Releasing genetically modified canola into the environment – deconstructing a decision of the Gene Technology Regulator under the Gene Technology Act 2000 (Cth)

Charles Lawson and Richard Hindmarsh*

This article deconstructs the decision of the Gene Technology Regulator to grant a license to Bayer CropScience Pty Ltd for the commercial release of genetically modified canola under the Gene Technology Act 2000 (Cth). The purpose of the article is to challenge the "science-based" decision making advocated by the Act that in practice relies almost exclusively on qualitative assessments by the Regulator. The article concludes that while more "science" will enhance the Regulator's decisions, this "science" alone is not enough to avoid a further loss of legitimacy with regard to the current regulation of commercial and general releases of genetically modified organisms (and genetically modified products) into the environment.

INTRODUCTION

The legislative intervention under the *Gene Technology Act 2000* (Cth) (the Act)[1] to formally regulate organisms[2] modified through "gene technology"[3] (genetically modified (GM) organisms, or GMOs)[4] replaced a voluntary scheme.[5] The Act was justified to "assess and manage the risks and to provide

* Charles Lawson: Senior Research Fellow, Australian Centre for Intellectual Property in Agriculture, TC Beirne School of Law, The University of Queensland, Queensland.
Richard Hindmarsh: Senior Lecturer, Biopolitics and Environmental Policy, Australian School of Environmental Studies, Griffith University, Queensland.

[1] *Gene Technology Act 2000* (Cth) is the Commonwealth's component of this regulatory scheme; under s 5, mirror legislation is required in each State and Territory for a comprehensive regulatory scheme; see also *Gene Technology Act 2001* (Vic), *Gene Technology Act 2001* (SA) and *Gene Technology Act 2001* (Qld).

[2] *Gene Technology Act 2000* (Cth), s 10, defines "organism" to mean "any biological entity that is: (a) viable; or (b) capable of reproduction; or (c) capable of transferring genetic material".

[3] *Gene Technology Act 2000* (Cth), s 10, defines "gene technology" to mean "any technique for the modification of genes or genetic material, but does not include: (a) sexual reproduction; or (b) homologous recombination; or (c) any other technique specified in the regulations for the purposes of this paragraph"; the *Gene Technology Regulations 2001* (Cth), Reg 4, presently declares "gene technology does not include somatic cell nuclear transfer if the transfer does not involve genetically modified material".

[4] *Gene Technology Act 2000* (Cth), s 10, defines "GMO" to mean a "genetically modified organism", which, in turn, is defined to mean: "(a) an organism that has been modified by gene technology; or (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms; but does not include: (d) a human being, if the human being is covered by para (a) only because the human being has undergone somatic cell gene therapy; or (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms"; the *Gene Technology Regulations 2001* (Cth) do not presently declare anything to be a GMO for the purposes of para (c), although Reg 5 does declare a number of organisms set out in Sch 1 as being not GMOs for the purposes of para (e) of the GMO definition.

[5] For a review of the early developments eventually leading to the *Gene Technology Act 2000* (Cth) see Hindmarsh R, "Genetic Engineering Regulation in Australia: An 'Archaeology' of Expertise and Power" (2005) 14 *Science as Culture* 373-392; see also Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes – A Report on the Gene Technology Bill 2000* (Commonwealth of Australia, 2000) pp 27-30; the major weaknesses in the voluntary system were insufficient capacity for independent legally enforceable auditing and monitoring, insufficient capacity for the imposition of

information to consumers and the community"[6] because, "in an objective aggregate sense, it may not be in their [industries'] best interests to draw the possibility of a risk to the attention of prospective consumers and the community generally" and "consumers might discount the usefulness of industry provided information on that basis".[7] Perhaps most significantly the pre-existing voluntary scheme was considered to lack "credibility in meeting the broad concerns of the community about the risks posed by not having in place, sufficient mechanisms to ensure adequate openness and transparency in its risk assessment and management roles, nor sufficient enforcement capabilities" with the consequence that a lack of credibility might "harm the ability of industry to market GMOs and GM products[8] assessed as safe".[9] In short, the Act's policy objective was to address the legitimacy (or public trust) of GMOs (and GM products) by regulating the assessment of risk,[10] thereby promoting commercial transactions in GMOs (and GM products) as safe for the broader community.[11] Put another way, the Act serves to provide for consumers and the broader community an independent, open and transparent assessment of the uncertainty posed by GMOs (and GM products) on human health and safety and the environment.[12]

The Act does not seek to avoid *all* risks posed by GMOs (or GM products), but rather to identify and evaluate risks (hazards) and manage them, acknowledging that a certain amount of risk is acceptable. The assessment of risk is built into the regulatory framework imposed by the Act that classifies different dealings according to their perceived risks,[13] and consideration of a "checklist" of possible hazards.[14] In addition to this, a methodology for identifying, evaluating and managing risks according to a *Risk Analysis Framework* is applied.[15] Other risks may also be identified through the

penalties or other action in the event of a breach and inadequate transparency in decision making: see *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, pp 9 and 12-13; also Flynn E, "Comparison between the Gene Technology Act 2000 and the System Overseen by the Genetic Manipulation Advisory Committee" (2002) 15 *Australian Biologist* 87; Hain M, Cocklin C and Gibbs D, "Regulating Biosciences: The Gene Technology Act 2000" (2002) 19 EPLJ 163 at 164-165.

[6] *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, p 10.

[7] *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, p 10.

[8] *Gene Technology Act 2000* (Cth), s 10, defines "GM product" to mean "a thing (other than a GMO) derived or produced from a GMO".

[9] *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, p 13.

[10] Australia, House of Representatives, *Debates* (22 June 2000) p 18104 (Minister for Health and Aged Care); see also Trantor M, "A Question of Confidence: An Appraisal of the Operation of the Gene Technology Act 2000" (2003) 20 EPLJ 245 at 245-246; Hain et al, n 5, p 165; for example, "[t]he Act … provides the public, farmers, researchers and companies involved in GMOs certainty, consistency and safety for people and the environment": Office of the Gene Technology Regulator, *First Application for Commercial Release of GM Canola in Australia Marks First Anniversary of the Office of the Gene Technology Regulator* (Press Release No GTR08/02, 21 June 2002).

[11] For a similar sentiment about generating trust through control in regulating GMOs generally, see Newell P, *Biotechnology and the Politics of Regulation*, IDS Working Paper 146 (Institute of Development Studies, 2002) pp 5-7; Scoones I, *Science, Policy and Regulation: Challenges for Agricultural Biotechnology in Developing Countries*, IDS Working Paper 147 (Institute of Development Studies, 2002) pp 2-3; although note that the causal link between legitimacy (or public trust) and regulation remains uncertain: see for a recent example, Frewer L, Scholderer J and Bredahl L, "Communicating about the Risks and Benefits of Genetically Modified Foods: The Mediating Role of Trust" (2003) 23 *Risk Analysis* 1117.

[12] See also Australia, House of Representatives, n 10; House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution* (Commonwealth of Australia, 2000) pp 123-124.

[13] *Gene Technology Act 2000* (Cth), s 32(1), providing for exempt dealings (ss 32(1) and 32(4) and *Gene Technology Regulations 2001* (Cth), Regs 6-11), notifiable low risk dealings (s 32(1) and Pt 6 Div 2 and Regs 12-13), licensed dealings (s 32(1) and Pt 5 and Regs 7-11), dealings with GMOs on the Register of GMOs (ss 32(1) and 76), or dealings with an organism, or class of organisms, declared to be outside the definition of a GMO (s 10 and Reg 5 (Sch 1 Pt 1); other formal statutory elements of the regulatory scheme for GMOs (and GM products) include the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) and the *Therapeutic Goods Act 1989* (Cth); there is, however, a "mass" of non-legal rules, codes, circulars, practice notes, international conventions and ethical codes: see also Black J, "Regulation as Facilitation: Negotiating the Genetic Revolution" (1998) 61 MLR 621 at 621.

[14] *Gene Technology Act 2000* (Cth), ss 49(2) and 51(1); and *Gene Technology Regulations 2001* (Cth), Reg 10.

