies, Funds and Programmes, Bretton Woods institutions and relevant parts of the UN Secretariat, in order to create a prioritized plan of action and coordinate its implementation. The CFA identified both immediate and longer term actions to address the food crisis. The longer term actions addressed underlying, structural issues to help build resilience and contribute to sustainable improvements in global food security and poverty reduction within the context of the Millennium Development Goals.

From 3-5 June 2008, the FAO convened a High-Level Conference on World Food Security to address the challenges of climate change and bioenergy. The Conference concluded with the adoption of a declaration calling on the international community to increase assistance for developing countries, in particular the least developed countries and those that are most negatively affected by high food prices.⁶⁴ Article 3 of the Declaration identified “an urgent need to help developing countries and countries in transition expand agriculture and food production, and to increase investment in agriculture, agribusiness and rural development, from both public and private sources.” It urged the international community, including the private sector, to increase investment in science and technology for food and agriculture.

The 2008 G8 Hokkaido Toyako Summit, held in the month following the FAO High Level Conference, issued a *G8 Leaders Statement on Food Security*⁶⁵ which expressed their concern that the steep rise in global food prices coupled with availability problems was threatening global food security and that this “trend could push millions more back into poverty, rolling back progress made towards achieving the Millennium Development Goals.”⁶⁶ In addition to pledging \$US10 billion for short-term food aid and other measures to increase agricultural output, the G8 Statement expressed strong support for FAO leadership of a co-ordinated programme to boost food security. The leaders undertook to “work toward the urgent and successful conclusion of an ambitious, comprehensive and balanced Doha Round” and expressed their support for the removal of export restrictions and for the expedition of the WTO negotiations on this subject.

⁶² FAO, Committee on World Food Security, ‘Progress in the Implementation of the Right to Food’, FAO Doc., CFS: 2002/ Inf.7, 6-8 June 2002.

⁶³ FAO, *Declaration of the World Food Summit: five years later, International alliance against hunger*, Operative paragraph 10, Report of the World Food Summit: five years later, part one, Appendix, 2002.

⁶⁴ http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf

⁶⁵ http://www.g8summit.go.jp/eng/doc/doc080709_04_en.html.

⁶⁶ *Ibid.*, para.1.

In analysing the policy options for dealing with food insecurity and the application of intellectual property in pursuing these options, it is useful to list the long term initiatives which were enumerated in the G8 Leaders Statement. They undertook to:

- (a) reverse the overall decline of aid and investment in the agricultural sector, and to achieve significant increases in support of developing country initiatives, including – in Africa – through full and effective implementation of the Comprehensive Africa Agricultural Development Programme (CAADP);
- (b) support CAADP’s goal of 6.2% annual growth in agricultural productivity, and work toward the goal of doubling production of key food staples in African countries meeting CAADP criteria in five to ten years in a sustainable manner, with particular emphases on fostering smallholder agriculture and inclusive rural growth;
- (c) promote agricultural research and development, and the training of a new generation of developing country scientists and experts focusing on the dissemination of improved, locally adapted and sustainable farming technologies, in particular via the Consultative Group on International Agricultural Research (CGIAR), and through partnerships such as the Alliance for a Green Revolution in Africa (AGRA);
- (d) support improvement of infrastructure, including irrigation, transportation, supply chain, storage and distribution systems and quality control;
- (e) assist in the development of food security early warning systems;
- (f) encourage the efforts of international financial institutions ... to address the needs of food-importing countries facing balance of payments difficulties, including through the Poverty Reduction and Growth Facility and the review of the Exogenous Shocks Facility;
- (g) accelerate research and development and increase access to new agricultural technologies to boost agricultural production; we will promote science-based risk analysis including on the contribution of seed varieties developed through biotechnology;
- (h) support country-led development strategies in adapting to the impact of climate change, combating desertification, and promoting conservation and sustainable use of biological diversity, while intensifying our efforts to address climate change;
- (i) ensure the compatibility of policies for the sustainable production and use of biofuels with food security and accelerate development and commercialization of sustainable second-generation biofuels from non-food plant materials and inedible biomass; in this regard, we will work together with other relevant stakeholders to develop science-based benchmarks and indicators for biofuel production and use;
- (j) promote good governance in developing countries with particular emphasis on their food security and market policies; and

(k) mainstream food security objectives into the development policies of donors and recipient countries, reaffirming our common commitment to the principles of the Paris Declaration on Aid Effectiveness.

Of these objectives, (a), (b), (f) and (k) are concerned with funding initiatives. All of the other objectives have a potential intellectual property implication, because they involve various forms of technological innovation.

11. A Legally Enforceable Right to Food?

As with all categories of rights, a critical question is the extent to which the right to food imposes legally enforceable obligations. Gonzalez-Pelaez⁶⁷ applies the analytical model developed by Kenneth Abbott et al⁶⁸ that legislation can be classified along the dimensions of: obligation, precision and delegation to the various international legal instruments which could underpin a right to food. According to this scheme, the Doha Declaration takes on the character of soft law in that it sets out the terms for negotiation, but does not require that these terms are met. Gonzalez-Pelaez discerns a stronger obligation embodied in the Declaration of the World Food Summit. This she sees in the large number of states (186) which participated in the Summit, the World Food Summit Plan of Action, supported by a number of governments in Latin America and Europe and in General Comment no.12 of the UN Committee on Economic, Social and Cultural Rights which “gave a specific legal framework to the right to food”. Set in the balance against this was the post-summit statement of the United States that “the fundamental right to be freed from hunger is a goal or aspiration to be realised progressively that does not give rise to any international obligations...the United States does not recognise any change in the current state of conventional or customary law regarding rights related to food, even if it accepts the right of everyone to have access to safe and nutritious food”.⁶⁹ A Report by Mary Robinson, United Nations High Commissioner for Human Rights which was presented to the *World Food Summit: Five Years Later*⁷⁰ identified some 20 countries which had “adopted constitutions that more or less explicitly refer to the right to food or a related norm”. For example, the South African Constitution, provides in section 27 that “Everyone has the right to have access to (...) sufficient food and water.” Norway was identified as leading the field in terms of comprehensive action. Its Ministry of Agriculture presented to Parliament *White Paper No. 19 on Agricultural Food Production*, which adopted a rights-based approach to agricultural policy expressly referring to the right to food and to General Comment No. 12.

An example provided by the High Commissioner for Human Rights of the justiciability of the right to food was a decision of the Indian Supreme Court which affirmed that where people are unable to feed themselves adequately, Governments have an obligation

⁶⁷ Ana Gonzalez-Pelaez, *Human Rights and World Trade. Hunger in International Society*. London and New York, Routledge, 2005, 69-77.

⁶⁸ Kenneth Abbott, Robert Keohane, Andrew Moravcsik, Anne-Marie Slaughter and Duncan Snidal, ‘The Concept of Legalisation’ (2000) 54:3 *International Organization* 420-456.

⁶⁹ ‘World Food Summit: Interpretative Statements by the Government of the United States of America’, www.fas.usda.gov/icd/summit/interpre.html.

⁷⁰ M. Robinson, *The Right to Food: Achievements and Challenges*, Report presented to the World Food Summit, Five Years After, Rome, 8-10 June 2002.

to provide for them, ensuring, at the very least, that they are not exposed to malnourishment, starvation and other related problems.⁷¹

⁷¹ People's Union for Civil Liberties v Union of India and Others, Writ Petition [Civil] No. 196 of 2001. Also cited in Commission on Human Rights, Background paper prepared by the Secretariat, *Selection of case law on economic, social and cultural rights* E/CN.4/2005/WG.23/CRP.1 15 November 2004

2. Food Waste

M. Blakeney, *Food Waste-Causes and Solutions*, Wallingford, Edward Elgar, 2018

6. Regulatory Options

Introduction

This chapter considers the possibility of regulatory options to minimise the generation of FLW. A threshold issue in the consideration of legislative options for the minimization of FLW is the definition of the terms which are going to be central to the regulation of FLW.

Critical in the formulation of regulatory options is an understanding of the drivers of FLW, as the regulation of food waste in a country is going to be more effective if it is addressed to the drivers of food loss and waste in that country. Regulation is probably the most effective when combined with educational programmes which raise awareness of food loss and waste along the food supply chain.

Regulatory Options

Until the last 20 years of the Twentieth Century, regulation typically emanated from the national legislature, sometimes in response to obligations imposed by international agreements to which the state had subscribed. In recent years, voluntary industry self-regulation has become an increasingly important source of regulation (See Teubner, 1997; Braithwaite & Drahos, 2000; Gunningham & Sinclair, 1999; Teubner, 2004; Gunningham, 2009). Industry self-regulation has been defined as “a regulatory process whereby an industry-level organization sets rules and standards relating to the conduct of firms in the industry” (Gunningham & Rees, 1997 at 364). However, self-regulation and government regulation are not mutually exclusive. In contrast with government-imposed laws, self-regulation is voluntary and is typically framed as corporate social responsibility with public welfare as its central feature. Among the advantages to the state of self-regulation is flexibility, consent of the regulated and the conservation of government resources. The consent of the governed raises the risks of weak standards or ineffective enforcement. In some jurisdictions these risks can be ameliorated by government scrutiny of self-regulation standards. For example, in Australia the self-regulatory codes are subject to the scrutiny of the competition law authority to ensure the conferral of public benefit.

The primary motivation for self-regulation has been the threat of legislative intervention because of social concerns (See Blakeney & Barnes, 1982; Haufler, 2001). Probably, the pioneering example in this regard is self-regulation by those industries whose activities have provoked environmental concerns (Gunningham et al, 2003) such as mining (Dashwood; Nysten-Haarala et al, 2015) and forestry. However, food and food-related industries have become an important field for industry self-regulation. This form of regulation has been adopted in relation to food marketing to children and youth (Institute of Medicine, 2006; Hawkes, 2007), the promotion of healthy foods to school children (Hawkes, 2005; Sharma et al, 2010) including the supply of sugar sweetened beverages to school children (Mello et al, 2008), television advertising to children (Smithers et al, 2014) and the advertising industry’s practices in relation to alcohol (Babor et al, 2013).

The representation of the public interest in industry self-regulation will depend in large part upon the strength of the tradition of corporate social responsibility in the country concerned. For example, in the USA in relation to the marketing of junk food to children it has been observed that “the government has maintained a hands-off policy” with the food industry being allowed to police itself, with modest guidance from federal regulators and none from consumer advocates. In relation to food waste minimization, as is explained below, the UK has an effective self-regulation regime, underpinned by government funding.

In countries without a significant self-regulatory tradition, or where the issue of food waste minimization is considered to be too important to be left to private regulation, the state has intervened with direct legislation. The examples of EU Member States such as Ireland, France, Italy and Japan are described below, as well as the USA and Japan.

Direct Regulation-EU

The EU has not legislated directly on the subject of food waste minimization, but has included the subject in its general waste minimization regime.

Food waste is touched upon indirectly in statutes such as Commission Regulation (EC) No 1221/2008 of 5 December 2008⁷², in which the European Commission approved the phasing out of previous legislation concerning the size and shapes of fruit and vegetable, removing the aesthetic requirements for many fruits and vegetables thereby preventing the unnecessary discarding of various types of produce, which are aesthetically imperfect but otherwise edible.⁷³

One potential use of food waste is as pig feed however, a 2002 EU regulation and a replacement regulation of 2009 prohibited the recycling of catering waste as animal feed.⁷⁴ The 2002 regulation was precipitated by the outbreak of swine fever in 2001, which resulted from a farmer illegally feeding uncooked food waste to pigs, costing the UK economy £8 billion (UK House of Commons, 2002). The 2009 regulation was precipitated by concerns about foot-and-mouth disease, the spread of transmissible spongiform encephalopathies such as bovine spongiform encephalopathy (BSE) and the occurrence of dioxins in feeding stuffs.⁷⁵

Within the EU, the regulation of food waste is included within its general regulation of waste disposal. Directive 2006/12/EC of the European Parliament and of the Council of 5

⁷² Commission Regulation (EC) No 1221/2008 of 5 December 2008 amending Regulation (EC) No 1580/2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector as regards marketing standards, OJ : JOL_2008_336_R_0001_01

⁷³ The current list of fruit and vegetables impacted are: apricots, artichokes, asparagus, aubergines, avocados, beans, Brussels sprouts, carrots, cauliflowers, cherries, courgettes, cucumbers, cultivated mushrooms, garlic, hazelnuts in shell, headed cabbage, leeks, melons, onions, peas, plums, ribbed celery, spinach, walnuts in shell, water melons, and witloof/chicory. The exception from marketing standards could be extended to another ten products such as apples, citrus fruit, kiwifruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes, https://ec.europa.eu/food/safety/food_waste/good_practices/policy_awards_certification_en.

⁷⁴ Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 Laying Down Health Rules Concerning Animal By products Not Intended for Human Consumption, OJ L 273, 10.10.2002, p. 1–95; replaced by Regulation (EC) No 1069/2009, OJ L 300, 14.11.2009, p. 1–33, Art. 11.1(b).

⁷⁵ Recital (1) Regulation (EC) No 1069/2009.

April 2006 on waste⁷⁶ defined key concepts such as waste, recovery and disposal and proposed a system for the registration of enterprises carrying out waste management operations. The subsequent European Waste Directive (2008/98/EC) of 19 November 2008⁷⁷ obliged member states in enacting waste legislation to consider the environmental impacts of waste disposal.

Article 22 of the European Waste Directive required Member States to take measures to encourage: (a) the separate collection of bio-waste with a view to the composting and digestion of bio-waste; (b) the treatment of bio-waste in a way that fulfils a high level of environmental protection; the use of environmentally safe materials produced from bio-waste. This Directive proposed a hierarchy of prevention, preparing for re-use, recycling, other recovery, such as energy recovery and disposal.⁷⁸

In December 2015, the European Commission presented its Action Plan for the Circular Economy (EC, 2015) which sought to increase the recycling of municipal and packaging waste, requiring Member States to take specific measures to prioritize prevention, re-use and recycling above landfilling and incineration. The Commission had originally presented proposals for new waste rules in 2014, but these were withdrawn and replaced by a proposal which supported awareness raising at national, regional and local levels and the dissemination of good practices in food waste prevention and which promised the creation of a platform dedicated to food waste for “Member States and all actors in the food chain” (EC, 2015). Annex to the Action Plan proposed a revised legislative proposal on waste. This was finalised on 30 May 2018 with Directive (EU) 2018/851 (“the Directive”)⁷⁹, amending the European Waste Directive (2008/98/EC).

Recital 31 of the Directive required Member States to take measures to promote the prevention and reduction of food waste in line with the UN Agenda for Sustainable Development, with its target of halving per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses, by 2030. It stated that Member States should aim to achieve an indicative food waste reduction target of 30 per cent by 2025 and 50 per cent by 2030 and that Member States should establish specific food waste prevention measures, including awareness campaigns to demonstrate how to prevent food waste, in their waste prevention programmes. It encouraged the exchange of good practices both between Member States and between food business operators and the establishment of a common methodology the measurement of progress.

Article 1 of the Directive, referred to the EU Food Safety Regulation⁸⁰, including food waste within the definition of food in that regulation, thereby enabling the application of the EU food safety regime to food waste (see Bremmers & Purnhagen, 2018). Article 1, also modified the definition of “bio-waste” in the previous Directive to mean “... food and kitchen waste from households, offices, restaurants, wholesale, canteens, caterers and retail premises and comparable waste from food processing plants”. Article 22 of the Directive required that by 31 December 2023 Member States had to ensure that bio-waste

⁷⁶ OJ L 114, 27.4.2006, p. 9.

⁷⁷ OJ L 312, 22.11.2008, p. 3–30.

⁷⁸ Ibid, Art.4.

⁷⁹ OJEU L 150, 14 June 2018, p.109.

⁸⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

was either separated and recycled at source or collected separately and is not mixed with other types of waste. Article 22(2) required Member States to take measures to encourage recycling, including composting and digestion of biowaste and to promote the use of materials produced from bio-waste.

In the list of waste prevention measures set out in Art.9 of the Directive, which Member States should undertake, were to:

(g) reduce the generation of food waste in primary production, in processing and manufacturing, in retail and other distribution of food, in restaurants and food services as well as in households as a contribution to the United Nations Sustainable Development Goal to reduce by 50 % the per capita global food waste at the retail and consumer levels and to reduce food losses along production and supply chains by 2030;

(e) encourage food donation and other redistribution for human consumption, prioritising human use over animal feed and the reprocessing into non-food products;

The Directive added to Art.4 of the European Waste Directive, paragraph 3, which required Member States to make use of economic instruments and other measures to provide incentives for the application of the waste hierarchy, such as those indicated in Annex IVa to the Directive. Annex IVa included fiscal incentives for the donation of food.

The recency of the Directive means that EU Member States have not yet had an opportunity to implement it, but a number of Member States, including the Republic of Ireland, France, Italy, Germany and the Netherlands, as well as Northern Ireland, have introduced direct legislation dealing with some aspects of food waste minimization. This is discussed below. In March 2017, the Polish Senate was reported to be considering food waste bill to combat food waste. Under which retail stores with a surface of more than 250 square metres will be required to pay a fee of PLN 0.1 (€0.02) per kg of food waste.⁸¹

Republic of Ireland

The Republic of Ireland was one of the first EU countries to introduce legislation specifically targeted at food waste. From 1996 it had enacted general waste management legislation in line with European waste management directives, such as the Landfill Directive (Directive 99/31/EC)⁸² Concern with the use of food waste at that time had been precipitated by various public health crises such as followed the various European food health crises, reflected in the Irish European Communities (Transmissible Spongiform Encephalopathies and Animal By-Products) Regulations 2008. This was followed by the first piece of legislation specifically dealing with food waste: *Waste*

⁸¹ See <https://iegpolicy.agribusinessintelligence.informa.com/PL046304/Polands-Senate-drafts-food-waste-law>, accessed 9 July, 2018.

⁸² Including: the Waste Management Act 1996 (No. 10 of 1996) as amended by the European Communities (Amendment of Waste Management Act, 1996); the Waste Management (Amendment) Act 2001 (No. 36 of 2001); Waste Management (Environment Levy) (Plastic Bag) Order 2007 (S.I. No. 62 of 2007); Waste Management (Landfill Levy) Order 2008 (S.I. No. 168 of 2008) and the Waste Management (Certification of Historic Unlicensed Waste Disposal and Recovery Activity) Regulations 2008 (S. I. No. 524 of 2008).

*Management (Food Waste) Regulations 2009*⁸³, which came into effect on 1 December 2010. These regulations focused on commercial enterprises, including any person organising a trade show, or exhibition⁸⁴ and required them to segregate food waste from non-biodegradable materials, other waste and contaminants.⁸⁵ Segregated food waste had to be collected by an authorised waste collector and transferred for an authorised treatment process.⁸⁶ Persons or enterprises governed by the regulations had to submit a waste management plan for approval by the environment authorities. Failure to comply with the regulations was a criminal offence.⁸⁷

The food waste regulations were extended to households in March 2013 by the European Union (*Household Food Waste and Bio-waste) Regulations 2013*.⁸⁸ These regulations required waste collectors to have a separate collection of household food waste to be provided at least fortnightly.⁸⁹ The producers of household waste were obliged to segregate food waste and to make it available for separate collection.⁹⁰ Alternatively householders could compost the food waste at home; or bring it themselves to authorised treatment facilities (such as civic amenity sites or anaerobic digestion sites).⁹¹ Householders were not permitted to macerate waste and dispose of it in a drain or sewer, or dispose of food waste in the residual waste collection(the black bin).⁹² The regulations also provided criminal penalties for infringers.⁹³

The 2013 regulations were replaced by the *European Union (Household Food Waste and Bio-waste) Regulations 2015*⁹⁴, which maintained the obligations imposed on householders and waste collectors by the 2013 regulations, but also obliged waste collectors to provide a receptacle to householders in which food waste would be placed for collection (brown bins).⁹⁵ By July 2017, brown bins were provided to most towns and villages. Population centres smaller than 500 persons were exempt, because it was considered not technically, environmentally or economically practical to separately collect such waste in these areas.

France

On 9 December 2015 the French National assembly adopted legislation prohibiting supermarkets throwing food away or making unsold food unfit for consumption through the addition of chemicals, the so-called Supermarket Waste Ban Law.⁹⁶ Under the law, supermarkets measuring over 400 square metres are required to sign an agreement with one or more organisations to redistribute their unused food. Non-compliance with these measures can attract fines of up to 75,000 euros.

⁸³ S.I. No. 508/2009.

⁸⁴ *Ibid.*, Sched. 1.

⁸⁵ *Ibid.*, cl.2(a).

⁸⁶ *Ibid.*, cl.2(b).

⁸⁷ *Ibid.*, cl.13.

⁸⁸ S.I. No. 71/2013.

⁸⁹ *Ibid.*, cl.5.

⁹⁰ *Ibid.*, cl.6.

⁹¹ *Ibid.*

⁹² *Ibid.*

⁹³ *Ibid.*, cl. 11.

⁹⁴ S.I. No. 430/2015

⁹⁵ *Ibid.*, cl.5(2).

⁹⁶ Proposition de Loi relative à la lutte contre le gaspillage alimentaire, 9 December 2015.

The legislation had originally passed through the National Assembly in May 2015 as Article 103 of an Energy Bill, but in August 2015 the Constitutional Council ruled that this article was procedurally invalid as it had been added as an amendment during the bill's second reading. Reacting to this court decision, Ségolène Royal, Minister for Ecology and Sustainable Development called upon the retail sector to adopt the legislative measure on a voluntary, contractual basis, threatening to name and shame companies who did not want to take part (Michail, 2015). However, with bipartisan support the Bill had been reintroduced by Guillaume Garot, the former Minister for the Food Industry, on February 11, 2016.⁹⁷

This legislation had been formulated as an element of a national food waste policy, released in April 2015.⁹⁸ This policy had 36 elements, the first of which was to “set into law a hierarchy of preferable actions to fight food waste” (Mourad, 2015). The legislation envisaged that by 2025, any organization producing waste above a given threshold will be required to direct those resources to their highest possible use, in the following order: “recovery of edible food for human consumption, animal feed, industrial uses, anaerobic digestion, and composting.”⁹⁹ Fines were proposed if food fit for human consumption was used for animal feed or composted.

The balance of the proposals involved public education and the promulgation of best practices and the policy envisaged that the French legislation might become part of a Europe-wide food waste code.¹⁰⁰

Italy

Until 2016 Italy had a range of laws which address aspects of food waste minimization. A Legislative Decree of 1992 deals with labelling, clarifying the difference between the expiration date for food and the "best before" date.¹⁰¹ Two decrees deal with the donation of food to charities¹⁰² culminating in the Good Samaritan Law which entered into force on July 16, 2003. This is modelled on equivalent legislation in the USA and limits the liability of food companies in relation to products which they donate to charities.¹⁰³ The Consolidated Environmental Decree (Testo Unico Ambientale) of 2006 introduced norms concerning waste management and remediation and treatment of polluted sites.¹⁰⁴ The 2013 Stability Law specified that both donors and beneficiaries of unsold/surplus food products must guarantee the proper state of preservation, transportation, storage and use of food.¹⁰⁵

On 2 August 2015, Italy became the second European country to introduce a supermarket waste law. The law made it easier for companies and farmers to donate food to charities and is encouraging greater use of “doggy bags” (renamed as “family bags”) at

⁹⁷ LOI no 2016-138 du 11 février 2016 relative à la lutte contre le gaspillage alimentaire

⁹⁸ *Lutte contre le gaspillage alimentaire: propositions pour une politique publique*, Mission Parlementaire menée par Guillaume Garot, April 14, 2015, <http://agriculture.gouv.fr/telecharger/72171?token=17ca3443c44991fa1f25c901dc7a66ce>.

⁹⁹ *Ibid* at 5.

¹⁰⁰ *Ibid* at 11.

¹⁰¹ Legislative Decree 109/1992 – Implementing EU Directives n. 89/395/CEE and 89/396/CEE concerning the labelling, packaging and advertising of foodstuffs.

¹⁰² Legislative Decree 4 December 1997, n.460/1997; Decree of the President of the Italian Republic, 26th of October 1972, n. 633

¹⁰³¹⁰³ Law n.155/2003.

¹⁰⁴ Consolidated Environmental Decree - n.152/2006 (amended in 2010).

¹⁰⁵ Law n. 147 of 27 December 2013

restaurants. It also allows stores to donate mislabeled food products if the expiration date and allergy information are properly indicated. The law arose out of the Italian National Plan for Food Waste Prevention (Piano Nazionale di prevenzione dello spreco alimentare) which the Ministry of Environment began to formulate in 2013, as well as the Zero Waste Charter launched in 2013 by Last Minute Market, a collector and distributor of surplus food) and the Municipality of Sasso Marconi (Bologna). The aim of these initiatives was to recover products discarded along the entire agro-food chain and to redistribute them to people living below the minimum income and to change the rules governing public contracts for food and catering services so as to favour firms that guarantee the free redistribution of recovered food.¹⁰⁶

On 14th September 2016, The Law Against Food Waste¹⁰⁷ came into effect. The Law has the objective **“to reduce waste for each of the stages of production, processing, distribution and administration of food, pharmaceuticals and other products” through the implementation of enumerated priorities.** These priorities are:

- Promoting the recovery and donation of food surpluses;
- Promoting recovery and donation of pharmaceuticals and other products;
- Contributing to limit the negative impacts on environment and natural resources, reducing the production of waste and promoting reuse and recycling to extend products' life cycles;
- Contributing to achieve of the general objectives set by the **“National Waste Prevention Program”** and the **“National Food Waste Prevention Plan”**, contributing to the “reduction of the amount” of biodegradable waste for landfill sites;
- Contributing to information, consumer awareness.

The Law provides for the donation of food, agricultural and agri-food goods that remain unsold or discarded from the food supply chain for commercial or aesthetic reasons, or proximity to the expiry date and food products that have passed the date of minimum durability, where packaging integrity and suitable storage conditions are guaranteed.

The donated goods are to be provided to the poorest citizens, but if not suitable for human consumption should be used for animal consumption and/or composting.

The Law provides that it is possible for receiving associations to collect free agricultural products directly from the farmers. These donations are carried out by and under the responsibility of the receiving association or non-profit organization.

The Italian law on the donation of food waste, unlike the [French Law No. 138/2016](#), does not impose the obligation of food waste donation upon processors and supermarkets, but seeks to establish incentives for donation, as well as simplifying the process of donation.

Germany

Germany has no food waste legislation comparable to that in France and Italy.¹⁰⁸ Not only does it not have “doggy bag” legislation, but it also criminalizes “dumpster diving”

¹⁰⁶ Zero Waste Charter, available from:

<http://www.unannocontrolospreco.org/images/CartaSprecoZero2.1.pdf>.

¹⁰⁷ **Law No. 166/2016, concerning provisions on the donation and distribution of food and pharmaceutical to limit food waste.**

¹⁰⁸ See www.eu-fusions.org/phocadownload/Reports/GERMANYper cent20FULLper cent20pdf.pdf

(opening commercial garbage containers and collecting food items) (Rombach & Bitsch, 2015).

Food waste is addressed in the 2013 Waste Prevention Programme of the Federal Government with the participation of the Federal States. The main law associated with waste is the 2012 “Kreislaufwirtschaftsgesetz” (Law on Life-Cycle Management) which includes regulations on the prevention, recycling and disposal of waste and waste management measures. One Federal law which implies food waste minimization is the Federal Pollution Control Act¹⁰⁹ and two provincial laws implying food waste minimization are those which regulate food services in correctional institutions in Baden-Württemberg and Brandenburg.¹¹⁰

The main German food waste minimization initiative which has attracted attention is a proposal by the Minister of Food and Agriculture. Announced in March 2016 to replace expiration dates with smart packaging, including the microchipping of dairy products to track freshness.¹¹¹

Netherlands

In common with Germany and most other EU Members the Netherlands does not have direct legislation dealing with food waste minimization; it merely implements the various EU regulations which have a bearing on marketing standards, food contamination, import controls, phytosanitary controls, food hygiene, novel food (GMOs), the provision of food information, fishery quotas and the use of by-products.¹¹² However, it is claimed that the Netherlands applies a more strict implementation of them (Waarts et al, 2011), which will exacerbate the food wastage problem in that country. In the absence of legislation, a number of voluntary organizations collect and distribute waste food (van der Meulen and G. Boin, 2015).

USA

Each of the US states has introduced legislation limiting the liability of food donors arising from foodborne illnesses (see Haley, 2013; Friedman, 2017). In 1977, California became the first state to adopt food donation legislation. This both limited the liability of individual and food donation agencies as well as providing tax incentives for donors (see Morenoff, 2002).

In 1990 Congress attempted to address the issues of liability and a lack of uniformity by developing a federal Model Good Samaritan Food Donation Act.¹¹³ This did not have the force of law and was only adopted by one state. To attempt to give the Model Act the force of law, in May 1996 Representative Pat Danner, with the co-sponsorship of

¹⁰⁹ Bundes-Immissionsschutzgesetz-Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge” (Act on the prevention of harmful effects on the environment caused by air pollution, noise, vibration and similar phenomena) (§ 5 Abs. 1 Nr. 3 BImSchG).

¹¹⁰ Verpflegungsordnung für die Justizvollzugsanstalten des Landes Baden-Württemberg Verpflegungsordnung für die Justizvollzugsanstalten des Landes Brandenburg Rundverfügung der Ministerin der Justiz.

¹¹¹ See <https://www.euractiv.com/section/agriculture-food/news/germany-plans-smart-packaging-to-cut-food-waste/>.

¹¹² Listed in <https://www.eu-fusions.org/phocadownload/country-report/NETHERLANDSpercent2023.02.16.pdf>, Table 2.

¹¹³ Pub. L. No. 101-610, §§ 401-02, 104 Stat. 3127, 3183-85 (1990).

Representative Bill Emerson, both of Missouri, introduced H.R. 2428, the Model Good Samaritan Food Donation Act. Representative Emerson died on June 22, 1996, before the final passage of the bill and in his memory, Congress amended the title of the statute to “The Bill Emerson Good Samaritan Food Donation Act”. This was signed into law by President Clinton on October 1, 1996.¹¹⁴ President Clinton noted that the complex web of inconsistent state legislation had acted as a hindrance to food donation.¹¹⁵

The Bill Emerson Act exempts a donor for liability arising from an injury caused by a food donation that was made in good faith, excluding liability for acts constituting gross negligence or for intentional misconduct.¹¹⁶ The Act provides civil or criminal liability shall not arise from the “nature, age, packaging, or condition”¹¹⁷ of the donated items as long as the donated item is either an “apparently wholesome food”¹¹⁸ or an “apparently fit grocery product”¹¹⁹ which is donated in good faith, to a nonprofit organization and distributed to needy individuals. The definition of “food” is quite broad because it includes “any raw, cooked, processed, or prepared edible substance, ice, beverage, or ingredient used or intended for use in whole or in part for human consumption.”¹²⁰

The Bill Emerson Act exempts from liability gleaners and non-profit organizations. A “gleaner” is a person that harvests an agricultural crop that has been donated by the owner for either free distribution to the needy directly or to a nonprofit organization for ultimate distribution to the needy.¹²¹ A “nonprofit organization” can be either an incorporated or unincorporated entity that “operat[es] for religious, charitable, or educational purposes; and does not provide net earnings to, or operate in any other manner that inures to the benefit of, any officer, employee, or shareholder of the entity.”¹²²

The Federal Food Donation Act 2008¹²³ supplemented the Bill Emerson Act by encouraging federal agencies to donate excess food to non-profit organizations. Federal contracts for the purchase of food valued at over \$25,000 had to make provision for contractors to donate apparently wholesome excess food to non-profit organizations.

Discussion of food waste legislation has been revived in the USA in recent years. On 23 March 2016 Congresswoman Chellie Pingree (Maine) introduced the Food Recovery Act (HR 4184) and the Food Date Labeling Act (HR 4184) into the House of Representatives. Senator Richard Blumenthal (Connecticut) introduced equivalent legislation into the Senate.¹²⁴ None of this legislation has progressed further than the committee stage in Congress. The Food Recovery Acts sought to establish an Office of Food Recovery to oversee the country’s efforts to reduce food waste and for education campaigns in

¹¹⁴ Pub. L. No. 104-210, 110 Stat. 3011, 3011 (1996) (codified at 42 U.S.C. § 1791 (2011)).

¹¹⁵ Presidential Signing Statement on Signing H.R. 2428, 32 *Weekly Comp. Pres. Doc.* 1943 (Oct. 7, 1996).

¹¹⁶ 42 U.S.C.A. § 1791.

¹¹⁷ *Ibid* at § 1791 (c)(1)

¹¹⁸ “means food that meets all quality and labeling standards imposed by Federal, State, and local laws and regulations even though the food may not be readily marketable due to appearance, age, freshness, grade, size, surplus, or other conditions”, 42 U.S.C.A. § 1791(b)(2).

¹¹⁹ “means a grocery product that meets all quality and labeling standards imposed by Federal, State, and local laws and regulations even though the product may not be readily marketable due to appearance, age, freshness, grade, size, surplus, or other conditions”, 42 U.S.C.A. § 1791(b)(1).

¹²⁰ 42 U.S.C.A. § 1791(b)(2)

¹²¹ *Ibid.* at § 1791(b)(5).

¹²² *Ibid.* at § 1791(b)(9).

¹²³ S.2420, Public Law No: 110-247 (06/20/2008).

¹²⁴ S.3108 - Food Recovery Act of 2016, (Introduced June 29, 2016); S.2947 - Food Date Labeling Act of 2016 (introduced May 18, 2016).

schools and for consumers on food waste and to encourage the donation to schools of so-called “ugly” produce, which did not meet high aesthetic standards. The House bill included tax incentives for donating uneaten food and several other anti-waste measures, but the Senate bill did not include the latter, as they were included in the omnibus spending bill that Congress passed in December 2016.¹²⁵

In February 2017, Congresswoman Marcia Fudge (Ohio), Congressman Jim McGovern (Maryland), Congressman Dan Newhouse (Washington) and Congresswoman Chellie Pingree introduced the Food Donation Act of 2017.¹²⁶ This sought to amend the Bill Emerson Act by expanding exemption from to resale of food to nonprofit retailers, donation or resale directly to individuals, donation or resale of past-dated foods that meet safety and labeling standards, and donation or resale of mislabeled food if the mislabeling does not affect food safety.

The Federal Tax Reform Act of 1976 increased the possibility for corporations to claim tax deductions for contributions to charities or foundations.¹²⁷ The Internal Revenue Code was amended to allow corporations to make tax deductions for contributions of “apparently wholesome food” to donees that care for the ill, needy, or infants.¹²⁸ This provision adopted the language of the Bill Emerson Act and was expanded in 2016 to a greater range of claimants.

A number of state legislatures have also recently introduced food donation legislation. In October 2014 Massachusetts banned the disposal of organic material including food waste.¹²⁹ From January 2015 Seattle has banned the disposal of all food waste.¹³⁰ From 1 July, 2015, New York requires food-service establishments above a certain capacity to separate their food waste and arrange for either composting, aerobic or anaerobic digestion, or other approved method of organic waste disposal.¹³¹

As in other countries, legislation has been supplemented by government initiatives to encourage voluntary action to reduce FLW. In 2013, the United States Department of Agriculture (USDA) and the Environment Protection Agency (EPA) jointly launched the U.S. Food Waste Challenge to “reduce, recover, and recycle food waste.”¹³² The Food Waste Challenge sought to engage producers, processors, manufacturers, retailers, communities, and other government agencies in programs to educate consumers about food waste and to streamline procedures for donating wholesome misbranded meat and poultry products, and facilitate the donation of products which were rejected for not meeting USDA standards.¹³³ In September 2015, the USDA and EPA announced the United States' first national food waste reduction goal: a 50 percent decrease by 2030.¹³⁴

Japan

¹²⁵ The Continuing *Appropriations Act, 2016* (Public Law 114- 53) H. R. 2029—800, s.113.

¹²⁶ H.R. 952, 115th Cong.(2017).

¹²⁷ Tax Reform Act of 1976, Pub. L. No. 94-455, 90 Stat. 1520, (codified in I.R.C. § 170).

¹²⁸ I.R.C. § 170(e)(3)(C)(iii)(vi) (West 2015).

¹²⁹ Massachusetts Commercial Organic Material Waste Ban Amendments, January 2014 (codified as 310 *Mass. Code Regs.* § 19.000).

¹³⁰ Seattle, Wash., Ordinance 124582 (Sept. 22, 2014).

¹³¹ New York Local Law 146 of 2013,

¹³² See <https://www.usda.gov/oce/foodwaste/>

¹³³ *Ibid.*

¹³⁴ See <https://www.usda.gov/media/press-releases/2015/09/16/usda-and-epa-join-private-sector-charitable-organizations-set>, accessed 3 July 2018.

The Promotion of Utilization of Recyclable Food Waste Act (or Food Recycling Law) came into force in May, 2001, driven by food security concerns in a largely food importing economy (Marra, 2013). The Food Recycling Law defines food waste as food materials which are disposed after being served or without being served as food and materials which are not able to be provided as food and can be obtained as a by-product in the process of manufacturing processing and cooking (See Parry et al, 2015). The Food Recycling Law provides for the registration of recycling operators and a certification system for recycling business plans for food related businesses. The registration system identifies business operators which undertake to conduct their recycling business according to government norms.

Registration secures preferential treatment under the Feed Safety Law and Fertiliser Control Act, eliminating the obligation to notify sales and production of feed and fertiliser and it enables special treatment under the Waste Disposal and Public Cleansing Law eliminating the requirement for a work permit for the transportation of municipal solid waste.

An approved business plan for the use of feed and fertiliser from recycled food materials also receives special treatment under the Feed Safety Law, Fertiliser Control Act, and the Waste Disposal and Public Cleansing Law. Under this system, food-related businesses can expect stable supplies of primary products from agriculture, livestock and fisheries, and recycling businesses.

