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Editorial

Special Issue on the Sustainable Regulation of Biotechnology

This double issue of the *Asia Pacific Journal of Environmental Law* is devoted to an investigation of the sustainable regulation of biotechnology from a range of interdisciplinary perspectives. As an environmental law journal, we focus on the release of genetically modified organisms (GMOs) into the environment. The potential risks presented by the release of GMOs include the impact on non-target organisms; gene transfer into related species; persistence or invasiveness of GM crops; presence of antibiotic resistant genes; and a range of concerns in relation to human health. Yet precisely what is needed to manage these potential risks, if they are indeed risks, is deeply contested, as are the underlying ethical issues. The sustainable regulation of biotechnology is challenging governments and regulatory agencies across the globe. This special edition of the Journal addresses the challenges from the perspectives a scientist, an economist, a social scientist and a non-governmental organisation, and it investigates the legal frameworks in China, Australia, the European Union, the United States, New Zealand and the Philippines.

This edition of the journal has its origins in a conference entitled "The Sustainable Regulation of Biotechnology" organised by the Australian Centre for Environmental Law Sydney (ACEL Sydney) held in July 2004. The conference was part of the AC21 International Forum, *Universities, Cities and Society in the 21st Century*, hosted by the University of Sydney. In addition to the University's support, the conference was generously supported by PriceWaterhouseCoopers Legal, which provided the conference venue and supporting facilities. Paul Gilding, founder of the Ecos Corporation and sustainability strategy consultant, opened the conference. The keynote speaker at the conference was Professor Alan Irwin, then Pro Vice-Chancellor (Research and Enterprise) and Dean of Arts and Social Sciences, Brunel University, London. Professor Irwin is an internationally renowned expert in science-public relations and environmental policy-making. International perspectives on regulating biotechnology were presented by Professor Wang Xi, Associate Dean of Shanghai Jiaotong University's School of Law, Director of the

University's Environmental and Resources Law Institute and legal advisor on biosafety to the Chinese government, and David Morgan, Visiting Fellow in the Department of Politics, University of Melbourne. David examined key issues arising from the interaction of WTO rules and regulation of GMOs. Australian perspectives were provided by the Office of the Gene Regulator (Michael Munro-Mobbs), by industry (Dr John Mason, Florigene Ltd) and Greenpeace (Jeremy Tager). Three University of Sydney academics also presented papers. Rosemary Lyster, Director of ACEL Sydney, presented a comparative perspective on legal frameworks in the European Union and the United States for regulating GMOs. David Kemp, Professor of Farming Systems in the Centre for Rural Sustainability, discussed the place of biotechnology within agricultural systems and Associate Professor Fredoun Ahmadi-Esfahani, Discipline Leader, Agricultural and Resource Economics in the Faculty of Agriculture, explored whether or not the regulation of agricultural biotechnology is economically justified.

Most of these conference papers are included in this edition of the Journal. Also included are perspectives from New Zealand, by Nicola Wheen, Senior Lecturer in Law, University of Otago, and from the Phillipines, by Manuel Solis, a Philippines solicitor.

Our investigation of sustainable frameworks for regulating biotechnology begins with the scientific perspective provided by Professor David Kemp. In his article "Biotechnology Regulation: GMOs, Agriculture, Science and the Environment", Professor Kemp observes that, unlike in medicine where there appears to be little debate about the merits of biotechnology, in agriculture the debate is often intense. Professor Kemp uses an ecosystem approach to assess possible impacts of GMOs on the functioning and biodiversity of ecosystems. From his overview it emerges that from an agricultural science perspective the area where a GMO may have an effect is more likely to be in biodiversity than in altering land use or affecting water, nutrient or energy flows in the ecosystems. His insights raise the issue of how best to regulate the use of GMOs. Professor Kemp discusses the framework used for making scientific decisions and contrasts this with the precautionary principle. The limitations of the precautionary principle and the nature of the errors involved are highlighted. It is argued that a better approach to evaluating the release of GMOs is to do a comprehensive benefit/cost analysis incorporating the cost of incorrect decision-making.