[15] Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (Office of the Gene Technology Regulator, 2002); notably a new framework was implemented in 2005 that included "risk communication" as a central element of "risk analysis", being "risk analysis = risk assessment + risk management + risk communication": see Office of the Gene Technology Regulator, *Risk Analysis Framework* (Office of the Gene Technology Regulator, 2005).

consultation process required by the Act,[16] and in considering the application and preparing the risk assessment according to the Act.[17]

The term "risk" is not defined in the Act,[18] although for the purposes of the *Risk Analysis Framework* the term has been applied "both separately and together" as the "probability (likelihood) of an event and consequence (the impact of the event when it happens)".[19] This takes into account "the level of hazard of the agent", and "the level of exposure of the receptor (human, animal, plant etc)".[20] While there is no universally acceptable or applicable process or procedure for conducting risk assessments with a multitude of possible techniques and methods,[21] common to any risk assessment[22] is an individual's conception of the worth of a particular activity that requires some kind of protection (such as a human fatality or an ecological harm like an unexpected biodiversity loss).[23] In addition, the risk posed by the proposed activity is considered to be acceptable.[24] Both these involve questions about the reasons for that opinion and perception, and values about the weight of opinion or perception.[25] The interplay of psychological, social and political factors influences this risk opinion and perception,[26] with the consequence that experts and lay people may disagree about risk.[27] It is these value judgments that are central to the Act's scheme. This is because once it is accepted that adverse events are possible, a decision under the Act to allow a dealing with a GMO (or GM product) is, in effect, a decision that any damage as a result of an adverse event is objectively acceptable.[28] The regulatory problem here comprises two aspects. First, that a consensus on what is objectively acceptable risk is the foundation of legitimacy. Secondly, that difference of opinion and perception in assessing risk have the potential to undermine that legitimacy, especially where the

[16] See *Gene Technology Act 2000* (Cth), ss 50, 52 and 56.

[17] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 19-20 and 28-67; see also Hayes K, *Robust Methodologies for Ecological Risk Assessment: Best Practice and Current Practice in Ecological Risk Assessment for Genetically Modified Organisms* (CSIRO Division of Marine Research, 2004) p 32.

[18] Noting that there is an ongoing controversy about the definition of "risk", with the presently dominant conception that "risk" involves some form of "danger"; for an overview of the different emphases and nuances, see Botterill L and Mazur N, *Risk & Risk Perception: A Literature Review*, RIRDC Publication No 04/043 (Rural Industries Research and Development Corporation, 2004) pp 1-2.

[19] Office of the Gene Technology Regulator, Risk Analysis Framework, n 15, pp 12 and 70.

[20] Office of the Gene Technology Regulator, Risk Analysis Framework, n 15, pp 12 and 70.

[21] For a recent overview of "best practice" ecological risk assessment for GMOs, see Hayes, n 17, pp 8-30; see generally Hayes K, *A Review of Ecological Risk Assessment Methodologies*, Technical Report No 13 (CSIRO Division of Marine Research, 1997).

[22] The term "risk assessment" is, however, defined in the *Marrakesh Agreement Establishing the World Trade Organization* [1995] ATS 8, Annex 1A (*Agreement on the Application of Sanitary and Phytosanitary Measures*), to which Australia is a member state, to mean "[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs" (Annex A); see also Peel J, "Science and Risk Assessment in International Environmental Law: Learning from the WTO SPS Experience" (2004) 98 *American Society of International Law Proceedings* 283.

[23] See for example, Lawson C, "Risk Assessment in the Regulation of Gene Technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)" (2002) 19 EPLJ 195 at 200-201.

[24] See for example, Lawson, n 23 at 201.

[25] See for example, Black, n 13, pp 621-622 (conceptualisations of the "problem"); Burgmann M, "Are Australian Standards for Risk Analysis Good Enough? Conserving Snails and Managing Genetically Modified Plants in Fragmented Landscapes" (1999) 12 *Australian Biologist* 125 at 127-129 (human frailties in the judgment of risk); Hayes, n 17, pp 25-26 (the place of new technology).

[26] See generally Pildes R and Sunstein C, "Reinventing the Regulatory State" (1995) 62 U Chi L Rev 1 at 33-43; Slovic P, "Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield" (1999) 19 *Risk Analysis* 689 and the references therein; for a recent overview of some contributing factors see Botterill and Mazur, n 18, pp 3-7.

[27] Slovic, n 26, at 697.

[28] Essentially an assessment that the technology's consequences are acceptable and that the aims of the technology are acceptable: see Jasanoff S, "Technologies of Humility: Citizen Participation in Governing Science" (2003) 41 *Minerva* 223 and the references therein; see also Newell, n 11, p 3 and the references therein pointing out the potential conflict between regulation for the benefit of the public and regulation for commercial interests where governments are both protector of the public interest and promoter of biotechnology.

"science" founding the decision is uncertain and the values and preferences supporting a decision have not been disclosed.

This article challenges the openness and transparency of the decisions about risk under the Act. It does this by assessing the recent license granted to Bayer CropScience Pty Ltd (Bayer) for the general or commercial release into the environment of herbicide tolerant hybrid system canola,[29] that had previously been licensed to Aventis CropScience Pty Ltd (Aventis) for limited or field trial release into the environment.[30] The general or commercial release of GMOs into the environment under the Act contrasts with other forms of intentional release into the environment (such as limited or field releases) in that these general or commercial releases involve minimal control.[31] Further, general or commercial releases follow prior limited releases into the environment "under strict conditions".[32] The decision to license a general or commercial release is thus likely to be based on the most comprehensive "science", including all the relevant data gathered during earlier licensed limited releases.[33] In these circumstances the decision to license a general or commercial release of a GMO into the environment under the Act might be expected to illustrate the requirements for objectively acceptable risks assessed under the Act. The authors' study illustrates the paucity of evidence about the GMO under consideration and the consequences of this for making decisions to license the release of GMOs into the environment under the Act.

The article is structured as follows:

- The Act's regulatory scheme and the methodology for assessing risk is outlined. This includes the formal requirements of the Act and the policy documents supporting a decision to either refuse a license or issue a license, and the conditions attached to that license according to the risk assessment applying the *Risk Analysis Framework*.
- A detailed description of the GMO construction and the key elements of the risk assessment and risk management plan for the limited (field trial) release of Aventis' GM canola and the subsequent general or commercial release of Bayer's GM canola is then given. The article then provides an analysis of the data and information relied on in reaching a conclusion about the risks posed by the general or commercial release of the GMOs. The significance of this detail is to show the complexity of the GMO construction and the breadth of analysis required to assess the likely risks and consequences of individual and composite components of the GMOs. This analysis illustrates the paucity of direct quantitative data and information available to support the risk assessment.
- The article then sets out a discussion, arguing that the social construction of both the "science" underpinning the risk assessment and the concept of "risk" itself belie value judgments about the opinion or perception of risk that undermine the Act's objective of a credible assurance (openness and transparency) about the safety of GMOs (and GM products). This arguably undermines the legitimacy of GMOs (and GM products) and thus also undermines the policy of objective of the Act in promoting commercial transactions in GMOs (and GM products). A deeper analysis of the Bayer license decision further highlights the sorts of contentions that are likely to undermine that legitimacy.
- Finally, the conclusion is that while *more* "science" will enhance the Gene Technology Regulator's decisions, "science" alone is not enough to avoid a further loss of legitimacy in applying the current regulation for the commercial and general releases of GMOs (and GM products) into the environment. The solution, in the authors' view, is to acknowledge the subjective judgments required in assessing the "science" and construct the regulatory scheme in a

[29] Bayer CropScience Pty Ltd, *Commercial Release of Genetically Modified (InVigor hybrid) Canola: Risk Assessment and Risk Management Plan*, DIR 021/2002 (Office of the Gene Technology Regulator, 2003).
[30] Aventis CropScience Pty Ltd, *Small and Large Scale Trialing of InVigor Canola (Brassica napus) for the Australian Cropping System and Seed Production: Risk Assessment and Risk Management Plan*, DIR 010/2001 (Office of the Gene Technology Regulator, 2002).
[31] Office of the Gene Technology Regulator, *Handbook on the Regulation of Gene Technology in Australia: A User's Guide to the Gene Technology Act 2000 and Related Legislation* (Office of the Gene Technology Regulator, 2003) p 91.
[32] Office of the Gene Technology Regulator, n 31, p 92.
[33] Office of the Gene Technology Regulator, n 31, p 92.

way that embraces the broader considerations about the potential risks of GMOs (and GM products).

OVERVIEW OF THE REGULATORY SCHEME AND RISK METHODOLOGY

The Act provides a detailed regulatory scheme with a number of formal requirements. These formal requirements are then complemented by a *Risk Analysis Framework* setting out a methodology for assessing risks. The following sections overview the formal requirements of the Act and the methodology set out in the *Risk Analysis Framework*.