The Food Recycling Law, requires its revision every five years and it was amended in 2007, requiring operators with more than 100 tonnes of annual food waste generation to report annually the status of generation and recycling of their food wastes. On the basis of these reports the Ministry of Agriculture, Fisheries and Forestry (MAFF) and at the Ministry of Environment (MoE) have established the target value for the control of food waste generation, For a two year period, from April 2012 they set target levels for 16 industry groups that dispose of edible parts of food due to over-production and since April 2014 have widened this to cover 26 industry groups. In October 2014 consumer education was adopted as a future focus for the legislation, as well as strengthening cooperation amongst local governments.

Northern Ireland

Interestingly, although, as we will see below, the UK has not enacted legislation concerning food waste, the province of Northern Ireland has enacted regulations dealing with food waste, the most recent of which were the Food Waste Regulations (Northern Ireland) 2015, which came into effect on 4th February 2015. These Regulations seek to implement the EU Waste Directive, 2008/98/¹³⁵, amending the Waste and Contaminated Land (Northern Ireland) Order 1997¹³⁶ and the Landfill Regulations (Northern Ireland) 2003¹³⁷ to provide for the separate collection of food waste. The Food Waste Regulations established a number of dates, by which action had to be taken. These were:

01/04/2015 - Where food waste is segregated, carriers must collect and transport food waste separately from other waste. No requirement for producers to segregate food waste but, if they choose to do so, carriers obligation applies.

¹³⁵ EC OJ L 312, 22.11.2008, p.3.

¹³⁶ S.I. 1997/2778 (N.I.) 19.

¹³⁷ S.R.2003 No.496.

01/04/2016 - Food businesses producing greater than 50kg of food waste per week, to secure the separate collection of that waste.

01/04/2017 - Food businesses producing greater than 5kg of food waste per week, to secure the separate collection of that waste. There is no legislative requirement for food businesses which produce less than 5kg of food waste, to collect it separately.

01/04/2017 - Food waste must not be deposited in a lateral drain or public sewer.

These Regulations required district councils to provide receptacles for the separate collection of food waste from households.

Voluntary Regulation – UK

A Food Waste (Reduction) Bill was presented to House of Commons on 9 September 2015 requiring large supermarkets, manufacturers and distributors to reduce supply-chain food waste by 30 per cent by 2025 in line with European Commission targets.¹³⁸ They would also have to report levels of food waste, and enter formal redistribution agreements with food banks and other civil society organisations. The Bill also sought to incentivise observance of the EU's Food Waste Reduction Hierarchy, to prioritise redistribution over the sending of edible food to the energy sector for Anaerobic Digestion. The Bill did not succeed in securing Parliamentary support, the Government's recycling minister, suggested that the "threat of future legislative action" meant that its aims could be achieved through voluntary schemes.¹³⁹

Direct regulation of food waste in the UK had been considered in 2016 and 2017 by the House of Commons Environment, Food and Rural Affairs Committee (House of Commons, 2017). The Committee did not recommend direct regulation by legislation, reporting that the majority of the witnesses which appeared before it were not in favour of legislation and that the practical difficulty in policing such legislation was mentioned, as well as the creation of more red tape (House of Commons, 2017, para 100). The Committee confined itself to recommending the better communication of current fiscal incentives that were available to companies, in order to support their efforts to redistribute surplus food and recommended the government assesses how it might further promote the redistribution of surplus food by additional fiscal measures. (House of Commons, 2017, paras 104-5).

The key ingredient of the voluntary FLW minimization regime in the UK is contained in the Courtauld 2025 commitment, which was an initiative of WRAP (Waste and Resources Action Programme). This is a registered UK charity working with businesses, individuals and communities to promote the reduction of waste and the development of sustainable practices. It was established in 2000 as a company limited by guarantee, receiving from the Department for Environment, Food and Rural Affairs, the Northern Ireland Executive, Zero Waste Scotland, the Welsh Government and the European Union. WRAP has launched a number of initiatives, including "Recycle Now" and "Love Food, Hate Waste" with a view to assisting businesses, local authorities, community groups and individuals to reduce food waste. In 2005 it launched the Courtauld Commitment a voluntary agreement signed by major UK supermarkets designed to reduce waste across the UK grocery sector. This was renewed in 2010 and again in 2015.

¹³⁸ <https://foodfoundation.org.uk/food-waste-reduction-bill/>, accessed 9 July 2018.

¹³⁹ Ibid.

Courtauld 2025 is the fourth iteration of the voluntary agreement between organisations across the food system.¹⁴⁰ It comprises a ten-year commitment by signatory organizations to identify priorities, develop solutions and implement and developing best practice across the UK. The shared objective is to cut the resource needed to provide food and drink by one-fifth in ten years.¹⁴¹ Signatories announced at the launch of the agreement included and all the major UK retailers representing over 93per cent of the 2016 UK food retail market.¹⁴² Commitment targets are estimated to deliver £20 billion worth of savings to the UK economy and to discharge its obligations under UN Sustainable Development Goal 12.3 to halve household and retail waste.

WRAP is to work directly with stakeholders to support actions in Courtauld 2015 under four main areas:

- Embedding sustainable principles and practices into the design, buying and sourcing of food
- Optimising resource efficiency throughout entire supply chains to help produce more goods using less resources
- To influence behaviours around consumption and reduce waste in the home
- To find innovative ways to make the best use of surplus and waste food.¹⁴³

As for the effectiveness of the various Courtauld initiatives, WRAP reports that Courtauld Phase 1 (2005-2009) resulted in 1.2 million tonnes of food and packaging waste being prevented, with a monetary value of £1.8 billion, and a saving of 3.3 million tonnes of CO₂e.¹⁴⁴ Phase 2 (2010-2012) resulted in an estimated reduction of 1.7 million tonnes of waste with a monetary value of £3.1 billion and equates to a reduction of 4.8 million tonnes of CO₂e.¹⁴⁵ Courtauld 3 (2012-2015) was reported to have met the manufacturing and retail target in full meaning with a reduction in grocery ingredient, product and packaging waste by 3per cent, equating to 219,000 tonnes of food and packaging waste prevented, representing a CO₂e saving of 555,000 tonnes.¹⁴⁶

In considering the efficacy of regulatory options for FLW minimization a question which logically springs to mind is whether in the UK greater results might have been obtained by a mandatory regulatory regime, rather than the voluntary regime which is in place.

A Food Waste (Reduction) Bill 2015-16 was introduced as a Private Members bill by an opposition MP, Kerry McCarthy, on 9 September 2015. The bill failed to make any progress during the 2015-16 session of Parliament and fell into abeyance. The Bill required the Secretary of State for the Environment, Food and Rural Affairs to make

¹⁴⁰ See <http://www.wrap.org.uk/content/what-courtauld-2025>.

¹⁴¹ See <http://www.wrap.org.uk/content/courtauld-commitment-2025-transform-uk-food-and-drink>.

¹⁴² Retailers: Aldi, ASDA, Central England Co-operative, Lidl, M&S, Morrisons, Musgraves, Sainsbury's, Tesco, The Co-operative Food and Waitrose; Brands & manufacturers: ABF UK Grocery Group, ARLA, Birds Eye UK, Coca Cola Enterprises, Heineken, Nestlé UK and Ireland, Premier Foods, Unilever, and Warburtons.; Hospitality and food service: apetito, Bidvest, Compass, Greene King Retail, KFC, OCS, Pizza Hut, Sodexo UK & Ireland; Local authorities: 23 authorities including the London Waste and Recycling Board representing more than 42per cent of the UK's population; Trade and sector organisations, Government and academia: British Hospitality Association, British Retail Consortium, Chilled Food Association, Dairy UK, Food & Drink Federation, Food Standards Agency, Institute of Hospitality, Sustainable Restaurant Association and WWF. Ibid.

¹⁴³ <http://www.wrap.org.uk/content/courtauld-commitment-2025-transform-uk-food-and-drink>.

¹⁴⁴ <http://www.wrap.org.uk/content/what-is-courtauld>.

¹⁴⁵ Ibid.

¹⁴⁶ <http://www.wrap.org.uk/content/courtauld-commitment-3-delivers-over-per-centC2per-centA3100-million-business-savings-reducing-food-waste-over-three-year-period>.

provision for a scheme to establish incentives to implement and encourage observance of the food waste reduction hierarchy; to encourage individuals, businesses and public bodies to reduce the amount of food they waste; to require large supermarkets, manufacturers and distributors to reduce their food waste by no less than 30 per cent by 2025 and to enter into formal agreements with food redistribution organisations; to require large supermarkets and food manufacturers to disclose levels of food waste in their supply chain.¹⁴⁷ The Bill contained a number of the features which were included in the French Supermarket Waste Ban Law, discussed in the next section.

The Government's recycling minister, Rory Stewart, expressed support for the Bill's core principles, but indicated that the "threat of future legislative action" meant that its aims could be achieved through voluntary schemes.¹⁴⁸ The sponsor of the Bill indicated that it would remain on the table "as a much-needed regulatory back-up plan if C2025 fails to deliver."¹⁴⁹

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¹⁴⁷ See <http://services.parliament.uk/bills/2015-16/foodwastereduction.html>

¹⁴⁸ See <http://foodfoundation.org.uk/food-waste-reduction-bill/>

¹⁴⁹ <http://www.ciwm-journal.co.uk/food-waste-reduction-bill-whats-next/>

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Climate change and intellectual property: Regulatory Issues

Introduction

Climate change is imposing significant stresses upon agriculture at a time when more food is required for an increasing world population. The breeding of stress resistant crops or their genetic engineering are possible responses to these difficulties. Intellectual Property Rights (IPRs) have been identified as a means for incentivising agricultural innovations. The creation of plant patents and plant breeders' rights date back to the beginning of the 20th Century when Carl Correns rediscovered Mendel's plant breeding experiments. As early as 1906 a Bill was introduced into Congress providing for the protection of plant patents. The later development of recombinant DNA technology provided the technological basis for the patenting of DNA. Climate change concerns has led to the identification of and patenting of stress-tolerant genes.

The international IPR regime based upon the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) establishes a global intellectual property regime which obliges states to provide legal protection for newly developed plant varieties and also enables the patenting and therefore commodification of stress-tolerant DNA in the 177 member states of the WTO. As a matter of practice, most of this patenting is confined to a relatively small group of life-sciences companies. This is resulting in a market concentration which has important agricultural policy implications particularly for developing countries. This chapter analyses these issues, concluding that the impact of patenting upon food security is becoming as significant as the impact of patenting upon access to medicines.

International Intellectual Property Infrastructure

The global commercial significance of climate technologies is assured by the global reach of the international intellectual property (IP) regime. Members of the World Trade Organization (WTO), which include some 153 countries as of 10 February 2011,¹⁵⁰ are obliged to introduce IP laws which implement the norms prescribed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). Key provisions in the present context are Article 23.1 which provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." This provision requires also that "patents shall be available and patent rights enjoyable without discrimination as to the ... field of technology". The effect of this provision is to establish a patenting regime which extends to all WTO Members. Additionally, Article 27.3(b) of the TRIPS Agreement requires that WTO Members

¹⁵⁰ See http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, accessed 10 April 2012.

“shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.”

Although the TRIPS Agreement does not prescribe a *sui generis* system for the protection of plant varieties, most countries have adopted the 1991 version of the International Convention for the Protection of New Varieties of Plants (UPOV). Thus to January 15 2011 the UPOV Convention has signatories, with 41 of those joining after 1 January, 1995.¹⁵¹ One of the reasons why countries have tended to adopt UPOV 1991, rather than to craft a *sui generis* alternative, is that the IPR chapters in the free trade agreements (“FTAs”) signed since the 1990’s by the USA and the EU with their various bilateral partners includes the obligation to subscribe to the 1991 version of UPOV. UPOV provides for the protection of new plant varieties which are “distinct”, “uniform” and “stable”. Excepted from protection under the 1978 version of UPOV, was propagating material which had been harvested by farmers and retained for further planting or for sale. Article 15 (2) of the 1991 version of UPOV Convention confined this seed saving exception to the use of saved material for propagating purposes farmers’ own holdings and in reasonable quantities. UPOV 1991 also permits the use of protected varieties for the purpose of breeding new varieties. As is indicated below, where a new variety can be patented, the seed saving and breeding exceptions become irrelevant.

Patenting of DNA

The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. These include: (i) pest control traits such as insect, virus and nematode resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage prone fruits; (ii) agronomic traits such as nitrogen fixation and utilisation, restricted branching, environmental stress tolerance, male and/or seed sterility for hybrid systems; and (iii) output traits such as plant colour and vitamin enrichment. The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies.

A key issue around the patenting of genetic resources was whether a DNA sequence could be characterised as an “invention”. In the early history of patent law an invention was thought to involve some kind of technical innovation and a distinction was drawn between patentable inventions and non-patentable discoveries. The US Supreme Court in its 1980 determination, *Diamond v Chakrabarty* (447 US 303 (1980)) held in a 4:3 majority decision that a bacterium genetically engineered to degrade crude oil was an invention. This decision provided the legal underpinning for the US biotechnology industry. The European Parliament’s belated response in 1998 was its Biotechnology Directive which provided in Article 3.2 that “biological material which is isolated from its natural environment or produced by means of a technical process is deemed to be an invention even if this material previously occurred in nature.”

The patentability of genetic materials and gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), as well as enabling gene-based technologies led to what has been described as a “genomic gold rush” in the 1990s as vast numbers of gene-based patent applications were filed, particularly in the USA (Yoly, 2003). Significant misgivings were expressed by numerous commentators. Probably the

¹⁵¹ <http://www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf>, accessed 8 December 2011.

most influential among these were Heller and Eisenberg (1998) who suggested that genetic research tool patents could create a “tragedy of the anticommons” in which multiple patent owners would tie-up genetic materials in a thicket of IP patent rights. This was perceived by Correa (2009) to be a particular problem for the genetic improvement of crops since this is an incremental process and each new patent would constrain the “freedom to operate” particularly of public agricultural research institutes.

Arguably, this gold rush has been brought to an end, at least in the USA, by 2005 in the *In re Fisher* decision of the US Court Of Appeals for the Federal Circuit (421 F.3d 1365 (Fed. Cir. 2005)), which upheld a ruling by the US Board of Patent Appeals and Interferences refusing to allow patent applications made on behalf of Monsanto Co on five ESTs encoding protein and protein fragments in maize plants grown by the Asgrow Seed Company of Des Moines, Iowa. Joly (2006) suggested that that the *Fisher* case was used by Monsanto Co, a significant downstream user of research tools, to urge upon the court a higher patentability standard in order to eliminate the thousands of research tool patents which were cluttering research efforts. Mainly for this reason, the case attracted amicus briefs filed by academic institutions as well as major biotechnology and pharmaceutical companies. The Board of Patent Appeals and Interferences was unable to identify any “substantial utility” or usefulness in the application for patentability of the ESTs. The Appeal Court agreed with this approach stating that that claimed inventions “ought to have a specific and substantial utility” to satisfy the requirements of the US patent statute. The Court observed that the application comprised asserted uses based upon “merely hypothetical possibilities” which had not yet been achieved in the real world. As the applicant did not identify the function for the underlying protein-encoding genes, the Court held that “the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent”.

Although this decision imposed a higher patent standard, which might result in the invalidation of previously granted patents over research tools, this was not specifically addressed by the Court. However, Joly (2006) optimistically suggested that “academic researchers. as well as a considerable portion of the biotechnology and pharmaceutical industry will be satisfied by this judgment as it should reduce the number of parasite patents on gene sequences, in the United States.”

Two recent US cases have raised the very question of the patentability of genetic material. In *Association for Molecular Pathology v. USPTO* (94 USPQ2d 1683 (S.D.N.Y. March 29, 2010)) a Judge of the United States District Court for the Southern District of New York delivered a summary judgement which invalidated patents related to the BRCA 1 and 2 breast and ovarian cancer susceptibility genes, which had been held by the company Myriad Genetics. He ruled that the claims to DNA sequences in isolation were held to be insufficiently distinct from naturally occurring genes in the body and were thus products of nature rather than inventions. He observed that DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature and that DNA in an “isolated” form alters neither this fundamental quality as it exists in the body nor the information it encodes”.

This decision was successfully appealed to the U.S. Court of Appeals for the Federal Circuit (CAFC) in Washington, D.C., which published its decision in August 2011. The Appeal Court considered that the District Court, Judge had fallen into error in considering not whether the isolated DNAs were markedly different from naturally occurring DNAs, but rather whether they had the same informational content as native DNA sequences.

Nevertheless, the CAFC considered that the District Court was correct in holding that Myriad's claims directed to comparing and analysing gene sequences were not patentable, as these claims contained no transformative steps and covered only patent ineligible abstract steps.

This reasoning was considered recently by the US Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (No. 10–1150. Decided March 20, 2012) which concerned patents obtained by Prometheus which instructed doctors in the use of thiopurine drugs to treat autoimmune diseases. Mayo had developed its own diagnostic test which Prometheus claimed infringed its patents. Justice Breyer, delivering the opinion of the Court, noted the long held view of the Supreme Court that laws of nature, natural phenomena, and abstract ideas are not patentable. He quoted from the Court's decision in *Diamond v Chakrabarty* that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.” (at p.309). The Court held that Prometheus' process was not patent eligible because the laws of nature recited by Prometheus' patent claims, ie the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm, were not themselves patentable.

The opponents of the patents in the Myriad Genetics litigation have claimed that the Prometheus decision calls into question the Appeal Court decision in that case whereas the supporters of the Appeal Court draw a distinction between the method claims in that case and the composition-of-matter claims in the Prometheus suit (Frankel, 2012). In any event on March 26, 2012 the Supreme Court remanded to Appeal to it in the Myriad Genetics litigation to the Court of Appeals for the Federal Circuit for further consideration in light of its decision in Prometheus.¹⁵²

4. DNA Patenting and Agriculture

The cultivation by farmers of GM crops has on occasion led to IP liability, where genetically modified (GM) seed is patented and the cultivation of that seed by the patentee is unauthorised. The cases are divided between those where farmers knowingly cultivate patented GM seed and those where the cultivation of patented seed is apparently inadvertent, for example, where crops are apparently pollinated by wind or insect-borne pollen.

An example of the first category of case is *Monsanto Co. v. Scruggs* (342 F. Supp 2d 584 (2004)) which concerned Monsanto's patented Roundup Ready (“RuR”) glyphosate tolerant seeds. This was licensed to seed companies, who were obliged to sell the seed to growers who signed technology license agreements acknowledging Monsanto's patent and on condition that they could only be used by growers for a single commercial crop, i.e growers could not save seed produced from a harvested crop for replanting during the following growing season. Scruggs, who had not signed a technology licensing agreement, purchased a small quantity of RuR soybeans and cotton seeds which were cultivated and from which he saved seed for further plantings. The Court decided that Monsanto's patent had been infringed by Scruggs, rejecting his defence that neither Monsanto's biotechnology nor the plants in their fields were covered by the patent and that the first sale of the seed embodying the invention exhausted the patent rights of Monsanto. The Court noted that Monsanto never made an unrestricted sale of its seed

¹⁵² <http://www.supremecourt.gov/orders/courtorders%5C032612zor.pdf>

technology, as it licensed its technology to seed companies with a proviso: subsequent sales of seed containing its transgenic trait must be limited to growers who obtained a license from Monsanto and for only a single growing season.

A recent variant of these facts occurred in *Monsanto Co v Bowman* (No. 10-1068, Fed. Circuit, Sept. 21, 2011), where a farmer, Bowman, purchased commodity seeds from a local grain elevator which were not subject to a technology agreement. Following the application of glyphosate to the crops grown from these seeds, Bowman identified those which were glyphosate resistant and these were saved and re-planted in subsequent years which enabled Bowman to use glyphosate-based herbicide. Monsanto filed a patent infringement claim against Bowman and in September 2009, the district court in Indiana granted summary judgment on patent infringement for Monsanto. Bowman appealed to the Court of Appeals for the Federal Circuit. Bowman argued that Monsanto's patent rights were exhausted under the first sale doctrine in relation to all second-generation Roundup Ready soybean seeds that were present in the grain elevators. He cited the 2008 Supreme Court case of *Quanta Computer, Inc. v. LG Electronics, Inc.* (553 U.S. 617 (2008)). In this case the Supreme Court held that sales of products that "substantially embody" the disputed patents will also be considered sales that exhaust the patent right. Bowman argued that the court should hold that subsequent generations of the seeds are "substantial embodiments" of the first generation seeds, and thus the sales of these seeds would be exhausting sales. The appeal Court held that even if Monsanto's patent rights in the commodity seeds were exhausted, such a conclusion would be of no consequence because once a grower, like Bowman, planted the commodity seeds containing Monsanto's RuR technology and the next generation of seed developed, the grower had created a newly infringing article. It observed that "The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder."

A case of apparently inadvertent infringement is illustrated by the Canadian litigation between Monsanto Canada, Inc and a farmer, Percy Schmeiser. Schmeiser grew canola commercially in Saskatchewan. He had never purchased Monsanto's patented RuR Canola nor did he obtain a licence to plant it. Yet, in 1998, tests revealed that 95 to 98 percent of his 1,000 acres of canola crop was made up of RuR plants. The origin of the plants is unclear. They may have been derived from RuR seed that blew onto or near Schmeiser's land. Monsanto brought an action for patent infringement. In finding patent infringement the trial judge ruled that the growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constituted taking the essence of Monsanto's invention, using it, without permission and in so doing infringed the patent. By a majority of 5:4 the Federal Court of Appeal ruled that Schmeiser's saving and planting seed, then harvesting and selling plants that contained the patented cells and genes appeared to the Court, on a common sense view, to constitute "utilization" of the patented material for production and advantage, within the meaning of s.42 the Canadian *Patent Act* (*Monsanto Canada, Inc. v. Schmeiser*. [2004] 1 S.C.R. 902, 2004 SCC 34). The argument that the infringing seed had merely grown, as the result of wind pollination, or through the pollinating activities of birds and bees was rejected by the majority Judges as denying "the realities of modern agriculture." What was at stake in this case was sowing and cultivation, "which necessarily involves deliberate and careful activity on the part of the farmer". They noted that he had actively cultivated RuR Canola as part of his business

operations, thus in light of all of the relevant considerations, Schmeiser had used the patented genes and cells, and infringement was established.

Patenting of stress-tolerant genes

Somvanshi in a 2008 study identified 30 patents relating to drought tolerant genes (2008). These included: (i) patents related to Proline biosynthesis; (ii) patented dehydration responsive element binding factors (DREB) and C-repeat sequences binding factors (CBF); (iii) patents related to Protein Kinases; (iv) various patents awarded for transcription factors involved in improving drought stress tolerance in plants, and (v) patents related to miscellaneous drought tolerance genes. A 2008 study by the ETC Group identified 55 patent “families” or related patent applications and/or issued patents published in more than one country or patent office (ETC, 2008). A total of 532 patent documents were identified which represented applications to patent offices by a group of biotechnology companies on so-called “climate-ready” genes at around the world Issued patents and/or applications that belong to the same family have the same inventor and they refer to the same “invention.”).

Its 2010 update of this study “examined patents containing claims concerned with abiotic stress tolerance (ie traits related to environmental stress, such as drought, salinity, heat, cold, chilling, freezing, nutrient levels, high light intensity, ozone and anaerobic stresses” (ETC, 2010). It noted “a dramatic upsurge in the number of patents published (both applications and issued patents) related to ‘climate-ready’ genetically engineered crops from June 30, 2008 to June 30, 2010, identifying 262 patent families and 1663 patent documents (ETC, 2010, Appendix A).

Debate on role of corporations in the patenting of stress tolerant genes

The 2008 ETC report was subjected to a close analysis by Dr Carol Nottenburg (2009), the Principal of a US Patent firm and it is useful to examine the claims and counter-claims to identify the significant elements of the debate about the patenting of stress tolerant genes, as her comments are equally applicable to the 2010 ETC report. The ETC report stated that the so-called “Gene Giants”, exemplified by BASF, Bayer, DuPont, Monsanto and Syngenta “are staking sweeping patent claims on genes related to environmental stresses” in patent offices around the world. Dr Nottenburg points out that the patenting of gene sequences is not permitted in a number of developing countries, including Andean countries and an examination of the patents which are identified in the 2008 report have been sought in Argentina, Brazil and China, leaving more than 200 countries “in which these patent applications will never be pertinent”. A similar argument was advanced by Attaran and Gillespie-White (2001), that patents did not stand in the way of access to HIV anti-retrovirals in most African countries, but the political impact of the patents in a few of those countries, far outweighed their practical significance and brought about the first amendment of the TRIPS Agreement (Hestermeyer, 2007).

Dr Nottenburg also pointed out that the number of patent families is the better indicator of the incidence of the patenting of stress-tolerant genes, than patent filings. This is certainly the case, as a number of filings are duplicated in different countries. The 2010 report identifies some 262 patent families which is a considerable advance on the 55 identified in the 2008 report. However, it should be noted that even a small number of patent families can have a considerable political impact. For example, if the number of

biopiracy incidents was totalled, they would probably not exceed around 20 causes celebres.

The 2008 report is critical of over-broad patent claims, but Dr Nottenburg considers this to be a matter dictated by the “eye of the beholder” and in one case involved an error in the published patent document. She concludes that “visions of gene-grabbing and holding farmers hostage are unwarranted”. A particular problem had been that patent applicants had been allowed to make bulk claims in relation to genetic material of which the use had not yet been identified. However, the 2010 report concedes that in 2001 the USPTO put a brake on “bulk claims” by issuing new guidelines requiring that claimed inventions must have “well-established” utility and that in 2007 the USPTO limited bulk claims by notifying its patent examiners that they the option of restricting claims to only a single nucleotide sequence in each patent application.

The 2010 report of the ETC contrasts the ownership of 9% patent families by public sector institutions (9% of the total) with the private sector which holds 91% of the total. As is the case with biotechnological patenting generally, proprietary biotechnologies are concentrated in the same few corporations (see also Lesser, 1998). The 2010 report points out that “just three companies – DuPont, BASF, Monsanto – account for two-thirds (173 or 66%) of the total.” This level of market concentration gives cause for concern for those who espouse the positive role of competition.

In addition to the possible adverse impacts this market concentration might have upon the vigour of competition, the market dominance of these private corporations also has an important influence upon the sort of biotechnological research which is undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research towards Northern concerns away from Southern Southern food priorities (Alston, 1998). It has been estimated that only 1% of research and development budgets of multinational corporations is spent on crops of interest be useful in the developing world (Pingali and Traxler, 2002). Almost entirely neglected by these corporations are the five most important crops of the poorest, arid countries - sorghum, millet, pigeon pea, chickpea and groundnut (Human Rights Council, 2008).

Patenting of Plant Varieties

The development of new plant varieties is protectable in most countries as a species of intellectual property right (IPR) derived from the International Convention for the Protection of New Varieties of Plants (UPOV) Countries which are members of the World Trade Organization (WTO) are obliged by Article 27.3(b) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to “provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.” The TRIPS Agreement does not specify which “*sui generis* system” will meet its requirements, but most of the Members of the WTO have promulgated domestic legislation based upon the 1991 version of UPOV.

UPOV allows the protection of new varieties of plants which are distinct, uniform and stable. A variety is considered to be new if it has not been commercialized for more than one year in the country of protection. A variety is distinct if it differs from all other known varieties by one or more important botanical characteristics. A variety is uniform if the plant characteristics are consistent from plant to plant within the variety. A variety is stable if the plant characteristics are genetically fixed and therefore remain the same from generation to generation, or after a cycle of reproduction in the case of hybrid

varieties. The 1991 version of UPOV recognizes the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as are not "essentially derived" from protected varieties. The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. From the perspective of farmers, probably the most contentious aspect of the 1991 Act is the limitation of the farmers' privilege to save seed for propagating the product of the harvest they obtained by planting a protected variety "on their own holdings," "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder." Earlier versions of UPOV permitted farmers to sell or exchange seeds with other farmers for propagating purposes.

The seed saving privilege and the permitted development of non-essentially derived new varieties from protected material were compromises built in to the legislation to take account of public policy concerns. It was appreciated that permitting individuals to privatise food varieties might compromise food security if breeding material was locked up and if farmers were prevented from saving seed for further harvests. However, from the perspective of plant breeders any derivation of new varieties from their protected varieties, whether essential or non-essential, was inconvenient for them and any seed saving by farmers deprived them of new sales. Consequently, they looked to patents law, which does not contain these exceptions, to protect their new varieties.

Plant varieties can be protected in the USA under a system of plant patents, or under a system of utility patents or under the Plant Variety Protection Act (PVPA). The Plant Patent Act makes available patent protection to new varieties of asexually reproduced plants. Under this scheme a plant variety must be novel and distinct and the invention, discovery or reproduction of the plant variety must not be obvious. One of the disadvantages of the scheme is that only one claim, covering the plant variety, is permitted in each application. The Federal Circuit Court of Appeals resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act (PVPA) in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc.* (200 F.3d 1374 (Fed. Cir. 2000), *cert. granted*, 148 L. Ed. 2d 954 (2001))

Pioneer's patents covered the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts . . . to regard each as effective".

This was illustrated by *Monsanto Co. V. McFarling* (302 F.3d 1291 (Fed. Cir. 2002)) which concerned Monsanto's patent for glyphosate-tolerant plants, the genetically modified seeds for such plants, the specific modified genes, and the method of producing the genetically modified plants. Monsanto required that sellers of the patented seeds obtained from purchasers a "Technology Agreement," in which they agreed that the seeds were to be used "for planting a commercial crop only in a single season" that the purchaser would not "save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting." Mr. McFarling, a farmer in Mississippi, purchased Roundup Ready soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1,500 bushels of the patented soybeans from his harvest during one

season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the Roundup Ready seed. Mr McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season, violated the seed saving provision of the PVPA. The Court declined to limit the patent law by reference to the PVPA and Mr McFarling was found to have infringed Monsanto's patent.

Patenting of Plant Breeding Methods

In addition to the patenting of the products of plant breeding, some patent laws allow for the patenting of plant breeding methods. For example, in the US a patent has been obtained for the "selective increase of the anticarcinogenic glucosinolates in brassica species" (US Patent 6,340,784, January 22, 2002) and an application published concerning a "method for breeding tomatoes having reduced water content" (US Patent Application 20100095393, April 15, 2010). This raises the possibility that methods of crop breeding to withstanding climate stress can be privatised in the USA, which permits so-called methods patents.

On the other hand in Europe the exclusion in its patent legislation of "essentially biological processes for the production of plants or animals" defined in Article 2.2 of the EU Biotechnology Directive as consisting "entirely of natural phenomena such as crossing or selection", resulted in the denial of patent protection for the same methods for breeding brassica and tomatoes (Blakeney, 2012). The Board of Appeals of the European Patent Organization (EBA) observed that with the creation of new plant varieties, for which a special property right was going to be introduced under the subsequent UPOV Convention in 1960, the legislative architects of the European Patent Convention were concerned with excluding from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those based on the sexual crossing of plants deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). These processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. On the other hand processes for changing the genome of plants by technical means such as irradiation were cited by the EBA as examples of patentable technical processes. On the other hand it pointed out that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion from patentability if that technical step only serves to perform the process steps of the breeding process.

Thus if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding and consequently, is not excluded

from patentability in Europe. This principle applies only where the additional step is performed within the steps of sexually crossing and selection, independently from the number of repetitions, otherwise the exclusion of sexual crossing and selection processes from patentability could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from the crossing and selection process. The EBA noted that for the previous or subsequent steps *per se* patent protection was available. This will be the case for genetic engineering techniques applied to plants which differ from conventional breeding techniques as they work primarily through the deliberate insertion and/or modification of one or more genes in a plant.

Patenting of Genetic Resources (GRs)

One of the problems with determining the legal protection of genetic resources through IPRs or any other kind of law is the fact that scientific constructs do not sometimes lend themselves to legal categorization. For example, the TRIPS Agreement in Article 27.3(b) provides that WTO Members may also exclude from patentability: “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” Adcock and Llewelyn observe that the division between plants and animals on the one hand and micro-organisms on the other is not as scientifically certain as the legal categories seem to suggest (2000). Additionally, a number of international organizations, with varying levels of scientific competence, are now concerning themselves with IPRs and genetic and biological resources. At its sixteenth session, held from May 3 to 7, 2010, WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) Member States identified the need for a glossary to clarify the meanings of key terms related to genetic resources to facilitate the negotiations of the Committee (WIPO, 2010). The Secretariat prepared a document drawing, as far as possible, from previous glossaries of the IGC and from existing United Nations and other international instruments, also taking into account definitions and glossaries which can be found in national and regional laws and draft laws, multilateral instruments, other organizations and processes and in dictionaries.

The term “genetic resources” is defined in the glossary by reference to Article 2 of the Convention on Biological Diversity (CBD) which defines the term as “genetic material of actual or potential value.” Further, it defines the term “genetic material” as meaning “any material of plant, animal, microbial or other origin containing functional units of heredity”. “Plant genetic resources” are defined in Article 2 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture as “any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity”. Article 2 of the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer defines plant genetic resources as “the reproductive or vegetative propagating materials of plants”.

Article 2.1 (a) of the FAO International Undertaking on Plant Genetic Resources (1983) defines plant genetic resources as “the reproductive or vegetative propagating material of the following categories of plants: i) cultivated varieties (cultivars) in current use and newly developed varieties; ii) obsolete cultivars; iii) primitive cultivars (land races); iv) wild and weed species, near relatives of cultivated varieties; and v) special genetic stocks (including

elite and current breeders' line and mutants)”).

Other legal instruments on IPRs do not use the term genetic resources and refer to “biological material”. For example, the EU Directive on the legal protection of biotechnological inventions defines it as “material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”

Disclosure of the Source of GRs, Access and Benefit Sharing – Recent International Developments

One of the foundational tasks of the WIPO IGC has been the formulation of guidelines on the IP aspects of access and benefit-sharing in relation to GRs. A draft set of guidelines was submitted to the seventh session of the IGC in November 2004 which sought to provide assistance in the negotiation of contracts for access to genetic resources and related information, including traditional knowledge, and for benefit-sharing arrangements (WIPO, 2004). This document has been through a number of drafts, the most recent of which was prepared for the third Intersessional Working Group which met from February 28 to March 4, 2011 (WPIO, 2011). This document, together with documents which have been prepared on the subjects of traditional knowledge and traditional cultural expressions, are to be taken into account in “text-based negotiations” by the IGC, ultimately with a view to formulating an international treaty.

At the Seventeenth Session of the IGC which met in Geneva, December 6 to 10, 2010, the Secretariat identified the options which were then under consideration. There were three categories of options: (i) those concerning the defensive protection of genetic resources; (ii) those in relation to disclosure requirements; and (c) those concerning the IP aspects of access and benefit-sharing.

In relation to defensive protection, one category of options was the compilation of an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the Patent Co-operation Treaty. The second option in this regard concerned the extension of the Online Portal of Registries and Databases, established by the Committee at its third session, to include existing databases and information systems for access to information on disclosed genetic resources. A third option was for the formulation of recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources.

Options on disclosure requirements, included: the development of a mandatory disclosure requirement. Alternatively, it was proposed that the IGC could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources, on the one hand, and national and international intellectual property law and practice, on the other. Another disclosure option was the development of guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources.

On May 6 2010, the delegations of Australia, Canada, New Zealand, Norway and the United States of America submitted a working document¹⁵³ on GR for the seventeenth session of the IGC held December 6 to 10, 2010. Comments on this document¹⁵⁴ were made by the Delegations of Chile, Colombia and the Russian Federation and a number of accredited observers, which resulted in a revised document identifying five objectives with underlying principles:¹⁵⁵ On December 8, 2010, the Delegation of Angola submitted the proposals of the African Group.¹⁵⁶ This suggested the commencement of negotiations on a mandatory disclosure requirement and an appropriate way to ensure prior informed consent and fair and equitable benefit sharing, in line with the Nagoya Protocol. The African proposal suggested that negotiations be based upon two current proposals on a mandatory disclosure requirement, and the incorporation of the “internationally recognized certificate of compliance” as stipulated in the Nagoya Protocol, together with any other submission that may be tabled by member countries. In relation to the option for guidelines and recommendations on defensive protection, the African Group proposed consideration of the use of available databases on GR and/or associated TK.

The African Group proposed a number of amendments to the Submission made by Australia, Canada, New Zealand, Norway and the United States of America. The common position between all groups of countries is that the objectives of the mandatory disclosure requirement should be: that: (i) the use of GRs and associated TK should be on the basis of benefit sharing; (ii) patents should not be granted for inventions that are not novel or inventive in light of genetic resources and/or associated traditional knowledge; (iii) patent offices should have available the information needed to make proper decisions on patent grant; (iv) the principles developed should consistent with other international and regional instruments and processes; and (v) Ip should maintain a role in promoting creativity and innovation. At the Third Intersessional Working Group of the IGC, which met from February 28 to March 4, 2011, a Working Group was appointed to review and rationalize the various Objectives and Principles which had been received by the IGC with a view to clarifying the key and divergent policy positions and issues, which the IGC would need to make informed decisions. This report¹⁵⁷ is to be transmitted to the IGC for its consideration at its 18th session (May 9 to 13, 2011).

Farmer’s Rights under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The concept of Farmers’ Rights was developed as “a counterbalance to intellectual property rights” (IWG, 2011) This was a moral commitment by the industrialised commitment to reward “the past present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in centres of origin/diversity. Farmers' rights were intended to promote a more equitable relation between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm which they had developed and conserved over time (Glowka, 1998). The first international enactment of Farmers’

¹⁵³ WIPO/GRTKF/IC/16/7.

¹⁵⁴ WIPO/GRTKF/IC/17/INF/10.

¹⁵⁵ WIPO/GRTKF/IC/17/7.

¹⁵⁶ WIPO/GRTKF/IC/17/10.

¹⁵⁷ ‘Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources Prepared at IWG 3’, WIPO/GRTKF/IWG/3/17, March 16, 2011.