The perspective of an agricultural economist is provided by Associate Professor Fredoun Ahmadi-Esfahani in "Is Regulation of Agricultural Biotechnology Economically Justified?" His article provides an overview of the economics of agricultural biotechnology regulation. Supply issues, including the cost of regulation on biotechnology companies and on further development of the biotechnology

sector, are considered. On the demand side, agricultural biotechnology companies, environmental groups and other interest groups appear to have concerns that diverge from those of consumers and producers, and are likely to exploit private information strategically to enhance their position, leading to a need for regulation. Also addressed is the distribution of benefits of biotechnology stemming from the pricing power of biotechnology companies, the nature of intellectual property rights and regulation of multinational corporations monopolising supply of biotechnology products. The political economy of protection is postulated to be an important determinant of the direction of both national and international biotechnology regimes, implying that there are local, regional and global considerations which may distort the process of developing an effective framework for regulation.

Professor Alan Irwin's article "Scientific Governance in Europe: Towards a Critical Perspective" begins with the European paradigm of public anxieties around science and technology. Europe, it seems, has assumed the role of technological sceptic and risk critic. This has made it progressively harder for policy makers and regulators in Europe to ignore public opinion or take it for granted. In this situation, many European nations have undertaken institutional initiatives aimed at opening up political processes to societal views and achieving some form of wider engagement with science and technology. Professor Irwin considers the relationship between the drive towards deliberation and more conventional modes of science policy-making. His aim is to look more analytically at what all this "talk about talk" has meant for governance practice. He considers three broad frameworks for understanding the current state of policy practice and discussion: the sequential model, in which there is a steady shift from the old expert-driven style of scientific governance to a new approach based on public participation and engagement; the heterogeneous model, which better captures the co-existence of several policy modes; and the critical model, which raises more fundamental questions about scientific governance, taking us beyond the specifics of institutional practice. Professor Irwin concludes:

> The principal purpose of public engagement in science and technology should not be to restore public trust or to ease the way for innovation... Instead, the purpose should be to facilitate democratic and open scrutiny of a major (perhaps *the* major) force for social change in our societies. One important aspect of this wider scrutiny and questioning will be consideration of the limitations of conventional democratic politics in addressing the international challenges of technical change. Current approaches to deliberative governance may represent a start to that larger consideration. Certainly, they are not an end point.

Following these interdisciplinary perspectives, the Journal presents various legal perspectives on the sustainable regulation of biotechnology. Professor Wang Xi, Qin Tianbao and Fu Lu provide readers with a comprehensive insight into China's law and practice in relation to the Cartagena Protocol on Biosafety. China has actively

promoted research, development and industrialisation of biotechnology. At the same time, it has actively participated in the negotiation and implementation of the Biosafety Protocol and put in place its own legislative framework for biosafety regulation. The authors explore the influences on China's accession to the Protocol from the perspective of biotechnology development and international trade and from the perspective of China's environment and human health. They trace the contours of the debate in China leading up to China's accession. The article outlines China's biosafety legislation and instructively uses two cases to highlight issues in its implementation. Central to both cases is the transnational dimension.

Jeremy Tager and Bob Phelp's article "A Critique of the Australian Gene Technology Act and its Implementation" provides a critical NGO perspective on biotechnology regulation in Australia. The authors claim that although the Australian legislation was introduced with promises that it would streamline and formalise a previously ad hoc system, would be rigorous and would meet community demands for enforceability, accountability and transparency, it has failed on all counts. They are of the view that without significant changes to the Act and the manner in which it is implemented, the conflicts surrounding the introduction of GM crops and other organisms in Australia will become more publicly divisive. The authors take particular issue with the ideological underpinnings of the legislation and the role of the Office of the Gene Technology Regulator (OGTR) in implementing the Act. The authors claim that the Act fails to impose the polluter pays principle on the developers of GMOs; that the OGTR's risk assessments, risk management and implementation processes are extremely poor; that relationships between the Federal and State governments with respect to assessment and regulation remain unclear; and that there are regulatory gaps. They also address the concerns of non-GE farmers in relation to crop contamination.

Rosemary Lyster's article "Sustainability, Regulatory Dilemmas and GMOs: The US and the EU Compared" picks up on a number of themes explored in Alan Irwin's article. She insists that the regulation of GMOs must adhere to the principles of sustainable development including the principles of intergenerational equity, the conservation of biological diversity, the precautionary principle, and the polluter pays principle. Public participation is another essential element in the sustainable regulation of GMOs, as endorsed in the Rio Declaration, Agenda 21, and the Convention on Biological Diversity – the international environmental instruments establishing the foundations of sustainable development. In this light, Lyster analyses the regulatory frameworks in the United States and the European Union. Her analysis highlights markedly different regulatory frameworks. Regulation in the US falls short of the sustainability benchmark, while regulation in the EU seems entirely consistent with it. Yet, in the US, there is little public concern about the fact