Formal requirements

The focus of the Act is to "protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs".[34] The Act's scheme, administered by the Gene Technology Regulator (the Regulator),[35] prohibits all "dealings with" GMOs,[36] unless the dealings are exempt,[37] notifiable low risk dealings,[38] licensed,[39] on the Register of GMOs,[40] or dealings with an organism, or class of organisms, declared to be outside the definition of a GMO.[41] For licensed dealings where the GMO is to be intentionally released into the environment,[42] the Regulator considers the characteristics and effects of the genetic modification to the organism,[43] and assesses the risks posed by the proposed dealings with the GMO.[44] There are minimum requirements for preparing a risk assessment and risk management plan.[45] A risk assessment requires a consideration, over the short and long term,[46] of a number of aspects. These include the properties of the organism, the effect (or expected effect) of the genetic modification, limits on the dissemination or persistence of the GMO (or its genetic material), or the spread or persistence of the GMO. In addition, the extent or scale of the proposed dealing, the impact of the dealing on the health and safety of people, the potential of the GMO to be harmful to other organisms, adversely affect ecosystems, transfer genetic materials, spread and persist in the

[34] *Gene Technology Act 2000* (Cth), s 3; see also *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, p 13.
[35] *Gene Technology Act 2000* (Cth), Pt 3; the Regulator is a statutory office holder appointed by the Governor-General (s 118(1)) and assisted by persons engaged under the *Public Service Act 1999* (Cth) and made available for the purpose by the Secretary of the Department of Health and Ageing (s 133): see Department of Finance and Administration, *List of Australian Government Bodies 2002-2003*, Financial Management Reference Material No 1 (2004) p 254; notably, the Regulator has set out a service charter of the Office of the Gene Technology Regulator articulating its "values" as being "the Australian Public Service Values and Code of Conduct in all aspects of its business. In addition, we value: Professionalism; through integrity, objectivity, excellence, commitment, and consistency. Accountability; through open and transparent processes. Achievement; through effective, efficient and flexible work practices which are focussed on delivering timely outcomes. Respect for each other and our stakeholders; through open and effective communication and quality service": Office of the Gene Technology Regulator, *OGTR Service Charter* (Office of the Gene Technology Regulator, 2005) p 3.
[36] *Gene Technology Act 2000* (Cth), s 10, defines "deal with, in relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paras (a) to (g)".
[37] *Gene Technology Act 2000* (Cth), ss 32(1) and 32(4); and *Gene Technology Regulations 2001* (Cth), Pt 3, Div 1.
[38] *Gene Technology Act 2000* (Cth), s 32(1) and Pt 6, Div 2; and *Gene Technology Regulations 2001* (Cth), Pt 3, Div 2.
[39] *Gene Technology Act 2000* (Cth), s 32(1) and Pt 5; and *Gene Technology Regulations 2001* (Cth), Regs 7-11.
[40] *Gene Technology Act 2000* (Cth), ss 32(1) and 76.
[41] *Gene Technology Act 2000* (Cth), s 10; and *Gene Technology Regulations 2001* (Cth), Sch 1, Pt 1.
[42] *Gene Technology Act 2000* (Cth), Pt 5, Div 4; noting that s 10 defines "environment" to include "ecosystems and their constituent parts", "natural and physical resources" and "the qualities and characteristics of locations, places and areas"; s 11 provides "a dealing with a GMO involves the *intentional release of the GMO into the environment* if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment".
[43] *Gene Technology Act 2000* (Cth), s 49(2).
[44] *Gene Technology Act 2000* (Cth), s 50(1).
[45] See *Gene Technology Act 2000* (Cth), ss 51(1) and 51(2).
[46] *Gene Technology Regulations 2001* (Cth), Reg 10(2).

environment, have a selective advantage, or be toxic, allergenic or pathogenic and various.[47] The identified risks must be manageable based on a risk management plan that considers ways to manage the risks, and based on advice from competent agencies.[48] Further, in making a license application, some information is prescribed by the *Gene Technology Regulations 2000* (Cth) (the Regulations),[49] including comprehensive information about the GMO, the dealing, the risks and the risk management.[50]

For the purposes of the Act, a risk assessment is the process of evaluating the adverse events that might occur, or may be occurring, to the health and safety of people or the environment, if a proposed dealing is undertaken.[51] For both the risk assessment and risk management plan, the Regulator is required to seek advice about matters relevant to the preparation of the risk assessment and risk management plan from the States,[52] the Gene Technology Technical Advisory Committee, prescribed Commonwealth agencies,[53] the Environment Minister, and any local council the Regulator considers appropriate.[54] After preparing the risk assessment and risk management plan, the Regulator is required to publish a notice and seek written submissions from the public, and again seek the advice of the States, the Gene Technology Technical Advisory Committee, prescribed Commonwealth agencies, the Environment Minister, and any local council the Regulator considers appropriate.[55] The Regulator is also empowered to take other "appropriate" actions, including holding public hearings, in order to determine the license application.[56] In making a decision whether the risks posed by the dealing can be "managed in such a way as to protect the health and safety of people and the environment",[57] and so to issue a license (with or without conditions),[58] or refuse to issue a license,[59] the Regulator "must have regard to" a number of policy measures. These include the risk assessment[60] and risk management plan,[61] any submissions received about the risk assessment and risk management plan[62] and any policy guidelines issued by the Ministerial Council relating to risks and ways to manage risks.[63] The Regulator's decision is also required to be consistent with any policy principles issued by the Ministerial Council,[64] and the Regulator must be satisfied that the license applicant is a "suitable person to hold a license".[65]

[47] See *Gene Technology Act 2000* (Cth), s 51(1); and *Gene Technology Regulations 2001* (Cth), Reg 10.
[48] See *Gene Technology Act 2000* (Cth), s 51(1); and *Gene Technology Regulations 2001* (Cth), Reg 10.
[49] *Gene Technology Act 2000* (Cth), s 40(2)(a); and *Gene Technology Regulations 2001* (Cth), Reg 7(1)(b).
[50] *Gene Technology Regulations 2001* (Cth), Sch 4, Pt 2.
[51] See *Gene Technology Act 2000* (Cth), ss 3 and 4.
[52] This includes the Australian Capital Territory and the Northern Territory: *Gene Technology Act 2000* (Cth), s 10.
[53] Prescribed by the *Gene Technology Regulations 2001* (Cth), Reg 9 to be the Australian New Zealand Food Authority, the Australian Quarantine Inspection Service, the National Health and Medical Research Council, the National Industrial Chemicals Notification and Assessment scheme, the National Registration Authority and the Therapeutic Goods Administration.
[54] *Gene Technology Act 2000* (Cth), s 50(3).
[55] *Gene Technology Act 2000* (Cth), s 52.
[56] *Gene Technology Act 2000* (Cth), s 53; s 51(1) clarifies that the Regulator is not confined to considering submissions and advice and may take into account other information, including relevant independent research.
[57] *Gene Technology Act 2000* (Cth), s 56(1).
[58] *Gene Technology Act 2000* (Cth), Pt 5, Div 6.
[59] *Gene Technology Act 2000* (Cth), s 55.
[60] *Gene Technology Act 2000* (Cth), s 56(2)(a).
[61] *Gene Technology Act 2000* (Cth), s 56(2)(b).
[62] *Gene Technology Act 2000* (Cth), s 56(2)(c).
[63] *Gene Technology Act 2000* (Cth), ss 23 and 56(2)(d); there are presently no policy guidelines in force.
[64] *Gene Technology Act 2000* (Cth), ss 21 and 57(1); the only policy principle in force is the *Gene Technology (Recognition of Designated Areas) Principle 2003*; *Commonwealth of Australia Special Gazette* (No S340 5 September 2003) requiring the Gene Technology Regulator to recognise a States' right to designate under State law special areas that are for either GM or non-GM crops for marketing purposes; see Ludlow K, "Cultivating Chaos: State Responses to Releasing Genetically Modified Organisms" (2004) 9 *Deakin Law Review* 1 at 18-20; McGrath C, "A System Under Strain: The Regulation of Gene Technology" (2003) 2 *National Environment Law Review* 32 at 36-37; Trantor, n 10, pp 256-258.
[65] *Gene Technology Act 2000* (Cth), ss 57(2) and 58; notably, in general or commercial release applications "[i]nformation gained from the field trials (and information about the suitability of the applicant based on their conduct of the trials) would be