Rights occurred in the FAO International Treaty on PGRFA. The preamble to the Treaty acknowledges that “the conservation, exploration, collection, characterization, evaluation and documentation of plant genetic resources for food and agriculture are essential in meeting the goals of the Rome Declaration on World Food Security and the World Food Summit Plan of Action and for sustainable agricultural development for this and future generations”. It also acknowledges that PGRFA “are the raw material indispensable for crop genetic improvement” and affirms “that the past, present and future contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available these resources, is the basis of Farmers’ Rights”.

The Preamble outlines that that “fundamental to the realization of Farmers’ Rights, as well as the promotion of Farmers’ Rights at national and international levels” are the rights “to save, use, exchange and sell farm-saved seed and other propagating material, and to participate in decision-making regarding, and in the fair and equitable sharing of the benefits arising from, the use of plant genetic resources for food and agriculture”.

Under Art. 5.1 (c) the Contracting Parties agree, subject to national legislation, to promote or support, as appropriate, farmers and local communities’ efforts to manage and conserve on-farm their plant genetic resources for food and agriculture and in Art. 5.1 (d) to promote *in situ* conservation of wild crop relatives and wild plants for food production, by supporting, *inter alia*, the efforts of indigenous and local communities.

In Art. 9(1) of the Treaty the Contracting Parties “recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.”

Article 9.2 of the WTO International Treaty on PGRFA envisages that “the responsibility for realizing Farmers’ Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments” and that national legislation should include measures relating to:

- (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
- (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

Finally, Article 9.3 provides that the Article shall not be interpreted “to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material”.

An assumption of Art. 9 is that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The traditional knowledge of local and indigenous communities is similarly perceived. Farmers in subsistence systems have tended to utilise a diverse selection of crop species in order to assure their annual harvests and thus to guarantee a minimal level of production and to prevent food shortage. Seed production in many instances has been on the collection of and domestication of locally known, wild varieties. Modern agricultural practices depend on crop species that promote productivity and resistance to disease that can only be maintained with the continuous input of new germplasm. The diversity of landraces and the associated information on their specific

qualities contribute invaluable information to formal breeding processes. It has been noted that the loss of biological diversity is paralleled by the loss of traditional knowledge. Where a plant variety becomes extinct, then the entire body of knowledge about its properties is condemned to irrelevancy.

As a means of remunerating these groups for their past contributions to the development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration. Inevitably, any calculation of the equitable share, which traditional farmers and indigenous communities might enjoy under a Farmers' Rights, or Traditional Knowledge regime will be arbitrary. However the intellectual property system is no stranger to arbitrary calculations, thus the 20 year length of a patent term is intended to provide an opportunity for the compensation of all inventors, whatever the area of technology. Similarly the 25 years exclusivity which the UPOV Convention provides for new varieties of trees and vines, takes no account of variations in R & D costs between the different varieties.

The principal ways in which plant genetic resources are translated into food and agriculture production is through plant breeding and plant patenting. Standing at the heart of a Farmers' Rights regime is the concept of the equitable benefit sharing of benefits with farmers for their contribution to innovations in plant breeding and plant patenting.

Article 9.2 obliges the Contracting Parties to the Plant Genetic Resources Treaty "to take measures", subject to their national legislation to protect and promote Farmers' Rights. The content of these rights is defined in the balance of that provision and embraces the protection of traditional knowledge, equitable benefit sharing and the right to participate in decision making. The Treaty leaves open the legal context within which Farmers' Rights are to be enacted.

To date the only measure which has been implemented to provide for Farmers Rights is the International Fund for Plant Genetic Resources, which was envisaged in the Undertaking which preceded the Treaty. This Fund was to operate as a means of capacity building in the field of agricultural biotechnology in developing countries rather than as a reward to individual farmers or farming communities for their contribution to the development or improvement of plant varieties. To date this fund has not been established because funds were not made available by donor countries.

Recent Developments on Farmers' Rights

At its Third Session in Tunis in 2009, the Governing Body of the ITPGRFA adopted a resolution on Farmers' Rights (Resolution 6/2009), in which it requested the Secretariat to convene regional workshops on Farmers' Rights, subject to the agreed priorities of the Programme of Work and Budget and to the availability of financial resources. The aim of the workshops was to discuss national experiences on the implementation of Farmers' Rights as set out in Article 9 of the International Treaty, involving, as appropriate, farmers' organizations and other stakeholders.

The fourth session of the Governing Body of the ITPGRFA held from 14 to 18 March 2011 in Bali, Indonesia adopted a resolution on Farmers' Rights that , *inter alia*:

- requests the Secretariat to convene regional workshops on Farmers' Rights, subject to availability of funding;

- encourages parties to submit views, experiences and best practices on the implementation of Farmers' Rights;
- invites parties to consider convening national and local consultations on Farmers' Rights with the participation of farmers and other stakeholders;
- requests the Secretariat to collect and submit these views, as well as reports from regional workshops to GB 5; and
- encourages parties to engage farmers' organizations and relevant stakeholders in matters related to the conservation and sustainable use of PGRFA, through awareness raising and capacity building.

Substantive Patent Law Treaty

In an endeavour to reach a consensus on substantive patent law issues a Committee of Experts and WIPO's Standing Committee on Patents (SCP) considered a draft Patent Law Treaty (PLT), which had been prepared by the International Bureau of WIPO. The Draft PLT dealt with various procedural aspects of patenting. At the third session of the SCP in September 6 to 14, 1999, the delegation of Colombia proposed the introduction into the PLT, as a means of achieving some global harmonization of patent registration procedures, an article which provided that:

1. All industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired made legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

This proposal generated a heated debate about whether, in the first instance, it raised a matter of procedural or substantive patent law. Agreement was eventually reached to defer consideration of this proposal to the occasion of the discussion of a proposed Substantive Patent Law Treaty. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The Working Group, at its meeting, the following month, recommended the establishment of nine projects related to the protection of inventions in the field of biotechnology. The Working Group decided to establish a questionnaire for the purpose of gathering information about the protection of biotechnological inventions, including certain aspects regarding intellectual property and genetic resources, in the Member States of WIPO.

An alternative approach to the protection of traditional knowledge, is its recognition as part of "prior art." As prior art it would call into question the novelty and inventive of inventions which are the subject of patent applications. The practical difficulty which patent examiners have in identifying relevant traditional knowledge as prior art, arises from the fact that they do not have access to traditional knowledge information in classified non-patent literature and because there are no effective search tools for the

retrieval of such information. The WIPO IGC has begun to address practical measures to establish linkages between IP Offices and traditional knowledge documentation initiatives. A number of the characteristics of traditional knowledge present difficulties in identifying the prior art effect of technological information. These include:

- (a) The transmission of traditional knowledge through oral communication. This requires the codification and fixation of traditional knowledge into what it is not.
- (b) Traditional knowledge systems tend to dynamic evolution without necessarily being identified as “new”.
- (c) Traditional knowledge is expressed in local languages and its expression is contingent upon such languages.
- (d) The transfer of knowledge from oral into written, printed, and electronic forms may involve a cultural, semantic and symbolic transformation of the knowledge, which may affect the value of databases as a tool for the conservation of culture and knowledge.
- (e) As knowledge must be in the public domain to be considered as prior art, this may provide some difficulties in those communities where knowledge is to be kept confidential.

The draft Substantive Patent Law Treaty, which was submitted to the fifth session of the WIPO’s Standing Committee on the Law of Patents (SCP), held in Geneva from May 14 to 19, 2001, contained two alternatives for a draft article on the definition of prior art. The draft provisions on the definition of prior art provide that any information made available to the public, anywhere in the world, in any form, including in written form, by oral communication, by display and through use, shall constitute prior art, if it has been made available to the public before the filing date, or, where applicable, the priority date.

TRIPS Agreement

A particular contemporary impetus for the formulation of an international positions on the protection of traditional knowledge has been the debate concerning the review of Art.27.3(b) of the plant variety provision of the TRIPs Agreement. Review of this provision was mandated by the TRIPs Agreement itself, to be completed by the end of 1999. Developing country participants in the review process have suggested the importation into the TRIPs Agreement of the provisions in the Convention on Biological Diversity, which provide for equitable sharing with indigenous peoples of the benefits of the utilization of traditional medical knowledge. The African Group of countries proposed the inclusion of this issue in the Ministerial Conference to set the agenda for the Seattle Round of the WTO.¹⁵⁸ On 25 July 1999 a federation of Indigenous Peoples groups issued a statement for the purposes of the review, pleading for a legislative structure which “Builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources” and which prevents the appropriation of traditional knowledge and integrates “the principle and practice of prior informed consent, of indigenous peoples’ as communities or as collectivities”. The Statement concluded with an affirmation of the commitment of Indigenous Peoples “to sustain our struggle to have our rights to our intellectual and cultural heritage and our lands and resources promoted and protected.”

¹⁵⁸ *Communication to the WTO from Kenya, on behalf of the African Group*, WT/GC/W/3026, August 1999.

On 4 October 1999 Bolivia, Columbia, Ecuador, Nicaragua and Peru specifically proposed that the Seattle Ministerial Conference establish within the framework of the Round a mandate

- (a) To carry out studies, in collaboration with other relevant international organizations in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights.
- (b) On the basis of the above-mentioned recommendations, initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge.
- (c) To complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of this round of trade negotiations.¹⁵⁹

A communication of 6 August 1999 from Venezuela proposed that the Seattle Ministerial should consider the establishment "on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders."¹⁶⁰

A practical proposal for the integration of traditional knowledge with intellectual property rights is India suggestion that material transfer agreements be required where an inventor wishes to use biological material identified by traditional knowledge. That obligation would be incorporated through inclusion in Article 29 of the TRIPS Agreement, the requirement that the country of origin of source material be identified in patent applications.¹⁶¹ Following the failure of the Seattle Ministerial this agitation for the inclusion of traditional knowledge within the international intellectual property regime, shifted to WIPO, until it was picked up again at the Doha Ministerial.

Article 19 of the November 2001 Doha Declaration, instructed the Council for TRIPS, in pursuing its work programme concerning both its review of Article 27.3(b) and its general review of the implementation of the TRIPS Agreement under Article 71.1 "to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1".

Following the Doha approach, amendments have been proposed to the TRIPS Agreement (Art. 29*bis*) which would require WTO Members to oblige patent applicants to disclose the source of any TK and evidence of compliance with legal requirements in the source country of prior informed consent for access and fair and equitable benefit sharing arising from the utilization of the TK. The African Group of Countries have proposed that as part of the review of Art. 27.3(b) TK should be protected as a "category of intellectual property rights".¹⁶² The scheme of protection which they proposed would include the grant of rights to local or traditional communities concerning (i) respect for those

¹⁵⁹ WT/GC/W/362 12 October 1999.

¹⁶⁰ WT/GC/W/282.

¹⁶¹ WT/GC/W/147.

¹⁶² IP/C/W/404, 26 June 2003.

communities on the commercialization of TK; (ii) prior informed consent to the use of that TK; (iii) full remuneration; and (iv) the prevention of unauthorized third parties from utilizing that TK and incorporating that TK into any article or product.

Debate is still continuing within the TRIPS Council as to the whether it has a mandate to amend TRIPS by the inclusion of an Art. 29bis or whether that discussion is to be confined to the implementation of the existing text.

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Legal liability arising from GM Agriculture

Abstract

This article examines best practices to deal with any legal liability arising from the development, cultivation and use of GM crops by: (i) governments; (ii) the agricultural research and development organizations; (iii) plant breeders; (iv) farmers; and (v) exporters. The heads of liability considered include: (i) tort; (ii) contract; (iii) trade practices and fair trade laws; (iv) intellectual property laws; and (v) biosafety laws

1. Potential Damage from GM Cultivation

The primary potential damage from GM crop cultivation arises from the possibility of the “contamination” of non-GM crops with GMOs. In industry circles the word “contamination” is replaced by the expression “adventitious presence”. Another dichotomy of terms used in the context of the potential dangers of GM crop cultivation which have either negative or neutral connotations is on the one hand: “genetic pollution,” “adulteration” or “contamination” and on the other: “pollen drift”. For the purposes of this article, all of these terms are used interchangeably.

In any analysis of the legal liability arising from GM cultivation, it is first necessary to identify areas of potential damage which might occur, since the gist of most civil legal actions is the harm which is caused by any impugned conduct. The exception to this is where strict liability is imposed for reasons of public policy, in which case neither damage nor fault is necessary to be proved.

The following areas of risk (damage) were identified in Australia in an unpublished report of September 2001 Report prepared by the Novel Crop Agricultural Risk (NCAR) Taskforce of the Industry Competitiveness Committee:

- Risks to agricultural production and sustainability of farming systems; and
- Risks to trade in differentiated agrifood products.
- Pest and disease protected crops, risk of selection for resistance to controlling agent in target or non target pests and disease
- For herbicide tolerant crops, risk of selection for resistance to the associated herbicide in target or non-target plants
- Risk of genetic transfer for the trait conferring herbicide tolerance or pest and disease resistance and thereby an unwanted survival advantage:
 - To other plants of the same type
 - To other crop types
 - To other plant or weed species
- Risk of unwanted crop proliferation (“weediness”) due to an introduced survival advantage:

- In herbicide tolerant crops, where use of the tolerated herbicide is an important controlling agent to avoid unwanted plant proliferation
- In pest and disease protected crops, where the pest or disease is a significant controlling agent to avoid unwanted plant proliferation
- Risk of changed pest or weed spectrum affecting other crops, either in other years of the rotation or nearby requiring new pest or weed control strategies.
- Risk of failing to meet safety and quality standards
- Risk of breakdown in Segregation and Identity Preservation (IdP)

Each of these risks translates into potential economic loss which would be recoverable through legal action where an appropriate cause of action can be identified. Those causes of action are identified below.

The NCAR Report does not consider the issues of public health and environmental safety, as this is a matter which in Australia falls within the Office of the Gene Technology Regulator (OGTR). The potential hazards to the environment which were considered by the OGTR as part of the assessment of GM canola included whether there would be any adverse consequences for the environment from the transfer of genes in GM canola to non-GM canola crops or other organisms.¹⁶³ The conclusion which was reached in the application by Bayer to introduce GM canola was that there would be some contamination of non-GM canola, but that the risks posed by the proposed commercial release of the GM canola were no greater than those posed by conventional (non-GM) canola because conventional canola also contaminates other crops.¹⁶⁴

The potential toxicity or allergenicity hazard resulting from the use of GM canola is identified by Monsanto in its application to the OGTR for the commercial release of its Roundup Ready[®] canola GT73.¹⁶⁵ The applicant noted that its GT73 canola differed from conventional canola in the expression of two additional proteins, CP4 EPSPS and GOXv247. The potential of canola expressing these proteins to be more toxic or allergenic to humans would be most likely to occur if the novel gene products were themselves toxins or allergens, if there were unforeseen or unintended effects of the genetic modification or if use of the herbicide on the crop produced toxic or allergenic metabolites.

If the genetically modified canola was toxic or allergenic, Monsanto noted that there could be impacts relating to:

- the safety of human foods containing canola oil (for example cooking and salad oil, margarine, mayonnaise, confectionery products, sandwich spreads, creamers and coffee whiteners);
- the safety of human foods where canola products are present in the food chain (for example livestock, poultry or fish that have been fed canola by-products);

¹⁶³ OGTR, Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No. DIR 021/2002 (1 April 2003).

¹⁶⁴ See OGTR, Full Risk Assessment and Risk Management Plan for Application for licence for dealings involving an intentional release into the environment. DIR 021/2002 (25 July 2003), 11.

¹⁶⁵ OGTR, Risk Assessment and Risk Management Plan, Application by Monsanto Australia Ltd for licence for dealings involving an intentional release into the environment, General Release of Roundup Ready[®] canola (*Brassica napus*) in Australia, DIR 020/2002.

- occupational health and safety (for example, for farm workers, or factory workers involved in canola processing);
- environmental exposure (for example, people breathing canola pollen); and
- toxicity of herbicide metabolites.¹⁶⁶

On the question of food safety Monsanto noted that oil extracted from Roundup Ready® canola GT73 had been approved in 2000 by Food Standards Australia New Zealand (FSANZ) for use in food for human consumption in Australia and New Zealand. In relation to the safety of herbicide metabolites, it noted that the Australia Pesticides and Veterinary Medicines Authority (APVMA) had approved a variation of the registration of glyphosate (as ‘Roundup Ready® herbicide by Monsanto’) to enable ‘in crop’ use on Roundup Ready® canola (APVMA 2003b).

Monsanto also noted the positive health advantages of canola oil compared with unimproved varieties of *B. Napus* (rapeseed) which “tend to have high levels of toxic compounds such as erucic acid and alkyl-glucosinolates.”¹⁶⁷

The conclusion reached in the Monsanto application, which was endorsed by the OGTR was that analysis of the compositional data of canola seed and toasted meal obtained from the Roundup Ready® canola GT73 “indicated that there were no meaningful differences in the levels of major constituents, nutrients, anti-nutritional factors or natural toxicants between GT73 and the control canola line Westar.”¹⁶⁸

Thus far, it seems that there is only one report of a possible health-related incident concerned with GM crops. Drew L. Kershen refers to an instance in the United States concerning the consumption of StarLink™ corn, even though it was not approved for human consumption as food.¹⁶⁹ The Center For Disease Control (CDC) concluded in relation to this case that:

Although the study participants may have experienced allergic reactions, based upon the results of this study alone, we cannot confirm that a reported illness was a food-associated allergic reaction. Although our results do not provide any evidence that the allergic reactions experienced by the people who file AERs were associated with hypersensitivity to Cry9c [StarLink™] protein, we cannot completely rule out this possibility, in part because food allergies may occur without detectible serum IgE to the allergens.¹⁷⁰

Because of the lack of approval for StarLink™ in human food and the CDC report, a class-action lawsuit on behalf of consumers alleging that they ate food not fit for human consumption was successfully concluded with a settlement against Aventis, the owner of StarLink.™.¹⁷¹ Transgenic crops that have not been approved for human

¹⁶⁶ Ibid., para 120.

¹⁶⁷ Ibid., para 125.

¹⁶⁸ Ibid., para 162.

¹⁶⁹ In re StarLink Corn Products Liability Litigation, No. 1403,01C1181, 2002 WL 1291790 (N.D. Ill. June 11, 2002), referred to in Drew L. Kershen, *Legal Liability Issues in Agricultural Biotechnology*, National Law Center, University of Arkansas, School of Law, Fayetteville 2002, 14.

¹⁷⁰ CDC, *Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn*, June 2001, at 10, cited *ibid.*

¹⁷¹ A. Harris, *Danger Uncertain, But Suits Multiply – Billions Could Be at Stake in Farmers’ Cases*, NATIONAL L.J., Sept. 9, 2002, at A12 (reporting a settlement valued at \$9 million for the consumer class action) cited *ibid.* at 15.

consumption thus present the legal liability risk of claims from consumers even if the consumer has not suffered a toxic, allergic, or other health-related harm.

The application to the OGTR by Monsanto for the commercial release of Roundup Ready® canola GT73¹⁷² considered the potential adverse effects upon the environment in terms of the potential toxicity hazards for organisms other than humans. It identified the potential impacts as those upon:

- grazing animals, including native animals;
- animal feed safety, for example, animals fed canola seed or canola meal; and
- invertebrates (including insects) or soil biota, with direct impact on growth of crops on farms, as well as secondary ecological effects with potential to harm the natural environment (for example, adverse impacts on native biodiversity).¹⁷³

Reiterating some of the information concerning potential impacts upon humans, Monsanto noted that:

- the novel proteins are expressed at very low levels;
- acute oral toxicity studies demonstrate that the CP4 EPSPS and GOXv247 proteins are not toxic, even at high doses;
- CP4 EPSPS and GOXv247 proteins are both rapidly degraded by mammalian digestive systems;
- the novel proteins do not share significant sequence homology with known protein toxins;
- the CP4 EPSPS and GOXv247 proteins are derived from common bacteria and are naturally ubiquitous in the environment;
- the composition of Roundup Ready® canola GT73 does not differ significantly from conventional canola;
- the levels of the naturally occurring toxicants of canola such as erucic acid and glucosinolates are not significantly different between GM and conventional canola; and
- the major metabolites of glyphosate are not toxic.¹⁷⁴

It reported that feeding studies in rats, bobwhite quail, trout, chickens, lambs, and pigs using canola meal supported the conclusion that the genetic modifications in the Roundup Ready® canola have not resulted in any additional toxicity or anti-nutritional effects and as such Roundup Ready® canola is comparable with conventional canola.¹⁷⁵

In July 2002 the OGTR itself produced a comprehensive report on *The biology and ecology of canola ((Brassica napus)*.¹⁷⁶ It noted that under field conditions, “canola has the ability to cross pollinate through physical contact between neighbouring plants and/or

¹⁷² Monsanto application, n.7 supra.

¹⁷³ Ibid at para 187.

¹⁷⁴ Ibid at para 188.

¹⁷⁵ Ibid at para 217.

¹⁷⁶ [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/canola-3/\\$FILE/brassica.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/canola-3/$FILE/brassica.pdf)

insect pollination and whose pollen can also become airborne and potentially travel at least

several kilometres downwind.¹⁷⁷ An Australian study of pollen dispersal distance and outcrossing rates between commercial fields of non-GM herbicide tolerant canola and conventional canola measured outcrossing in 63 % of the fields, but only a few had outcrossing rates greater than 0.03 %. This compares with current EU standards which allow for accidental contamination of GM foodstuffs up to 1 %.¹⁷⁸

The OGTR report noted a number of studies in Australia, Canada and the UK which concluded that canola is not considered a significant weed, nor invasive of natural undisturbed nonarable habitats in as due to selective breeding, crop plants only function optimally under managed agricultural conditions, such as high soil fertility or low plant competition.¹⁷⁹

The OGTR report concluded that outcrossing levels of 10-50 % can occur between canola crops, but that outcrossing between canola and other *Brassica* species can occur but at a lower frequency due to lesser genetic compatibility.¹⁸⁰ There have been no documented occurrences of gene introgression between canola and the Brassicaceous weeds.

The OGTR reported no allergic reaction of humans to fats (including canola oil) although it referred to a number of European studies which reported allergic sensitisation to canola via the lungs (through inhaling pollen) or through skin contact (e.g. during handling). “Volatile organic compounds given off by growing canola plants have been shown to play a role in respiratory mucosa and conjunctiva irritation associated with airborne releases from oilseed rape”.¹⁸¹ However, has been reported that data collected on the allergenicity of canola pollen is often confounded by the other flowering plants, particularly grasses, which flower at similar times.¹⁸² Studies have shown that exposure to oilseed flour (contained in animal fodder) may be a possible cause of occupational asthma in farmers.¹⁸³

Some of the economic losses which might be asserted have been itemized by The Network of Concerned Farmers which is “an Australia wide network of conventional and organic farmers who are concerned about the economic, environmental and social impacts of genetically modified crops.”¹⁸⁴ Its concerns about GM canola relate to: “impact on the non-GM growers, costs and liability, contamination and loss of markets for all agricultural produce, herbicide resistance, environmental impacts, patents and corporate control of farming.”¹⁸⁵ It has prepared a “Legal Letter” to be sent to farmers contemplating growing GM crops which threatens “legal recourse if GM crops result in any costs, damage or economic loss including, but not limited to:

¹⁷⁷ Ibid at 5-6.

¹⁷⁸ Ibid at 7-8.

¹⁷⁹ Ibid at 11.

¹⁸⁰ Ibid at 25.

¹⁸¹ Ibid at 12.

¹⁸² Ibid.

¹⁸³ Ibid.

¹⁸⁴ <http://www.non-gm-farmers.com/about.asp>.

¹⁸⁵ Ibid.

- Testing costs or additional contractual requirements required due to market perception that your choice to grow GM crops will cause contamination of our crops and/or produce.
- Segregation costs over and above what is currently required.
- Loss of market access or market premium due to detection of GM in our produce or an inability to prove a GM-free status. (ie. Currently WA's key market is Europe, which is GM sensitive, and Australia's key market is domestic which dominantly requests GM-free produce.)
- Loss of organic certification if applicable.
- New control measures required to remove canola from grain sold, including any grading at outturn.
- Any payments due or deducted as end-point royalty or user fees from GM companies for unintentional GM use.
- Any fines associated with any adventitious presence of GM crops.
- Any costs associated with destroying unauthorised GM crops on our property.
- Spray drift from post-emergent glyphosate or glufosinate ammonium.
- All associated and consequent costs and all legal costs.¹⁸⁶

On the opposite side of the argument a 2005 report by ACIL Tasman Pty Ltd¹⁸⁷ states that:

The evidence is clear that damage caused by the co-mingling of GM crops with conventional crops is almost non-existent. Virtually all analyses conducted on the market impact of GM crops in Australia¹⁸⁸ ... have concluded that there are few if any price premiums available in conventional markets for non-GM crops proven to be free of co-mingling with GM product. To that extent, the question of "loss" for farmers producing non-GM crops who may incur some GM adventitious presence (AP) that exceeds allowable tolerances hardly arises.¹⁸⁹

Of course, if these studies prove to be accurate, then the question of the economic loss suffered by non-GM farmers from the development, approval, cultivation and carriage of GM canola becomes a non-issue. Thus in any sort of damages action, although liability for the various economic risks identified above might be established, the quantum of damages to be awarded would not easily justify the bringing of a damages action. One study which does suggest that a premium price might be attracted by GM-free crops is the 2003 study by the UK's Agriculture and Biotechnology Commission.¹⁹⁰ It referred to a 2001 survey of US organic farmers by the Organic Farming Research Foundation which found that 8% had suffered direct financial loss from GMOs and that price

¹⁸⁶ http://www.non-gm-farmers.com/news_details.asp?ID=2964.

¹⁸⁷ ACIL Tasman Pty Ltd, *Managing genetically modified crops in Australia. GM crops, segregation and liability in Australian agriculture* Prepared for Avcare, October 2005.

¹⁸⁸ Citing Foster, M, *GM Canola: What are its Economics under Australian Conditions?*, Canberra, Australian Grains Industry 2003; Western Australian Department of Agriculture, *Assessment of the International Markets for Genetically Modified Canola*, Perth, Department of Agriculture, 2003; and ACIL Tasman, *Genetically Modified Canola: Market Issues, Industry Preparedness and Capacity for Segregation in Victoria*. Prepared for the Victorian Interdepartmental Canola Steering Committee, 2003.

¹⁸⁹ *Ibid.*, para. 1.3.

¹⁹⁰ Agriculture and Environment Biotechnology Commission, *GM Crops? Coexistence and Liability*. London, November 2003.

premiums were apparently available in Spain of about 15% for non-GM maize for the snack food sector, with growers meeting specific contracts to deliver GM free produce.¹⁹¹ However, the Agriculture and Biotechnology Commission concluded that there was “no unambiguous evidence on which to draw from abroad” and that there was “therefore considerable uncertainty about what lessons if any may reasonably be drawn about the probable frequency of economic loss from adventitious presence in the UK from the limited (and in some cases disputed) evidence from commercial production overseas.”¹⁹² Notwithstanding the paucity of the evidence, the Agriculture and Biotechnology Commission took the view that “compensation should be available to farmers or other parties who suffer economic loss from breaches of the statutory adventitious presence threshold.”¹⁹³ To give some idea of the magnitude of potential economic losses from adventitious presence, the Commission made the following estimates of the amount that a farmer stood to lose because an individual crop failed to meet the organic standard. For organic forage maize which failed to meet the standard, it estimated the loss to amount to over £500/ha where an organic farmer who intended to use it as fodder for his own animals would lose what he has spent on producing the crop (estimated at around £360/ha), and the purchase of substitute fodder (likely to cost at least the equivalent of £360/ha, assuming that supplies are available), against which could be set any proceeds from selling the crop at the conventional price (£200/ha).¹⁹⁴ For grain maize, the Commission estimated a price premium of £20-£30 per tonne for conventional non-GM grain over GM grain and assuming that the organic price premium (for sweetcorn) might be as much again, on the basis of yield of around 5.75 tonnes per hectare, the Commission estimated the loss of the organic price premium as at £150/ha.¹⁹⁵ In the event that ACIL Tasman’s conclusion of the minimal risk of economic harm from GM crop cultivation proves not to be well-founded the cost of segregation becomes an issue. In a 2003 report ACIL Tasman indicated that the cost of segregation of GM from non-GM canola is minimal.¹⁹⁶ It reported that “the Australian Seed Federation, following extensive consultation with its members, established a 0.5% tolerance of GM canola in non-GM canola¹⁹⁷ and that the Australian Oilseeds Federation established AP standards for GM canola in conventional canola of 0.9%. Its 2003 report concluded that “experience in the Australian grains industry suggests that meeting a 0.9% tolerance can be achieved at minimal cost to farming enterprises, farm contractors, storage and handling companies and marketers. Moreover, bulk handling companies state that they routinely manage segregation for a number of crop types and do not view GM crops as presenting any additional challenges.”¹⁹⁸ In other words, in comparing the potential economic loss from litigation with the cost of minimising the risk of litigation, ACIL Tasman appeared to indicate that risk avoidance is an inexpensive option.

¹⁹¹ Ibid., paras. 249-250.

¹⁹² Ibid., para 251.

¹⁹³ Ibid., para 252.

¹⁹⁴ Ibid, para. 2.54.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid.

¹⁹⁷ Department of Agriculture Fisheries and Forestry from the *Canola Industry Stewardship Protocols for the Co-existence of Production Systems and Supply Chains*, 2002.

¹⁹⁸ Cited in ACIL Tasman, n.4 supra at para 2.3.

Aside from the issue of economic loss, if legal liability is established there would remain the risk of an action for injunctive relief to prevent GM cultivation, since one of the principles of equity law is that injunctive relief is available where damages are considered to be an inadequate remedy.¹⁹⁹ One of the criteria of inadequacy is the difficulty of quantifying damages.²⁰⁰

Of course, the issue of damages or injunction does not arise unless some category of legal liability can be established.

2. Legal Liability

Legal liability of seed developers arising from the possible contamination by GM crops of organic or other “GM free” canola under tort law was comprehensively examined by the Saskatchewan Court of Queen’s Bench in *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*.²⁰¹ This case also contains a useful summary of the various categories of tort liability arising from the development and use of canola applicable also to: (i) the Government of Western Australia; (ii) the agricultural research institutes; (iii) plant breeders; (iv) farmers; (v) bulk handlers; (vi) food processors; and (vii) exporters.

The plaintiffs in *Hoffman v Monsanto* claimed damages for organic grain farmers allegedly resulting from the development and commercial introduction into Canada of GM canola by the two defendants. The nature of the damage suffered by the plaintiffs was the loss of the principal foreign markets for organic grain: the United States, Japan and Europe.

It was not disputed that in field trials were conducted in Canada between 1990 and 1994 by AgrEvo Canada, the predecessor of Bayer Cropscience (BCS) for a gene which, when inserted in canola, rendered it resistant to glufosinate ammonium based herbicides such as Liberty, a herbicide marketed and sold by BCS. Approval for the unconfined release of “Liberty Link” canola was granted by the Canadian Food Inspection Agency in 1995. In 1996 Monsanto had been granted approval for the sale of its Roundup Ready (RuR) canola. By 2003 approximately 70 percent of all canola grown in Western Canada was either a Roundup Ready or Liberty Link variety.

Canola in general and Roundup Ready and Liberty Link varieties in particular are open-pollinated. As a result, there is inevitable pollen drift as a result of wind and cross-pollination can occur with non-GM (“conventional”) canola grown nearby. This can result in the production of GM seeds in conventional canola, which can, in turn, result in GM progeny. Volunteer plants of GM canola can also result in fields where canola is not grown at all as a result, *inter alia*, of spillage of GM canola seeds from passing trucks, or from neighbouring farmland where GM crops are cultivated. The resulting presence of GM canola or canola seed on cultivated land where it is not intentionally cultivated was referred to by the plaintiffs as “contamination of the environment”. The term, “adventitious presence” was proposed by the defendants. This also included including mechanical mixing during the harvesting, processing, handling and storage of seed and grain.

A critical factor in the decision by the court to disallow the plaintiffs’ claims was the determination by the Canadian Food Inspection Agency that the genetically modified

¹⁹⁹ *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 at 408-409

²⁰⁰ *Pacific Hotels Pty Ltd v Asian Pacific International Ltd* (1986) 7 IPR 239 at 245-246.

²⁰¹ 2005 SQKB 225.

canolas were not harmful. The damage alleged to organic grain farmers was “solely the damage resulting from loss of use of canola as an organic crop or for cleanup costs for fields “contaminated” by GM canola, due to standards imposed by organic certifiers or by foreign markets or individual customers for organic products.”²⁰²

The legal bases of the plaintiffs’ claims were that the defendants were liable in negligence, nuisance, trespass and for breach of statutory duty. The general principles of law in relation to each of these actions is considered below.

2.1 Negligence

Liability for negligence occurs where a legal duty to act as a reasonable and prudent person exists and is breached, and the breach of duty causes damages to others or their property. The principal elements of the tort of negligence are: (i) the defendant must owe a duty of care to the plaintiff; (ii) the defendant causes damage to the plaintiff; and (iii) that damage was reasonably foreseeable. With respect to GM crops, a negligence claim could be brought by a person claiming personal damage based on an allergic response to food products containing GMOs. Negligence has been claimed in cases involving the contamination of organic crops by GM crops

In *Hoffman v Monsanto*²⁰³ the court was not prepared to find a duty owed by the defendants (developers and marketers of GM canola) to the plaintiffs (organic grain farmers in Saskatchewan) to prevent or to minimize the extent of adventitious presence of their respective GM canola varieties on the plaintiffs’ farmland or in their crops. The principle of law which the Court applied was that which had been laid out by the House of Lords in *Anns v. Merton London Borough Council*.²⁰⁴

In *Anns* Lord Wilberforce explained the test for negligence in the following terms:

First one has to ask whether as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity of neighbourhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause the damage to the latter—in which case a *prima facie* duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negative, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise.²⁰⁵

It should be noted that the *Anns* principle defines the law of negligence in Canada and New Zealand, but it has been rejected in Australia and England. In Australia in *Pyrenees Shire Council v Day*²⁰⁶, the High Court advocated the three stage test which is now generally applied in England²⁰⁷. That test involves firstly, foreseeability, secondly, the existence of a relationship between the parties of "proximity" or "neighbourhood" and finally, a consideration of policy to determine whether it is "fair, just and reasonable" to impose the duty of care in question. Thus the liability principles applied in *Hoffman v*

²⁰² Ibid. at para.22.

²⁰³ 2005 SQKB 225.

²⁰⁴ 1978] A.C. 728 (H.L.).

²⁰⁵ Ibid., at 751-52.

²⁰⁶ (1998) 192 CLR 330 at 419-420.

²⁰⁷ See *Caparo Industries Plc v Dickman* [1990] 2 AC 605; *X (Minors) v Bedfordshire County Council* [1995] 2 AC 633; *Marc Rich & Co AG v Bishop Rock Marine Co Ltd* [1996] AC 211.

Monsanto have to be distinguished from those which would be applied in Australia and England.

Applying *Anns* Case the Saskatchewan court was not prepared to find that the defendants were in a sufficiently proximate relationship to the plaintiffs that it could be said that a duty of care was owed. Mere foreseeability of loss was not sufficient under the law of negligence to establish a *prima facie* duty of care.

The Court held that the plaintiffs had alleged facts sufficient to support a finding that it was reasonably foreseeable that release of the defendants' GM canola into the general environment would result in the adventitious presence of GMOs in the plaintiffs' crops and fields. The defendants' GM canola varieties were open-pollinated varieties which, due to the "natural" process of crosspollination can pollinate conventional canola conferring genetic modification upon the seed of the formerly conventional canola. However, the Court found that what was missing from the plaintiffs' claim was any specific allegation that the loss and damage to organic farmers (*viz.*, loss of the use of canola as a marketable organic commodity and loss of canola for use in crop rotation, plus the clean-up costs and loss of use of fields as a result of GM canola volunteers) was foreseeable.

The Court noted in addition, that there were policy considerations that, in accordance with the second leg of the test in *Anns* Case, would bar or limit the imposition of the duty of care alleged on the defendants. First, both defendants received approval of the federal government for the unconfined release of their GM canola varieties prior to their release. Thus the imposition by the courts of a duty of care not to release these substances into the environment would therefore appear to be in conflict with express governmental policy. Further, the alleged damage was not of physical harm to the plaintiffs' crops, but arises from the alleged inability to meet the requirements of organic certifiers or of foreign markets for organic canola. There was no allegation that GM canola was unhealthy or caused detrimental physical problems to humans or plant life.

A similar result to that in like *Hoffman v Monsanto* was the decision of the United States District Court for the Eastern District of Missouri in *Sample v. Monsanto Co.*²⁰⁸ The plaintiffs argued that farmers, such as themselves, who did not grow genetically modified crops "lost revenue because the European community rejected Monsanto's genetically modified products and boycotted all American corn and soybean as a result."²⁰⁹ The plaintiffs brought an action for negligence against Monsanto for introducing the non-genetically modified seeds into the market. Monsanto moved for summary judgment, arguing that the economic loss doctrine barred negligence claims that are not based on physical injury to persons or property.

The Court ruled that as the plaintiffs did not sustain physical contamination or injury to their property, the economic loss doctrine precludes recovery of damages.

The different approach to negligence in Australia, producing an opposite result to that in *Hoffman v Monsanto* was the Australian High Court decision in *Perre v. Apand Pty. Ltd.*²¹⁰ The defendant had provided defective potato seed to Sparnons, commercial growers of potatoes and other vegetables. The seed caused an outbreak of bacterial wilt in Sparnons' potato crop. The plaintiff owned farms near the Sparnons' land and sold potatoes in the lucrative Western Australia market. Their potatoes were not directly

²⁰⁸ 283 F.Supp.2d 1088 (E.D.Mo.2003).

²⁰⁹ *Ibid.* at 1091.