that 81 per cent of soybeans, 40 per cent of corn, 73 per cent of cotton and over 50 per cent of canola and papaya are derived from GMO seeds. The Grocery Manufacturers of America estimates that 70 per cent of food on grocery shelves is GM food. This can be contrasted with general scepticism in the EU about GMOs and GM food despite extensive Directives and Regulations, which require detailed environmental risk assessment before the release of GMOs into the environment and the introduction of GM food onto the market. Lyster argues that given the scientific uncertainty about the risks inherent in the use of GMOs, and public attitudes to them, there is an urgent need to penetrate the "GM psyche" of a nation. She argues that it is time to develop a more extensive and cohesive interdisciplinary research project to help explain a nation's GM psyche and shape appropriate regulatory responses to it.

Nicola Wheen's article "Genetic Modification, Risk Assessment, and Maori Belief under New Zealand's *Hazardous Substances and New Organisms Act* 1996" assesses the restrictive approach adopted by the New Zealand government to genetic modification. There have been no deliberate releases of genetically modified organisms into the environment, for commercial or any other reasons. However, agriculture is New Zealand's most important industry, and considerable pressure to test and release genetically modified organisms has arisen and seems likely to increase. Wheen analyses New Zealand's *Hazardous Substances and New Organisms Act* 1996, enacted to control the development, importation and testing of genetically modified organisms. Importantly, regulation incorporates social and cultural as well as scientific and economic values. Her article examines the decision-making record of New Zealand's Environmental Risk Management Authority concerning proposals to develop and field-test genetically modified cattle. This examination finds that the Authority's approach overvalues science and undervalues cultural and social issues, and suggests that this could result in the Authority losing the necessary community confidence to support the deployment of biotechnology in New Zealand.

David Morgan's article "International Trade Rules and the Implications for Biotechnology Regulation" addresses one of the most critical issues confronting all domestic attempts to regulate GMOs; namely, the potential impact of international trade rules, especially those agreed by the members of the World Trade Organisation (WTO), on a nation's sovereign right to regulate GMOs. This question has an immediacy because of the dispute in the WTO in which the US, Canada and Argentina have challenged a *de facto* moratorium in the EU, and associated bans by EU Member States, on genetically modified (GM) food and feed. Further, US industry has lobbied for a WTO challenge to the EU's labelling and traceability requirements for GM food. Like Irwin and Lyster's articles, Morgan reflects on the different philosophies underlying domestic regulation of GMOs in the EU and US.

His article sets out the key rights and obligations in the relevant WTO Agreements and multilateral environment agreements (MEAs) and examines attempts to develop international standards in the Codex Alimentarius Commission and the Interim Commission on Phytosanitary Measures. This leads to an examination of some of the contentious issues. Which WTO agreements apply to regulation that has multiple purposes? Are GMOs "like products" to their non-GM counterparts? Should labelling of GM foods be mandatory? How should the rights and obligations in MEAs, especially the Biosafety Protocol, influence the interpretation and implementation of rights and obligations contained in the WTO Agreements? And what is the relationship between the precautionary principle and the WTO Agreements? In conclusion, Morgan suggests that it is possible for governments to meet their obligations and exercise their rights under both the WTO Agreements and MEAs. He observes that recent trends in WTO jurisprudence, according substantial deference to environmental and other domestic regulatory policies, suggest that some of the fears of critics of the WTO are misplaced. He concludes that a negotiated solution to the problems arising from the regulation of GMOs seems a better, albeit unlikely, alternative to resolution through litigation.

In the final article, "Harvest for the World: Notes on Modern Biotechnology Regulation in the Philippines", Mauel Solis analyses the regulation of biotechnology in the Philippines as a developing country – the fragmented institutional arrangements and the system for risk assessment, public participation, decision-making and review. He tests the system against the precautionary principle and the need for transparency and coherence, particularly in balancing the competing needs of environmental protection, public health and safety and food security. Solis concludes that the Philippines has taken a relatively less cautious attitude despite being highly vulnerable. National policy is geared towards embracing the perceived benefits along with the potential risks. Yet its regulatory framework and institutional capacity is weak.

We believe that this issue of the Journal makes a substantial contribution to the scholarship in the Asia Pacific region concerning the sustainable regulation of biotechnology. We look forward to continuing the discussion in future issues.

ROSEMARY LYSTER AND NICOLA FRANKLIN
Co-Editors in Chief