Risk assessment and risk management methodology

The Office of the Gene Technology Regulator has issued guidelines (the *Risk Analysis Framework*) about how the Regulator, assisted by the staff of the Office of the Gene Technology Regulator, will assess risks.[66] Applying the *Risk Analysis Framework* is intended to provide "a transparent and consistent risk analysis process",[67] and lead to a "science-based conclusion" about risks and their management so that "[e]ither risk will be too great to permit the dealing to proceed, or the risk will be manageable through imposed license conditions, or there will be no risk that requires management".[68] The assessments being made need to appear as "an assessment of the likelihood of the hazard occurring and, if it does, the likely consequences of that occurrence".[69] A potentially significant limitation imposed by the Regulator on every risk assessment is that the *Risk Analysis Framework* is applied in the context of the "[r]isks posed by GMOs will be considered in the context of the risks posed by the non-modified parental organisms in the receiving environment".[70]

For the intentional release of GMOs into the environment, the *Risk Analysis Framework* involves steps of hazard identification,[71] risk assessment,[72] risk management[73] and risk communication,[74] together with consultative steps.[75] The Regulator's standard approach to risk assessment is to consider each identified hazard, to assess "the magnitude of the consequence if the hazardous event does occur, and the likelihood (in terms of frequency or probability) of the occurrence of each of the hazards noting, where appropriate, that these may differ from region to region or under different circumstances".[76] The Regulator appears to favour quantitative data and information.[77] If this is not available, other methods are used, or may be used, in addition to quantitative approaches. These include "expert opinion from committees/groups of experts or from individual experts", "information on potential hazards provided through public consultation", "published material on analogous situations" and "risk assessments or information/advice from other regulatory agencies".[78] This assessment is then conducted within "parameters", including:

(a) "The risk assessment will be transparent, objective and scientifically based. It is purely based on risk, not on a balance of risk and benefit";

(b) "When examining risks to the health and safety of people and the environment, risks and potential risks to all living organisms and relevant ecosystems will be considered, for both long and short term effects";

---

used by the Regulator as part of his/her assessment of any subsequent application for commercial release of the GMO": Office of the Gene Technology regulator, n 31, p 92.

[66] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 1.

[67] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 2.

[68] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 17.

[69] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 9.

[70] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 16; this is the "doctrine of substantial equivalence" that does not have unanimous support as a base line for an objective method of assessing risk: see for supportive review McHughen A, *A Consumer's Guide to GM Food: From Green Genes to Red Herrings* (Oxford University Press, 2000) pp 137-139.

[71] "Hazard" meaning "the capacity of a GMO to produce a particular type of adverse health or environmental effect, directly or indirectly; or an event, sequence of events or combination of circumstances that could potentially have adverse consequences": Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 12 and 70.

[72] "Risk assessment" means "the process of estimating the potential impact of a hazard on a specified human population or the environment under a specific set of conditions within an identified timeframe": Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 12 and 70.

[73] "Risk management" means "the process of evaluating alternative actions, selecting options and implementing them in response to risk assessments": Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 12 and p 70.

[74] "Risk communication" means "ensuring that: an open and transparent process of identification of risks associated with (in this case) gene technology and GMOs has been rigorously followed, and; the community is adequately informed about what these risks are and how they are being managed; and public confidence in the regulatory system is maximised": Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 13 and p 70.

[75] See Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 8-14.

[76] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 20.

[77] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 21-22.

[78] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 22.

(c) "Where there are threats of serious or irreversible environmental damage, the lack of full scientific certainty should not be used as a reason for postponing cost effective measures to prevent environmental degradation";

(d) "If data are unavailable or incomplete, the significance of that absence or incompleteness in undertaking an evaluation of the risks of a proposal to the health and safety of people or the environment will be considered and, if the Regulator considers that the lack of data creates a level of risk that is not manageable, a license may not be granted"; and,

(e) "Risks posed by GMOs will be considered in the context of the risks posed by the non-modified parental organisms in the receiving environment. For example, the identified characteristics flowing from the genetic changes to the GMO and its use, which have the potential to cause adverse effects may be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations".[79]

Significantly, the Regulator accepts that if data is unavailable or incomplete, the significance of that absence or incompleteness in undertaking an evaluation of the risks of a proposal to the health and safety of people or the environment will be considered and, if the Regulator considers that the lack of data creates a level of risk that is not manageable, a license may not be granted.[80]

Further, the Regulator accepts that, "[w]here the level of risk is uncertain, but the consequences of the risk being realised would be significant, one might adopt conservative professional judgment in implementing management strategies".[81] The Regulator contemplates that the uncertainty might be addressed with "sensitivity analysis" to gain "a better 'feel'" for the impact or importance of the assumptions made.[82]

The Regulator is *only* required by the Act to make a decision to either issue, or refuse to issue, the license,[83] and this decision need only be disclosed to the applicant in writing.[84] The Regulator's decision to refuse to issue, or issue the license subject to conditions, is a "reviewable decision" for the purposes of the Act,[85] with standing for administrative review expressly limited,[86] although judicial review is probably widened to include a State (including the Australian Capital Territory and the Northern Territory) initiated review.[87] The Act only requires the Regulator to make copies of the application and prepared risk assessment and risk management plan available to the public[88] (excluding any confidential commercial information),[89] or in order to seek advice[90] or invite submissions.[91] The Regulator is not required to disclose any updated risk assessment and risk management plan that takes into account any further advice, and any written submissions upon which the Regulator finally relies. Further, some information provided in the application and during the risk assessment process may be characterised as information about "relevant convictions" and thus be restricted.[92]

Significantly, in the present matter of the Bayer GM canola application, "some detailed technical information on precise gene constructs and molecular characterisation data" supplied in the application and during the risk assessment process was declared "confidential commercial

[79] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, pp 15-16.
[80] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 16.
[81] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 20.
[82] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 21.
[83] See *Gene Technology Act 2000* (Cth), s 55.
[84] *Gene Technology Act 2000* (Cth), s 59.
[85] *Gene Technology Act 2000* (Cth), s 179.
[86] See *Gene Technology Act 2000* (Cth), s 183; the term "eligible person" is confined by s 179 to the applicant for the licence and the licence holder.
[87] See *Gene Technology Act 2000* (Cth), s 183A; although there remains the original jurisdiction of the Federal Court under the *Federal Court Act 1976* (Cth), ss 22 and 23.
[88] See *Gene Technology Act 2000* (Cth), s 54.
[89] See *Gene Technology Act 2000* (Cth), s 54(2)(a) and Pt 12, Div 3.
[90] See *Gene Technology Act 2000* (Cth), s 52(3).
[91] See *Gene Technology Act 2000* (Cth), s 52(2)(c).
[92] See *Gene Technology Act 2000* (Cth), ss 54(2)(b) and 58.

information" and access to that information restricted.[93] Without the determinative risk assessment and risk management plan and this other information,[94] any analysis of the Regulator's methods and analysis are thus speculative. As a result, the following discussion is confined to the prepared risk assessment and risk management plan and other publicly available documents. While these documents may not be definitive, they provide some insight into the matters the Regulator takes into consideration in determining a risk assessment and risk management plan before issuing a general or commercial release license.

THE GM CANOLA UNDER CONSIDERATION

The Act contemplates that each application for a license to release a GMO into the environment requires a complete consideration of the risks, and how might they be managed.[95] Earlier licenses for limited or controlled releases into the environment might be expected to provide useful and directly relevant information as they apply the same processes and requirements.[96] This is because "the Regulator's assessment processes, and conditions applied to the license, will differ" for the general or commercial releases.[97] Further:

> it is expected that before applying to the Regulator to commercially release a GMO throughout Australia (or in certain regions of Australia), the GMO will have been previously licensed by the Regulator as a field trial under strict conditions. The results of the field trials will be used by the Regulator as part of his/her assessment of whether it is safe for the GMO to be more generally commercially released in Australia.[98]

This article sets out the key elements of the risk assessment and risk management plan for the general or commercial release of Bayer's GM canola and the earlier limited release of Aventis' GM canola. It then examines in detail the decision of the Regulator to license the general or commercial release of Bayer's GM canola. This includes a detailed description of the genetic construction of the GMO (Table 1) to illustrate the complexity of the assessment required by the Regulator of the various components and their possible effects. The article also presents a "gap" analysis of the data and information relied on by the Regulator in undertaking the risk assessment (Table 2) to illustrate the paucity of direct quantitative data and information available to support the risk assessment.