²¹⁰ (1999), 164 A.L.R. 606.

affected by potato wilt, but legislation of Western Australia prohibited the import of potatoes that were grown within 20 kilometres of a bacterial wilt outbreak. The plaintiff's therefore lost the most lucrative market for their potatoes.

At trial and in the Court of Appeal the plaintiffs were unsuccessful, these Courts holding that, as the plaintiffs had suffered no physical damage, their claim was for pure economic loss and was not recoverable. The High Court ruled that where a defendant knows or ought reasonably to know that its conduct is likely to cause harm to the person or tangible property of the plaintiff unless it takes reasonable care to avoid that harm, the law will prima facie impose a duty on the defendant to take reasonable care to avoid the harm.²¹¹ The loss to the plaintiffs was on the facts clearly foreseeable and they were known to be a vulnerable class.

2.2 Actions based on the rule in *Rylands v. Fletcher*

The principle of law set out in *Rylands v. Fletcher*²¹² was propounded in the case where Fletcher, was mining coal on land adjacent to land owned by Rylands, who operated a mill. Rylands, who had no knowledge of the mining operation on the adjacent land, built a reservoir to supply water for the mill. The reservoir gave way and flooded the mining site. The House of Lords, outlined the elements of this cause of action as: (i) the defendant has made a non-natural use of its land; (ii) the defendant brought onto his land something which was likely to do mischief if it escaped; (iii) the substance in question escaped; and (iv) damage was caused to the plaintiff's property or person as a result of the escape.²¹³

In *Hoffman v Monsanto* two different allegations were made in relation to the *Rylands v. Fletcher* claim, the first relating to the growing of GM canola in confined field plots in 1990 to 1994 and the second relating to the escape of genetic material from the fields of conventional farmers growing varieties of Liberty Link or Roundup Ready canola after its commercial release.

The Court ruled that regardless of whether one considers GM canola a "dangerous substance", or the field trials for GM canola an "unnatural" or "non-natural" use of land, it was not reasonably arguable that the commercial release and sale of Roundup Ready canola seed and Liberty Link canola seed constituted an "escape" of a substance, dangerous or otherwise, from property owned or controlled by the defendants in the sense of "escape" required by the rule in *Rylands v. Fletcher*. Thus the pleadings did not disclose a reasonable cause of action based on the rule in *Rylands v. Fletcher*.²¹⁴

It should be noted however that the High Court has ruled that *Rylands v. Fletcher* no longer forms part of the law of Australia²¹⁵ whereas in England the House of Lords affirmed in a 2004 decision that this action remains part of the law of England.²¹⁶

2.3 Nuisance

²¹¹ Ibid at para 68.

²¹² (1866), L.R. 1 Ex. 265; (1868), L.R. 3 H.L. 330.

²¹³ (1868), L.R. 3 H.L. at 339.

²¹⁴ 2005 SQKB 225 at para 97.

²¹⁵ *Burnie Port Authority v General Jones* (1994) 179 CLR 520.

²¹⁶ *Transco plc v Stockport Metropolitan Borough Council* [2004] 2 AC 1.

The tort of private nuisance is concerned with conditions or activities that cause physical injury or damage to land or that interfere with the use or enjoyment of land. The common law has distinguished between activities or conditions that cause physical injury or damage to another's land from activities and injuries that interfere with the use or enjoyment of land, without actual physical damage.

In *Hoffman v Monsanto* the plaintiffs took the position that there had been physical damage to the land of organic farmers and to organic crops as a result, at least, of the presence of invading GM volunteer plants. The defendants argued that the damage alleged was not caused by the release of GM canola at all, but by the actions of third parties who had promulgated the standards affected by the inevitable adventitious presence of GM canola and by the decisions of individual organic farmers to seek to adhere to those standards. Secondly, the defendants pointed out that agricultural activity in Saskatchewan generally involves the production of open-pollinating crops, that the release of GM canola was subject to federal approval and that the growing of GM canola was widespread and was therefore a "usual and ordinary" activity. The Court, however, noted that the crops and land of organic farmers was effectively contaminated by the presence of GM canola and that it was not "plain and obvious that they cannot succeed in showing that the damage or interference they have alleged constitutes a legal nuisance."²¹⁷

The defendants argue that they could not be liable unless the alleged nuisance emanated from land they occupied or controlled. The Court noted that although it is true that nuisance is typically a claim by one landowner or occupier against his neighbor, in Canada responsibility for private nuisance is not restricted to the occupiers of adjoining lands. However, as with the negligence claim, the Court considered that the damage suffered by the plaintiffs was caused by the European legislation, rather than by the introduction of GM canola.

A nuisance claim in relation to GM corn was considered by the US District Court in Illinois in *In re StarLink Corn Products Liability Litigation, Marvin Kramer v. Aventis CropScience USA Holding Inc.*²¹⁸ The plaintiffs in that case sought to bring a class action claim against the defendant manufacturer and creator of genetically modified StarLink corn. It was alleged that StarLink had contaminated the entire corn supply in many states resulting in increased farming costs and depressed corn prices. The genetic modification of StarLink corn caused it to produce a protein (Cry9C) toxic to certain insects and containing several attributes similar to known human allergens. Accordingly, the defendant had obtained only qualified approval for release for use for animal feed, ethanol production and seed increase by the Environmental Protection Agency ("EPA") under the Federal Insecticide, Fungicide, and Rodenticide Act. The EPA prohibited its use for human consumption and imposed on the defendant manufacturer stringent requirements of warning and monitoring to ensure implementation of mandatory segregation methods in the cultivation, harvesting, handling, storage and transport of StarLink corn, including a mandatory 660-foot "buffer zone" around StarLink corn crops. It was alleged that the defendant had failed to comply with the EPA requirements resulting in the crosspollination and commingling of StarLink with non StarLink corn.

The plaintiffs' actions included private nuisance, alleging that the defendant created a private nuisance by distributing corn seeds with the Cry9C protein, knowing that they would cross-pollinate with neighbouring corn crops. The defendant moved to have the

²¹⁷ Ibid., para 110.

²¹⁸ (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois).

claim dismissed as disclosing no cause of action, arguing that they could not be liable for any nuisance caused by StarLink corn because they were no longer in control of the seeds once they were sold to farmers.

The Court first ruled that the cross-pollination of a crop from neighbouring land constituted nuisance as the StarLink corn was not considered fit for human consumption.²¹⁹ On the question of whether liability in private nuisance could extend to a manufacturer after the point of sale, the Court relied on the American Restatement para. 834, stating that one can be liable in private nuisance “not only when he carries on the activity but also when he participates to a substantial extent in carrying it on.” The question was what counted as “participation to a substantial extent” in carrying on the nuisance beyond the point of sale. It was clear that the general rule was that liability for nuisance could not be imposed on the manufacturer in these circumstances. However, the Court pointed to a number of cases in which the normal pattern of nuisance liability (imposed on a neighbouring land owner or occupier) had been extended. In the case of some manufacturers, the liability had been extended on the basis of foreseeability of the harm alleged coupled with some malfeasance on the part of the manufacturer. In this case, it was alleged that the defendant had itself violated the EPA’s mandates in failing to adequately warn of the need for segregation and to enforce farmers’ compliance with the EPA requirements. The Court concluded “All parties who substantially contribute to the nuisance are liable. The unique obligations imposed by the limited registration arguably put Aventis in a position to control the nuisance.”²²⁰

In *Hoffman v Monsanto* the court distinguished the *StarLink* decision on the grounds that it was not alleged that contamination of organic crops by GM canola was harmful per se or that it rendered the organic crops unfit for consumption or otherwise harmful. Nor was it alleged that the defendants failed in any way to conform to the requirements imposed on them. Indeed, it will be recalled that they had received federal approval for the unconfined release of the GM canola varieties. Thus there were no facts alleged in this case that could support a finding that the defendants substantially caused the nuisance alleged.

2.4. Trespass

To sustain a cause of action in trespass, the plaintiffs must establish intentional and direct interference with another’s possession of land, usually an unauthorized entry upon another’s land. It has been suggested by a number of scholars that planting a crop which, several months later, produced pollen which was carried by the wind onto a neighbor’s property would not be a sufficiently ‘direct’ interference to satisfy the requirements of trespass to land.²²¹ In *Hoffman v Monsanto* the plaintiffs alleged that the defendants had released a self-propagating and proliferating product into the environment, without any, or in the alternative, inadequate, controls that they knew, or ought to have known, would eventually trespass on lands farmed by organic farmers. The plaintiffs cite authorities that suggested that a defendant should be liable in trespass when he has deliberately placed a

²¹⁹ Ibid., at 841.

²²⁰ Ibid., at 847.

²²¹ R. A. Repp, ‘Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift’ (2000) 36 *Idaho L Rev* 585; C. Flood, ‘Pollen Drift and Potential Causes of Action’ (2003) 28 *Iowa J Corp L* 473; T. N. Vollendorf, ‘Genetically Modified Organisms: Someone is in the Kitchen with DNA – Who is responsible when someone gets burned?’ (2001) 21 *Miss C L Rev* 4.

contaminant (oil, soot, pesticide, etc.) so that natural forces, such as wind or water, has then carried onto neighbouring land. However, the Court noted that the authority of a number of English and Canadian cases which required more direct interference with land for trespass to be established. The Court ruled that the commercial marketing and sale of GM canola seed that subsequently finds its way onto the land of another was not an action sufficiently direct to constitute trespass. It was only after conventional farmers grew GM canola varieties and with the intervention of natural processes (or because of the actions of others who have processed or handled the seed) that the GM canola genes could find their way onto the land of organic grain farmers. This was insufficiently direct to lay at the door of the defendants. However, harvesting a crop where the spread of seed to adjoining fields is an immediate consequence of the harvesting could satisfy the directness requirement.

2.5 Breach of Statutory Duty

Hoffman v Monsanto also considered the possibility of the liability of a plant developer being responsible for adverse environmental effects in breach of *The Canadian Environmental Management and Protection Act, 2002*, (“EMPA, 2002”) and for failure to obtain an environmental assessment under *The Environmental Assessment Act 2002*, (“EAA”). The Court noted that this legislation applied only to discharges of substances that may cause an adverse effect, and did not apply to discharges authorized by governments or government agencies, (as was the release of GM canola).²²²

Section 23 of the EMPA imposed civil liability on any person (a term which includes a corporate body) who proceeds with a “development” (a term defined in s. 2 (d)) for which ministerial approval is required without obtaining that approval. Section 8 of the Act requires ministerial approval before any person proceeds with any “development” unless a specific exemption is sought and obtained. Failure to comply with this section results in civil liability, under s. 23. The section makes the person who proceeds with the development without approval liable to any other person who has suffered loss, damage or injury as a result of the development without proof of negligence or intention to inflict loss, damage or injury. Further, the section imposes the burden of proving that any loss, damage or injury was not caused by a development on the person who proceeds with the development without ministerial approval.

The statement of claim in the case alleged that the defendants had tested, developed and commercially released GM canola to be grown on a widespread basis in Saskatchewan and that they did not obtain ministerial approval before doing so. The court did not consider that the testing, development and commercial release of GM canola constituted a “development” within the meaning of the Act.

In particular, the plaintiffs do not allege that GM canola is likely to have an effect on any unique, rare or endangered feature of the environment...; that the activities would likely substantially utilize any provincial resource; or that they would cause the emission of pollutants or by products that require handling and disposal in a manner not regulated by any other Act or regulation... It is not in my view plain and obvious that the plaintiffs could not prove that the development of GM canola caused widespread public concern because of potential environmental changes or that it is (or was) likely to have a significant impact on the

²²² 2005 SQKB 225 at para 165.

environment, particularly given the relatively broad definition of “environment” in s. 2(e).

Of course in situations where the testing or release of GM seed is likely to cause “widespread public concern” then the EMPA might be applicable.

The general tort principles applicable to GM agriculture, discussed above are applied below.

3. Liability of the governments in Tort

3.1 Negligence

Given the extensive debate in most countries about the potential risks of GM crops the governments would be aware of the arguments about the likelihood of the harm which could be caused from GM agriculture. Arguably, the measures which governments take to inform themselves of the relevant risks and the best practices adopted by governments in other jurisdictions are factors which will be taken into account in attributing any liability for negligence. Among the more significant guidelines are the *guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming* which were recommended by the European Commission (EC) on 23 July 2003. The relevant portions of these guidelines are detailed below.

The fundamental approach adopted by the EC is that farmers should be able to cultivate the types of agricultural crops they choose: GM crops, conventional or organic crops, subject to the provision of the choice to European consumers between GM food and non-GM food. To this end the EC has recommended the combination of an agricultural system which enables farmers to make a practical choice between conventional, organic and GM-crop production, together with an effective traceability and labelling system, which sets out the tolerance thresholds requiring a crop to be labelled as containing GMOs.

As the EC points out in its guidelines the co-existence of different production types is not a new issue in agriculture, referring to the segregation of yellow dent field maize for animal feed, which successfully co-exists in European agriculture with several types of “speciality maize” grown for human consumption and waxy maize grown for the starch industry.

It should be noted that any co-existence guidelines dealing with negligence and other economic liability issues, are subordinated to risk assessments conducted under relevant environmental legislation, particularly that enacted pursuant to the Cartagena Biosafety Protocol. Where the risk of an adverse effect to the environment or health that cannot be managed is identified, the EC has recommended the refusal of an authorisation. If a risk to the environment or health is identified *after* the authorisation has been granted, a procedure for the withdrawal of the authorisation will be initiated under the European legislation.

The EC, whose recommendations are for the member states of the EU, recommends that national strategies and best practices for co-existence should be developed in cooperation with all relevant stakeholders and in a transparent manner and that management measures for co-existence should permit the cultivation of GM and non-GM crops, whilst ensuring that non-GM crops remain below the legal thresholds for labelling and purity standards

with respect to genetically modified food and feed, and seeds, as defined by European legislation.

The EC guidelines recommend that management measures for co-existence should build on and take into account already existing segregation practices and methods and should be efficient and cost-effective, and proportionate, avoiding any unnecessary burden for farmers, seed producers, cooperatives and other actors.

The EC guidelines recommend that priority should be given to farm-specific management measures and to measures aimed at coordination between neighboring farms. They recommend that region-wide measures should only be considered if sufficient levels of purity cannot be achieved by other means.

Consequently, best practices for co-existence should take into account the differences between crop species, crop varieties and product type and that differences in regional aspects (e.g. climatic conditions, topography, cropping patterns and crop rotation systems, farm structures, crop-specific GMO share in a region) that may influence the degree of admixture between GM and non-GM crops, should also be taken into account to ensure the suitability of the measures.

The European guidelines provide that farmers who plan to introduce GM crops for cultivation on their farms should inform the neighbouring farmers about their intention and that as a general principle, during the phase of introduction of a new production type in a region, they should bear the responsibility of implementing the farm management measures necessary to limit gene flow.

In relation to liability, farmers, seed suppliers and other operators should be fully informed about the liability criteria that apply in the case of damage caused by admixture. The EC recommends that Member States may want to explore the feasibility and usefulness of adapting existing insurance schemes, or setting up new schemes.

The EC guidelines propose that management measures and instruments adopted should be subject to ongoing monitoring and evaluation to verify their effectiveness and to obtain the information necessary for improving the measures over time and that adequate control and inspection systems should be established to guarantee the proper functioning of co-existence measures. Best practices for co-existence should be revised periodically to take account of new developments brought about by scientific and technical progress and which could facilitate co-existence.

The EC Guidelines provide an open-ended catalogue of farm management and other measures for co-existence that can be used for the formulation of national co-existence strategies and best practices.

The liability of governments in negligence for any possible physical harm to the health of consumers resulting from its approval of the cultivation of GM crops would appear on the basis of current knowledge about such risks to be too remote. No court case has yet found that the cultivation of GM foods poses a risk to the health and safety of consumers. On the other hand there are a number of lobby groups and civil society groups which assert that such a risk exists. The so called “precautionary principle” has been developed, principally by the World Trade Organization in the context of its Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) as a means of bridging the gap between scientific uncertainty and risk regulation.²²³ Almost all of the

²²³ See C.A. Raffensberger and J. Tichner, Eds, *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, Washington DC, Island Press, 1999 and B. Goldstein and R.S.Carruth, ‘The Precautionary Principle and/or Risk Assessment in World Trade Organization Decisions: A Possible Role for Risk Perception’ (2004) 24 *Risk Analysis* 491.

discussion has concerned whether measures which have already been taken, were justified by the scientific proof which existed of relevant risk to health and the environment. It is possible to glean some operating principles from the literature. A useful summary which is applicable to GM agriculture is contained in Cosbey.²²⁴ In relation to labelling practices, he identifies the following as precautionary: (i) preventative anticipation (taking action in advance of full scientific proof of its necessity); room for error (leaving open a deliberate margin for error); proportionality of response (the cost of proposed measures should not be out of proportion with expected benefits); (iv) onus of proof (this should be imposed on the proponent of a new product); (v) search for greater certainty (precautionary measures should be open to periodic review); (vi) openness of process (transparency of decision making); and (vii) emphasis on finding alternative products or technology without the risks of negative effects. It should be noted that in the USA²²⁵ and in the EU²²⁶ an attempt has been made to separate risk assessment and risk management, although, in practice this has been difficult to achieve because of the inter-relationship between the two processes.²²⁷

3.3 Breach of statutory duty

A UK case in which the question of liability for breach of statutory duty in an agricultural context was: *R. v Watson, (On the application of) v Secretary of State for Environment, Transport & Regions & Anor*²²⁸ Under Part VI of the UK Environmental Protection Act 1990 GM seed could not be released into the environment without a consent issued by the Secretary of State for the Environment Transport and the Regions under section 112 of the Act. Sharpes a firm of seedsmen had developed a genetically modified strain of maize seed known as T25. They wished to have a seed trial conducted so that if plants grown from the seed demonstrated the qualities required by Schedule 2 of The Seeds (National Lists of Varieties) (Amendment) Regulations 1982, the seed could be listed in the National List published in the Plant Varieties and Seeds Gazette published under the Plant Varieties Seeds Act 1964. Inclusion of a plant or seed in the National List is an aid to marketing it in the United Kingdom. Accordingly, Sharpes made application for T25 to be included in the list. The Ministers arranged that a body called "NIAB" should conduct a trial on land it occupied for the purpose of such trials. However, because T25 seeds were genetically modified organisms, before a consent could be given the Secretary of State had to be satisfied that the release would be safe. The Secretary of State was satisfied and granted a consent to Sharpes.

What was not realised when the consent was given was that the Applicant, whose farm was in the same area as NIAB's land, was an organic farmer and that a question could

²²⁴ A. Cosbey, *A Forced Evolution? The Codex Alimentarius Commission, Scientific Uncertainty and the Precautionary Principle*, Winnipeg, International Institute for Sustainable Development, 2002 at 11, Cited in T. Epps, *International Trade and Health Protection. A Critical assessment of the WTO's SPS Agreement*, Cheltenham UK, Edward Elgar, 2008, 171-172.

²²⁵ National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, Washington DC, National Academy Press, 1983.

²²⁶ See A. Alemanno, *Science and EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review*, Milan, Università Commerciale L. Bocconi, 2007.

²²⁷ See P.C. Stern and H.V. Fineberg, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC, National Academy Press, 1996.

²²⁸ [1998] EWHC Admin 737.

arise whether a crop of organic maize grown by him could be pollinated by pollen from the T25 plants. The Applicant was a member of the Soil Association which certified organic crops. The value of crops sold "organically grown," would be seriously depreciated, without this certification. The Applicant knew of the trial of T25 which was taking place and was warned by the Soil Association that if there was a risk of pollination from it his crop certification of it would be withdrawn. Faced with this warning the Applicant sowed his own crop, but at a point as far away as he could sow it from the land on which T25 was being grown - 2 km away, in fact. No question of risk to the Applicant's crop arose if the T25 plants were not allowed to flower. The question was taken up with the Secretary of State. He decided that it was appropriate to take a decision nearer the time as to whether the crop should be allowed to flower. He took advice from the body known as "ACRE" and decided to allow the trial to continue and not to prevent the plants from flowering.

The Applicant sought an order requiring the Secretary of State to prevent the crop from flowering. The Secretary of State has sought the advice of the Advisory Committee on Releases to the Environment (ACRE) on this matter. That advice stated that as the applicant's sweet corn crop had been planted at a site approximately 2 km from the nearest genetically modified maize, ACRE consider the amount of cross-pollination was likely to be zero.

On this basis the Court ruled that the Secretary of State's decision was not open to challenge. However, if the risk of cross-pollination was higher, this case illustrates the possibility of liability for breach of statutory duty.

The question of the liability of government agencies for liability for harm emanating from GM crops was also considered recently by the United States Court of Appeals for the Ninth Circuit in *Geertson Seed Farms and others v. Forage Genetics, Inc and Monsanto Company and Others*²²⁹ This case concerned a decision by the Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture, concerning the environmental impact of Round-up Ready Alfalfa. APHIS had initially classified the genetically modified alfalfa as a regulated article under the National Environmental Policy Act (NEPA). After being petitioned by the manufacturer it had made a finding of no significant environmental impact and unconditionally deregulated the alfalfa.

In its Environmental Assessment ("EA") prepared in accordance with NEPA and its implementing regulations, APHIS explained that alfalfa is pollinated by insects, primarily bees, and that insect pollination has been documented as occurring up to 2 miles from the pollen source. However, with regard to the threat of possible genetic contamination of non-genetically engineered alfalfa, it explained that the National Organic Program mandates buffer zones around organic production operations, the size of which are decided by the organic producer and the certifying agent on a case-by-case basis. The EA concluded that it was therefore unlikely that Roundup Ready alfalfa would have a significant impact on organic farming.

In May 2007, the District Court had granted the plaintiffs a permanent injunction to prohibit all future planting of Roundup Ready alfalfa, as well as the harvesting of any Roundup Ready alfalfa seed already planted, pending the completion of an EIS and a new decision on deregulation. APHIS agreed that any future planting should be subject to certain conditions, including requiring isolation distances from other crops and requiring certain harvesting conditions to minimize gene flow to non-genetically engineered alfalfa

²²⁹ 2008 U.S. App. LEXIS 18752

seeds. The District Court found that genetic contamination had occurred. Monsanto and its licensee, Forage Genetics appealed the injunction, arguing it was too broad.

On appeal, the Court considered the principles of law which applied to the grant of a permanent injunction. It noted that applying these principles an injunction did not "automatically issue" when a NEPA violation is found and said that it was required to "engage in the traditional balance of harms analysis." With respect to harm, the court found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed.

The Appeal Court agreed with the District Court that the harm to growers and consumers who wanted non-genetically engineered alfalfa outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The courts also agreed that in considering the public interest, while recognizing that agricultural biotechnology has social value, they held that it would be in the public interest to enjoin the expanded use of Roundup Ready alfalfa before its impact was studied, because failing to do so could potentially eliminate the availability of non-genetically engineered alfalfa.

A dissenting judgement in the Appeal Court noted that the facts were sharply disputed by the parties, including a dispute as to the risk of genetic contamination that could occur while APHIS prepared the EIS.

4. Liability of agricultural research and development organizations

Agricultural research and development organizations could be liable in negligence for inadvertently supplying GM seed to farmers who do not wish to cultivate GM crops. That liability would be mitigated where the agricultural research and development organizations have implemented a proper system for the avoidance of this possibility, based upon best practices. As a matter of practice agricultural research and development organizations will seek to limit any legal liability arising from the supply of GM seed, in the exclusion clauses which they will insert into the material transfer agreements (MTAs) which they use governing the supply of their seed.

The use by an agricultural research and development organization of proprietary GM material or enabling technologies could render it liable as an infringer of IP rights. Another possibility, raised by *Monsanto Co. v. Parr*²³⁰ is that an agricultural research and development organization by utilizing proprietary material in seed which it makes available to farmers might be "authorizing" or aiding a patent infringement by those farmers. The defendant, Parr, in that case operated a seed and grain cleaning business in Indiana. Seed cleaning is a process where a harvested crop is run through a mechanical cleaner that sifts trash such as stems, leaves, dirt, and broken/split seed from the whole seed. The primary reason for cleaning seed is to have it prepared for replanting. Monsanto was concerned that Parr's activities would facilitate the saving and planting of its patented RuR seed and it wrote to Parr requesting that he cease any actions which would induce farmers to breach its patent. From 2002 through 2007, approximately 87.3% to 94.3% of the soybeans planted in Indiana contain Monsanto's patented RuR

²³⁰ 2008 WL 1808365 (N.D. Ind. 2008).

trait and the Court noted the strong likelihood that seed cleaned by Parr for replanting would infringe Monsanto's patent.

In overseas jurisdictions there is a research or experimental use exception to patent liability for researchers. For example, Art. 31(b) of the European Community Patent Convention of 1975, which was transposed into Art. 27(b) of the Community Patent Convention, provides that a "Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention".

In the UK section 60(5)(b) of the Patents Act, 1977 incorporates the experimental use defence using the same words as that of the CPC. Under this provision: (a) the acts must be done for experimental purposes; and (b) those purposes must relate to the subject matter of the invention. The exception was considered by the court in *Monsanto v Stauffer*.²³¹ Stauffer had developed a market variant 'Touchdown' of Monsanto's successful patented weed-killer 'Roundup' for which they had obtained provisional clearance from relevant authorities. In order to obtain final clearances, Stauffer had run tests at its own research farm and also organised a series of tests outside their research farm where interested parties could observe the results. Monsanto moved for an interlocutory injunction on the grounds of patent infringement. Both the Patent Court and Court of Appeal ruled that the outside tests could not qualify for an experimental use exception.

5. Liability of plant breeders

5.1 Tort Liability

The liability of plant breeders in tort for any damage suffered by an acquirer of seed was canvassed in *Hoffman v Monsanto* and is discussed above. Biosafety liability issues may arise for plant breeders where germplasm is supplied to farmers adulterated by the unintended presence of GMOs. The supply of GM germplasm by a under a Material Transfer Agreement (MTA), generally contains a provision that the provider makes no warranties as to the safety of or title to the Material, nor as to the accuracy or correctness of any passport or other data provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished. The recipient generally assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material."

Supply of germplasm under an MTA should be considered as a supply under a contract. In this situation one has to note both the express terms of the MTA, as well as any terms which might be implied by operation of law. The sale of goods legislation might be applicable in implying terms and warranties in the supply transaction. If an acquirer of germplasm seeks an express term that it is free of GM contamination, the supply of adulterated germplasm would be a clear breach of that contractual term, even where the contamination might have occurred in the seed in planting, growing, harvesting, transporting, and storing the crop.

Where germplasm is acquired for use in organic farming, or for supply into markets which prohibit GM crops, the supply of contaminated germplasm would breach the implied warranty of fitness for purpose. This warranty is imposed where the seller has reason to know of any particular purpose for which the goods are required and the buyer

²³¹ [1985] RPC 515 CA.

relies on the seller's skill and judgment in providing the goods. Usually warranties implied by the law may be excluded or modified by the seller by a conspicuous, written or where the goods are being sold "as is" or "with all faults".²³²

Of assistance in formulating best practices for plant breeders are the testing guidelines for both phenotypic traits and genetic markers at points in the production and marketing chain provided under the Rules for Seed Testing of the International Seed Testing Association (ISTA) and the Association of Official Seed Analysts (AOSA), as well as by official regulatory agencies in both international and domestic jurisdictions.

5.2 Intellectual Property Liability

In addition to tort liability, IP liability may apply where proprietary genetic material or research tools is utilised by plant breeders.

An area of IP liability for plant breeders is breach of confidentiality. Information which has been originated by a person and which is not in the public domain and in relation to which efforts have been made to keep it confidential may be protected by the law of confidence. For example, where plant breeding information has been kept confidential, the theft of that information in documentary form would be actionable. Similarly, it has been held that the theft of genetic material is actionable. For example in *Franklin v Giddins*²³³, the Queensland Supreme Court was concerned with the theft by a defendant of budwood cuttings from the plaintiffs' orchard which enabled the defendant after grafting to grow Franklin Early White nectarines, in competition with the plaintiffs. The Court held this to involve a theft of confidential information embodied in the genetic composition of the budwood.

In *Pioneer Hi-Bred Int'l v. Holden Found Seeds*²³⁴ the US Eighth Circuit Court of Appeals was concerned with a dispute between competing breeders of corn seed Pioneer and the defendant, Holden. Pioneer claimed that Holden had developed a seed from misappropriated seed which it claimed were its trade secrets. Holden disputed the genetic similarity between its seed and Pioneer's H3H/H43SZ7. In an attempt to evaluate the parties' competing claims, the court oversaw three series of tests: electrophoresis, reverse phase high-performance liquid chromatography and growouts. Each test was supervised by the court, performed by independent experts, and monitored by the parties. Although the court found that each of the three tests had its own set of limitations and inadequacies they served to demonstrate the unlikelihood of Holden's explanation of the parentage of the seeds and the greater likelihood of Pioneer's theory of parentage. At first instance, the district court awarded Pioneer \$US46 million for misappropriation of its trade secrets.

The case is not a particularly good authority for the proposition that genetic information can qualify as trade secrets as Holden did not dispute this point, therefore the court assumed "without deciding that genetic messages can qualify for trade secret status." The appeal focussed upon the District Court's application of trade secrets doctrine. Under Iowa law, a plaintiff must generally show: (1) existence of a trade secret, (2) acquisition of the secret as a result of a confidential relationship, and (3) unauthorized use of a secret. Holden argued that it should not be liable for misappropriating Pioneer's seed because Pioneer failed: (1) to keep the genetic messages secret; (2) to prove that Holden actually

²³² See Roger A. McEowen, 'Legal Issues Related to the Use and Ownership of Genetically Modified Organisms' (2004) 43 *Washburn Law Journal* 610.

²³³ (1978) Qd R 72.

²³⁴ 35 F.3d 1226 (8th Cir. 1994).

possessed the protected genetic messages; and (3) to prove that Holden obtained the material by improper means.

Holden argued that H3H/H43SZ7 were not trade secrets because Pioneer failed to maintain their secrecy. The district court found that the genetic messages of H3H and H43SZ7 were trade secrets as the "formula" did not exist outside Pioneer's and its contractors' fields, and that Pioneer took reasonable precautions to protect the secrecy of the genetic message. Pioneer took several measures to preserve the secrecy of its inbreds. Growers operated under contracts which prohibited disclosure of the seed. Fields have no labels indicating what seed is being grown, and all seed bags were coded to avoid identification. Pioneer removed male inbred lines and commingled them with other corn, thereby frustrating those seeking to obtain the inbred seed. The Appeal Court considered there to be sufficient evidence to support the district court's finding that Pioneer took reasonable precautions to protect the secrecy of the genetic message of H3H/H43SZ7.

Holden contended that since none of the scientific tests could conclusively prove parentage, the District Court erred in finding possession. Holden points out particular shortcomings with each of the tests. The Appeal Court held that there was sufficient evidence to warrant a finding that Holden had derived its seed from H3H/H43SZ7.

The Appeal Court noted that a confidential relationship was not a prerequisite to a trade secret action, since a plaintiff may prevail in the absence of such a relationship by showing that the secret was obtained by improper means. The Appeal Court noted that Pioneer presented no direct evidence regarding how Holden obtained H3H/H43SZ7. However, direct evidence of industrial espionage was rarely available and not required.

The Appeal Court noted that the record displayed a long history of Holden attempts to obtain Pioneer's genetic material. These efforts included searching "friendly farms" for stray inbred plants. Although the court concluded that Pioneer has not specifically shown that these efforts were the exact source of Holden's seed the testimony supported such an inference. Holden's inadequate explanation of its faulty record-keeping and the untimely disposal of all its impugned seed also gave rise to an inference of misappropriation.

6. Liability of farmers

6.1 Tort Liability

The legal liability of farmers growing crops was addressed in a 2006 research paper by Mark Lunney and Robert Burrell for the Australian Department of Agriculture, Fisheries and Forestry.²³⁵ The conclusions reached by the paper were that:

...under the existing law of negligence and private nuisance, the chances of a successful action against a farmer growing a crop by a neighbour in most cases are small. This conclusion is premised on the fact that in the torts considered the conduct of the plaintiff is judged at the time of the conduct – here, at the time of the planting of the crop – and risk and damage is assessed at that time. A farmer is not liable merely because the consequences of planting the crop turn out to be different from what was predicted at the time the crop was planted. Much depends on the existing scientific evidence, but certainly where a new crop has gone through an

²³⁵ M. Lunney and R. Burrell, *A Farmer's Choice? Legal Liability of Farmers Growing Crops*. Canberra, Department of Agriculture, Fisheries and Forestry and the Australian Centre for Intellectual Property in Agriculture, 2006.

existing regulatory approval process – as for GM crops – the farmer planting the crop has strong arguments to defeat claims brought in negligence and private nuisance. This conclusion is reinforced by the failure to discover any reported cases where such actions have been brought, although this might be explained by the fact that many of the innovations behind new crops are relatively recent.²³⁶

This conclusion is qualified by the date of the paper, but is supported by some of the reasoning in *Hoffman v Monsanto*, although that case was brought against seed developers and it was an interlocutory proceeding.

Lunney and Burrell take the position that for farmers to be liable to their neighbours in tort for any GM pollen or seed which may be transmitted onto the land of their neighbours, there must be a physical impact upon the neighbours land. As there is no case law involving GM cultivation, the authors look at a series of UK cases under the Nuclear Installations Act 1965 (UK), concerning whether the leakage of radioactive material onto a neighbour's soil caused "physical damage to property" as required by that Act. In *Blue Circle Industries v Ministry of Defence*²³⁷ the Court of Appeal held that the property had been damaged by the intermingling of radioactive plutonium with the soil on the plaintiff's land. Aldous LJ stated: "The land itself was physically damaged by the radioactive properties of the plutonium which had been admixed with it. The consequence was economic, in the sense that the property was worth less and required the owner to expend money to remove the topsoil, but the damage was physical."²³⁸ Similarly in *Merlin v British Nuclear Fuels Plc*²³⁹ the plaintiff claimed damages for the loss in value of his home after it was discovered that radionuclides from the defendant's plant were present in the house. It was held that the notion of damage to property required there to be physical damage to tangible property and as the radionuclides did not damage the fabric of the property there was, accordingly, no damage to property for the purposes of the Act.

On the other side of the coin is the Scottish Court of Session decision in *Magnohard Ltd v United Kingdom Atomic Energy Authority*.²⁴⁰ The amount of intermingling in that case was much less than in the *Blue Circle case*, with only sporadic particles of nuclear material being deposited on a beach, however the Court found that there was damage to property under the relevant legislation. The Judge observed that [P]hysical damage has occurred and continues to occur by reason of the sporadic and unpredictable deposit of tiny radioactive particles, which become immixed with the fine grains of sand on the beach without leaving any visible sign to alert a user of the beach as to which parts of the beach might contain a radioactive particle. Damage in my view occurs as soon as a radioactive particle is deposited on the beach."²⁴¹ An analogy can be drawn with the deposit of GM pollen onto land. It would be virtually undetectable by a farmer and arguably would change the biological structure of that land in much the same way as in *Magnohard*.

Before a deliberate release of a GM crop such as canola into the environment, eg through cultivation, may take place the person planting the crop must have the authority of a

²³⁶ Ibid., para A.3.

²³⁷ [1999] Ch 289.

²³⁸ Ibid 300-301.

²³⁹ [1990] 2 QB 557.

²⁴⁰ [2004] Env LR 19.

²⁴¹ Ibid [155].

licence to do so issued by the Gene Technology Regulator.²⁴² Part of the process requires the Gene Technology Regulator to engage in a risk assessment before granting a licence.²⁴³ This requires the Regulator to consider, amongst other things, the risks posed to health or safety of humans and to the environment and the long and short term potential of the GMO (“genetically modified organism”) to be harmful to other organisms and its ability to transfer, spread, or persist in the environment. Unless satisfied that the risks are insignificant or able to be managed, a licence cannot be granted.

The relevance of this legislation to the tort liability of a farmer is that a licence might be used as evidence by that the risk present in planting the GM crop was thought by the regulatory authorities as being sufficiently low that a licence should be granted and thus that damage to neighbouring properties was not reasonably foreseeable and therefore that no duty of care would be owed in negligence and no liability would arise in nuisance. Alternatively, the presence of a licence may lead a court to deny the existence of a duty of care in relation to the release of the GM crop into the environment because this would be inconsistent with express government policy.⁷⁶ Conversely, even if this hurdle is overcome, the existence of the licence might be used to argue that might be evidence that any risk was insignificant and thus there would be no breach of duty. *R v Secretary of State for the Environment, Transport and the Regions ex parte Watson*, discussed above, is cited by Lunney and Burrell as to the way in which the grant of a licence would limit tort liability.

In a September 2003 paper for the Australian Department of Agriculture, Fisheries and Forestry, David Dalton²⁴⁴ advises that GM farmers should be careful to comply with any relevant licence conditions imposed by the Office of the Gene Technology Regulator (OGTR) and any directions of the GM seed supplier included under the Technology Use Agreement (TUA) as while “compliance or non-compliance is not conclusive of the question of negligence, compliance is likely to be highly persuasive.” He advises that canola growers should comply with the “Canola Industry Stewardship Protocols”.²⁴⁵ These Protocols provide that “farmers, when growing GM canola and/or non-GM canola, should incorporate and give attention to:

- maintaining complete farm records for all paddocks and crops;
- incorporating sound crop rotation and production practices in farm management;
- selecting crop varieties and seed treatments suitable for local conditions;
- using certified or quality assured seed for planting a crop in preference to farmer-saved planting seed;
- using farmer-saved planting seed grown only from a crop established with certified seed;
- establishing base weed control and cultural practices on the weed spectrum and the herbicide resistance status;
- declaring and identifying product at first point of delivery in the supply chain;

²⁴² See Gene Technology Act 2000 (Cth) Part IV.

²⁴³ Ibid, s 50.

²⁴⁴ D. Dalton, *Liability Issues Associated with GM Crops in Australia*, Canberra, Department of Agriculture, Fisheries and Forestry, September, 2003, 11.

²⁴⁵ Gene Technology Grains Committee, *Canola Industry Stewardship Protocols for Coexistence of Production Systems and Supply Chains*, May 2003, <http://www.jcci.unimelb.edu.au/GMCanola2007/CISP%201%20July%202003.pdf>

- implementing farm hygiene practices in relation to:
 - farm equipment (spraying, seeding, cultivation, harvesting);
 - seed and grain handling, transport and storage; and
 - chemical storage and handling;
- incorporating integrated crop and weed management practices, such as:
 - consulting the Crop Management Plan for details before planting;
 - consulting the Stewardship Plans for non-GM herbicide tolerant crops;
 - rotating herbicide groups and modes of action, as well as cultural practices;
 - minimising the adventitious presence of off-type seed or grain; and
 - minimising gene flow.”²⁴⁶

Where a farmer employs a contractor to implement a management practice (for example, crop spraying, windrowing, harvesting, transport), the Protocols require that the contractor must “be adequately informed of the standard required for undertaking the assigned task and, if required, can prove recommended procedures were followed “concerning eg, keeping records, cleaning machinery “for the optimal and safe management of the seed, crop and harvested product.”²⁴⁷

In following the Protocols, as David Dalton points out a farmer is not necessarily exonerated from liability for negligence, but “compliance is likely to be highly persuasive” in the sense of going a long way towards discharging a farmer’s duty of care to non-GM neighbouring farmers.

As was mentioned above in relation to the US StarLink™ litigation,²⁴⁸ it would seem to be important to keep pharmaceutical traits from transgenic crops segregated from food and feed crops to protect against claims of harm arising from contamination with toxins or allergens. Where pharmaceutical transgenic crops are grown effective stewardship systems should be implemented to ensure segregation.²⁴⁹

²⁴⁶ Ibid at 17.

²⁴⁷ Ibid 17-18.

²⁴⁸ In re StarLink Corn Products Liability Litigation, No. 1403,01C1181, 2002 WL 1291790 (N.D. Ill. June 11, 2002), referred to in Drew L. Kershen, *Legal Liability Issues in Agricultural Biotechnology*, National Law Center, University of Arkansas, School of Law, Fayetteville 2002, 14.

²⁴⁹ Note USDA-APHIS, *Information for Field Testing of Pharmaceutical Plants* <http://www.aphis.usda.gov/ppq/biotech/pdf/pharm-2002.pdf> , which identifies three segregation techniques: geographical isolation (separation distances), temporal isolation (planting time differences), and field monitoring for control of volunteer plants. Similarly, the Federal Drug Administration(FDA) has issued *Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals* , 67 Fed. Reg. 57,828 (Sept. 12, 2002). Part III on environmental considerations, sets out confinement measures meant to control pharmaceutical traits from transgenic crops from entering the food or feed chain.

Plant Variety Rights Protection

M. Blakeney, *Intellectual Property Rights and Food Security*. Wallingford. CAB International. 2009, ISBN 978-1-84593-560-3

4. Plant Variety Protection and Food Security

4.1 Historical Background

The first legislative proposal for the protection of agricultural innovations was the Papal States Edict of 3 September 1833 concerning the declarations of ownership of new inventions and discoveries in the fields of the technological arts and agriculture.²⁵⁰ This general measure was never implemented. The inclusion of agriculture in this instrument could not be attributed to the incentivisation of innovations in plant breeding, as it anticipated, by two decades, the 1865 publication of the experiments of Mendel on the principles of heredity and, by almost seventy years, the rediscovery of his work by Correns, von Teschermak and de Vries in 1900.²⁵¹

With the dissemination of Mendellian theories in the early 1900s the establishment of plant breeding on genetic principles became feasible. Prior to this time farmers had, of course, selected and harvested seeds from plants which had desirable traits, such as disease resistance, and suitability to their local conditions, without being aware of the genetic mechanisms which produced these results. The significance of the publication of Mendel's theories is that it made possible the establishment of a plant breeding industry. A significant food security aspect of this industry is that agricultural innovation shifted away from farmers to corporations. The primary corporate objective of seed companies, to secure repeat purchases of seed, was in direct contradiction to the practice of farmers to save seed for future plantings. The subsequent history of the seed breeding industry has been characterised by the development of legal and technological means to preserve innovations and to secure repeat purchases of seed.

The development of high yielding hybrid varieties was a technological guarantee of future seed sales, as hybrid vigour tended not to be transmitted between generations. Trade secrets law could also be used to prevent access to breeding information.²⁵² A parallel development was the growth of large scale, mechanised agriculture in which seed saving and cleaning by farmers was apparently less convenient than the purchase of farm-ready seed from dealers.²⁵³

The first national proposal that foreshadowed the protection of agricultural innovations under patent law was the introduction, in the United States Congress of 1906, of a "Bill to

²⁵⁰ B. Laclavière, La protection des droits des obtenteurs sur les nouvelles espèces ou variétés des plantes et la Convention de Paris du 2 décembre 1961 pour la protection des obtentions végétales, (April, 1962) No.168, Bulletin D'Information des Ingenieurs des Services Agricoles, cited in A. Heitz, 'The History of the UPOV Convention and the Rationale for Plant Breeders' Rights, Paper delivered at UPOV Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention (Buenos Aires, 26-27 Nov. 1991).

²⁵¹ See R.W. Allard, *Principles of Plant Breeding*, New York, John Wiley & Sons, 1960, 7 et seq.

²⁵² See J. R. Kloppenburg, *First the Seed: the Political Economy of Plant Biotechnology, 1492-2000*, 2nd Edition, Madison, University of Wisconsin Press, 2004.

²⁵³ See C. Fowler, *Unnatural Selection: Technology, Politics and Plant Evolution*, Yverdon, Gordon and Breach Science Publishers, 1994.

amend the laws of patents in the interest of the originators of horticultural products.”²⁵⁴ This bill was unsuccessful, as were similar bills introduced in 1907, 1908 and 1910. It was not until the Townsend-Parnell Act of 1930, the “Plant Patent Act,” that agricultural innovations were recognised by Congress. This statute endures as sections 161-164 of the current United States patent law.²⁵⁵

Although part of the U.S. Patents Code, the Plant Patents Act created a *sui generis* system of protection for agricultural innovations that anticipated a number of the features of the International Convention for the Protection of New Varieties of Plants (UPOV).²⁵⁶ For example, section 161 of the Plant Patent Act confined protection to asexually reproduced plants, because of the view that sexually reproduced varieties lacked stability.²⁵⁷ The section also excluded tuber-propagated plants principally because of a concern that this would lead to monopolies in basic foodstuffs, such as potatoes.²⁵⁸

Applicants for plant patents were accordingly required to asexually reproduce the plant in relation to which protection was sought, in order to demonstrate the stability of the characteristics that were claimed.

Section 161 also required that eligible new varieties should be “distinct.” The statute did not define this requirement, although the Senate Committee Report accompanying the Act stated that “in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties” and that it was not necessary for the new variety to constitute “a variety of a new species.”²⁵⁹

Legislation similar to the U.S. Plant Patents Act was adopted in Cuba, 1937; South Africa, 1952 and the Republic of Korea, 1973, in an endeavour by those countries to align their patent systems with that of the United States.²⁶⁰ The U.S. Act was further emulated in the draft Seeds and Seedlings Law, which was submitted to the German Parliament in 1930, the year in which the US Act was adopted.²⁶¹ The German legislation provided protection to plant breeders for new varieties that were distinguishable from existing varieties in characteristics that were inheritable or transferable by vegetative propagation. The UPOV Convention’s later concern with “essentially derived varieties”²⁶² was anticipated by the German Law’s denial of protection to a variety obtained by a mere selection without important or substantial improvement of an existing protected variety.²⁶³ The Law also authorised the registration of protected varieties as trade marks. However, this draft Law was never adopted by the German Parliament.

²⁵⁴ A Bill to Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, H.R. 18851, 59th Cong. (1906), quoted in Arguments Before the House Comm. on Patents on H.R. 18851, To Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, 59th Cong. 3–18 (1906).

²⁵⁵ 35 U.S.C. §§ 161-164 (2000).

²⁵⁶ International Convention for the Protection of New Varieties of Plants (UPOV), 2 December 1961, as revised in 1972 and International Convention for the Protection of New Varieties of Plants 23 October 1978]. [hereinafter UPOV 1978]. A further, important revision occurred in 1991. See below n. et. seq..

²⁵⁷ 35 U.S.C. § 161 (2000). See S.B. Williams, Intellectual Property Aspects of Plant Variety Genetic Engineering: View of an American Lawyer, in UPOV, GENETIC ENGINEERING AND PLANT BREEDING 23 (1983).

²⁵⁸ S. REP. NO. 71-315 (1930).

²⁵⁹ Id., cited in J. Rossman, The Preparation and Prosecution of Plant Patent Applications, 17 J. PAT. OFF. SOC’Y 632 (1935).

²⁶⁰ See Heitz, above n. 1, at 23.

²⁶¹ GRUR 244 [1930].

²⁶² UPOV 1978, above n. 9, art. 5.

²⁶³ Law on the Protection of Varieties and the Seeds of Cultivated Plants, 1953

4.2 The Road to UPOV

In Europe, the first formal suggestion for a *sui generis* type of protection for plant varieties occurred in the Congrès pomologique de France of 1911. A French Decree of 5 December 1922 introduced a Register for Newly-bred Plants,²⁶⁴ and a similar system of seed certification was established by the Netherlands in 1932. The first national statute that clearly anticipated the UPOV Convention was the Czech Law of 1921 on the Originality of Types, Seeds and Seedlings and the Testing of Horticultural Types.²⁶⁵ It provided that registration of plant seed types entitled the registrant to place its material in commerce under a registered indication. The horticulturalist or producer who produced the original material obtained the exclusive right to make use of a registered trade mark covering the type.

A more obvious precursor to the UPOV Convention was the German Law of 27 June 1953, on the Protection of Varieties and the Seeds of Cultivated Plants. Article 1 of this statute stated that the purpose of protection was to promote the creation of useful (*wetvoll*) new varieties of cultivated plants. An exception was provided for non-food plants and varieties intended for export. A precondition for protection was that a variety should be “individualised” and stable. This anticipated the UPOV requirements of distinctiveness and stability. The registered owner of a protected variety had the exclusive right to produce and sell seed of the variety. The Law also permitted the use of a protected variety for the creation of new varieties.

Also anticipating UPOV was the requirement that anyone who marketed seed of the protected variety was obliged to use the registered designation for the variety. As with UPOV, where under the German Law the variety designation was a registered trade mark, the trade mark proprietor could not object to the use of the designation where such use was compulsory.

Attempts had been made with varying degrees of success in a number of European jurisdictions to obtain patents covering plant varieties. In Germany, there were a number of decisions of the *Beschwedesenat* in 1934 and 1936 that approved the acceptance of applications for patents on tobacco and lupin seed, and in relation to the “seed of a small-seeded garden pea.” However, these applications were withdrawn because of concerns about compromising agricultural policy that had been expressed by the *Reichsnärstand*.²⁶⁶ In France, a patent had been secured on a rose variety in 1949, by a celebrated Rose breeder, Roger Meilland.²⁶⁷ He then pursued successful patent applications in Belgium and Italy, but failed in an application in Switzerland. There were no applications in any of these countries outside the field of ornamental plants.

As with other categories of intellectual property, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. Mention has been made of the Congrès pomologique de France, held in 1911, which had called for special protection of plant varieties. The International Union of the Horticultural Profession, also considered the matter at its Congresses in Luxemburg (1911), London (1912) and Ghent (1913). The International Institute of

²⁶⁴ PI 28-29 (1923).

²⁶⁵ PI 70-71 (1922).

²⁶⁶ See Heitz, above n. 1, at 27.

²⁶⁷ See B. Laclavière, *The French Law on the Protection of New Plant Varieties*—10 *INDUS. PROP.* 44 (1971).

Agriculture in its 1927 Congress had stated that the protection of a denomination was insufficient and that a way had to be found to require “any grower who engaged in reproduction of those breeds for the purposes of sale to pay a royalty to the producer.”²⁶⁸ The International Federation of Breeders of Staple Crops had, in its 1931 conference, expressed the hope that the legal status of new varieties should be assimilated to that of industrial inventions. Discussions concerning the creation of a new organization to agitate for the promulgation of an international legal regime for the protection of plant varieties occurred at the meetings of the International Breeders’ Congress at Leeuwarden in 1936 and the 1937 Conference of the International Organization of Agricultural Industries, also held in the Netherlands. The direct result of these discussions was the foundation in Amsterdam, on November 17, 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). The first ASSINSEL Congress, held in Paris on 8-9 July 1939 adopted a three-point resolution:

- To accept internationally the filing of trademarks and appellations as a means of protection (pending introduction of a patent);
- To adopt the principle of a licence, to be drawn up by ASSINSEL for the purposes of multiplication and sale; and
- To accept internationally the definition of the word ‘original’ [as] seed produced, offered or sold by the breeder of the variety or under his control by his licensees or successors in title.

The Second World War interrupted these developments. At its Semmering Congress in June, 1956, a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of plant varieties. The French Government had been approached by ASSINSEL, because it had indicated a favourable attitude.²⁶⁹ Invitations were issued to 12 Western European countries²⁷⁰ to attend a diplomatic conference in Paris, from 7 to 11 May 1957. The notes of invitation to the conference referred to the conclusions that had been reached at the 1954 conference on the Development of Seed Production and Trade, held in Stockholm, that there should be an international agreement favourable to the protection of new plant varieties.

4.3 Plant Variety Protection under the Paris Convention

Meanwhile, the German delegation to the London Congress of the International Association for the Protection of Industrial Property (AIPPI) in 1932, which was led by Franz and Freda Wuesthoff, had proposed that patent rights should be established for plants manifesting entirely new characteristics, and that a lesser right, in the nature of a new denomination, should be provided for lesser creations. Other delegations opposed this initiative, particularly the British, which fought the extension of patenting to plants because of the damage that might be done to the patent system if protection became over-broad.²⁷¹

²⁶⁸ Quoted in UPOV, *The History of Plant Variety Protection*, in *THE FIRST TWENTY-FIVE YEARS OF THE INTERNATIONAL CONVENTION OF THE PROTECTION OF NEW VARIETIES OF PLANTS* 80 (UPOV 1987).

²⁶⁹ *Id.* at 82.

²⁷⁰ I.e. Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.

²⁷¹ See UPOV, above n. 20, at 78.

The matter was taken up again in 1939, when it was decided to address the issue in the 1940 Congress of the IAPPI. However, with the interruption of war, the subject was not taken up again in any serious way by AIPPI, until its 1952 Congress in Vienna, when a variety of proposals were advanced. The Wuesthoffs renewed their proposal for a hybrid system of protection that would depend on the level of inventiveness. The delegations from Luxemburg, the Netherlands, Switzerland and the United Kingdom proposed a specific protection system. The Congress unanimously adopted the following text:

The Congress expresses the view that, in order to achieve effective protection for new plant varieties, the legislation of the countries of the [Paris] Union must:

1. Provide, in so far as it is not yet granted, for patent or equivalent protection for plants that possess important new properties, with a view to their exploitation, provided that their propagation is assured;
2. Place on an equal footing an invention's suitability for use in agriculture, forestry, market gardening and other comparable fields, and an invention's suitability for use in industry as provided in the patent laws of many countries.²⁷²

Another text was submitted to the subsequent AIPPI Congress at Brussels, which met in 1954. It declared that

The Congress expresses the wish that, in the legislation of each country of the Union:

1. Inventions relating to the plant kingdom be assimilated, with respect to their legal protection, to industrial inventions, in accordance with Article 1(3) of the text of the Paris Convention for the Protection of Industrial Property;
2. For plants that possess definable new characteristics, in so far as their faithful reproducibility is assured, there be provision for protection, where it is not yet granted, by the patent law, amended where appropriate, or by any other legislative or regulatory measure.

The various delegations adopted separate negotiating positions, and the final resolution of the Congress expressed the wish that "in the legislation of each of the countries of the Union, inventions relating to the plant kingdom be assimilated, with respect to legal protection, to industrial inventions and that plant varieties be also protected."²⁷³ In practice, however, AIPPI was unable to interest the contemporaneous Paris Revision conferences to adopt plant variety protection as a subject for discussion.

4.4 The Paris Conferences on Special Protection of 1957 and 1961

On 22 February 1957, the French Government issued invitations to twelve Western European countries²⁷⁴ to attend a diplomatic conference in Paris, to be held from 7 to 11 May 1957, to consider establishing an international regime for the protection of plant varieties. Participation was limited by the French to those states who were known to share its own concerns on this subject. Thus, the United States was not invited because it

²⁷² Id.

²⁷³ Id. at 80.

²⁷⁴ I.e. Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.

had “confined itself to plant patents for vegetatively reproduced varieties, with at best only a minor part to play as foods.”²⁷⁵

The conclusions of the 1957 Conference were set out in its Final Act, adopted on 11 May 1957. This instrument recognised the legitimacy of breeders’ rights and established, as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection in each country. It proposed that these principles be enshrined in an international Convention and that a Drafting Committee and a Committee of Experts be established.

Following three meetings of the Drafting Committee and two meetings of Committees of Experts, the second session of the Conference was held in Paris from 21 November to 2 December, 1961. An International Convention for the Protection of New Varieties of Plants (UPOV) was presented for the Consideration of the Conference. An important question debated there was whether the UPOV Convention would be compatible with the Paris Convention. The debate on that subject produced the inclusion of Article 2(1), which stated that “each Member of the [UPOV] Union may recognise the right of the breeder...by the grant of a special title of protection or a patent. Nevertheless, a Member State of the Union, whose national law admits of protection under both these forms may only provide one of them for one and the same genus or species.”

Article 4(1) applied the draft UPOV Convention to “all botanical genera and species,” but it was envisaged that the Convention would have a gradual introduction. A list of thirteen genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, Lucerne, red clover, ryegrass, lettuce, apples, roses or carnations. Article 4(3) required each member State on entry into force of the Convention to apply it to at least five genera from this list and, within eight years, to all the listed genera.

The UPOV Convention was signed on 2 December 1961 by the representatives of Belgium, France, the Federal Republic of Germany, Italy and the Netherlands. On 26 November 1962, the signatures of Denmark and the United Kingdom were added, followed by Switzerland on 30 November 1962. The Convention entered into force on 10 August 1968, following its ratification by Netherlands, the Federal Republic of Germany and the United Kingdom. Denmark deposited its instrument of ratification on 6 September 1968 and France on 3 September 1971. Sweden deposited an instrument of accession on 17 November 1971.

4.5 Additional Act of 1972

Article 27 of the 1961 UPOV Convention provided for its periodic review, with the first revision scheduled for 1972. A Diplomatic Conference for this purpose was held on 7-10 November 1972. The primary objective of this Conference was to arrange the financial contribution rates of member states. The Additional Act for this purpose was signed by Belgium, Denmark, France, Federal Republic of Germany, Italy, Netherlands, Sweden, Switzerland and the UK. The Additional Act entered into force on 11 February 1977, after which it also obtained the accession of South Africa (7 October 1977) Israel (12

²⁷⁵ See UPOV, above n. 20, at 82.

November 1979) and Spain (18 April 1980). Thus, within the first nineteen years of its life, the UPOV Convention had attracted the accession of only twelve states. One reason for the reluctance of States to adopt the Convention was the stringency of its provisions, in particular the obligation of states to select either patent or UPOV-style protection for plant varieties. Work on a revision had begun as early as 1973, and in October 1974, the UPOV Council set up a Commission of Experts for the Interpretation and Revision of the Convention. Six sessions of this Commission were held between February 1975 and September 1977, and in December 1977, the Council called for a Diplomatic Conference to be held on 9-23 October 1978.

4.6 Revision of 1978

In an endeavour to broaden the membership of the Convention, invitations were widely circulated, to permit non-member states to participate as observers. In the end, some 27 non-member states attended, including the U.S. and a number of developing countries. One result was an amendment of Article 2 of the Convention to permit the accession of countries like the United States, which had laws allowing the double protection of varieties under patent and *sui generis* laws.²⁷⁶

The list of genera, annexed to the 1961 Convention was removed. This list had contained mainly species from temperate climates. Under the new Article 4, member states agreed to apply the Convention to at least five genera or species, rising to 24 genera or species within eight years. Additionally a grace period was introduced to permit the marketing of varieties twelve months prior to an application for plant variety protection being made. The revised Convention attracted the ratification of the United States on 12 November 1980.²⁷⁷

4.7 The Revision of 1991

A further broadening of the UPOV Convention occurred with the 1991 Revision.²⁷⁸ The 1991 Act requires states to protect at least fifteen plant genera or species upon becoming members of the Act, and to extend protection to all plant varieties within ten years.²⁷⁹ In response to demands from breeders in industrialized countries, the 1991 Act required signatory states to make dual protection mandatory. The 1978 text merely permitted states to grant dual protection if they so desired. Through the definition of a “breeder” in Art. 1(c) as including a “person who bred, or discovered and developed, a variety,” the 1991 Act makes explicit the requirement that even discovered varieties should be protected.²⁸⁰

The 1991 Act recognizes the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as are not

²⁷⁶ See N. Byrne, Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties London, CCLS, 1991, 13 at n.20.

²⁷⁷ See <http://www.upov.org/eng/convntns/1978/act1978.htm> The United States became a party to the 1978 UPOV in 1981 by Executive Agreement. See H.R. REP. NO. 103-699, at 9 (1994).

²⁷⁸ Act of 1991, International Convention for the Protection of New Varieties of Plants (official English transl.) (1991), at <http://www.upov.org/eng/convntns/1991/act1991.htm>. [UPOV II].

²⁷⁹ UPOV II, above n. 30, art 3(2).

²⁸⁰ UPOV II, above n. 30, art. 1(c).

"essentially derived" from protected varieties.²⁸¹ The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.²⁸²

From the perspective of farmers, probably the most contentious aspect of the 1991 Act is the limitation of the farmers' privilege to save seed for propagating the product of the harvest they obtained by planting a protected variety "on their own holdings," "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder."²⁸³ Unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes. This has been criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.²⁸⁴ According to ASSINSEL, the "reasonable limits" referred to in Article 15(2) requires states to restrict the acreage, quantity of seed and species subject to the farmers' privilege, while the requirement to safeguard breeders' "legitimate interests" requires farmers to pay some form of remuneration to the breeder for their privileged acts.²⁸⁵

It has been suggested that for both social equity and food security reasons there are justifications for providing a 'farmers privilege' for smallholder and resource poor farmers, especially in developing countries, whereby poorer farmers who do not represent an immediate or lucrative market would enjoy the 'farmer privilege' to save seed, while their richer counterparts would be required to pay royalties on saved proprietary seed.²⁸⁶

A number of developing countries have resisted adopting the 1991 Act as the standard for plant variety protection laws. The foreign ministers of Organization for African Unity issued a statement at a January 1999 meeting calling for a moratorium on IPR protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities.²⁸⁷ This option is not open to those 90 or more countries that have entered into free trade agreements with the United States, since it insists that signatories adopt the 1991 version of UPOV.²⁸⁸

4.8 The TRIPS Agreement 1994

²⁸¹ UPOV II, above n. 30, arts. 14(5), 15.

²⁸² See L. Helfer, *Legal Study on Intellectual Property Rights in Plant Genetic Resources*, Rome, FAO 2001, ¶ 1.1.1.4.

²⁸³ UPOV II, above n. 30, art. 15(2).

²⁸⁴ D. Leskien & M. Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, in *ISSUES IN GENETIC RESOURCES* NO.6, at 60 (June 1997).

²⁸⁵ ASSINSEL, *Development of New Plant Varieties and Protection of Intellectual Property*, Statement approved by the CSTA Board of Directors as a CSTA Position Document, No.A.99.47 (21 July 1999), available at cdnseed.org/press/A.99.47IP.htm.

²⁸⁶ C. Spillane, *Recent Developments in Biotechnology as They Relate to Plant Genetic Resources for Food and Agriculture*, Background Study Paper No. 9, Commission on Genetic Resources for Food and Agriculture, April 1999, 41-42.

²⁸⁷ See Helfer, n33 *supra* at ¶ 2.2.3.

²⁸⁸ See P. Drahos, 'BITS and BIPS: Bilateralism in Intellectual Property', 4 (2001) *Journal of World Intellectual Property* 791-808.

Probably the most notorious requirement of the TRIPS Agreement is that in Article 27.3(b), which requires that Members “shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.” Article 8 of the Agreement, in enunciating the principles which are to animate it, provides that “consistent with the provisions of the Agreement, signatories may “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”²⁸⁹ It would not be too difficult to construct an argument that the obligation to protect plant varieties might be inconsistent with a given nation’s need for food security. However, the opening words of Article 8 suggests that, in case of a conflict between these provisions, the obligations within the Agreement, such as Article 27.3(b), are paramount.

4.9 Technical Issues Concerning the *Sui Generis* Protection of Plant Varieties Under Art. 27.3 (b).

The principal technical issues concerning the implementation of effective *sui generis* protection of plant varieties under article 27.3(b) of the TRIPS Agreement²⁹⁰ are: (a) what are “plant varieties”? and (b) what *sui generis* options are open to Member states?

As noted above, a crucial issue in the establishment of a *sui generis* regime would be the definition of the protected subject matter. Article 27.3(b) of the TRIPS Agreement requires the protection of “plant varieties,” but it does not provide a definition of this term. Therefore, national laws have ample room to determine what is to be deemed a plant “variety” for the purposes of protection.

There have been lengthy discussions about the concept of “plant variety,” particularly within the framework of UPOV. The scientific notion does not necessarily coincide with the legal concept. The law may require certain characteristics for a *protected* variety that may not be essential for a scientific definition. When breeders seek protection under the traditional plant breeders’ rights (PBR) system, plant varieties must meet the criteria that require them to be distinct, uniform and stable (DUS).²⁹¹ It has been suggested that “uniformity” and “stability” could be replaced by a criterion of “identifiability,” which would allow the inclusion of plant populations that are more heterogenous, and thus take into account the interests of local communities.²⁹² The scope of protection could be limited to cover only the reproductive parts of plants, or it could be extended to include also harvested plant materials.

The TRIPS Agreement does not prescribe any particular form of protection for plant variety innovations. It could have prescribed the UPOV Convention as the legislative norm, as it did with the Berne Convention for copyrights and the Paris Convention for industrial property.²⁹³ Thus Members have the option of enacting UPOV-like protection, of including plant varieties within their patent laws, of combining both forms of protection, or of combining UPOV-like protection with biodiversity conservation

²⁸⁹ Id. art. 8.

²⁹⁰ See above nn. 43-35 and accompanying text.

²⁹¹ See, e.g., UPOV II, above n. 30 art. 6(1).

²⁹² A. Seiler, *Sui Generis Systems: Obligations and Options for Developing Countries*, 34 BIOTECH. & DEV. MONITOR 2 (1998).

²⁹³ See id. arts 2(1), 9(1).

legislation.²⁹⁴ The TRIPS Agreement does not prohibit the development of additional protection systems. Nor does it prohibit the protection of additional subject matter to safeguard local knowledge systems or informal innovations, as well as to prevent their illegal appropriation.

As is discussed below, the possibility of sui generis options for the protection of plant varieties has been used as an opportunity to introduce into the TRIPS agreement, principles of prior informed consent and benefit sharing, which were first enunciated in the context of the Convention on Biological Diversity. It has also been suggested that it is possible to include within the sui generic protection of plant varieties some of the Doha principles: the development dimension and the protection of traditional knowledge.

*Among the suggestions relevant to food security is the inclusion within protected varieties, those developed by local communities and national/public research institutes.*²⁹⁵

4.10 Review of Art.27.3(b)

The concluding words of Article 27.3(b) envisaged its review by the Council for TRIPS by the end of 1999. At the 23 March 2001 meeting of the Council for TRIPS, the Chairman set out a list of key issues which had arisen in the review of Article 27.3(b).²⁹⁶ Most of these issues are relevant to the subject of food security. These key issues were identified as:

- the link between Article 27.3(b) and development;
- technical issues relating to patent and plant variety protection under article 27.3(b);
- technical issues relating to the *sui generis* protection of plant varieties;
- ethical issues relating to the patentability of life-forms;
- the relationship to the conservation and sustainable use of genetic material; and
- the relationship with the concepts of traditional knowledge and farmers' rights.

(a) The Link Between Article 27.3(b) and Development

A number of developing countries had noted the tension between the development and technology transfer objectives of the TRIPS Agreement and the way in which the Agreement made it possible for rights owners to impose unreasonable terms for technologies. It will be recalled that Art.7 identified the objectives of the TRIPS Agreement as including the facilitation of the transfer and dissemination of technology. India, noting the difficulties faced by developing countries to obtain access to foreign technology urged that “the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them”.²⁹⁷

²⁹⁴ See, e.g., Various Systems for Sui Generis Rights Systems, 36 BIOTECH. & DEV. MONITOR 3 (1998), available at <http://www.biotechmonitor.nl/new/index.php?link=publications>.

²⁹⁵ F. Mangeni, [Technical Issues on Protecting Plant Varieties by Effective Sui Generis Systems](#), Geneva, South Centre, 2001.

²⁹⁶ WTO Doc., IP/C/M/26

²⁹⁷ WT/GC/W/171.

This argument was reflected in part in clause 19 of the Doha Ministerial Declaration of November 2001, which instructed the Council for TRIPS, “in pursuing its work programme including under the review of Article 27.3(b), ... [to] be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.” The Doha Ministerial had set the deadline of December 2002 within which the review, referred to in Clause 19 of the Doha Declaration had referred, was to be finalised and reported to the Trade Negotiations Committee (TNC) “for appropriate action”. However, after Doha, the discussions in the TRIPS Council were dominated by the consideration of the public health and patenting issue and the question of plant variety protection under Article 27.3(b) was somewhat neglected. However, in anticipation of the Cancun Ministerial, Morocco, on behalf of the African Group of countries made a Joint Communication to the Council for TRIPS, on 20th June 2003, in an endeavour to finalise the longstanding issues relating to the review of Article 27.3(b) (i) indicating the solutions that the African Group considered needed to be found; (ii) setting out possible areas of agreement on issues that have arisen; (iii) providing suggestions on how to resolve issues on which members had not been able to reach a common understanding.²⁹⁸

The Joint Communication maintained that the requirement to protect plant varieties should be consistent with and supportive of the public policy goals of Member States relating to food security, nutrition, the elimination of rural poverty, and the integrity of local communities. Also asserted was the importance of the preservation of the system of seed saving and exchange as well as selling among farmers in which the legitimate rights of commercial plant breeders should be protected and but balanced against the needs of farmers and local communities, particularly in developing Members.

The Joint Communication urged that in implementing the TRIPS Agreement, the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources in a mutually supportive and consistent manner, Members should retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing.

Areas that were identified as those where delegations had not reached a common understanding concerned the possibility under Article 27.3(b) for members to grant patents on micro-organisms and on non-biological and micro-biological processes for the production of plants or animals.

The Cancun Ministerial Meeting terminated before any TRIPS issues could be raised, but the Ministerial Declaration which was issued by the Hong Kong Ministerial meeting on 18 December 2005 reaffirmed in clause 1 the Declarations and Decisions adopted at Doha and renewed the “resolve to complete the Doha Work Programme fully and to conclude the negotiations launched at Doha successfully in 2006.” Clause 2 of the Hong Kong Declaration emphasized “the central importance of the development dimension in every aspect of the Doha Work Programme” and the signatories recommitted themselves “to making it a meaningful reality” both in relation to the negotiations on market access and to a number of specific development-related issues discussed below.

The development implications of Article 27.3(b) in relation to food security have been raised in two contexts: (i) the privatisation of rights in genetic material and plant varieties, as well as in enabling technologies; and (ii) the securing of intellectual property rights in biological resources obtained from developing countries (“biopiracy”).

²⁹⁸ WTO Doc., IP/C/W/404, 20 June 2003.

As is discussed in subsequent chapters, the privatisation of biological material could compromise agricultural innovations by developing countries, first, by depriving them of advantageous traits, such as disease resistance, early ripening and post-harvest storage capacity. The unauthorised acquisition and privatisation of the biological materials developing countries, deprives the latter of exploitable resources.

A communication to the WTO from Kenya, on behalf of the African Group, to assist in the preparations for the 1999 Ministerial Conference, proposed that “after the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any *sui generis* law for plant variety protection can provide for:

- (i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;
- (ii) the continuation of the traditional farming practices, including the right to save, exchange and save seeds, and sell their harvest;
- (iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.”²⁹⁹

(b) Relationship of Article 27.3(b) to the Convention on Biological Diversity

In the TRIPS Council meeting of 5-7 March 2002 the WTO Secretariat was requested to prepare a report on the agenda items related to review of the provisions of Article 27.3(b), the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore. In a summary of the issues which had been raised in the TRIPS Council on the relationship between the TRIPS Agreement and the CBD, the WTO Secretariat reported³⁰⁰ that opposing arguments had been raised as to whether or not there was conflict between the two instruments.

Conflict was perceived by those Members which argued that the possibility which the TRIPS Agreement provides for the privatisation of genetic material by patents or plant variety rights is inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD³⁰¹ and does not ensure that the provisions of the CBD, including those relating to prior informed consent and benefit sharing, are respected.³⁰² The proponents of this view have suggested that Article 27.3(b) should be amended so as to oblige all Members to make life forms and parts thereof non-patentable, or if this was not possible, at least those inventions based on traditional or indigenous knowledge and essentially derived products and processes should be excluded from patentability.³⁰³ In addition there has been a suggestion that patents inconsistent with Article 15 of the CBD not be granted and that such an obligation be incorporated into the TRIPS Agreement.³⁰⁴

The alternative argument which was raised by a number of Members in the TRIPS Council was that the TRIPS Agreement and the CBD have different objects and purposes

²⁹⁹ WTO Doc., WT/GC/W/302. 6 August 1999.

³⁰⁰ WTO Doc., IP/C/W/368, 8 August 2002.

³⁰¹ Ibid., para 7.

³⁰² Kenya, IP/C/M/28, para. 144.

³⁰³ India, IP/C/M/25, para. 70.

³⁰⁴ India, IP/C/W/196.

and deal with different subject-matter³⁰⁵ and that the granting of patent rights over inventions that use genetic material does not prevent compliance with the provisions of the CBD regarding the sovereign right of countries over their genetic resources, prior informed consent and benefit sharing.³⁰⁶

A third view taken in the TRIPS Council is that, while there may be no inherent conflict between the two agreements, there is considerable interaction between them³⁰⁷ and a need international action to ensure that the two agreements are implemented in a mutually supportive manner.³⁰⁸ China has submitted that consideration should be given as to how the TRIPS Agreement could be implemented in a way supportive of the CBD.³⁰⁹

4.11 Plant Variety Protection in Developing Countries

From a food security perspective it should be noted that the UPOV Convention was originally designed to serve the interests of principally European seed breeders and in this respect reflects the industrial interests of European agriculture. Although the TRIPS Agreement does not oblige countries to follow the UPOV model in implementing their plant variety protection obligation in Art.27.3(b) of the TRIPS Agreement, developing countries have tended to adopt legislation on the 1991 UPOV model. As is mentioned above, this model circumscribes the seed-saving possibilities for farmers.

The value of PVRs for encouraging agricultural innovation in developing countries has not been authoritatively established. A UPOV study in 2005 looked at the impact of PVP laws in Argentina, China, Kenya, Poland and the Republic of Korea.³¹⁰ It concluded that the impact of PVP varies country-by-country and crop-by-crop. In Argentina, the introduction of new, protected varieties from non-resident breeders was observed in important agricultural crops (e.g. soybean, lucerne) and in horticultural crops (e.g. rose, strawberry). The demand for new, protected varieties was shown by their increased proportion of the certified seed area by 80-90%, particularly , in soybean and wheat. An increase of horizontal cooperation in the seed industry, involving foreign seed companies and agreements for technology transfer between national research institutes and breeding entities with other national companies resulted in more rapid movement of germplasm.

As China's PVP systems have only been in operation for 5 years and for a limited number of genera and species and it was not yet possible to evaluate their full impact. Nevertheless, a rapid uptake by farmers of new, protected varieties seen, for example, in maize and wheat in Henan Province was noted, with an increase in the number of breeders in that province, as well as the introduction of new, protected varieties for major staple crops (e.g. rice, maize, wheat), horticultural crops (e.g. rose, Chinese cabbage, pear), including traditional flowers (e.g. peony, magnolia, camellia) and for forest trees (e.g. poplar).

In Kenya, an increase in the number of varieties developed and released in the six-year period after the introduction of PVP (1997-2003), compared to the previous six-year

³⁰⁵ EC, IP/C/M/30, IP/C/W/254; Japan, IP/C/M/26, IP/C/M/25,, IP/C/W/236; Norway, IP/C/M/32,, IP/C/W/293; United States, IP/C/W/209, IP/C/W/162.

³⁰⁶ EC, IP/C/W/254, IP/C/M/30, para. 143.

³⁰⁷ EC, IP/C/W/254.

³⁰⁸ Australia, IP/C/W/310; Czech Republic, IP/C/M/33, para. 126; EC, IP/C/M/35, para. 233; Japan, IP/C/M/32, para. 142; Norway, IP/C/M/32, para. 125, IP/C/W/293.

³⁰⁹ China, IP/C/M/35, para. 248.

³¹⁰ UPOV, Report on the Impact of Plant Variety Protection, Geneva, UPOV, 2005.

period (1990-1996), across a number of agricultural crops and for maize in particular was noted. Also the study noted the diversification of the horticultural sector (for example the emergence of the flower industry) and the increased introduction of foreign germplasm in the form of new, protected varieties (especially of horticultural crops).

In the Republic of Korea a particular impact was the extension of protection to a range of agricultural and horticultural crops, including traditional crops (e.g. ginseng) and varieties of ornamental crops such as rose. The report also noted the stimulation of rice breeding.