Bayer's GM canola

Bayer lodged an application for the general or commercial release of "seven similar" "lines"[99] of GM canola[100] in seeking a license to release the GMOs "in all canola growing regions of Australia[101] and continued product development and research programs".[102] The license was granted on 25 July 2003 for the "GMOs" being GM canola "containing the transformation event[s]" T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3,[103] and "InVigor[104] hybrid canola (hybrids of canola containing

[93] Bayer CropScience Pty Ltd, n 29, p 37; notably the Regulator asserts that "this declaration in no way limited the thorough risk assessment of the individual GMOs".
[94] Note, however, that the Regulator has previously stated that the risk assessment and risk management plan, and summary information, will be made publicly available: see, for example, Office of the Gene Technology Regulator, *Risk Assessment and Risk Management Plan: Agronomic Assessment and Seed Increase in Eastern Australia of Transgenic Cotton Expressing cry1Ac and cry2Ab Genes from Bacillus thuringiensis*, DIR 005/2001 (Office of the Gene Technology Regulator, 2001) p 68.
[95] *Gene Technology Act 2000* (Cth), ss 48-67; see also Office of the Gene Technology Regulator, n 31, pp 90-92.
[96] See Office of the Gene Technology Regulator, n 31, p 91.
[97] Office of the Gene Technology Regulator, n 31.
[98] Office of the Gene Technology Regulator, n 31, p 92.
[99] Defined as, "to denote canola with a specific genetic modification derived from a single transformation event", although "this usage is intended to be inclusive of the introduction of the modification into other canola genetic backgrounds by conventional breeding": see Bayer CropScience Pty Ltd, n 29, pp 15 and 38.
[100] Being canola T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3: see Bayer CropScience Pty Ltd, n 29, pp 15-16.
[101] This includes all Australian States and Territories: see Bayer CropScience Pty Ltd, n 29, p 16.
[102] Bayer CropScience Pty Ltd, n 29.
[103] Bayer CropScience Pty Ltd, n 29, pp 143-144.
[104] "InVigor" is a registered trade mark owned by Bayer CropScience GmbH, Frankfurt am Main for the class of goods and services described as "[a]gricultural, horticultural and forestry products and their reproductive material; seeds; grains; live

transformation event MS8 and canola containing transformation event RF3)",[105] and permitting "all dealings with the GMOs".[106]

The canola (Brassica napus), an exotic plant in Australia,[107] were all modified to incorporate tolerance to the herbicide glufosinate ammonium (either the pat or bar genes).[108] Some "lines" also included a hybrid breeding system (either the barnase or barstar genes),[109] and some included an antibiotic resistance marker (the nptII gene).[110] Each line was prepared using Agrobacterium-mediated transformation.[111] The application related to canola "lines" with modifications for:

(a) Glufosinate ammonium detoxification (pat or bar genes) – tolerance to the herbicide glufosinate ammonium through detoxifying the effects of the herbicide compound in the plant by catalyzing the conversion of the herbicide to a non-toxic compound in the plant.[112] The T45 and Topas 19/2 lines were constructed from the phosphinothricin acetyl transferase gene derived from Streptomyces viridochromogenes (pat gene) and lines MS1, MS8, RF1, RF2 and RF3 were constructed with a gene with the same function from Streptomyces hygroscopicus (bar gene).[113] Both the pat and bar genes were modified for plant-preferred codon usage to ensure optimal expression in B. napus, and the N-terminal two codons of the bar gene in lines MS8 and RF3 were substituted.[114] The pat gene construct included the constitutive 35S promoter (P-35S) and 35S mRNA polyadenylation (T-35S) signals from cauliflower mosaic virus.[115] The bar gene construct included the plant promoter PSsuAra from the S1A ribulose-1,5-bisphosphate carboxylase (Rubisco) small subunit gene from the plant Arabidopsis thaliana, and mRNA polyadenylation signals derived from the 3" non-translated region from the T-DNA gene 7 (3"g7) of Agrobacterium tumefaciens.[116] Additional modifications in lines MS1, RF1 and RF2 included the chloroplast transit peptide coding sequence of the S1A Rubisco gene from A. thaliana.[117]

(b) Hybrid breeding system (barnase or barstar genes) – enables hybrid generation with one "line" being male sterile (barnase gene, MS line), and the other containing a "fertility restorer" (barstar gene, RF line) so that a cross between the lines (such as MS1 with RF1) restores fertility. This is achieved by the anther-specific expression of the barnase gene in the MS line producing cytotoxic ribonuclease only in the tapetum cell layer of the pollen sac during anther development. This destroys those cells and prevents pollen formation that is neutralised by a ribonuclease inhibitor protein in the RF line binding to the ribonuclease and suppressing the latter's activity.[118] The MS lines MS1 and MS8 were constructed from

plants" subject to the condition that "the word INVIGOR will not be used as the name, or part of the name, of a plant variety": Australian Registered Trade Mark 741414, 13 August 1997.

[105] Bayer CropScience Pty Ltd, n 29, p 143.

[106] Bayer CropScience Pty Ltd, n 29, p 139; notably the term "GMOs" means, "the genetically modified organisms covered by this licence, described at Attachment A" and Attachment A provides that the "GMOs covered by this licence are: (a) InVigor hybrid canola (hybrids of canola containing transformation event MS8 and canola containing transformation event RF3); (b) the GMOs described in the table below" and the table identified the GMOs as "Canola containing transformation event" T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3 (pp 138 and 143).

[107] See generally, Office of the Gene Technology Regulator, *The Biology and Ecology of Canola (Brassica napus)* (Office of the Gene Technology Regulator, 2002).

[108] Being pat – T45 and Topas 19/2; bar – MS1, MS8, RF1, RF2 and RF3: Bayer CropScience Pty Ltd, n 29, pp 16-17 and 38-39.

[109] Being barnase – MS1 and MS8; barstar – RF1, RF2 and RF3: Bayer CropScience Pty Ltd, n 29, pp 16-17 and 38-39.

[110] Being canola Topas 19/2, MS1, RF1 and RF2: see Bayer CropScience Pty Ltd, n 29, pp 16-17 and 38-39.

[111] Bayer CropScience Pty Ltd, n 29, p 44; line Topas 19/2 with a binary transformation vector and lines T45, MS1, MS8, RF1, RF2 and RF3 with co-integration vectors (pp 44-45).

[112] See Bayer CropScience Pty Ltd, n 29, pp 41-42.

[113] Bayer CropScience Pty Ltd, n 29, pp 41-43.

[114] Bayer CropScience Pty Ltd, n 29, p 42.

[115] Bayer CropScience Pty Ltd, n 29, p 43.

[116] Bayer CropScience Pty Ltd, n 29, p 42.

[117] Bayer CropScience Pty Ltd, n 29, pp 42-42.

[118] Bayer CropScience Pty Ltd, n 29, pp 40-41.

a ribonuclease gene (the barnase gene) derived from Bacillus amyloliquefaciens, an anther-specific promoter PTA29 derived from Nicotiana tabacum, and mRNA polyadenylation signals derived from the 3" non-translated region of the nopaline synthase gene (3" nos) from A. tumefaciens.[119] The RF lines RF1, RF2 and RF3 were constructed from a bacterial ribonuclease inhibitor protein from B. amyloliquefaciens (barstar gene) and then the same anther-specific promoter PTA29 and 3" nos mRNA polyadenylation signals;[120] and

(c) Antibiotic resistance (nptII gene) – an artifact from the selection and transformation of plants during the early stages of development in tissue culture.[121] The nptII gene product neomycin phoshotransferase catalyzes the conversion of aminoglycoside antibiotics and butirosins to non-toxic compounds in plants.[122] The lines Topas 19/2, MS1, RF1 and RF2 were constructed from a nptII gene from transposon Tn5 from Escherichia coli, a nopaline synthase promoter (P-nos) from A. tumefaciens and the mRNA polyadenylation signals derived from the 3" non-translated region of the octapine synthase gene (3" cos) from A. tumefaciens.[123]

A summary of the modifications to each line are set out in Table 1. Notably, not disclosed were some of the additional nucleotides associated with the constructs[124] and relic sequences from the Agrobacterium-mediated transformation.[125] Presumably these were characterised and disclosed in the Confidential Commercial Information.[126] Further, comparison of left and right flanking sequences of the transformation sites in lines T45, Topas 19/2 and RF3, the left flanking sequence in lines MS1 and RF1, and the right flanking sequence in line RF2, with sequence databases using standard algorithms revealed "no significant homology to known genes".[127] Perhaps surprisingly, "significant homology" was detected in the right flanking sequence of lines MS1 and RF1 and the left flanking sequence of line RF2 to A. thaliana. But "in each case the homology was not to any genes with a known function" and was considered "not surprising" given that "the entire genome of A. thaliana has recently been sequenced".[128]