4.3 IP Protection of Plants and Seeds in Developing Countries

This discussion on how PVP affects food security and nutrition in developing countries leads one to consider in more general terms the applicability of such an IPR to these countries. Unfortunately, we have very few empirical studies to go on. One of the few was a joint project of the Anti-American Institute for Cooperation in Agriculture and the University of Amsterdam carried out in 1994, which examined 'the (expected) impact of plant breeders' rights (PBR) on developing countries with respect to: private investment in plant breeding, breeding policies of public institutes, transfer of foreign germplasm, and diffusion of seed among farmers'.³¹¹

Five countries were used as case studies of which three (Argentina, Chile and Uruguay) had PVP systems already in place, and two (Colombia and Mexico) were about to introduce them. These countries are similar in the sense that there are basically two seed markets. The hybrid seed market is controlled by transnational corporations, whereas the seed market for self-pollinating varieties is dominated by domestic firms.

However, Argentina differs from the others in that it is the only country in which PVP right owners have successfully enforced their rights to the extent that their control over seed supply for wheat and soya is comparable to that of their counterparts in the United States. This leads the authors of the study report to conclude that in all probability, PVP in that country has 'prevented the local wheat companies from reducing or even terminating their breeding activities and triggered the reactivation of some soya bean breeding programmes'.

In a 2002 study for the UK Commission on Intellectual Property Rights (CIPR), Rajnekar observed that the release of new varieties as an indicator of the impact of PVPs was equivocal evidence as a number of inquiries remain before a conclusive statement on the impact of PBRs on varietal release rates can be accepted as an economic good. First, there is only partial evidence on rates of varietal release in the pre- and post-PVR period. Secondly, the availability of varieties is not necessarily an economic good in itself, as it might be that the increase in varieties may be part of wider appropriation strategies involving planned obsolescence as a means of maintaining market shares, which result in faster rates of varietal turnover and higher varietal release rates.

³¹¹ W. Jaffé and J. van Wijk, *The Impact of Plant Breeders' Rights in Developing Countries: Debate and Experience in Argentina, Chile, Colombia, Mexico and Uruguay*, Directorate General International Cooperation, Ministry of Foreign Affairs, The Hague, 1995.

The Final Report of the CIPR noted that the evidence relating to the impact of plant variety protection on research was sparse and mainly from developed countries and indicated that there was little or no evidence that total R&D activity had increased as a result of the introduction of PVP, suggesting that that the main impact of PVP was as a marketing tool.³¹²

A 1995 study conducted in middle income developing countries in Latin America found little evidence of an increased range of plant material available to farmers or increased innovation as a result of PVP protection.³¹³ A UNEP study of 1996 stated that there was “mixed and inconclusive evidence” about the direct benefits of introducing IPRs in plant varieties in developing countries.³¹⁴

Rajnekar concludes that existing evidence of the focus of private sector plant breeding is not entirely promising because “the range of crops focussed on and the type of agro-ecological niches being targeted do not cater to the wider needs of the majority farming populations in developing countries.”³¹⁵

Many resource-poor farmers cultivate minor food crops that enable them to meet the nutritional needs of rural communities much better than if major crops such as wheat, rice and maize alone are cultivated. In the hills and valleys of Nepal, for example, villages may grow more than 150 crop species and cultivated varieties.³¹⁶ However, plant variety protection generally does not encourage breeding related to minor crops with small markets. This is because the returns on breeders’ research investment will be quite small. Rather, they encourage breeding targeted at major crops with significant commercial potential. Moreover, protected varieties of plants may not even be food crops. In Kenya, for example, until very recently, about half the protected new varieties were foreign-bred roses cultivated for export.

No country has yet introduced food security concerns as a factor in implementing plant variety rights protection. However, Kenya, one of the first developing countries to have PVP legislation when it passed the Seeds and Plant Varieties Act, 1975 contains a requirement that ‘the agro-ecological value [of the variety] must surpass, in one or more characteristics, that of existing varieties according to results obtained in official tests.’ It should be noted however, that there was little demand from domestic breeders for this legislation; it being precipitated more by foreign horticultural firms.

³¹² CIPR, Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, CIPR, 2002, 67.

³¹³ J. Van Wijk and W. Jaffe, W. Impact of Plant Breeders Rights in Developing Countries, Inter-American Institute for Cooperation on Agriculture, San Jose, and University of Amsterdam, 1995.

³¹⁴ UNEP, The Impact of Intellectual Property Rights System on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its use, 1996.

³¹⁵ Rajnekar, n.60 supra.

³¹⁶ See A. Kothari, and R.V. Anuradha, Biodiversity, intellectual property rights, and GATT Agreement: how to address the conflicts? (1997) 32 Economic and Political Weekly, 2814-282.

Biopiracy

M. Blakeney, Access to Biological Resources: Domestic and International Developments and Issues (1998) 5 (3) *E-Law Murdoch University Electronic Journal of Law*
<<http://www.murdoch.edu.au/elaw/indices/issue/v5n3.html>>

1. Allegations of Biopiracy

The 14 February 1998 issue of *New Scientist* contained an editorial and leading article on the alleged biopiracy of two Australian agricultural agencies. The two agencies: Agriculture Western Australia and the Grains Research and Development Corporation (GRDC) had apparently applied for Plant Breeder's Rights (PBR) under the Australian Plant Breeder's Rights Act, 1994 (the Act), in relation to two species of chickpea which had been bred from material which had been provided by the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT). These PBR applications had to meet the statutory tests prescribed in s.43 of the Act that the new variety has a breeder, that it is distinct, uniform and stable and that it has not been or has only recently been exploited. The Australian Plant Breeder's Rights Office did not have an opportunity to make a determination on these matters because the furore caused by these applications led to their withdrawal, prior to determination.

The *New Scientist* editorialised that "it was hard to imagine what two Australian government agricultural agencies thought that they were up to when they applied for property rights on chickpeas grown by subsistence farmers in India and Iran".ⁱ A feature article in the *New Scientist* carried an accusation from a spokesperson from the South Asian Network on Food, Ecology and Culture which described the PBR applications as "blatant biopiracy" by "privatising seeds that belong to our farmers and selling them back to us".ⁱⁱ

Since ICRISAT is a member of the Consultative Group on International Agricultural Research (CGIAR), this controversy prompted other CGIAR members to examine their own intellectual property arrangements. Coincidentally this examination threw up other Australian PBR applications made by the Centre for Legumes in Mediterranean Agriculture in relation to a peavine and a lentil which had been bred from genetic stock obtained from the International Centre for Agricultural Research in the Dry Areas (ICARDA). ICARDA was accused by the Rural Advancement Foundation International (RAFI) of fundamentally "misinterpreting its authority" by allowing its genetic stock to be utilized in patent claims.ⁱⁱⁱ

These controversies impelled an examination of the legal status of the material held in the genebanks of international agricultural research institutes and an examination of the management practices applied in relation to the intellectual property rights generated from that material.

2 Germplasm Collections of the Centres of the Consultative Group on International Agricultural Research (CGIAR)

2.1 Structure

The GGIAR, established in 1971, is an informal association of 57 public and private sector members that supports a network of 16 international agricultural research centres.^{iv} The mission of the CGIAR is to contribute through its research to promoting sustainable agriculture for food security in the developing countries. The CGIAR is co-sponsored by the World Bank, the Food and Agricultural Organization of the United Nations (FAO), the United Nations Development Programme (UNDP) and the United Nations Environment Programme (UNEP). A key administrative organ within the CGIAR system is the Technical Advisory Committee (TAC)^v. The Executive Secretary of TAC is appointed by the FAO, following consultations with members of the CGIAR. The TAC, supported by its own Secretariat located at FAO in Rome, comprises a group of distinguished scientists and experts from developed and developing countries. The TAC is intended to provide independent advice and judgements on strategic issues and on the quality of the scientific programmes supported by the CGIAR. Among the principal functions of the TAC is to monitor the compliance of centres with approved plans and CGIAR priorities.

One of CGIAR's principal research objectives is to contribute to the preservation of biodiversity by establishing an *ex situ* collection of plant genetic resources. This collection currently comprises over 600,000 accessions of more than 3,000 crop, forage and pasture species.^{vi} In addition to ICRISAT and ICARDA, the agricultural research centres of CGIAR which maintain genebanks include: Centro Internacional de Agricultura Tropical (CIAT), Center for International Forestry Research (CIFOR), Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), Centro Internacional de la Papa (CIP), International Center for Living Aquatic Resources Management (ICLARM), International Center for Research in Agroforestry (ICRAF), International Livestock Research Institute (ILRI), International Institute of Tropical Agriculture (IITA), International Plant Genetic Resources Institute (IPGRI) International Rice Research Institute (IRRI) and the West Africa Rice Development Association (WARDA).

2.2 Mid-Term Meeting, Brasilia, 25-29 May, 1998

The controversy surrounding the allegations of bio-piracy, mentioned above, formed a back-drop to CGIAR's Mid-Term Meeting in May 1998. Prior to this meeting CGIAR had published a report, *The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centers*^{vii} which identified the necessity for a more rigorous approach by CGIAR centres to the management of intellectual property rights arising from the use of CGIAR materials.^{viii} At the meeting a comprehensive audit of the MTAs of CGIAR centres was agreed upon, together with a common approach to be taken when a MTA has been breached.^{ix} Additionally, the meeting agreed on a review of the intellectual property policies of centres and the formulation of "Guiding Principles on Intellectual Property Rights and Genetic Resources".

3. International Undertaking on Plant Genetic Resources

3.1 Introduction

In 1983 the Conference of the FAO adopted the International Undertaking on Plant Genetic Resources (the Undertaking) as a non-legally binding instrument. The

Undertaking provides for the exploration and collection of genetic resources (Art.3), for conservation *in situ* and *ex situ* (Art.4), for the availability of plant genetic resources (Art.5), for international cooperation in conservation, exchange and plant breeding (Art.6), for international coordination of genebank collections and information systems (Art.7) and for funding (Art.8). By September 1996 the Undertaking had attracted the subscription of some 111 countries, excluding the USA.^x

3.2 The International Undertaking and Plant Breeder's Rights

The Undertaking was originally predicated on the principle that plant genetic resources should be freely exchanged as a “heritage of mankind” and should be preserved through international conservation efforts. In subsequent years the principle of free exchange was gradually narrowed. In November 1989 the 25th Session of the FAO Conference adopted two resolutions providing an “agreed interpretation” that plant breeders’ rights were not incompatible with the Undertaking.^{xi} The acknowledgment of plant variety rights obviously benefitted industrialised countries, which were active in seed production. In exchange for this concession, developing countries won endorsement of the concept of “farmers’ rights”. This was a moral commitment by the industrialised commitment to reward “the past present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in centers of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers.”^{xii}

A further narrowing of the free-flow principle occurred at the 26th Session of the FAO Conference in November 1991 which in Resolution 3/91, while reaffirming that plant genetic resources were the common heritage of mankind, subordinated it to “the sovereignty of states over their plant genetic resources”.

3.3 The International Undertaking and the CBD

In November 1993 the 27th Session of the FAO Conference unanimously adopted Resolution 7/93 calling for The Commission to undertake “the adaptation of the International Undertaking on Plant Genetic Resources in harmony with the Convention on Biological Diversity” which had been concluded by the Rio Earth Summit the previous year. The Resolution instructed the Commission to consider “the issue of access on mutually agreed terms to plant genetic resources including *ex situ* collections not addressed by the Convention” and “for the realization of Farmers’ Rights”.^{xiii} Negotiating Texts have been considered by the Commission in a series of sessions between 1994 and 1997. Its 1997 sessions have prepared a simplified draft text concentrating on articles: 3 (scope), 11 (availability of plant genetic resources) and 12 (Farmers’ Rights).^{xiv}

3.4 Fifth Negotiating Session, 8-12 June 1998

The draft text was considered in a negotiating session between 8-12 June 1998. The negotiation divided on North-South lines, in which the South conceived of access to the genetic resources of developing countries in terms of an exchange of nature for debt and maintained the right of farmers to save, exchange and enhance seed as a traditional right.^{xv} Malaysia, speaking on behalf of the developing economies of Asia, “emphasized

that the revision of the International Undertaking had to recognise (i) facilitated access, (ii) benefit sharing, (iii) Farmers' Rights and (iv) the international fund as inseparable components of equal importance".^{xvi} The EU and European States proposed the establishment of "a mechanism to promote and better channel the flow of funds from available sources" to developing countries and economies in transition.^{xvii} This was supported in principle by the countries of the North American Region, Japan and the Republic of Korea.

The position taken by the Australian delegation at the Negotiating Session was trenchantly criticized by a RAFI report on the proceedings.^{xviii} The Australian delegation was castigated for suggesting that Farmers' Rights was a mere concept and for asserting that the country was "too young" to have traditional agricultural practices.^{xix} RAFI reported that the negotiations were stalled when Australia refused to withdraw its proposed text, suggesting that "the Australian position amounted to a filibuster. There had been modest progress to that point. When the Aussies refused to back down, that progress ground to a halt".^{xx} RAFI concluded that "combined with the country's inexcusable string of public sector biopiracies, there is no longer any credible support for allowing the delegation to remain in the negotiations. Neither the European Region nor the South would want to join any club that would admit Australia as a member".

RAFI delivered a report on global instances of biopiracy to the negotiating session, stating that "every State in Australia except the Northern Territory was involved in possible abuses along with several universities and research centres".^{xxi} Even discounting RAFI's traditional polemic, it would appear that Australia has aligned itself against the bloc of developing countries and may find itself isolated even within the industrialised world.

4. FAO Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture

In 1983 the FAO Conference had established the Commission on Plant Genetic Resources as a permanent intergovernmental forum to deal with questions concerning plant genetic resources. The International Undertaking on Plant Genetic Resources was adopted as the formal framework for its activities. The 1995 FAO Conference adopted Resolution 3/95 which broadened the Commission's mandate to embrace all components of biodiversity of relevance to food and agriculture. This broader mandate was reflected in the renaming of the Commission as the Commission on Genetic Resources for Food and Agriculture. The FAO considered that this would "facilitate an integrated approach to agrobiodiversity".^{xxii} The statutes for the broadened Commission provide for cooperation between the FAO and other governmental and non-governmental bodies, in particular the Conference of the Parties to the Convention on Biological Diversity (CBD). The Commission was specifically required to cooperate with the CBD in the area of genetic resources of relevance to food and agriculture.

In the discharge of its mandate, the Commission has coordinated the development of the *Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture*. The objectives of the Global System are "to ensure the safe conservation and promote the availability and sustainable utilization of plant genetic resources by providing a flexible framework for sharing the burdens and benefits".^{xxiii} The Global System mediated through the International Undertaking on Plant Genetic Resources comprises three elements. The first element consists of voluntary codes of conduct for

plant germplasm collecting and transfer and on biotechnology, as well as the 1994 FAO/CGIAR Agreement on Genebanks. The second element is a “Global Mechanism” comprising A World Information and Early Warning System, networks of *ex situ* and *in situ* and on farm collections and crop specific networks. The third element consists of three global instruments: an inventory of the “State of the Worlds Plant Genetic Resources”, a “Global Plan of Action on Plant Genetic Resources” and the “International Fund for the Implementation of Farmers’ Rights”.

The Global Plan of Action on Plant Genetic Resources was adopted by the Intergovernmental Fourth International Technical Conference on Plant Genetic Resources held in Leipzig, 17-23 June 1996.^{xxiv} The *Leipzig Declaration*, adopted by the conference, emphasized the importance of completing the revision of the International Undertaking and the adjustment of the Global System in line with the Convention on Biological Diversity.

5. United Nations Convention on Biological Diversity

The Rio Earth Summit, which was convened in June 1992, promulgated the Convention on Biological Diversity (CBD), The Rio Declaration on Environment and Development and Agenda 21. Agenda 21 was the strategic plan of the Rio participants for achieving sustainable environmental and developmental goals into the next century.^{xxv}

5.1 General Principles

The Convention on Biological Diversity represented an attempt to establish a programme for the preservation of the world’s biological resources.^{xxvi} Article 1 declared the objectives of the Convention to be “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources”. The Convention noted in Art.3 the sovereign right of nations “to exploit their own resources pursuant to their own environmental policies”, but in Art.15 requires contracting parties to “endeavour to create conditions to facilitate access to genetic resources for environmentally sound purposes” by other contracting parties on mutually agreed terms and conditions on the basis of "prior informed consent". A detailed code of access to biotechnology is prescribed in Art.16. Access and transfer is stated to be “provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights”. The Article provides that developing countries which provide genetic resources shall be granted “access to and transfer of technology which makes use of those resources”. Article 19.2 provides for the grant of access on a fair and equitable basis and on mutually agreed terms, to contracting parties, “particularly developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those contracting parties”.

It has been noted that the Convention distinguished between genetic resources collected prior to 29 December 1993, when the Convention entered into force, and subsequently collected genetic resources.^{xxvii} Thus Art.15.2 limits sovereign rights to genetic resources which a country of origin provides, or other countries acquire in accordance with the Convention. “Country of origin” is defined in Art.2 as the country which possesses the genetic resources in *in situ* conditions.

After originally proposing a convention on biological diversity at the 14th Governing Council Meeting of the United Nations Environment Council (UNEP) at Nairobi in June 1987, the USA had declined to accede to the Convention. This refusal was attributable to the widespread criticism of US biotechnology policy, largely by developing countries and the resultant access regime contained in the Convention.^{xxviii} Some measure of comfort for the US position was assured by Art.16.5 which provides for the harmonization of the Convention with national legislation and international law concerning intellectual property rights.

5.2 Traditional Resource Rights

The Rio Declaration in Principle 22 stated that ‘Indigenous peoples and their communities...have a vital role in environmental management and development because of their knowledge and traditional practices’. Chapter 26 of Agenda 21 detailed the relationship which conference participants recognised between indigenous peoples and their lands. The Agenda, at para.26.3(a), required governments

to establish a process to empower indigenous peoples and their communities’ through measures that include:

- recognition of their values, traditional knowledge and resource management practices with a view to promoting environmentally sound and sustainable development;
- enhancement of capacity- building for indigenous communities based on the adaptation and exchange of traditional experience, knowledge and resource-management practices, to ensure their sustainable development;
- establishment, where appropriate, of arrangements to strengthen the active participation of indigenous peoples and their communities in the national formulation of policies, laws and programs relating to resource management and other development processes that may affect them.

The Preamble to the CBD recognised the

...close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and sustainable use of its components.

Article 8(j) of the Convention required each signatory

...subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

In February 1992 the Commonwealth and State and Territory Governments had already signed the Intergovernmental Agreement on the Environment (IGAE) in which they formally recognised that “biological diversity is a major and valuable component of the

environment and should be protected". Pursuant to this Agreement a Task Force on Biological Diversity was established by the Australia and New Zealand Environment and Conservation Council (ANZECC) to report on the implications and manner of implementation of the Convention on Biological Diversity. Pursuant to the recommendations of the Task Force, the Committee on Australian Government (COAG) in December 1992 agreed to implement a National Strategy for Ecologically Sustainable Development, one of the central objectives of which is "to protect biological diversity and maintain essential ecological processes and life support systems".^{xxxix}

A National Strategy for the Conservation of Australia's Biological Diversity was drafted by an Advisory Committee which was established for this purpose. Recommended Action 6.1.7 of the strategy highlighted the importance of the knowledge of indigenous people in enhancing knowledge and understanding of biological diversity:

Recognise the value of traditional knowledge and practices of Aboriginal people and Torres Strait Islanders and integrate this knowledge and those practices into biological diversity research and conservation programmes by:

- encouraging the recording (with the approval and involvement of the indigenous people concerned) of traditional knowledge and practices;
- assessing their potential value for nutritional and medicinal purposes, wildlife and protected area management and other purposes; and
- applying traditional knowledge and practices in ways which ensure the equitable sharing of the benefits arising from their use

The House of Representatives Standing Committee on Environment Recreation and the Arts in its report *Biodiversity. The Role of Protected Areas* observed that the identification of traditional practices and culture was much more than an exercise in information gathering as it raised "questions of authenticity, knowledge and power".^{xxx}

The Committee proposed that the first dot point of Recommended Action 6.1.7 be amended to provide that indigenous communities be encouraged "to undertake or otherwise collaborate in research projects which utilise traditional knowledge and practices in the study of biodiversity and in conservation".^{xxxi}

The Task Force on Biological Diversity, which had been established by the ANZECC, had recommended that a Commonwealth, State and Territory Working Group be established to investigate and report on the strengthening of existing controls governing access to genetic resources including legislation. This Working Group was established in February 1993 with the task of ensuring, inter alia, that Australia's national and international obligations are honoured.

To assist informed debate on these matters the Coordination Committee on Science and Technology (CCST) in March 1994 prepared a discussion paper *Access to Australia's Biological Resources*. This discussion paper high-lighted the significance of the ILO Convention No. 169, The Convention on Biological Diversity, Agenda 21 and the Rio Declaration on Environment and Development and the United Nations Working Group on Indigenous Populations in recognising the obligations owed to indigenous peoples for the contributions made by them in promoting environmentally sound and sustainable development.

The discussion paper observed that although only the Convention on Biological Diversity imposed legal obligation on Australia the other instruments could not be ignored with impunity.^{xxxii} It stated that:

Together these instruments represent important manifestations of current international thinking on the subject of the rights of indigenous peoples and Australia, as part of the international community, has actively contributed in several international forums to the development of the views, ideas and ideals expressed in these instruments. Moreover, to the extent that certain common themes appear in these instruments, they reinforce each other and inevitably have the effect of exerting greater pressure upon Governments to implement the obligations contained therein.^{xxxiii}

Among the common themes identified in the discussion paper were the need to :

- respect, preserve and maintain knowledge, innovations and practices of indigenous relevant to the conservation and sustainable use of biological diversity
- promote the wider application of such knowledge, innovations and practices with the approval and involvement of indigenous peoples; and share equitably benefits arising from the use of traditional knowledge, innovations and practices with indigenous peoples.^{xxxiv}

Pursuant to the need to harmonise the CBD with other international intellectual property conventions, a fact-finding mission of the World Intellectual Property Organization (WIPO) visited Australia in June 1998, to examine, inter alia,

- the role of intellectual property rights in the preservation, conservation and dissemination of global biological diversity;
- the intellectual property rights aspects of biotechnology; and the use of intellectual property rights in the transfer of technology under multilateral environmental agreements.

5.3 Commonwealth-State Working Group on Access to Australia's Biological Resources

The Commonwealth-State Working Group on Access to Biological Resources (CSWG) was established in 1994 to formulate a national approach on access to Australia's biological resources, to identify benefits from a national approach, to develop management principles and "to suggest mechanisms which could be used to govern access, collection, processing, development and export of Australia's indigenous biological resources"^{xxxv} In 1998 the CSWG released its discussion paper: *Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach.*^{xxxvi} As the title of the discussion paper indicates, the CSWG considered that in the face of administrative and political difficulties in securing a national policy on access to genetic resources, a nationally consistent approach on the part of States and Territories was the preferred option.^{xxxvii} The CSWG promulgated 12 principles, derived from the CBD, to guide the management of access to genetic resources in Australia. These principles were:

1. Facilitate access to, and use of Australia's biological resources, in ecologically sustainable ways.
2. Foster a balanced approach to access to biological resources which promotes the conservation of biological diversity and which encourages the development of ecologically sustainable uses of biological resources for the benefit of Australia.

3. Ensure that Australia captures appropriate economic and other benefits from access to its biological resources and ensure the widest possible sharing of those benefits.
4. Ensure that administrative and regulatory practices are transparent, consistent and minimise duplication and regulation, building wherever possible on existing regulatory mechanisms.
5. Ensure continued access for Australia to biological resources in other countries for research and commercial purposes by developing an approach which Australia would be prepared to comply with if the same approach was used by other countries.
6. Be based on consultation with affected communities who should be given sufficient information to make informed decisions.
7. Be comprehensive, in terms of the coverage of biological resources on Australian territory and in waters under Australian sovereignty....
8. Take into account with the interests of Aboriginal and Torres Strait Islander peoples, rural communities and rural landholders/owners.
9. Be consistent with:
 - Australia's responsibilities and interests in international instruments such as the Convention on Biological Diversity, the United Nations Food and Agricultural Organization (FAO) International Undertaking on Plant Genetic Resources and the United Nations Convention on the Law of the Sea.
 - The Intergovernmental Agreement on the Environment
 - National Competition Policy and the Trade Practices Act.
10. Provide for sharing of information between the Commonwealth, States and Territories on biological resources and their conservation and management.
11. Provide adequate mechanisms for monitoring and enforcing the requirements of contracts and permits.
12. Where possible, provide opportunities for active participation by Australia in all stages of the development of biological resources, including collection, screening, research and product development.^{xxxviii}

As a mechanism to govern access, collection, processing, development and export of Australia's indigenous biological resources, the discussion paper proposes an multi-purpose contract system (MSC). This was proposed on the basis that it would require minimal changes to existing legislation, that it was consistent with Australia's international obligations and was flexible and cost-effective.^{xxxix} The development of a MSC to cover all aspects of access to biological resources was recommended as a means of eliminating the existing complicated system of permits. Despite its suggestion that a nationally consistent approach is preferable to a national approach, it is difficult to see the MSC device working without the exercise of national sovereignty over biological resources.

In relation to the recognition of the rights of indigenous peoples, the discussion paper rejects intellectual-property style protection in favour of bioprospecting contracts entered into prior to the divulging of traditional knowledge.^{xl}

5.4 Proposed Commonwealth Biodiversity Act

In February 1998 the Commonwealth Minister for the Environment issued a Consultation Paper *Reform of Commonwealth Environment Legislation*. The Consultation Paper foreshadows three new Commonwealth Acts; an Environment Protection Act, a

Biodiversity Conservation Act and new heritage legislation. These proposals arise out of an Agreement on Commonwealth/State Roles and Responsibilities for the Environment which was settled at the November 1997 meeting of the Council of Australian Governments (COAG). The central tenet of the Agreement was that "the Commonwealth should be focussed on matters of national environmental significance".^{xlii} Consequently, the Minister announced the withdrawal of the Commonwealth "from matters of only local or State significance".^{xliii} The question of access to biological resources was not directly identified in the COAG Agreement as a matter of national significance. The Consultation Paper refers to the unified national approach on access to biological resources which is being developed by the CSWG.

In a chapter of the Consultation Paper on the question of access it is stated that "the Commonwealth Government currently has no specific legislative ability to implement the provisions of the Convention on Biological Diversity dealing with the control of access to biological resources" and that the Biodiversity Conservation Act will provide it with that ability "by allowing regulations to be made in relation to the management of access to biological resources on Commonwealth land and in marine environments under Commonwealth control".^{xliiii} The Consultation Paper provides no hints as to the form or scope of these regulations.

The Consultation Paper infelicitously expresses the legislative ability of the Commonwealth in this area. Legislation pursuant to the external affairs power in placitum 51(xxix) of the Constitution would permit the Commonwealth to implement the access provisions of the Biodiversity Convention in full force. Indeed as the joint submission on the Consultation Paper of the Australian Conservation Foundation and others, points out on the subject of threatened species the Consultation Paper states "This provision will apply to all of Australia and its waters. It will not be restricted to Commonwealth areas".^{xliv} The joint submission also addresses the issue of the prior informed consent of traditional and other owners as the cornerstone of access to biodiversity.^{xlv}

6. World Trade Organization Agreement on Trade Related Intellectual Property Rights (TRIPs) and the International Convention for the Protection of New Varieties of Plants (UPOV)

Paralleling the formulation of the Convention on Biological Diversity, were the negotiations of the Uruguay Round of the General Agreement on Tariffs and Trade. Attempts by the World Intellectual Property Organization to revise the Paris Convention on Industrial Property, 1883, which deals with the international patents, industrial designs and trade marks regime, had foundered on the irreconcilability of the position of developing countries and industrialised countries on the compulsory licensing of patents.^{xlvi} For this and other reasons, the US proposed that the GATT formulate legislative norms for intellectual property protection and that it require the introduction of a range of mechanisms for the enforcement of intellectual property rights.^{xlvii} The resultant Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) was annexed as a condition of membership to the Agreement Establishing the World Trade Organization (WTO).^{xlviii}

Article 27.3 of the TRIPs Agreement permits signatories to exclude from patentability "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological

processes”. However, the provision requires that “Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”. Article 65.2 permits developing countries a period of five years for compliance with TRIPs commencing from the date of entry into force of the WTO Agreement, in April 1994. Least developed countries are permitted an additional five years for the implementation of TRIPs.

In all probability, to comply with this TRIPs obligation, countries will introduce legislation based on the International Convention for the Protection of New Varieties of Plants (UPOV), which was amended in March 1991. The UPOV Convention provides for the registration and grant of intellectual property rights^{xlix} in relation to new, distinct, stable and uniform plant varieties. Article 6 of the UPOV Convention deems a variety to be new if at the date of filing the application, “propagating or harvested material of the variety has not been sold or otherwise disposed of, for purposes of exploitation of the variety” earlier than one year within the date of filing the application in the territory of the contracting party, or earlier than four years, or in the case of trees and vines, earlier than six years in a territory of a non-contracting party. This formulation of novelty, which is much more liberal than the requirement of novelty under patent law, facilitates the acquisition of plant variety rights in relation to germplasm acquired from CGIAR centres.

7. Intellectual Property Rights and the Obligations of Trustees of CGIAR Genebanks

A paramount issue raised by the recent controversies concerning the Australian agricultural research institutes which utilized germplasm from ICRISAT and ICARDA in developing registrable plant varieties, concerns the legal status of the germplasm collections of the CGIAR agricultural research institutes. This issue arises in two principal contexts. First, what will happen to these genebanks upon the dissolution of the relevant centre and, secondly, what authority do the centres have to permit third parties to exploit their genetic resources. The starting place for these inquiries commences with an analysis of the legal status of these institutes themselves.

The legal status of these collections has always been problematic. In 1986 the FAO had conducted a review of the legal status of all national and international institutions operating genebanks.¹ In relation to the CGIAR centres, the FAO report concluded that as control over their operation was shared between national and international representatives, they were not international in the strict sense, as they were not created by any international instrument or organization. On the other hand the report concluded that because they were not either in the private sector or under the control of any State or national authority, the CGIAR centres were *sui generis*. Consequently, the report reached no firm conclusion on the ownership of the genetic resources controlled by the Centres.

A similar study by the TAC suggested that genebanks established as a result of international collaboration should be considered to be held on trust for CGIAR purposes.^{li} This study highlighted the importance of the agreements of genebanks with their host countries and recommended that where necessary these agreements be amended to provide that in the event of closure of a research institute the geneplasm be transferred to an alternative institution to be held on trust, as recommended. This trustee concept was adopted as CGIAR policy in 1989. Its 1989 policy statement on plant genetic resources, under the heading “ownership”, states that “it is the CGIAR policy that collections assembled as a result of international collaboration should not become the property of

any single nation, but should be held in trust for the use of present and future generations of research workers in all countries throughout the world”.

A joint meeting of the TAC and CGIAR Directors’ Working Group on Intellectual Property in January 1992 issued a statement on intellectual property, biosafety and the conservation of plant genetic resources. It recommended that the distribution of germplasm to other than national agricultural research centres should be on the basis of material transfer agreements (MTAs). Breeding material made available to users in industrialised countries, whether private or public, could be the subject of plant variety protection “provided (a) it did not restrain the future use of the material by the Centres, and (b) financial gains were paid into an international fund for the benefit of developing countries”^{lii}.

A number of Centres have adopted policies which provide for the use of MTAs in the transfer of germplasm. These are outlined below.

In 1994 twelve of the CGIAR centres entered into Agreements in 1994 with the FAO which placed their collections into an International Network under the auspices of the FAO. Through these agreements, the centres accepted that their designated germplasm was held “in trust for the international community” and that they would not “claim ownership, or seek intellectual property rights over the designated germplasm and related information”.

Reacting to the biopiracy controversy, which reached its climax in February 1998, CGIAR called for a moratorium on the granting of intellectual property rights over plant germplasm held in its centres. CGIAR Chairman, Dr Ismail Serageldin, explained the call for a moratorium as “the strongest signal the CGIAR can send governments to ensure that these issues be resolved and the materials in the CGIAR remain in the public domain”.^{liii}

8 Trusteeship and the Legal Status of the Gene Collections of Individual CGIAR Centres

The trusteeship principle adopted by CGIAR in 1989 admits of a number of problems. A threshold, but not insuperable problem was the fact that the concept of the trust, although well defined in legal systems deriving their law from the equity courts of English origin, was largely unknown in the civil law system. This may be remedied in large part by the negotiation in 1984 of the Hague Convention on the Law Applicable to Trusts and on Their Recognition.^{liv} This Convention provides for the recognition of trust principles such as the sanctity of trust property, and the binding obligations of trustees. Thus, for example, genebanks established as trusts for CGIAR purposes could not be used for purposes inconsistent with CGIAR principles. This Convention has not yet secured wide support. To date the only non-common law countries which have ratified it are Italy, Luxembourg and the Netherlands. However, it has also been signed by the United Kingdom and the USA, which should attract greater support for the instrument.

A more difficult problem is the fact that a number of the CGIAR agricultural research institutes, such as CIAT, CIMMYT, IITA,IRRI and WARDA, predate the establishment of CGIAR. This presents a problem in ascertaining the legal status of their gene collections established prior to their membership of CGIAR. In 1994, each CGIAR centre placed its genebank under the superintendency of FAO, through the administration of the Commission on Plant Genetic Resources.^{lv} An additional question raised by this 1994 action is the status of dispositions of genetic material prior to 1994. An illustration of this problem is the transmission by ICARDA of the Syrian legumes to the Australian

Centre for Legumes in Mediterranean Agriculture, which became the subject of an Australian Plant Breeder's Rights Application. The director General of ICARDA was reported to have defended its actions by explaining that the legumes were sent to Australia prior to the implementation of the 1994 Agreement.^{lvi}

Another problem with the CGIAR policy on plant genetic resources is that it does not specifically define the obligations of trustees of CGIAR genebanks. The CGIAR policy contains the general statement that genebanks should be held in trust "for the use of present and future generations of research workers in all countries throughout the world". CGIAR policy is silent on the use which these workers would make of this resource. A reasonable interpretation would be that these workers would be allowed to use CGIAR geneplasm for purposes within CGIAR's general objects, for example, to make the agriculture of developing countries more productive and to protect the environment and to preserve biodiversity. As trustee, could a CGIAR centre permit a third party to secure intellectual property rights over geneplasm held by the centre?

Under the trust concept a trustee is under a duty both to keep control of and to preserve trust property. Should a third party be permitted to obtain intellectual property rights, for its own benefit, over geneplasm held by a centre, a breach of trust could be argued. On the other hand, if those intellectual property rights were held for the benefit of the centre or for the benefit of CGIAR objectives, this may well be consistent with the trustee's obligations to secure the preservation of geneplasm. However, it is difficult to conceive of a situation where a third party will assume the very considerable trouble and expense of intellectual property protection in order to preserve plant genetic resources for CGIAR purposes. This is conceivable where, for example, a patentee might waive its rights in developing countries. But to accomplish this the rights owner would have to have secured those rights in the country in which they are to be waived, which is not likely to occur.

The more usual situation will be that the geneplasm will be modified by the third party and intellectual property protection will be sought to permit the commercial exploitation of the modification. In this situation any payment by the third party to the CGIAR centre for the use of its geneplasm would, in augmenting the centres revenues, support the attainment of CGIAR objectives. The production of a modified organism could also be argued to be supportive of the preservation of genetic diversity.

Where the genetic modification is sufficiently novel to satisfy the requirements of patents or plant breeder's rights laws, the underlying geneplasm would still be available to other researchers to devise their own modifications. The trust obligations discussed above assume that the genetic resources of individual CGIAR centres can be impressed with trust obligations. Where a centre predates the establishment of the CGIAR system and it has not been reconstituted to subject itself to the over-riding authority of the CGIAR, the rights of the centre may well be governed by the laws of the host country or by intergovernmental agreements.

9. Intellectual Property Policies of CGIAR Centres in Relation to Germplasm

The Commission on Genetic Resources for Food and Agriculture is currently examining the status of germplasm acquired by CGIAR centres prior to the establishment of CGIAR and also prior to their subscription to CGIAR authority. This status will be determined in part by the instrument establishing the centre and any agreement between the centre and the host country. Following a number of meetings of Centre Directors, mentioned above, some CGIAR Centres have adopted policies which deal with intellectual property rights

arising from germplasm distributed to third parties. Probably the touchstone intellectual property policies are those which have been developed by the International rice Research Institute (IRRI).

Pursuant to an agreement between IRRI and CGIAR dated 26 October 1994, the Board of IRRI placed its collections of plant germplasm under the auspices of FAO. The following year IRRI promulgated its *Policy on Intellectual Rights* which purports to implement the agreement with the FAO. To implement its intellectual property policy, IRRI adopted four protocols on intellectual property rights. Protocol I comprises general principles concerning intellectual property rights and plant genetic resources. This protocol provides

1. The rice genetic resources maintained in the genebank at IRRI are held in trust for the world community.
2. IRRI adheres to the unrestricted availability to the rice genetic resources it holds in trust (except germplasm held in “black box storage” on which the donor of germplasm has placed distribution restrictions) including related information.
3. IRRI will not protect the rice genetic resources it holds in trust by any form of intellectual property protection.
4. IRRI is opposed to the application of patent legislation to plant genetic resources (genotypes and/or genes) held in trust.
5. The rice genetic resources held in trust by IRRI will be made available on the understanding that the recipients will take no steps which restrict their further availability to other interested parties.^{lvii}

This protocol forms part of IRRI’s *Policy on Intellectual Property Rights*^{lviii} and under this policy IRRI has declared that it will supply its genetic resources under MTAs which are subject to the principles propounded in its Protocols. Protocol II concerns intellectual property rights in breeding lines, elite germplasm and parental lines of hybrid rice emanating from its conventional breeding programme. This protocol reiterates IRRI’s policy of free availability and declares that this material will be provided to both public sector institutions and private organizations on the understanding that:

- a. The material is not intended for exclusive use by any single organization.
- b. IRRI retains the right to distribute the same material to other organization.
- c. The use of IRRI materials will be publicly recognized when a derived variety or hybrid is released.^{lix}

This protocol is stated not to apply to materials derived from genetic engineering. This subject matter is covered in part by Protocol III concerning intellectual property rights and inventions and materials derived from biotechnology. Where these are derived through collaboration, Protocol III provides that “IRRI will seek to ensure free access to the products of research”. To “ensure the availability to developing nations of advanced biological technologies or biological materials such as microbiological strains”, this Protocol envisages that IRRI may exceptionally apply for intellectual property protection or provide them to a collaborator on a restricted basis “but only after a specific judgement that such arrangements best serve IRRI’s client developing nation farmers”.

Similar intellectual property policies are being developed by the other CGIAR Centres, thus, for example, the Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT) on 31 March 1993 adopted a Policy on Intellectual Property requiring that “plant genetic resources held in trust will be made available to recipients who agree to take no steps that restrict the further availability of those resources in their original form to other interested parties”.

In August 1993 CIMMYT issued a “Policy on Use of Bread, Wheat, Durum Wheat, *Triticale* and Barley Germplasm Distributed by CIMMYT” under which genebank material is freely available. In relation to breeding material, segregating populations (F2-F5) are distributed without conditions. Advanced lines (F6 and higher) are distributed on condition that no Plant Breeder’s Right will be obtained without CIMMYT’s permission. Similarly, the Intellectual Property Policy of Centro Internacional de Agricultura Tropical (CIAT), formulated in April 1993, provides for restrictions to be placed on the utilization of germplasm in three situations: (a) to prevent appropriation of CIAT research products; (b) to protect property of research collaborators; and (c) to enable the commercialization of CIAT research products through others. In the case of genebank material, CIAT permits the development of new varieties to be protected under plant varieties protection laws. This material will be distributed under MTAs on condition that it remains in the public domain.

New impetus for the development of a common CGIAR intellectual property policy has been precipitated by the biopiracy controversy. The expert drafting group appointed following the CGIAR Mid-Term Meeting in Brasilia in May 1998 is following the model provided by IIRI and this will be integrated with draft standard form material transfer agreements.

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- iii *Ibid*.
- iv See 'About the CGIAR', <http://www.cgiar.org:80/whatis.htm>
- v See 'Technical Advisory Committee', <http://www.cgiar.org:80/tacsec.htm>.
- vi *Ibid*.
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- ix CGIAR Mid-Term Meeting 1998, Preliminary End of Meeting Report, <http://www.worldbank.org/html/cgiar/publications/mtm98/endofmtg.html>.
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- xiii CGRFA, 'Revision of the Undertaking. Issues for Consideration in Stage II: Access to Plant Genetic Resources and Farmers' Rights', <[http:// web.icppgr.fao.org/cpgr6.1/CPGR6.1-6.html](http://web.icppgr.fao.org/cpgr6.1/CPGR6.1-6.html)>.
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- xviii 'Repeat the Term', (July, 1998) 5(2) *RAFI Occasional Paper Series* <http://www.rafi.ca/papers/op52.html>.
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- xx *Ibid*.
- xxi *Ibid*.

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- xxvi See F.McConnell, *The Biodiversity Convention. A Negotiating History*, London, The Hague, Boston, Kluwer, 1996.
- xxvii See J.H.Barton and W.E.Siebeck, *Material Transfer Agreements in Genetic Resources Exchange- The Case of the International Agricultural Research Centres*, Rome: IPGRI, 1994, 27.
- xxviii See McConnell, n.28, *supra*.
- xxix *National Strategy for Ecologically Sustainable Development*, December 1992, 4.
- xxx House of Representatives Standing Committee on Environment, Recreation and the Arts, *Biodiversity. The Role of Protected Areas* (Canberra: AGPS, January 1993), para.4.70.
- xxxi *Ibid.*, para.4.72.
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- xxxvii *Ibid.*, 14.
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- xli Sen. The Hon. Robert Hill, Commonwealth Minister for the Environment, *Reform of Commonwealth Environment Legislation* (Canberra, 1998), 3.
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- xlvii See Blakeney, 'Intellectual Property in World Trade' [1995] 1 *International Trade Law & Regulation* 76.
- xlviii See M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement*, London: Sweet & Maxwell, 1996.
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- li TAC, *CGIAR Policy on Plant Genetic Resources*, TAC Doc. AGR/TAC:IAR/88/4 Feb.1988.
- lii Barton and Siebeck, n.29 *supra*, 32.,
- liii CGIAR Press Release 'CGIAR Urges Halt to Granting of Intellectual property Rights for Designated Plant Germplasm', Feb. 11, 1998, <http://www.cgiar.org:80/germrel.htm>.
- liv See 23 *International Legal Materials* 1388 (1984).
- lv In 1995 the Commission was renamed as the Commission on Genetic Resources for Food and Agriculture (CGRFA).
- lvi See Edwards and Anderson, n.2 *supra*, 15.

lvii IRRI, *Policy on Intellectual Property Rights*, IRRI, Manila, 1995, 5.
lviii *Ibid.*
lix *Ibid.*, 6.

Geographical Indications

‘Introduction’ in M. Blakeney, ed., *Geographical Indications*, vol.1, Cheltenham, Edward Elgar, 2015, xiii-lii. ISBN 978 1 78254 775 4

Geographical Indications. An Introduction to the Literature

OVERVIEW

The subject of geographical indications (GIs) has generated a considerable body of scholarship in recent years. A number of reasons can be advanced to explain the burgeoning popularity of this subject. First, it is a nice discrete subject within the general field of intellectual property (IP) law, which can be dealt with fairly comprehensively without too much overlap with other IP topics, other than trade marks. Secondly, the inclusion of GIs within the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) is considered to be a European (“Old World”) IP agenda item, attracting the ire of the “New World” both in scholarship and in the WTO dispute brought on a complaint by Australia and the USA against the EU. This conflict has led to a search for allies among the countries of the “South” and this has generated a body of scholarship investigating the advantages of GIs for developing countries. This scholarship has generally taken the form of European case studies as exemplars for the South, as well as case studies in a range of developing countries. A separate strain of this scholarship overlaps with analyses of the possibility of extending the special protection for wines and spirits in the TRIPS Agreement to other products such as agricultural products and handicrafts. This scholarship parallels and embraces the inconclusive debates in the TRIPS Council on this subject. A separate inconclusive debate in the TRIPS Council, also reflected in GIs scholarship, concerns the nature of the “multilateral system of notification and registration” of GIs which is envisaged by Article 23.4 of the TRIPS Agreement. Is this to be a French-style AOC registration system? Is it to extend to products other than wines and spirits? What is to be its legal effect?

This book reproduces the principal English language scholarship on GIs^{lix}, but as with the institution of origin product labelling itself, it should be acknowledged that the oldest and most comprehensive monographs on this subject are by French scholars (see: Lacour, 1904; Guérillon, 1919; Plaisant and Jacq, 1921; Jaton, 1926; Vivez, 1943; Capus, 1947; Auby and Plaisant, 1974; Guyet, 1983; Vletian, 1989; Rochard, 1992; Denis, 1995; Olszak, 2001; Rochard, 2002). Also a number of the recent English language books and articles on GIs have been written by French scholars participating in the EU-funded DOLPHINS and Siner-GI projects (eg Barjolle and Sylvander, 2000; Sylvander, 2004; Barham and Sylvander, 2011). However, in recent years an impressive corpus of English language scholarship on GIs has been published. The first significant monograph, O’Connor, 2004, explores geographical indications within English trade marks and passing off law. The most recent text, Gangee, 2012, seeks to locate geographical indications within international intellectual property law.

Given the plethora of recent writings on GIs, particularly in the context of the TRIPS Agreement, it has been necessary to select between some fairly similar items. As will be seen below many authors adopt the same methodology of surveying the international treaties and agreements on GIs before addressing their particular concerns. For this reason in a compendium of writings on GIs there is inevitably some repetition in descriptions of the international landscape, but some selection has been made to avoid too much replication. A comprehensive bibliography is annexed to this outline and mention is made herein of a number of articles which could not be included primarily for reasons of repetition, space and also because they may have contained a large number of photographs which would not work in a book such as this. Also excluded from this compilation are a number of economic analyses of GIs which because of the large number of mathematical formulae are probably out of place in a law text.

The close examination which GIs have received since the TRIPS Agreement has raised questions about GIs as a valid category of IP and this is considered in Part I of the book. The various functions which have been claimed for GIs are addressed in Part II. The evaluation of the effects of GIs is considered in Part III. Part IV contains a number of items which describe the European sui generis system for the registration of GIs and Part V contrasts this with the New World trade marks-based systems for the protection of GIs. The international dimension of GIs protection is considered in Part VI and the particular implications of GIs for developing countries is considered in Part VII. The book concludes in Part VIII with a number of case studies.

GIs JURISPRUDENCE

The Old World/New World dispute over GIs in the context of the TRIPS agreement has generated a body of scholarship questioning the jurisprudential basis of GIs protection. Stern, 2007 questioned whether GIs are IP, pursuing a line of scholarship initiated by van Caenegem, 2003 and pursued by Hughes, 2006. A number of commentators have commented on the uniqueness of GIs as a category of IP. Jókúti, 2009 contrasted the protection of GIs with patents or trade marks whose variants are at least comparable. Dawson (2000) explained that GIs are “an intellectual property right in the making surrounded by a complex debate lacking common terminology”. The terminological confusion surrounding the discussion of GIs was highlighted by Gangjee, 2012 as a symptom of the conceptual, institutional and epistemic “mess” characterising GIs jurisprudence. Distilling the analyses of the ECJ and the WTO Secretariat he identifies at least four ways in which GIs are described: as “signs which indicate (1) merely a product’s origin, (2) its reputation associated with a specific origin, (3) its distinctive qualities associated with origin, or (4) its unique qualities that are reliant upon origin”. This diversity of approaches obviously affects the functions, described in Part II of this book, which are ascribed to GIs and the correlative scope of protection. A study commissioned by DG Trade, European Commission describes the protection of GIs in the 160 countries surveyed (O’Connor & Co, 2007a and 2007b.) which can be explained by the disparate terminology and functions which GI protection is intended to achieve. At the same time this diversity confuses the debates in the TRIPS Council on both the extension of protection and the scope of the multilateral registered which are described in the extracts in Part VI of this book.

FUNCTIONS OF GIs

The obligation of WTO Members to protect GIs, the possible extension of that protection and the various models for GIs protection which are competing for the attention particularly of developing countries, has raised questions about the functions and utility of GIs protection. As authors such as van Caenegem, 2003 and Ibele, 2009 point out the principal functions which have been identified for GIs are: the promotion of rural development; the certification of product quality; marketing and consumer protection; environmental protection and cultural protection. These functions are explored in Part II of the book.

(a) Rural Development

There is a significant corpus of scholarship on the contribution of origin products to rural development (Ray, 1998; Banks and Marsden, 2000; Marsden, T., J. Banks, G Bristow, 2000; Ilbery and Kneafsey 2000a and 2000b; Pacciani et al 2001; Babcock, 2003, Barham, 2003; Treagear, 2003; Babcock & Clemens, 2004; Beletti and Marescotti, 2004; Rangnekar, 2004; O'Connor and company, 2005; Tregear et al, 2007; Blakeney and Mengistie, 2011b) which is reviewed in Réviron and Paus, 2006 and updated in Belletti and Marescotti, 2011). However, Barcock (2003) criticises this evidence as predominantly theoretical, signifying the need for more empirical evidence. However, the increasing number of case studies, a number of which are extracted in Part VIII of this book, confirm the proposition that GIs assist in the promotion of sustainable rural development. Most of the case studies come from France, Italy, Portugal, Greece and Spain which until recently account for three quarters of the GIs found in Europe (Morgan et al, 2006). Ilbery and Kneafsey (2000b) contrast this with the UK, dominated by homogenous brands, attributable to the fact that the GI movement in the UK is a recent development.

As Pacciani et al, 2001 and O'Connor and Company, 2005 point out the protection of GIs accords with the EU policy on rural development. The Preamble to the the EU Regulation, 510/2006 governing GIs identifies that:

The diversification of agricultural production should be encouraged so as to achieve a better balance between supply and demand on the markets. The promotion of products having certain characteristics can be of considerable benefit to the rural economy, particularly in less favoured or remote areas, by improving the incomes of farmers and by retaining the rural population in these areas".^{lix}

The creation of local jobs through the protection of GIs is a factor influencing rural exodus (O'Connor and Company, 2005). Young people are considered the most disadvantaged in rural areas (Chapman and Shucksmith, 1996) their departure from rural areas creates challenges to the sustainability of rural communities (Jentsch, 2006). An increase in employment has for example been observed for the Comté cheese industry (Requillart, 2007).

Kop et al (2006) estimate that the production of Comté cheese generates five times more jobs in processing, maturing, marketing, packing, etc. than does its generic equivalent, Emmental and that migration away from the countryside in the Comté area is only half that of the origin-protected area. They estimate that at the national level, although Comté cheeses account for only 10% of total French cheese output, they are responsible for 40% of the job offers for students who have been trained in cheese-making in vocational

schools. Similar results have been identified for origin protected cheeses supporting the milk supply from cattle in Northern Italy and the sheep of Southern Italy (Belletti et al, 2001). Belletti et al (2001) estimated that origin agro-products in Italy generated around 6 billion euros of GNP and employment for 300,000 persons.

However, as noted by Williams (2007) based on the EU case studies, the potential for job creation is dependent on the labour intensity of the protected products.

GIs also have a wider territorial impact that extends beyond the direct GI stakeholders. GIs can lead to employment creation and agro-tourism within the region (Paus and Réviron, 2011). GIs are also likely to stimulate investment and the price of land within the borders of the GI region (Zografos, 2008. Giovannucci et al (2009) also point to the potential “complementary effect” a GI may have on other products in the area.

Bessière (1998) states that that the specific processes involved with food linked to a particular region can invite tourism. However the development of tourism in association with local food and gastronomy does hold some fears of “Disneyfication” (Barham, 2003). The Comité Interprofessionnel du Vin de Champagne has requested "The landscapes of the Champagne region" to be included on UNESCO's World Heritage List.^{lix} The objective is to protect the famous sites of the Champagne region, which include the great diversity of vineyards and the outstanding character of the area's cellars carved from the surrounding chalk and the unique landscapes of the Champagne region.

Finally, Sylvander (2004) observes that that the importance of GIs for sustainable rural development should be assessed by keeping in mind its “multifactorial” nature, which extends beyond market-related benefits to include also positive social and environmental externalities within the region.

(b) Certification of Product Quality

Scholarship on the importance of information and information about the quality of products for the proper functioning of markets dates back more than 40 years (see Akerlof, 1970). Klein and Leffler (1981) investigated the causes of and remedies for market failures due to the lack of information on product quality. It is common in the economics literature to distinguish goods according to whether their quality can be identified by consumers (Antle, 1996; Mojduszka and Caswell, 2000; Giannakas, 2002). Kreps and Wilson, 1982, Shapiro, 1983 and Verbeke and Roosen, 2009 have shown that this information search can be improved through labelling which signals reputation. Zago and Pick, 2004 considered the welfare impact of the introduction of EU GIs legislation which allows producers of agricultural commodities with specific characteristics to differentiate and label their products accordingly. They found that both consumers and high-quality producers were unambiguously better off from this labelling, while producers of the low-quality commodity were unambiguously worse off. They noted that the impact on economic welfare can be negative when the administrative costs of the regulation are relatively high and quality differences low and relatively expensive to obtain.

GIs can play an important role in signalling the quality of goods (see Becker, 2008). Hobbs, 2003 and Hobbs and Kerr 2006 explain that the attributes of goods may be classified as: (a) search attributes which can be identified by consumers prior to purchase (eg ripeness); (b) experience attributes that can only be discerned upon consumption (eg taste); and (c) credence attributes that cannot be identified by consumers even after consumption (eg product origin and production methods). Although origin brands may

assist in the signalling of search or experience attributes, they are mainly important in signalling credence attributes, particularly where the origin brand is underpinned by a registration and certification system. As Winfree and McCluskey, 2005 indicate, it enables producers to signal quality and the associated reputation that has been developed over time. Moschini et al, 2008 claim that producers are incentivised by an origin indication to maintain product quality. The reputation signalled by the origin indication attaches to all stakeholders in the supply chain. Zago and Pick (2004) explain that this signalling of quality improves consumer welfare through lowering the costs of searching for information about products. It should be noted that the influence of origin branding in communicating quality information will differ between products. Landon and Smith, 1997 examine the use by consumers of quality and reputation indicators in relation to Bordeaux Wine, which is protected by GIs. Van der Lanse al, 2001 analyse the role of the region of origin and EU certificates of origin in consumer evaluation of food products.

In order for the perceived benefits of GI labelling to be realised, such as the promotion of sustainable rural development, there needs to be consumer awareness that origin labelling represents qualities linked to natural and human factors. Since there is already a consumer awareness of value added foods and a consumer demand for traceability in agro-food products (Marsden et al., 2000; Murdoch et al 2000; Van der Ploeg and Renting, 2000) this awareness can be developed for origin products.

Rural product certification schemes have proliferated since the mid-1990s. They include the certification of organic agriculture, fair-trade certification of products from developing countries and food produced in compliance with sanitary and traceability protocols (Giraud, 2003; Mutersbaugh et al, 2005). For smallholder producers in developing countries certification provides quality market niches at a time of declining agricultural and forest commodity prices (Gonzales and Nigh, 2005). Consumers have been identified as placing increasing value on the integrity of food, such as the social and environmental standards involved in the production and processing of agrifood products (Giraud and Amblard, 2003; Renting et al., 2003; Hobbes et al, 2005; Murdoch et al., 2000). This is particularly the case following recent food crises. As it is not unusual for food to be grown, processed and packaged in different places consumer trust in products is eroded, particularly as a consequence of these crises. Studies indicate a willingness of consumers to pay a premium price to producers who offer transparency in relation to the composition and origin of their products. In situations where uncertainty about quality or safety is elevated, such as in a health crisis, origin labelling can become an important means of inferring product quality, eg meat labels after the BSE crisis in Europe (Verbeke and Viaene, 1999; Becker, 2000, Lees, 2003 and dairy product labels after the Melamin crisis (Xu and Wu, 2010).

GIs are identified as providing a means for the legal regulation of the use of origin product designations as a means of avoiding the deception of consumers as to the true origin of products, production methods and as to the specific quality of products (See O'Connor, 2004; van Caenegem, 2004; Tregear and Giraud 2011; Barjolle et al, 2011).

In Europe, where GIs have been longest developed there are some empirically based suggestions that consumers' and producers both have expectations of about the quality of origin products in the European market (see Teuber, 2011 and Stasi et al 2011). This is discussed in the next section.

(c) GIs as a means of product differentiation for enhanced market access and the capturing of price premiums

Agricultural producers in developing countries have the challenge of ensuring market access by differentiating their products from other agricultural producers in both industrialised and developing countries. P. Evans, 2006 and Bramley and Bienabe, 2012 explain that GIs provide mechanisms that facilitate the creation of territorially differentiated niche markets. Part VI of this book examines the advantage which this presents for developing country producers. They cite the work of Révion and Paus, 2006 and Pacciani et al, 2001 who explain that GIs disconnect the origin product from commodity markets by capturing attributes of the locality such as environmental factors and local knowledge in the GI product. Agarwal and Berone, 2005 point out that an understanding by producers of the potential to protect regionally embedded value added products through origin branding, allows a sustainable competitive advantage for the future of agricultural firms.

Ittersum et al, 2003 have made the point that although origin-based marketing has a long history, its contemporary relevance is increasing, partly as a reaction to globalization as local producers need to be able to distinguish their product in the eyes of consumers from generic competition. In the newly urbanising developing countries consumers and people from a particular region or ethnic group look to the products from their places of origin as being reliable and known. Gradually, these local products begin to gain a commercial reputation among a wider group of traders and consumers.

A number of researchers have identified the capacity of origin labelling to differentiate otherwise homogeneous commodities as the basis for charging premium prices. Révion et al, 2009 refer to value addition from a mix of economic, cultural and social characteristics leading to the capturing of a premium. Marette, 2005 and Williams, 2007 assert the higher value which consumers attach to products differentiated according to their origin. Agarwal and Barone, 2005 suggest that the exotic nature of origin products allow their producers to charge premium prices. Révion et al, 2009 argue that this premium might grow over time as consumer recognition of the origin label increases. Teuber, 2010 documents the premium prices that can be charged for coffee in the European market and in a study of Hessian apple wine, Teuber 2011 indicates that the willingness of consumers to pay a premium price is because of their view of the positive impacts of GIs on the local economy. Wongprawmas, 2012 questions the extent to which foreign producers, such as Thais can rely upon this assumption.

A number of studies of European products refer to the premiums that are charged. Babcock 2003, reports that Bresse poultry in France receives quadruple the commodity price for poultry meat; Italian “Toscana” oil gains a 20% premium above commodity oil; and milk supplied to produce French Comté cheese sells for a 10% premium. The case study of Comté cheese in France by Gerz and Dupont, 2006 indicates that French farmers receive an average of 14% more for milk destined for Comté and that dairy farms in the Comté area have become more profitable since 1990, and now are 32% more profitable than similar farms outside the Comté area. The retail price of Comté has risen by 2.5% per year (against 0.5% for Emmental), while the wholesale price has risen by 1.5% a year (no change for Emmental). The French Ministry of Agriculture claims that part of this added value accrues to producers and other actors in the Comté supply chain, whereas retailers have appropriated all of the 0.5% rise in the retail price of Emmental (MAAPAR, 2004). (O’Connor and Company, 2005) refer to the protection of ‘Lentilles vertes du Puy’ which is said to have increased the production of lentils from 13,600 quintals in 1990 to 34,000 quintals in 1996 and 49,776 quintals in 2002, the number of

producers almost tripling from 395 in 1990, to 750 in 1996, and 1,079 in 2002. On the other hand Bonnet and Simioni, 2001 in a study of designation of origin labelling found that consumers did not value the quality signal provided by the PDO label. For example, they observed that at the same price, only a small proportion of consumers would prefer to buy a similar Camembert brand with a PDO label than without it and that brand appeared to be more relevant information in the consumer's valuation of available products.

There are fewer studies of premium prices for origin products outside Europe. Kireeva et al, 2009 examine a number of examples of the use certification marks in the Peoples Republic of China. The price of “Zhangqiu Scallion” per kilogram was raised from 0.2 - 0.6 yuan before the use of the certification mark to 1.2 - 5 yuan in 2009. “Jianlian” lotus seed was registered as a GI in 2006, leading to a rise in price from 26-28 yuan per kilogram to 32-34 yuan per kilogram. Clemens and Babcock, 2004 mention that although New Zealand lamb is protected indirectly as a geographical indication, although a premiere product, it has only managed to reach a premium price for a small percentage of exported produce. Menapace et al, 2011 have observed the willingness of Canadian consumers to pay a premium price for origin branded olive oil.

(d) Aggregation of market power

The proposal that farmers enhance their incomes by the collective marketing of their produce dates back around 100 years (Carver and Wilson, 1916). The proposals to achieve this result have included: producer cooperatives, mandatory government acquisition and marketing; government supported marketing agencies and boards. Gordon et al., 1999 explain that to escape the commodity trap where each producer of a particular product is a direct competitor with every other producer, farmers need to band together, cooperate, differentiate their products and then commit resources to shifting out their now downward sloping demand curve. Yeung and Kerr, 2011, citing Giovannucci et al. 2009, characterise the current popularity of GIs in the EU as the latest manifestation of this theme.

The stronger the product/origin nexus, the greater will be the competitive advantage created by the differentiation of the origin branded product from the general commodity group. By creating grounds for competitive advantage based on territorial specificities and reducing competition with non-differentiated products, GIs potentially assist producers in appropriating a larger income from the production of origin-based goods (Zografos, 2008; Rastoin, 2012). Bramley and Bienabe, 2012 point out that a niche marketing strategy entails an increase in production and marketing costs, particularly promotional costs to secure consumer recognition. Barjolle and Sylvander, 2000 suggest that those promotional costs can be recouped through increased sales volumes and as is indicated below through premium product pricing. Giovannucci et al, 2009 identify some of the pros and cons of establishing GI systems. Mérel, 2009 details some of the “deadweight” cost of production requirements for agricultural products sold under GIs.

Belleti et al, 2007 explain the international success of Tuscan firms producing: Olio Toscano PGI, Olio Chianti Classico PDO, Pecorino Toscano PDO and Prosciutto Toscano PDO to the aggregation of the market power of a number of small enterprises.

Babcock 2003 and Lence et al, 2006 suggest that the protection of origin brands provides an incentive for producers to develop new origin brands. Stasi et al, 2011 in a study of the Italian wine market establish the existence of a differentiation effect of GIs in terms of

magnitude of elasticities and substitution effects. GIs corresponding to higher quality generate lower price sensitiveness and product substitution compared with wine without origin protection. Blakeney, 2012 describes the process whereby Australia's obligation to respect EU GIs for wines and spirits has created a national impetus to create Australian GIs for the same products.

(e) *Redistribution of added value through the product chain*

The principal justification for origin labelling is the enhancement of profits and their distribution through the supply chain. As a general rule agri-food producers in long food supply chains obtain a decreasing share of any added value, whereas short food supply chains offer greater chances for added value to be enjoyed by all actors (Marsden et al, 2000). There are a number of studies which indicate that the primary beneficiaries from origin labelling are those at the distribution end of the value chain. Ilbery and Kneafsey (2000) report from a study on GIs in the UK that only a small number of food managing companies and their shareholders benefit from added value from GIs and that most farmers and small businesses involved were unlikely to benefit. Yeung and Kerr (2011) point out that all participants in the value chain must understand and buy into the protection of a GI's quality and/or reputation. Young and Hobbs (2002) advise proactive value chain management where incentives are provided for all persons in the supply chain, as there is no reason for producers in developing countries to go to the trouble of creating an origin product if other supply chain participants capture all the extra value that is created by the origin label.

Bowen. and De Master, 2011 in case studies of agricultural production in France and Poland note that while quality initiatives create the capacity for maintaining rural livelihoods in the face of the homogenizing trends in the global agro-food system, "they also have the potential to undermine local specificity and privilege powerful extralocal actors at the expense of local communities." A study by Dentoni et al, 2011 of the "Prosciutto di Parma" Consortium' indicated that the high heterogeneity of size between different members negatively affects members' agreement on the future level of the definition of its GI standard and therefore the effectiveness of collective action.

(f) *Sustainable use of natural resources and biodiversity conservation*

Bramley and Bienabe (2012) observe that while environmental sustainability was not the primary aim of GI development, the fact that GIs derive from local, including natural, resources means that environmental benefits are increasingly seen as a potential GI externality. The codes of practices which are collectively adopted in relation to origin labelling often incorporate biodiversity objectives (Larson, 2007). Biénabe et al, 2009 refer to the Rooibos industry in South Africa as an example of an industry which has explicitly considered biodiversity concerns in designing its product specification. This is because Rooibos production takes place in a biodiverse and environmentally sensitive area. Kop et al, 2006 point out that as the registered Comté PDO specifications limit the intensification of farming, so farmers use fewer inputs and the environment is better protected, contributing to maintaining the open landscape of both pasture and woodland that is typical of the Jura region. Profitable traditional livestock raising in the Comté area has limited the loss of pastureland to 7% in the PDO area, compared with 18% in the non-PDO area.

Producers are encouraged to act in a responsible manner towards the local environment as negative publicity would damage the product's image in the mind of the consumer (Williams, 2007). Thus producers are likely to be concerned with environmental factors such as pollution and sustainable management of natural resources. These environmental considerations are increasingly incorporated into the codes of practices associated with origin products.

As origin labelling increases the value of the product, it may lead to the continued use of traditional resources which may otherwise have been replaced by otherwise more economically profitable species or breeds (Berard and Marchenay, 2006; Lybbert, 2002; Thénevod-Mottet, 2010). However, it is also important to point out that the success of an origin product may lead to an increase in demand and therefore to increased pressure on local resources. Sustainable production guidelines need to be agreed upon by means of a participatory process in order to prevent pressure being placed on fragile environments and to ensure in particular that the GI does not lead to "genetic erosion" (Downes and Laird, 1999; Boisvert, 2006).

Rural sustainability achieved through the preservation of biodiversity, landscapes, and traditional knowledge may be promoted by the protection of GIs (Barham, 2002). For example, Guerra, 2004 has observed that in the Mexcal region of Mexico the Agave sugar needed to make Tequila is cultivated and managed from wild or forest Agave species, which encourages the biodiverse Agave species. GIs can also serve as a tool for encouraging sustainable agricultural practice by legally limiting the scale of production and production methods (Guerra, 2004). Penker, 2006 notes that origin products impose an increased responsibility of producers to their place of production. Lampkin et al, 1996 have noted that "organic standards provide a mechanism by which farmers pursuing sustainability goals can be compensated by the market for internalizing external costs".

(g) *Aiding the preservation of traditional knowledge*

Bérard and Marchenay, 2006 describe GIs as a means of "enabling people to translate their long-standing, collective, and patrimonial knowledge into livelihood and income. De Sainte Marie and Bérard, 2005, Panizzon, 2006, Singhal, 2008, Blakeney, 2009b and Dagne 2010 have pointed out that GIs share many of the characteristics of TK as both seek to preserve communal rights and like TK GIs can be held in perpetuity, for as long as a community maintains the practices which guarantee the distinctive quality of a local product. Similarly, in its *Review of Existing Intellectual Property Protection of TK* WIPO's IGC Secretariat observed that "Goods designated and differentiated by geographical indications, be they wines, spirits, cheese, handicrafts, watches, silverware and others, are as much expressions of local cultural and community identification as other elements of traditional knowledge."^{lix} Graber and Lai (2012) on the other hand doubt that origin branding is appropriate for the protection of traditional cultural expressions (TCEs) because it is "difficult to create standards (particularly those that can be consistently certified) for handicrafts." Mulik and Crespi 2011, in an analysis of the potential for GIs to protect Basmati rice against the marketing of similarly trademarked US products, have suggested that the extension of TRIPS Article 23 protection to agricultural products could provide more effective assistance to for the protection of products incorporating TK.

The GI process on the other hand involves documenting specific methods into a code of practices that fall within the public domain. In doing this it prevents the appropriation of the knowledge embedded in the GI product, including potential traditional knowledge

components (Rangnekar, 2002). However, despite the *a priori* link between GIs and traditional knowledge, the use of GIs for protecting traditional knowledge is not without limitations. Most notably GIs protect the collective reputation of a product linked to a specific territory and not the underlying knowledge embedded in the good or production process (Kur and Knaak, 2002). The knowledge as such thus remains available for use by outside parties. The GI does nevertheless allow for a commercial value to be attached to products linked to a specific territory that build on traditional knowledge and thereby allow those local communities that produce the GI to economically benefit from their traditional knowledge. GIs can therefore promote the continued use of the knowledge. As such, Bramley, 2011 suggests that GIs are thus more a means for “preserving rather than protecting” traditional knowledge. It should be acknowledged that some academic commentators (Kur and Cocks, 2007 and Hughes, 2006) regard “the assertions on the part of the EU and other nations with vested interests in a worldwide regime of vigorous GI protections-such as Switzerland-that such a scheme would aid developing countries in expanding their economies by ensuring the maintenance of knowledge bases related to the growth and manufacture of traditional indigenous products are unfounded and inherently flawed.” Blakeney, 2009a) interprets this to mean that they mean that mere registration of a GI will not create a premium price, as investment is required in advertising and promotion. He suggests that the advantage of the GI system in this regard is that it provides a mechanism for the aggregation of promotional expenditure on the part of agricultural producers, which can be supported by the national agricultural marketing authorities.

(h) Preservation of cultural values

Echols, 2008 points out that the 2005 UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions reaffirms as one of its objectives the link between culture and development of all countries, particularly developing countries. By attaching an economic value to locally embedded products, an origin brand allows the local population to sustain its way of life and uphold its cultural heritage. This strengthens the region’s identity, which in turn reinforces the origin brand. These mutually fortifying linkages are likely to boost the rural development impact of the brand, while Williams, 2007 mentions “social cohesion” as a positive outcome of the GI process that facilitates greater cooperation and information sharing. Arfini et al, 2003 in a study on 15 specific Origin Labelled Products located in 7 European countries found that the GIs; Taureau de Camargue, Cherry of Lari, and Culatello di Zibello strengthened producer pride and self-esteem, and encouraged local population participation in the creation of a common identity.

Broude, 2005 and Zographos, 2006 apply the discussion mentioned in (g) above on the role of GIs in protecting traditional knowledge to their role in the protection of expressions of culture. This research is updated by Sanders, 2010 who considers the role of GIs in protecting traditional cultural expressions consonant with the adoption of UNESCO’s Universal Declaration of Cultural Diversity

EVALUATING THE EFFECTS OF GIs

As will be observed in the writings described in Part VII of the book, the useful functions performed by GIs which are canvassed above are urged as justifications for the adoption of GIs systems by developing countries and these functions are also advanced in support of the extension of the international regime for GIs protection which is described in the

writings in Part VI of the book. To meet these arguments in support of GIs a body of scholarship has developed which disputes the advantages claimed for GIs and which seeks to identify the disadvantages of GIs. A more general body of scholarship subjects GIs to economic evaluation.

At the heart of the justification for GIs is the assumption that product origin can play a part in consumer preference. Ittersum et al, 2003 examined the role which origin played in consumer preference for beer and potatoes in seven regions in the Netherlands. Their conclusion was that origin played a larger role in relation to potatoes than for beer. This confirmed both earlier and later studies which found that the influence of origin is product-specific. (e.g. Nagashima, 1970; Gaedeke, 1973; Insch and McBride, 2004). Reviewing the place-of-origin literature, Verlegh and Steenkamp (1999) conclude that although the place of origin can have a large effect on product evaluation, the processes behind this effect are not yet well understood. As Yeung and Kerr, 2011 explain a particular problem in evaluating the financial and economic effects of GIs labelling, even in advanced economies is not easy, particularly as most GIs are used in association with individual producer brands.

Among the disadvantages identified in establishing GIs are: the organizational difficulties in establishing collective producer organizations, the costs of certification, administration and promotion and enforcement.

Collective Organization

The collective mobilisation of all actors in the supply chain is identified as the key to the success of schemes for origin labelling (Barjolle and Sylvander, 2000). This may require a change to the independent mentality of producers in some countries (Réviron and Chappuis, 2011). This will also require the inculcation of entrepreneurial skills (Arfini, et al 2003) as well as a willingness to accept internal discipline and to entrust decision-making to the collective body (Sylvander, 2004). Réviron and Chappuis (2011), looking at the successful example of the EU identify inter-professional associations, with representation from various levels in the supply chain as the key to this success (Bérard et al, 2000 ; Barjole and Sylvander, 2002). Replicating this model in countries with different cultural traditions may present a problem.

Certification costs

Establishing an origin labelling system is inevitably going to involve direct certification costs the decision taken by the firms whether to use or not use such a system will depend on the overall balance between costs and benefits (see Raynaud and Sauvée, 2000; Verhaegen and Van Huylenbroeck, 2001). In addition to the direct certification costs are all the costs producers will incur in arranging their structure, organization and production process to the contents of the certification code. Belletti et al, 2007 examine the effects of certification costs on the success of EU GIs established for Chianina PGI beef, Pecorino Toscano PDO cheese and Olio Toscano PGI extra-virgin olive oil. They found that the reorganization costs for firms producing Chianina PGI beef were quite high because the certification Rules established strict conditions for exclusive transportation of the PGI livestock (separated from non-PGI livestock) to the slaughterhouses. In relation to the Pecorino Toscano PDO cheese, the Rules required use of milk from sheep bred in Tuscany instead of cheaper sheep milk with other origins. Belletti et al, 2007 found that

when producers want to use the certified label only for a part of the whole production, there may be some organization costs due to the need of keeping separate the production lines, that may cause some inefficiencies in managing processes and require dedicated assets (storage structures, plants, transport vehicles, etc.), thus increasing the overall costs.

Administrative costs

Opponents of proposals advanced at the WTO to extend the special protection of GIs for wines and spirits to agricultural products and handicrafts have pointed to the additional costs and administrative burdens of implementing these proposals.^{lix} Yeung and Kerr, 2011 distinguish between the costs of a “greenfield” establishment of a sui generis GI system where none exists and the “switching costs” incurred where origin labelling is already provided for under trademarks law. In the greenfield situation the costs have to be incurred if GIs are to be protected, whereas switching costs are an extra imposition. Kur and Cocks, 2007, looking at the EU example, refer to “the huge bureaucracy capable of scrutinizing applications for GI protection, verifying GI specifications, and monitoring use of protected GIs.” Citing Hughes, 2006 they question as “unfounded and inherently flawed” the assertions on the part of the EU and other supporters of vigorous GI protection “that such a scheme would aid developing countries in expanding their economies by ensuring the maintenance of knowledge bases related to the growth and manufacture of traditional indigenous products”.

Promotional effort

Giovanucci, et al, 2009; Teuber, 2010 and Rastoin, 2012 point out that educational and promotional efforts are required even before a GIs labelled product is placed on the market. Obviously promotional efforts will be more profitable in markets such as the EU where origin labelling is a feature, but Josling 2006 comments on the limited success of some GIs even in the EU. In the US, mandatory country of origin labelling for food has been proposed as a means of reducing consumer concerns about quality, safety and production methods. However, much of the literature on the effects of this mandatory labelling suggests that the costs of implementation for producers may very likely outweigh estimated consumer benefits (Brester, Marsh, and Atwood, 2004; Lusk and Anderson, 2004) and constitute a barrier to market entry (Chambolle and Giraud-Héraud, 2005). Suh and MacPherson (2007) in their case study on Boseong tea from South Korea that since GIs often use already well-known names of regions, marketing costs at the early stage are often not very high. However, Grote, 2009 points out that their study also shows that a concerted effort by the government, research institutes and the private sector is needed to promote the development of the GI product.