Aventis' GM canola

The earlier license to Aventis of 30 July 2002 to release GM canola into the environment was to carry out a limited and controlled release (field trials) commencing in 2002.[129] This was, "to conduct plant breeding (including agronomic assessments) and seed production trials for the development of canola cultivars for the Australian, North American and European cropping systems".[130] In assessing the risk for this license other earlier releases of GM canola were considered that had been assessed and conducted under the pre-existing voluntary scheme.[131] No reports were made of adverse effects on human health and safety, or the environment.[132] However, the limited and controlled release (field

[119] Bayer CropScience Pty Ltd , n 29, p 40.
[120] Bayer CropScience Pty Ltd, n 29, pp 40-41.
[121] See Bayer CropScience Pty Ltd, n 29, p 43.
[122] Bayer CropScience Pty Ltd, n 29, p 43.
[123] Bayer CropScience Pty Ltd, n 29, p 43.
[124] These nucleotides are associated with the inserted genes and are not characterised in the application: see Bayer CropScience Pty Ltd, n 29, pp 46-48.
[125] These nucleotides are not characterised in the application, and includes a partial T-DNA containing a portion of the T-DNA including the barstar gene in line RF3 and the pat and nptII genes in Topas 19/2: see Bayer CropScience Pty Ltd, n 29, p 47.
[126] See Bayer CropScience Pty Ltd, n 29, pp 44-45.
[127] See Bayer CropScience Pty Ltd, n 29, pp 47-48.
[128] Bayer CropScience Pty Ltd, n 29, pp 47-48; notably there was no report of flanking sequences for line MS8 (p 46).
[129] See Aventis CropScience Pty Ltd, n 30, p 4.
[130] Aventis CropScience Pty Ltd, n 30, p 7.
[131] These were recorded as approvals PR-63, PR-63X, PR-63X(2), PR-63X(3), PR-63X(4), PR-63X(5) and PR-63X(6): see Aventis CropScience Pty Ltd, n 30, p 8.
[132] Aventis CropScience Pty Ltd, n 30, p 9; although a number of instances of non-compliance with conditions were recorded: see, for example, Interim Office of the Gene Technology Regulator, *Quarterly Report*, March 2001 (Office of the Gene Technology Regulator, 2001) pp 23-24 where sheep were recorded grazing on canola.

trials) risk assessment and risk management plan undertaken by the Regulator for this application *only* considered lines MS8 and RF3,[133] and concluded that the limited release of these lines:

> in the canola growing regions of southern Western Australia, south-west New South Wales, Victoria and south-east South Australia will not pose any additional risks to human health and safety or to the environment as a result of the genetic modification of the canola.[134]

The Regulator asserts that she is, "reviewing all license conditions for licenses carried over from the voluntary system" and "[i]f as a result of this review, new information becomes available about risks relevant to the release, the license issued to Aventis would be amended if necessary".[135]

The main conclusions from the MS8 and RF3 risk assessment were:

- that the GM canola lines were not likely to prove more toxic or allergenic to humans or other organisms than conventional canola;
- that the risk of the GM canola establishing as a weed was low and not likely to be greater than that of conventional canola;
- that there was potential for transfer of the introduced genes into non-GM canola crops although the level of out-crossing would be very low;
- that there was potential for transfer of the introduced genes to weedy relatives of canola through out-crossing although this was also extremely low; and
- that the likelihood of transfer of the introduced genes to other organisms was also extremely low.[136]

To address these risks the management plan called for restricting the use, spread and persistence of the GM canola lines,[137] and this was reflected in the license conditions.[138] Further conditions imposed data collection requirements about rate of outcrossing and the efficacy of pollen traps "to obtain information to refine management conditions for future limited and contained releases of [genetically modified] canola in order to ensure that the conditions imposed are adequate to manage the risks of gene flow".[139]

Other data identified in the MS8 and RF3 risk assessment and risk management plan was considered relevant for future applications. This included: the reasons for European regulators refusing field trials;[140] the efficacy of pollen traps in limiting the spread of GM pollen; the efficacy of isolation zones, including the rate of out-crossing from canola under Australian conditions at short distances; the persistence of canola in non-agricultural habitats; the factors determining the persistence of canola in non-agricultural habitats; and, whether such releases were likely to result in changes to agricultural practices that might have environmental impacts.[141] In justifying the conditions restricting the use, spread and persistence of the GM canola lines the Regulator applied conditions to a standard of "necessary" and "adequate" to manage the identified risks.[142]

[133] See Aventis CropScience Pty Ltd, n 30, pp 11-16.
[134] Aventis CropScience Pty Ltd, n 30, p 56.
[135] Aventis CropScience Pty Ltd, n 30, p 59.
[136] Aventis CropScience Pty Ltd, n 30, p 56.
[137] Aventis CropScience Pty Ltd, n 30, pp 56-57.
[138] Aventis CropScience Pty Ltd, n 30, pp 58-59 and 62-84.
[139] Aventis CropScience Pty Ltd, n 30, p 79.
[140] The Belgian Government refused to approve field tests with GM herbicide tolerant canola, expressing concerns about pollen transfer, although no details of the assessment were available, "but further information is being actively sought and will be considered in assessing an application from Aventis for the commercial release of InVigor canola": Aventis CropScience Pty Ltd, n 30, p 10.
[141] Aventis CropScience Pty Ltd, n 30, p 20; perhaps surprisingly, barnase gene expression was *only* correlated with an anther-less phenotype, as there was no evidence of barnase gene expression through Northern analysis in MS8, although MS8 and RF3 crosses were reported to be fully fertile and might have provided evidence of barnase gene expression through Northern analysis (p 17).
[142] See Aventis CropScience Pty Ltd, n 30, pp 78-84.

Significantly, however, the earlier licensed limited releases to Aventis on 30 July 2002 related to "InVigor canola". [143] This was described as, "two GM lines of canola based on a dominant nuclear male sterility gene, and a restorer of fertility gene … [and containing] a gene conferring tolerance to the herbicide glufosinate ammonium".[144] This was further limited to the planting seasons 1 March 2002 to 28 February 2005.[145] The outcome and results of this limited release license might have been expected to provide useful background for Bayer's general or commercial release application on 25 July 2003.[146] In particular, data collection during the field trials might have been expected to have addressed uncertainties in the available data and provide further confirmation about the presumptive risks identified in the Aventis application.[147] However, the overlap of the Aventis and Bayer applications meant that any data would be limited and its usefulness as quantitative data limited by the power of any statistical analysis.

The Regulator's decision about Bayer's GM canola

In assessing whether to impose conditions to manage the risks posed by Bayer's general or commercial release under the Act, the Regulator "consider[ed] the need to impose conditions to manage any risks to human health and safety or the environment", including a "consideration of whether any conditions would be effective in managing risks", and a "consideration of whether any conditions imposed could be effectively implemented and compliance monitored and enforced".[148] The standard the Regulator applied was that, "the release should only be approved if the risks to human health and safety or the environment are low to non-existent and therefore do not require a range of specific license conditions for them to be managed".[149] The relevant issues were identified as those required by the Act, those raised in the consultation process, and the prepared risk assessment and risk management plan.[150] The Regulator also took into account issues raised during the public consultation process in applying a standard of "considered carefully and weighed against the body of current scientific information".[151]

As a consequence of the consultations and preparing the risk assessment and risk management plan, the Regulator concluded that "the proposed release does not pose risks to the health and safety of people or the environment in Australia that require management through specific licensee conditions … [a]ccordingly, the license … contains only minimal oversight conditions".[152] The "general conditions" included a restatement of the Act's licensing condition[153] and an additional requirement that:

> The license holder must provide the Regulator, on the Regulator's written request, signed statements from persons covered by this license that the license holder has informed those people of the conditions of this license that apply to them.[154]

[143] Aventis CropScience Pty Ltd, n 30, p 4; notably, the GMO is not defined in the license conditions other than as "GMO" (see pp 62-84), although the "object of most of the conditions is to limit the potential for spread and persistence of the GM InVigor canola in the environment outside the release site or the Isolation Zone, in order to reduce the potential for risks to human health and safety or the environment" (p 78).
[144] Aventis CropScience Pty Ltd, n 30, p 4.
[145] Aventis CropScience Pty Ltd, n 30, pp 64-65.
[146] "The purpose of this [limited] release is to conduct breeding trials to develop lines suitable for use under Australian conditions and produce seed for potential commercial lines and export. Any future releases in Australia would be subject to separate applications and assessments": Aventis CropScience Pty Ltd, n 30, p 4.
[147] See Hayes, n 17, pp ii and 27-30; "[c]urrent field trials only appear to gather information on crop performance. These trials are an ideal opportunity to gather the types of data needed to improve the science of GMO risk assessment" (p ii).
[148] Bayer CropScience Pty Ltd, n 29, p 27.
[149] Bayer CropScience Pty Ltd, n 29, p 27.
[150] See Bayer CropScience Pty Ltd, n 29, pp 7, 9 and 27.
[151] Bayer CropScience Pty Ltd, n 29, p 27; notably the Regulator received 256 written submissions and 531 "campaign" letters and e-mails (p 150).
[152] Bayer CropScience Pty Ltd, n 29, p 13.
[153] Bayer CropScience Pty Ltd, n 29, pp 139-140.
[154] Bayer CropScience Pty Ltd, n 29, p 139.