Enforcement

As is the case with other IPRs the greater the value of an origin indication, the greater will be the likelihood of unfair business practices such as free riding at the expense of the reputed origin produce. This will require the establishment of an institutional framework which confers the right of exclusive use to those producers within the designated area who comply with the code of production practices (Belletti, 2000; Ilbery and Kneafsey, 2000;

Belletti et al 2007). On the other hand Teuber, 2011 indicates that the most important motivation for producers to apply for a protected GI is to secure the established reputation of Hessian apple wine against misuse by competing producers. Monteverde, 2012 provides a brief overview of GIs enforcement issues in Europe.

Economic analysis

Viewed from the perspective of neoclassical economic theory, Moran, 1993 observed that appellation systems are a type of collective monopoly that impose entry barriers on producers wishing to begin production. This competition analysis reflects the considerable scholarship analysing the economic effects of GIs referred to in Part III of this book.

Conceptually, a geographical indication can be considered as a club asset shared by firms acting on a specific territory in the production of a given and specified good. A club good is characterised by partial excludability, no or partial rivalry of benefits and congestion phenomena (Buchanan, 1965; Thiedig and Sylvander, 2000). The immaterial asset represented by a GI can appreciate or depreciate over time and, in particular as a consequence of the behaviour of its owners, the members of the GI club (Benavente, 2010). Collective action among GI-right holders appears to be critical in order to avoid free-riding, which consists in the opportunistic behaviour of one or several members of the GI club, benefiting from the club asset without respecting the constraints attached to it and putting the reputation of the GI good, that is the value of the club asset, at risk (Coulet, 2012). As reputation is at the core of the value of a GI, coordination of club members is essential. However, Paus and Révion, 2011 warn that this coordination may lead to anti-competitive behaviour as the market equilibrium for a GI-labelled product could well be similar to a cartel equilibrium, characterised by a higher producer surplus, a lower consumer surplus and a substantial reduction of the overall surplus, that is the global economic welfare (see also Winfree and McCluskey, 2005).

Benavente (2010) explores the relationship between the size of the membership to the GI club, the quality of the product and the value of the club asset which the GI protection constitutes. She demonstrates that there could be an inflexion point in the size of the membership to a GI club of producers to an equilibrium level after which product quality decreases. Rangnekar, 2009a applies a club analysis to GIs protection for Goan Feni.

Musungu, 2008 has surveyed the economic literature to identify the principal advantages and disadvantages of GIs protection. His analysis is amplified by Coulet, 2012.

As with other distinctive signs, the economics underlying the protection of localized products is founded on the economic theories of information and reputation. These theories illustrate the importance of (1) preventing the market distortions that arise when there is asymmetry of information between producers and consumers and (2) averting the consequences of such asymmetry of information on the level of output quality (OECD, 2000). Reputation, as used studies of markets characterized by imperfect information (Stiglitz, 1989; Tirole, 1988), aids to an extent to overcome the market failure associated with asymmetry of information. However, the successful use of reputation to restore efficiency to the market through averting the consequences of information asymmetries requires that reputation be protected through a process which can be viewed as the “institutionalisation of reputation” (Belletti, 1999). Distinctive signs such as geographical indications can achieve this by institutionalising the relationship between the product and the region and/or tradition through the use of legal instruments that prevent the

misappropriation of benefits. Geographical indications can thus be viewed as the result of a process whereby reputation is institutionalised in order to solve certain problems that arise from information asymmetry and free riding on reputation. This highlights a fundamental feature of GIs protection i.e. that it functions as both a consumer protection measure (through addressing information asymmetries and quality) and a producer protection measure (through its role in protecting reputation as an asset) (OECD, 2000). Paus and Révion, 2011, note the difficulties which have been identified in measuring the economic impact of GIs research, but review the leading assessments based upon “objective methods”; diachronic evaluations (before/after historical approach) and synchronic evaluations “with/without approach). They note the particular difficulties of measuring impacts in emerging markets. Bramley et al, 2009 undertake an analysis of the economic impacts of GIs in developing countries.

SUI GENERIS GIs SYSTEMS

As will be seen in the writings in Part VI of this book the international debates on the protection of GIs involves a competition between the European sui generis model and the New World countries’ assertion that GIs can be adequately protected by trade mark and consumer protection laws.

The historical origins of GIs in the 19th Century French Appellation d'Origine Contrôlée (AOC) system is traced by Stanziani, 2004 and 2009. There is a voluminous scholarship on the modern European sui generis system. Van Leeuwen and Seguin, 2006 describe ‘the concept of terroir in viticulture and relate it to the protection of GIs’. The characteristic uniqueness of products which justifies their protection by GIs is described by French commentators as their “typicity”. As Allaire et al, 2011 explain that typicity requires a knowledgeable consumer interacting with producers who have an *air de famille*.

Relevant to the portability of the sui generis GIs system outside Europe are Casabianca et al, 2005 observations that establishing wine GIs can be complex process mentioning that identifying the 690 distinctive terroirs in the Burgundy area for Pinot Noir wines took centuries. On the other hand there is a body of quite detailed scholarship on the recent establishment of wine GIs in Australia (Stern and Fund, 2000; Anderson and Wood, 2006; and Aylward, 2008), some with a focus on the Coonawarra wine region in South Australia (Banks and Sharpe, 2006; Edmond, 2006; and Banks and Overton, 2010).

Beier and Knaak, 1994 contain the first descriptions of the modern European sui generis system. This is advanced by Gutierrez, 2005; Kur and Cocks, 2007; Teil, 2010; and Gragnani, 2012. The most recent EU legislation on GIs, particularly in relation to foodstuffs is described in Evans, 2010a; 2012 and in her 2013 writings. The impact of the EU legislation on national rights in EU member states is explored by Bently and Sherman, 2006. O’Connor and Kireeva, 2004 and Charlier and Ngo, 2012 survey the European case law on GIs. Evans, 2009 compares the jurisprudence of the European Court of Justice with the WTO Appellate Body.

The extra-territorial effect of the European GIs system is explored by Josel, 1994, Barham, 2003 and Marette, 2009. The specific conflict between European GIs and US brands is examined by Zacher, 2005, Hughes, 2006 and Evans, 2013. As a consequence of these disputes Ricolfi 2009b, asks whether the European GIs policy is in need of rethinking.

Relevant to the debate about the appropriate model for GIs systems, particularly in developing countries is Boisvert, 2006 who questions whether the AOC French model

can be exported to facilitate the conservation of genetic diversity and the promotion of quality foodstuffs.’

ALTERNATIVES TO SUI GENERIS GIs PROTECTION

The discussion about the extraterritorial impacts of the European GIs system and the complaint made to the WTO about the EU foodstuffs legislation by Australia and the USA has led to a number of writings on the trade marks system as an effective alternative to sui generis GIs protection. Gevers, 1990 is the pioneering piece on geographical names and signs used as trade marks. Corte-Real, 2005 uses an analysis of the Budweiser Case in Portugal to consider the tension between trade marks and geographical indications. Stern, 2001 looks at the overlap between geographical indications and trade marks in Australia. Ayu, 2006 extends this analysis of Australian law to the protection of GIs for products other than wines and spirits. Gangjee, 2007 reviews the principal conflicts between trademarks and geographical indications. US discussions of the role of trade marks in protecting GIs mainly focus upon wines (Lenzen, 1968; Maher, 2001; Silva, 2005; Hughes, 2006; Kemp and Forsythe, 2006; and Brauneis and Schechter, 2006).

The economic significance for the EU of its wine trade is of course at the heart of its concern to have GIs included in the TRIPS Agreement and for the additional protection and multilateral system of protection and registration for wines and spirits included in that agreement. An alternative approach which has been adopted by the EU to protect its wine and spirits industry is the negotiation of wine agreements with those countries with which it has had the greatest difficulties. Vivas-Egui and Spennemann, 2006, describe the inclusion of GIs within bilateral investment treaties. Josling, 2006 and Kemp and Forsythe, 2006 describe the wine disputes in the USA with Rose, 2007 assessing the 2005 wine agreement between the US and the EU. Blakeney, 2012 undertakes a similar analysis in relation to the Australian wine industry and explores the opportunity which the Australian wine agreements with the EU provides for the establishment of Australian wine GIs and for their marketing in Europe. Van der Merwe 2009 looks at GIs protection for wines in South Africa with particular reference to the EU.

The interface between trade marks and sui generis protection for GIs in developing countries is explored by Balganesh, 2002 (India); Kireeva and Vergano, 2006 (China, Thailand and Vietnam); Bashaw, 2008 (China); Ali, 2011 (Pakistan).

THE INTERNATIONAL DIMENSION

Unquestionably, a significant impetus has been given to GIs scholarship by the negotiations on the subject in the TRIPS Council. Article 23.4 of the TRIPS Agreement provides that: “In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system”. Article 24 of TRIPS provides in Article 24.1 that “Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23”. This provision, it will be recalled, provides “additional protection” for GIs in relation to wines and spirits.

Over the years some overlap has developed between the negotiations on the multilateral register and the so-called extension debate, as it has been argued that the multilateral register for wines and spirits could be extended to products beyond wines and spirits. This proposal was originally made in a submission by Turkey dating from 9 July 1999.^{lix}

This proposal was endorsed by the African group of countries. In a document from 6 August 1999^{lix} Kenya, on behalf of the African Group, noted that paragraph 26 of the WTO's Singapore Ministerial Declaration that the Article 23.4 negotiations concerning a multilateral register for wines had been extended to include spirits. Consequently, it was submitted in paragraph 27 of Kenya's communication on behalf of the African Group that since the Ministers made no distinction between wines and spirits the African Group took the position that the negotiations envisaged under Article 23.4 should be extended to "other products recognizable by their geographical origins (handicrafts, agro-food products)." In the meetings of the TRIPS Council held on 21 and 22 September 2000 the representative of Switzerland provided an example illustrating why the additional protection under Article 23 "was also needed for geographical indications other than those for wines and spirits pointing out that:

"Rice that was sold under the Indian geographical indication "Basmati", but which was clearly marked as originating from another region or country, would not mislead the public as to the place of origin of that product; nevertheless, such use would free-ride on the worldwide famous and therefore commercially valuable geographical indication "Basmati". The same applied with regard to the famous Swiss cheese "Vacherin Mont d'Or", for example. There was no systematic or logical explanation for the distinction made in Section 3 of Part II of the TRIPS Agreement and this distinction ignored that geographical indications for categories of goods other than wines and spirits were equally important for trade."^{lix}

As is pointed out in the writings in Part IV(b) of this book the negotiations on these subjects have been long and vigorously debated and continue without any resolution.

(a) TRIPS in the international GIs landscape

General descriptions locating the TRIPS GIs provisions in the international IP landscape abound. Comprehensive descriptions of these provisions at different stages of the international negotiations are contained in: Heald, 1996; Agdomar, 2008; Kireeva, and O'Connor, 2010. Paralleling this scholarship is Conrad, 1996; Blakeney, 2001a; Martin, 2004; Cortes, 2004a; Zou, 2005; Beresford, 2007; O'Connor & Co, 2007a; Echols, 2008; Geuze, 2009; Gangjee, 2012 and Munzinger, 2012. Land, 2004 seeks to provide an EU perspective on the TRIPS GIs provisions. Kazmi, 2001 relates them to NAFTA and Kongolo, 1999 to the agreement establishing ARIPO. Heath, 2005 also provides an international, regional and bilateral overview of TRIPS.

Almeida, 2005 locates the TRIPS Agreement within the philosophy of the WTO and Taubman, 2008, now a WTO functionary, specifically analyses the negotiations over GIs in a fair trade context.

(b) TRIPS Revision

The writings in Part VI(b) of the book deal with the tortuous negotiations in the TRIPS Council dealing with the issues of extension and the multilateral register. Adegbomire and Taylor, 2004 attempt to define the unclear boundaries of the debates. Similarly Rangnekar, 2002 reviews the GI proposals at the TRIPS Council after the WTO's Doha Ministerial in 2001. Murphy, 2003 castigates the "Conflict, Confusion, and Bias under TRIPs Articles 22-24." Blakeney, 2001b and 2006; Rangnekar, 2003; Calboli, 2006; Credditt, 2008 and Blakeney et al, 2012 set out the extension issues. Bowers, 2003 and

Staten, 2005 make the case against extension as opposed to Addor and Grazioli 2002 and Lang, 2006 who support the expansion of Article 23. Vincent, 2007 identifies the beneficiaries of extension. Evans, and Blakeney, 2006 and 2007 place the negotiations in their post Doha context, Banerjee and Majumdar, 2011 and Gangjee, 2012 bring the negotiations more or less up to date. Snyder, 2008 identifies potential conflicts under the U.S. constitutional and statutory regimes for TRIPS extension. Musungu, 2008 examines the strategic and policy considerations for Africa from the GIs negotiations. Cortes, 2004b characterises the negotiations as Old World/New World conflict. Cotton, 2007 merely considers it a conflict which has not been resolved for in excess of 120 years. Vivas-Egui, 2001 considers the implications for developing countries of the TRIPS Council negotiations on GIs in light of the WTO agricultural negotiations. Vittori, 2010 provides the perspective of the Global Coalition of GI Producers (origin).

(c) The WTO GIs Dispute

As mentioned above the EU GIs regime was the subject of a WTO dispute initiated by Australia and the USA. Lindquist, 1999, Haight, 2000, Hughes, 2006 and Nieuwveld, 2007 provide the US perspective on this dispute and Handler, 2004, 2006 and Handler and Burrell, 2011 provide an Australian perspective. Kur and Cocks, 2007 contains comments on this dispute from a European view point.

(d) Revival of the Lisbon Agreement

With the impasse in the negotiations to revise the TRIPS Agreement the World Intellectual Property Organization (WIPO) has dusted off its Lisbon Agreement for the Protection of Appellations of Origin and their Registration, 1958, which had primarily been of interest to European wine producing countries. Gervais, 2010 has made the case for “re-inventing Lisbon” but Zylberg, 2002 has questioned whether the Lisbon Agreement might be “a Violation of TRIPS”.

GIs AND DEVELOPING COUNTRIES

In the conflict between the EU and its New World opponents allies have been sought from the developing world and Part VII of the book identifies part of the body of scholarship which has been produced identifying the potential interests of developing countries in having GIs regimes. Révion, et al, 2009; Sautier, et al, 2011 look at the general role of GIs in the creation and distribution of economic value in developing countries. Zographos, 2008, now with WIPO, explores the role of GIs as a development tool, as does Bowen, 2010. Hughes, 2009; Anders and Caswell, 2009 carry forward Musungu’s, 2008 review of the benefits and costs of proliferation of GIs for developing countries. Yeung and Kerr, 2011 apply an economic analysis to question whether GIs are “a wise strategy for developing country farmers”. Grote, 2009 perceives an economic advantage for developing countries in environmental labelling. Bramley and Bienabe, 2012 survey the “considerations” around GIs in the developing world’.

Blakeney, et al, 2012 contains a 12 African case studies which seek to explore the advantages of GIs for the countries surveyed. One of those countries was Ethiopia which has opted for a trade marks based system to protect its origin products. Roussel and Verdeaux, 2007 and O’Kicki, 2009 look at the lessons which might be taken by developing countries from the Ethiopian branding of its high quality coffees. Further case

studies are contained in Part VIII of this book. Kolady, et al, 2011 examine the economic effects of GIs on developing country producers of Darjeeling and Oolong teas..

CASE STUDIES

An important tool in the evaluation of the benefits or the detriments of GIs protection, particularly in developing countries, is the results of case studies of specific industries in those countries. Indeed, Blakeney, et al, 2012 arose out of a project to generate empirical evidence about the value of GIs for countries of the African, Caribbean and Pacific (ACP) Group “to generate empirical evidence, based on country/sub-regional and product case studies, regarding the benefits that African members of the ACP Group can obtain from enhanced multilateral Geographical Indication (GI) protection as a basis for the African Group to engage in the Doha negotiations on the establishment of the multilateral register for wines and spirits and the proposed extension of protection to products other than wines and spirits under Article 23 of TRIPS.”^{lix} The project was designed to produce “a replicable methodology for analysing the dynamics of capturing economic value out of GIs; access to GI-protected products by local populations; the role of government in the GI framework; the costs of establishing and administering a GI regime in a country; and the costs of developing, registering and enforcing individual GIs.”^{lix} This methodology is intended to be applied in other ACP regions. An ACP-EU Regional Workshop on the protection of GIs held in Cape Town with the collaboration of ARIPO, 10 – 11 May 2010 in considering “GIs Experiences in African ACP Member States”, received reports on Vanilla from Madagascar, Bark cloth from Uganda and Argane oil from Morocco. A similar workshop organised under the auspices of OAPI in Douala, Cameroon, 27 – 28 April 2010 discussed the GIs potential of Penja white pepper, Cameroon (Poivre blanc du Penja), Onions from Dogon, Mali (Echalote du Pays Dogon), Attiéké from Grand-Lahou, Côte D’Ivoire, Korhogo cloth - Côte d’Ivoire and products of Argan trees in Morocco.^{lix}

These ACP projects were funded by the EU within its aid programme under the the Partnership Agreement between the members of the ACP Group of States and the EU, signed 23 June 2000 (Cotonou Agreement) for a twenty-year period from March 2000 to February 2020. The garnering of political support for the EU’s position on GIs in the TRIPS Council and WIPO might be an incidental result of this activism.

A number of case studies have been conducted by European-based research institutes to identify the opportunities and pitfalls related to GIs. The Royal Tropical Institute (KIT) Amsterdam and the French Agricultural Research Centre for International Development (CIRAD), Montpellier, published case studies of: Gari Missè in Benin, Mantecoso cheese in Peru, Rooibos tea in South Africa, Costa Rican Arabica coffee and Comté cheese in France (Kop et al, 2006). Barham and Sylvander, 2011 is largely derived from an EU project conducted from 2000-2004: “the Development of Origin Labelled Products, Innovation and Sustainability (DOLPHINS)” which looked at the organization and management of supply chains for GIs. The researchers involved in the DOLPHINS project subsequently collaborated in another EU-funded project, under the punning acronym SINER-GI (Strengthening of International Network Research on GIs) 2005-2008 which sought to examine the global impacts impact of GIs and particularly their impact in developing countries. The book contains six European case studies which are reproduced in an appendix: Cherry of Lari (Italy), L’Évitaz cheese (Switzerland), Cariñena wine (Spain), Roquefort Cheese (France), Salumi Tipici Piancentini (Italy) and

Beacon Fell Traditional Lancashire Cheese (England). Musungu, 2008 reported that through a cooperation agreement between the French National IP Institute and OAPI the following products are being developed as GIs: Oku white honey and njombe pepper from Cameroon; Atcheke of Grand Lahou and the Khorogho garment from Coted'Ivoire; Diama coffee and the Mafeya pineapple from Guinea; and Massina Kwite butter and the Souflou green beans from Burkina Faso.

Switzerland has played a leading role in urging the extension of the additional protection for GIs for wines and spirits to other products. The Agri-food and Agri-environmental Economic group (Institute for Environmental for Environmental decisions- IED) of ETH Zurich conducted seven case studies in different parts of the world (see El Benni and Réviron, 2009): Argan Oil – Morocco; Cashmere Wool – Mongolia; Coffee – Colombia and Costa Rica; Habana Cigars – Cuba; Rooibos Tea - South Africa; and Mexico - Tequila. These case studies were then deployed in a paper supporting GIs for developing countries (Réviron, Thevenod-Mottet and El Benni, 2009).

Augustin-Jean et al, 2012 edited a recent collection of paper on the implications of GIs protection for Asia. This includes case studies of Japanese Sake and Kobe and Matsusaka beef; specialty rice in Ifugao Province of the Phillipines and Jinhua Ham from China.

The International Trade Commission (Giovannucci, et al, 2009) has sought to demystify GIs with an analysis of the and evidence from eight case studies: Antigua Coffee, Guatemala; Darjeeling Tea, India; Gobi Desert Camel Wool, Mongolia; Blue Mountain Coffee, Jamaica; Kona Coffee, Hawaii; Mezcal, Mexico; Café Nariño, Colombia; and Café Veracruz, Mexico. Some of these appear in Part VIII of this book which contains a selection of the case studies conducted under the auspices of the above projects and case studies by independent scholars. Eliminated from selection were those case studies prefaced by extensive discussions of the international legal framework for GIs regulation which have already been detailed in other parts of the book and those which are replicated in the studies published here. Two case studies are selected from Europe: Prosciutto di Parma and Parmigiano Reggiano cheese (Arfini, 2000) and French Cassis (Gade, 2004) and one from the USA: Kona Coffee, Hawaii (Giovannucci and Smith, 2009). The balance of the case studies are of industries in developing countries: Boseong green tea from Korea (Suh and MacPherson 2007); Jasmine rice from Thailand (Kuanpoth and Robinson 2009); Gobi Desert Camel Wool (Oosterom and Dévé 2009); Kashmiri Handicrafts (Mir and Ain 2010); Moroccan Argan Oil (Réviron and El Benni, 2012); Meijiawu Dragon Well (Longjing) tea from China (Chan, 2012).

A general review of developing country cases is contained in Russell, 2010.

One case study subject which has attracted a good deal of attention is in relation to Basmati rice from the Indian Sub-continent. Blakeney and Lightbourne, 2005, first drew attention to the possibility of protecting Basmati as a GI as a means of protecting the traditional knowledge surrounding the product. This was followed up by Chandola, 2006 who was concerned about the misappropriation of this indication by US rice producers. Jena and Grote, 2012 undertake an “impact evaluation” of traditional Basmati rice cultivation in Uttarakhand State of Northern India to identify the implications for GIs. Rangnekar. and Kumar, 2002 consider the dual issues of Basmati genericity and the problems of the GI as a transborder issue between India and Pakistan. Marie-Vivien, 2008 glides over this latter problem in her examination of looks at the relationship between the plant variety right designation for Basmati and “the India/Pakistan” GI. Mulik and Crespi, 2011 has been included as the case study of Basmati because of its particular focus on the rice export trade.

Among other useful case studies, covered by extracts in this book are: Parmigiano Reggiano Cheese (De Roest and Menghi, 2000); Comte Cheese in France (Colinet et al, 2006); Tequila (Bowen and Zapata, 2009); and Prosciutto di Parma (Dentoni et al, 2012). Finally, mention should be made of the case studies of Zagora apples from Greece (Foutopolis and Krystallis, 2003); Virovitica pepper from Croatia (Radman et al, 2006); Ladotyri Mytilinis cheese from Greece. Finally, a comprehensive case study which combines empirical analysis with economic doctrine is Rangnekar, 2009a, which examines Goan Feni.

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M. BLAKENEY, GEOGRAPHICAL INDICATIONS AND ENVIRONMENTAL PROTECTION,
(2017) 12(2) *Frontiers of Law in China* 162-173, ISSN: 1673-3428

Abstract The protection of geographical indications (GIs) is required of all members of the World Trade Organization (WTO), as this is mandated by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Among the primary justifications for the protection of GIs is to enable producers to secure the premium prices which are attracted by products which have a unique quality that is attributable to their place of production. As this article

points out, one reason for this premium price, in the case of agricultural products is that traditionally produced goods are often free from contaminants, such as herbicides and pesticides. Not previously discussed in the literature is the fact that from an environmental protection perspective, GIs applied to agricultural products provides some consumer confidence in their purity, as well as in their traceability. In securing higher returns for agricultural producers, GIs play an important role in securing rural development and the maintenance of rural landscapes. Finally, the article points out that the international GIs regime provides an important means of protecting the traditional knowledge of agricultural producers.

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INTRODUCTION

Geographical Indications (GIs) are signs used to designate the place of origin of goods where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin. The obligation of countries to protect geographical indications is contained in Article 22.2 of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This provision requires WTO Members to provide the legal means for interested parties to prevent:

(a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;

(b) any use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (1967).

GIs are particularly advantageous for the producers of agricultural products in allowing them to differentiate their products from general commodity products such as rice, coffee and tea, thereby enhancing market access.^{lix} At the same time a number of researchers have identified the capacity of GIs to capture premium prices because of the higher value that some consumers attach to products differentiated according to their origin. For example, Babcock reported that Bresse poultry in France received quadruple the commodity price for poultry meat^{lix}; a case study by Gerz and Dupont of Comté cheese in France indicated that French farmers receive an average of 14% more for milk destined for Comté and that dairy farms in the Comté area since 1990 are 32% more profitable than similar farms outside the Comté area.^{lix} Kireeva et al, examining the use of origin marks in the Peoples Republic of China reported that the price of “Zhangqiu Scallion” per kilogram was raised from 0.2 - 0.6 yuan before the use of the origin mark to 1.2 - 5 yuan in 2009.^{lix} “Jianlian” lotus seed was registered as a GI in 2006, leading to a rise in price from 26-28 yuan per kilogram to 32-34 yuan per kilogram.

The principal reasons which have been identified for GI-marked goods attracting premium prices, is that consumers prize their exoticism^{lix} and the greater care which has gone into their production compared with undifferentiated commodity products.^{lix} Another factor, which this article will examine, is the increasing realisation that traditionally produced goods are often freer from contaminants, such as herbicides and pesticides and that GIs applied to these goods provides confidence in their traceability.

I. CERTIFICATION OF ENVIRONMENTAL PRODUCT QUALITY

GIs can play an important role in signalling the quality of goods.^{lix} They are important in signalling credence attributes, particularly as an origin brand will be underpinned by a registration and certification system. These will be administered by a producers association, which will secure compliance with agreed production standards. Producers can thus signal quality and the associated reputation that has been developed over time^{lix} and which is incentivised by the premium prices attracted by a GI to maintain product quality.^{lix}

Of course, in order for the perceived benefits of GI labelling to be realised, such as the promotion of environmental sustainability, there needs to be consumer awareness that origin labelling represents qualities linked to natural and human factors. This ties in with the consumer demand for traceability in agrifood products.^{lix} Rural product certification schemes have proliferated since the mid-1990s. They include the certification of organic agriculture, fair-trade certification of products from developing countries and food produced in compliance with sanitary and traceability protocols.^{lix} Consumers have been identified as placing increasing value on the integrity of food, such as the social and environmental standards involved in the production and processing of agrifood products.^{lix} This is particularly the case following recent food safety crises. As it is not unusual for food to be grown, processed and packaged in different places consumer trust in products is eroded, particularly as a consequence of these crises. Studies indicate a willingness of consumers to pay a premium price to producers who offer transparency in relation to the composition and origin of their products. In situations where uncertainty about quality or safety is elevated, such as in a health crisis, origin labelling can become an important means of inferring product quality, eg meat labels after the BSE crisis in Europe^{lix} Lees, 2003 and dairy product labels after the Chinese Melamin crisis.^{lix}

Concerns about the safety of agrifoods in China has stimulated an interest in mechanisms for assuring traceability in food chains.^{lix} In this context GIs “may convey assumed ‘local’ (traceability) and ‘natural’ (nutritiousness and safety) characteristics thereby acting as proxies for quality”^{lix}

In Europe, where GIs have been longest developed, there are some empirically based suggestions that consumers' and producers both have expectations of about the quality of origin products in the European market.^{lix} However, studies indicate that although in shaping the quality of the product European producers have not not necessarily specifically address positive environmental effects in the way in which they have formulate product specifications, more recently there has been a “greening” of product specifications reflecting environmental considerations.^{lix} Thus, GIs “provide the

opportunity for territorialisation of environmental-friendly production rules, taking into account local specificities”^{lix}.

II. SUSTAINABLE USE OF NATURAL RESOURCES AND BIODIVERSITY CONSERVATION

The current literature on GIs does not directly address their environmental implications. Bramley and Bienabe observe that environmental sustainability was not the primary aim of GIs development, but the fact that GIs derive from local, including natural, resources means that environmental benefits are increasingly seen as a positive potential GI externality.^{lix} Responsible environment stewardship has been mentioned by policymakers as a justification for GI protection.^{lix}

Indeed, the evolution of the specifications of origin products are the result of long-standing farming practices involving a composite of agricultural, cultural and environmental practices.^{lix} Traditional crop management practices have been identified as a rich resource for understanding the interactions between biodiversity and ecosystem function to identify the principles needed to develop more sustainable agricultural systems.^{lix}

The codes of practices which are collectively adopted by producer associations for the purpose of origin labelling often incorporate biodiversity objectives.^{lix} Biénabe et al, refer to the Rooibos industry in South Africa as an example of an industry which has explicitly considered biodiversity concerns in designing its product specifications.^{lix} This is because Rooibos production takes place in a biodiverse and environmentally sensitive area.

With greater knowledge of the interdependence between agricultural products and the local environment, producer associations also have a greater awareness of threats to the environment in production practices.^{lix} Consequently, it is suggested that the “GI registration process can be expected to have a positive impact upon the key components of ecological embeddedness and, in particular, on the way actors involved in the chain address the ecological elements of food production....”^{lix}

Kop et al point out that as the registered Comté PDO specifications limit the intensification of farming, so farmers use fewer inputs and the environment is better protected, contributing to maintaining the open landscape of both pasture and woodland that is typical of the Jura region.^{lix} Profitable traditional livestock raising in the Comté area has limited the loss of pastureland to 7% in the GI-approved area, compared with 18% in the non-GI area.

Belletti et al in their empirical study of the European olive oil industry, which is characterised by an extensive use of GIs, identify this industry as a good example of agriculture with many associated positive environmental impacts such as lower rates of soil erosion, improved fire-risk control, water efficiency, lower pollution and higher levels of biodiversity and genetic diversity in olive-tree varieties.^{lix}

Lamarque and Lambin, in a study of cheese producers in the French Alps marketing their cheese as “Tomme de Savoie” and “Emmental de Savoie”^{lix}, found that farmers used GIs to attract price premiums and generally adopted environmentally sustainable cropping practices.^{lix} However, it was conceded that the data from this study might be skewed by the effect of product subsidies under the European Common Agricultural Policy.

Williams has suggested that the producers of origin products are encouraged to act in a responsible manner towards the local environment as negative publicity would damage the product's image in the mind of the consumer.^{lix} Thus producers are likely to be concerned with environmental factors such as pollution and sustainable management of natural resources.

However, it is also important to point out that the success of an origin product may lead to an increase in demand and therefore to increased pressure on local resources. Sustainable production guidelines need to be agreed upon by means of a participatory process in order to prevent pressure being placed on fragile environments and to ensure in particular that the GI does not lead to "genetic erosion".^{lix}

Rural sustainability achieved through the preservation of biodiversity, landscapes, and traditional knowledge may be promoted by the protection of GIs.^{lix} For example, Guerra has observed that in the Mexcal region of Mexico the Agave sugar needed to make Tequila is cultivated and managed from wild or forest Agave species, which encourages the biodiverse Agave species.^{lix} GIs can also serve as a tool for encouraging sustainable agricultural practice by legally limiting the scale of production and production methods. Penker notes that origin products impose an increased responsibility of producers to their place of production.^{lix} Lampkin et al, have noted that "organic standards provide a mechanism by which farmers pursuing sustainability goals can be compensated by the market for internalizing external costs".^{lix}

Larson has analysed 30 case studies in both developed and developing countries, concluding that GIs can promote biodiversity conservation both directly, through the use and conservation of specific genetic resources, and indirectly, through the management of the rural landscape and ecosystem.^{lix}

In general, the studies indicate that the development of GIs as a tool for biodiversity and environmentally sustainable land use management is more effective when there is a consensus among all actors in the supply chain as to the definition of the relevant geographical area, agricultural practices, product specifications and the collective objectives of those actors.^{lix}

III. RURAL DEVELOPMENT

One of the justifications advanced for the establishment of an early GIs system for the protection of wines produced in France was the role that they played in preserving agriculture and rural employment in areas which were unsuitable for cereals and other crops.^{lix} The maintenance and promotion of rural development has been repeatedly advanced as a justification for GIs.^{lix} However, more empirical, rather than theoretical evidence is required to establish this justification. Most of the case studies come from France, Italy, Portugal, Greece and Spain which until recently account for three quarters of the GIs found in Europe.^{lix} The protection of GIs accords with the EU policy on rural development. Recital 4 to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs, governing GIs identifies that:

Operating quality schemes for producers which reward them for their efforts to produce a diverse range of quality products can benefit the rural economy. This is particularly the case in less favoured areas, in mountain areas and in the most remote regions, where the farming sector accounts for a significant part of the economy and production costs are high. In this way quality schemes are able to contribute to and complement rural development policy In particular, they may contribute to areas in which the farming sector is of greater economic importance and, especially, to disadvantaged areas.^{lix}

The creation of local jobs through the protection of GIs is a factor influencing rural exodus^{lix} n increase in employment has for example been observed for the Comté cheese industry. Kop et al estimate that the production of Comté cheese generates five times more jobs in processing, maturing, marketing, packing, etc. than does its generic equivalent, Emmental and that migration away from the countryside in the Comté area is only half that of the origin-protected area.^{lix} They estimate that at the national level, although Comté cheeses account for only 10% of total French cheese output, they are responsible for 40% of the job offers for students who have been trained in cheese-making in vocational schools. Similar results have been identified for origin protected cheeses supporting the milk supply from cattle in Northern Italy and the sheep of Southern Italy.^{lix}

However, in the interests of maintaining environmental sustainability, the commercial attractiveness of GI-protected products should be balanced against maintaining rural landscapes.^{lix} The Comité Interprofessionnel du Vin de Champagne has requested "The landscapes of the Champagne region" to be included on UNESCO's World Heritage List.^{lix} The objective is to protect the famous sites of the Champagne region, which include the great diversity of vineyards and the outstanding character of the area's cellars carved from the surrounding chalk and the unique landscapes of the Champagne region. Similarly, Blakeney has pointed to the value to Mauritius in preserving its sugar field landscapes in maintaining their attractiveness for tourism, which has become an important secondary industry.^{lix}

IV. AIDING THE PRESERVATION OF TRADITIONAL KNOWLEDGE

Bérard and Marchenay describe GIs as a means of "enabling people to translate their long-standing, collective, and patrimonial knowledge into livelihood and income" which may also underpin the maintenance of biodiversity.^{lix} It has been pointed out by a number of authors that GIs share many of the characteristics of traditional knowledge (TK) as both seek to preserve communal rights and like TK GIs can be held in perpetuity, for as long as a community maintains the practices which guarantee the distinctive quality of a local product.

Panizzon and Cottier observed that

Traditional Knowledge (TK) and Geographical Indications (GIs) share a common element insofar as they both protect accumulated knowledge typical to a specific locality. While TK expresses the local traditions of knowledge, GIs stand for specific geographical origin of a typical product or production method. GIs and TK relate a product (GIs), respectively a piece of information (TK), to a geographically confined people or a particular region or locality.^{lix}

Similarly, in its Review of Existing Intellectual Property Protection of TKlix, WIPO's IGC Secretariat explained that

GIs as defined by Article 22.1 of the TRIPS Agreement and appellations of origin, as defined by Article 2 of the Lisbon Agreement ... rely not only on their geographical connotation but also, essentially on human and/or natural factors (which may have generated a given quality, reputation or other characteristic of the good). In practice, human and/or natural factors are the result of traditional, standard techniques which local communities have developed and incorporated into production. Goods designated and differentiated by geographical indications, be they wines, spirits, cheese, handicrafts, watches, silverware and others, are as much expressions of local cultural and community identification as other elements of traditional knowledge can be.^{lix}

Three examples provided by the Secretariat of TK protected by GIs are: 'Cocuy the Pecaya' liquor from Venezuela, 'Phu Quoc' fish sauce and 'Shan Tuyet Moc Chau' tea, both from Vietnam.^{lix}

It has been suggested that GIs are more a means for "preserving rather than protecting" traditional knowledge.^{lix} However, from the perspective of environmental sustainability this is a desirable result.

CONCLUSION

It is increasingly realised that the environmental attributes of an agricultural product can play an important part in its appeal to consumers. From the perspective of producers, the GI registration system provides the opportunity to incorporate the environmental attributes of products into the product specifications. The authorities involved in GI protection can play an important role when requiring producers to substantiate the link between product quality and the territory of production to include environmental factors in the formulation of product specifications.

An even more activist role can be taken by the public authorities in developing GIs on behalf of agricultural communities. An example of this is the development by the Department of Horticulture (DoH) of the government of Karnataka in India of a GI for Coorg orange (Kodagina kittale, *Citrus reticulata*), an ecotype of the mandarin orange.^{lix} This variety had almost disappeared because of diseases and lack of interest among farmers eager to involve themselves in more lucrative cash crops: coffee and pepper. The DoH filed a GI application for a "Coorg Orange", which was registered in 2004. Among the objectives of the DoH were to protect and revive a traditional crop variety and to provide high quality (disease-free) plant material, bringing economic development to the region and protecting the ecosystem where the orange is grown.^{lix} The strategy of the DoH is to educate the local farmers about the GI and then to gather them in a registered society to which the ownership of the GI will be transferred.

Public policies can also play an important role in promoting the linkage of product qualities with environmental factors. This can be done through educational initiatives to explain the importance of these factors in the design of product specifications, labelling and marketing; assisting research and development activities and the promotion of environmentally sensitive agricultural techniques. The public authorities can also require

the elaboration in product specifications of the environmental stewardship which is required to preserve the biophysical attributes of the *terroir*^{lix} associated with the unique characteristics of products. *Terroir* is linked to the unique biophysical and cultural properties of specific places for example, microclimate, geological features including soil type, altitude, latitude and indigenous plant species.^{lix} The notion of *terroir* also embraces the cultural and agricultural practices that have maintained biological diversity and landscapes over multiple generations.^{lix} Thus the need to maintain *terroir* attributes of goods to qualify for GI protection over the long term inevitably requires the adoption of environmentally sustainable land-use practices.