The only other "specific condition" required a written description of a test methodology for detecting the presence of the licensed GMO and any transferred genetic modified materials, and an annual reporting requirement for:

> (a) Information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs;
>
> …
>
> (d) Other information on the progress of the release of the GMOs, including annual surveys, the details of which will be determined in consultation with the OGTR.[155]

Preparing the risk assessment and risk management plan first involved a process of identifying "potential hazards", and then assessing the risks posed by these hazards as being "negligible", "very low", "low", "moderate", "high" or "very high", by considering "the likelihood of the hazard occurring", "the likely consequences (impact) of the hazard, were it to be realised" and "risk management options to mitigate any significant hazards".[156] In preparing the risk assessment and risk management plan the Regulator identified the following hazards:

- Toxicity or allergenicity, in particular for humans, vertebrates (including grazing animals, birds and native animals), invertebrates (including insects), and soil biota;
- Weediness, in particular persistence in the environment, agricultural environments, non-cropped disturbed environments, undisturbed environments and spread in the environment; and
- Gene transfer, in particular to other canola crops, B. napus vegetables and forage canola, related Brassica species (such as B. rapa, B. juncea, B. oleracea), other Brassicaceous weeds (such as Raphanus raphanistrum, Hirschfeldia incana, Sinapis arvensis), and other organisms (such as humans, other animals, microorganisms (including bacteria, viruses and fungi)).[157]

To assess the risks posed by these hazards the following were considered:

- Toxicity or allergenicity: this hazard was characterised as the possible toxicity or allergenicity posed by the GM canola lines T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3 (but not the crosses MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3); from the four additional expressed proteins (PAT, Barnase, Barstar and NPTII); or, that their might be unforeseen or unintended effects from the genetic modification (pleotropic effects).[158] These toxicity and allergenicity risks were then assessed by considering the toxicity and allergenicity of conventional canola, the toxicity and allergenicity of the new proteins expressed, the changes to the levels of naturally occurring toxicants and nutritional factors, the potential for altered metabolism of the herbicide, and the likely levels and routes of exposure to GM canola and the introduced proteins.[159] After considering the risks the Regulator concluded the risks to humans were "very low",[160] and that there were no risks to other organisms.[161] A summary of the data and information relied on by the Regulator are set out in Tables 2A and 2B;
- Weediness: this hazard was characterised as "the potential for the GM canola lines to be harmful to the environment due to possible weediness or increased potential for weediness",[162] and "the possibility that the genetic modification has, either directly or as a result of "pleotropic" effects, increased the weediness of the canola plants".[163] The latter being GM canola lines T45, Topas 19/2, MS1, MS8, RF1, RF2 and RF3 (but not the crosses MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3).[164] The risks were then assessed by considering the inherent weediness of conventional canola and the weediness of GM canola in agricultural

[155] Bayer CropScience Pty Ltd, n 29, p 141.
[156] Bayer CropScience Pty Ltd, n 29, p 27.
[157] Bayer CropScience Pty Ltd, n 29, pp 29-36 (summary).
[158] Bayer CropScience Pty Ltd, n 29, pp 53 and 54.
[159] Bayer CropScience Pty Ltd, n 29, pp 54, 62 and 67.
[160] Bayer CropScience Pty Ltd, n 29, p 66.
[161] Bayer CropScience Pty Ltd, n 29, p 76.
[162] Bayer CropScience Pty Ltd, n 29, p 79.
[163] Bayer CropScience Pty Ltd, n 29, p 79.
[164] See Bayer CropScience Pty Ltd, n 29, p 78.

environments, non-cropped disturbed environments, and undisturbed environments.[165] After considering the risks the Regulator concluded that the risks "that the GM canola lines will be more likely than conventional (non-GM) canola to spread in the environment, and result in more detrimental environmental impact is negligible".[166] A summary of the data and information relied on by the Regulator are set out in Table 2C;

- Transfer of introduced genes to increase weediness: this hazard was characterised as "the hazards that might result from transfer of the genes introduced into the GM canola[167] lines T45, Topas19/2, RF1, RF2, RF3, MS1 and MS8 to other organisms could include the production of herbicide-tolerant weeds, some of which may have the potential to compete with native flora thereby reducing biodiversity"[168] (but not the crosses MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3).[169] The risks were assessed by considering the likelihood of genes transferring into other canola, other plants and other organisms.[170] After considering the risks, the Regulator concluded that gene transfer to other canola was "inevitable"[171] although the consequences were "negligible" and require no management conditions.[172] The Regulator considered gene transfer (and introgression) with B. napus vegetables and forage rape was "very low" or "negligible",[173] with other Brassica species was "high",[174] and with Brassicaceous weeds was "extremely low".[175] In each case it was concluded the risks were "very low" or "negligible" and required no management conditions.[176] A summary of the data and information relied on by the Regulator are set out in Table 2D;
- Transfer of introduced genes to other organisms – this hazard was characterised as the hazards that might result from transfer of the genes introduced into the GM canola lines T45, Topas19/2, RF1, RF2, RF3, MS1 and MS8 to other organisms, such as humans, animals, micro-organisms, bacteria, fungi and plant viruses[177] (but not the crosses MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3).[178] The risks were assessed by considering the likely mechanisms of gene transfer and considered to be "negligible", although there was no positive evidence of gene transfer from any of the GM lines or their crosses to other organisms, the evidence at best being inferences from the low probability of occurrence and persistence.[179] A summary of the data and information relied on by the Regulator are set out in Table 2D; and
- Herbicide resistant weeds – this hazard was characterised as the "potential development of herbicide resistant weeds if the InVigor crop-Liberty herbicide combination is used inappropriately".[180] The risk was not assessed but it was considered that it could be managed by complying with the existing conditions imposed by the Australian Pesticides and Veterinary Medicines Authority.[181]

Based on these materials and evaluations the Regulator "considered" that "the risks to human health and safety, or to the Australian environment, from the commercial release of any of Bayer's

[165] Bayer CropScience Pty Ltd, n 29, pp 79-94.
[166] Bayer CropScience Pty Ltd, n 29, p 94.
[167] Noting that the risk assessment distinguishes between "hybridisation" and "introgression", and the potential of plants to hybridise between species: see Bayer CropScience Pty Ltd, n 29, p 95.
[168] Bayer CropScience Pty Ltd, n 29, p 95.
[169] See Bayer CropScience Pty Ltd, n 29, p 95.
[170] Bayer CropScience Pty Ltd, n 29, p 95.
[171] Bayer CropScience Pty Ltd, n 29, p 107.
[172] Bayer CropScience Pty Ltd, n 29, p 107.
[173] See Bayer CropScience Pty Ltd, n 29, pp 122 and 123.
[174] See Bayer CropScience Pty Ltd, n 29, pp 122-123.
[175] See Bayer CropScience Pty Ltd, n 29, pp 123-124.
[176] Bayer CropScience Pty Ltd, n 29, pp 122, 123 and 124.
[177] Bayer CropScience Pty Ltd, n 29, pp 126-133.
[178] See Bayer CropScience Pty Ltd, n 29, pp 127-128.
[179] See Bayer CropScience Pty Ltd, n 29, pp 132-133.
[180] Bayer CropScience Pty Ltd, n 29, p 134.
[181] Bayer CropScience Pty Ltd, n 29, p 134.

seven GM canola lines are no greater than those posed by non-GM canola ie they are as safe as conventional canola".[182]

DISCUSSION

The advent of GMOs promised improved healthcare, food security, poverty alleviation, environmental sustainability, and other benefits.[183] However, despite these promises, public and scientific concerns have been consistently raised about the health and environmental safety of GMOs (and GM products),[184] with the consequence that they have attracted regulatory intervention in many jurisdictions.[185] In Australia, the Act sets out part of the regulatory scheme addressing "dealings" with "GMOs" with a risk assessment methodology set out in the *Risk Analysis Framework* about human health and safety and the environment that is theoretically objective and "science-based":

> For the Regulator, the objective of the risk assessment is to identify potential for adverse effects that GMOs may pose for human health and the environment and their potential impact. It should be noted that risk assessment is a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account.[186]

The Act's approach to assessing risk assumes that physical and natural processes can be reduced to objectively quantifiable probabilities (or rates) and consequences (risk = frequency x consequence).[187] By applying a regulatory framework to constructing the "problem" of GMO risks, the Regulator's decision provides a solution that establishes a rational dominance over what otherwise might be (whether in reality or otherwise) an uncontrollable health and environmental problem.[188] Put another way, the Act seeks to provide certainty to an uncertain "problem" by appealing to an apolitical and objective scientific approach, without acknowledging the uncertainty of science as a methodology for making interpolations (where a given value will occur between two known values) and extrapolations (where a likely value is outside the range of known values but estimated) about likely and unknowable future events. This approach reflects the modern industrialisation of science applied to promoting economic growth and national power based on a scientific tradition that relies on the control and management of health and the environment.[189] The problem with this approach,

---

[182] Bayer CropScience Pty Ltd, n 29, p 10.

[183] The promises of GMO literature is considerable: see, for summary examples, Hindmarsh R and Lawrence G, "Bio-utopia: FutureNatural?" in Hindmarsh R and Lawrence G (eds), *Altered Genes II: The Future?* (Scribe Publications, 2001) pp 11-23; Report of the Subcommittee on Basic Research, "Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology" (2000) 19 *Biotechnology Law Report* 449.

[184] For recent overviews see Hoffmann D and Sung L, "Future Public Policy and Ethical Issues Facing the Agricultural and Microbial Genomics Sectors of the Biotechnology Industry" (2005) 24 *Biotechnology Law Report* 10; Stewart P and McLean W, "Fear and Hope over the Third Generation of Agricultural Biotechnology: Analysis of Public Response in the Federal Register" (2004) 7 *AgBioForum* 133; see generally Hindmarsh R and Lawrence G (eds), *Recoding Nature: Critical Perspectives on Genetic Engineering* (UNSW Press, 2004).

[185] For an overview of the international regulatory risk assessment schemes See for example, Hayes, n 17; Nap J-P, Metz P, Escaler M, Conner A, "The Release of Genetically Modified Crops into the Environment" (2003) 33 *The Plant Journal* 1 at 8-13.

[186] Office of the Gene Technology Regulator, *Risk Analysis Framework*, n 15, p 12; noting also that the risk assessment is to be founded on a "science-based approach" and "objective information"; *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, n 5, pp 14 and 63.

[187] See Slovic, n 26 at 690.

[188] See Rutherford P, "The Administration of Life: Ecological Discourse as "Intellectual Machinery of Government"" (1994) 21 *Australian Journal of Communication* 40 at 40; Levidow L, "Whose Ethics for Agricultural Biotech?" in Moser I and Shiva V (eds), *Biopolitics: A Feminist and Ecological Reader on Biotechnology* (Zed Books, 1995) p 184; some authors highlight this contention by comparing and contrasting the "product" regulation and "process" regulation in the United States and Europe respectively, the former restricting uncertainties to available knowledge about the product use and its characteristics, the latter encompassing broader debates about the place of technology in society: see, for example, Jasanoff S, "Product, Process or Programme: Three Cultures and the Regulation of Biotechnology" in Bauer M (ed), *Resistance to New Technology* (Cambridge University Press, 1995) p 324.

[189] See for an overview of the historical and cultural context, Worster D, *Nature's Economy: A History of Ecological Ideas* (Cambridge University Press, 1987); Foucault M, *The Will to Knowledge: The History of Sexuality* (Robert Hurley trans, Vintage, 1990) Vol 1. Policy articulations of this contention in Australia include Biotechnology Australia, *Australian Biotechnology: A National Strategy* (Commonwealth of Australia, 2000) that provides: "[b]iotechnology holds the promise of

however, is the faith accorded to "science" as a foundation on which to establish regulatory decisions[190] and the particular narrow framing of the "problem"[191] organised around an assessment of known risks and their management[192] that the "science" seeks to address.[193] However:

> risk does not exist "out there", independent of our minds and cultures, waiting to be measured. Instead, human beings have invented the concept of risk to help them understand and cope with the dangers and uncertainties of life. Although these dangers are real, there is no such thing as "real risk" or "objective risk." The nuclear engineer's probabilistic risk estimate for a nuclear accident or the toxicologist's quantitative estimate of a chemical's carcinogenic risk are both based on theoretical models, whose structure is subjective and assumption-laden, and whose inputs are dependent on judgement.[194]

The principal actors framing the "problem" are the expert scientists (in universities and industry) granted the status of an objective voice,[195] and a "dialogue" between the Regulator and the (industry) applicant through the regulatory process.[196] The broader public is only provided with a very limited opportunity to participate in the regulatory decision-making being recognised primarily in their capacity as consumers, either buying or refusing to buy GMOs and GM products.[197] In short, the Act sets out a regulatory scheme for framing hazards, assessing the risks and the accepting those risks considered by the Regulator to have a low probability and/or with manageable consequences as objectively acceptable masked in the rhetoric of apolitical and objective "science".

Perhaps most importantly, most releases of GMOs into the environment will refer to unique and infinitely variable risk situations, and so involve a "non-statistical" or subjective probability assessment[198] relying on, at best, partial and imperfect information that may be, at best, informed by some form of "science-based" study (see also Table 2).[199] Even where rigorous and comprehensive

improved health and welfare for all Australians through better understanding of disease, improved diagnosis, and treatment with more specific biopharmaceutical products. Biotechnology, including the genetic modification of agricultural and food products, also has the potential to deliver productivity, competitiveness and sustainability benefits to Australia" (p 4).

[190] See for example, Knorr-Cetina K, *Epistemic Cultures: How the Sciences Make Knowledge* (Harvard University Press, 1999) examining the differences in knowledge as a result of difference epistemic cultures of high energy physics and molecular biology; Feyerabend P, "Democracy, Elitism, and Scientific Method" (1980) 23 *Inquiry* 3 suggesting that scientific standards cannot be separated from their practice and use of these standards presupposes immersion in the practice.

[191] Jasanoff, n 28 at 240-241.

[192] Black, n 13 at 625 and 626; Lee M and Burrell R, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" (2002) 65 MLR 517 at 518-520; see generally Jasanoff S, "The Songlines of Risk" (1999) 8 *Environmental Values* 135; noting that cognitive frameworks will also inform the uncertainties considered relevant (see Levidow, n 188, p 181) and the cultures of science developed in genetics and molecular biology capture the metaphor of building using innovative laboratory based methods rather than manipulating a complex genomic system in the broader environment (see Scoones, n 11, pp 4-5); see also Jasanoff S, *The Fifth Branch: Science Advisers as Policy Makers* (Harvard University Press, 1990); Latour B, *Science in Action* (Harvard University Press, 1987).

[193] For example, the harm from a GMO might be constructed as a direct risk from the GMO or an indirect risk from the agricultural uses of the GMO, the choice is a an assumption about risk: see Levidow, n 188, p 181; Black, n 13 at 625; importantly, but not addressed in this article, the scientific knowledge derived from this "science" only provides a relative "truth about nature" governed by a particular scientific paradigm (see Kuhn T, *The Structure of Scientific Revolutions* (2nd ed, University of Chicago Press, 1970) pp 23-34; for example molecular biologists and biochemists might be expected to emphasis different risks reflecting their different values and assumptions about their disciplines: See for example, Newell, n 11, pp 15-16), that is "a socially constructed interpretation with an already socially constructed natural-technical object of inquiry": Bird E, "The Social Construction of Nature: Theoretical Approaches to the History of Environmental Problems" (1987) 11 *Environmental Review* 255 at 255 and the references therein.

[194] Slovic, n 26 at 690.

[195] Black, n 13 at 622; see also Hindmarsh R, "Constructing Bio-utopia: Laying Foundations Amidst Dissent" in Hindmarsh and Lawrence, n 183; Fischer F, *Technology and the Politics of Expertise* (Sage Publications, 1990).

[196] Black, n 13 at 625; often forming "epistemic communities" with a common view about the risks and the most appropriate form of regulation: see Haas P, "Obtaining International Environmental Protection through Epistemic Consensus" (1990) 19 *Millennium* 347.

[197] Black, n 13 at 625 and 628; thus, the broader community are left "incompetent in matters of their own affliction": Beck U, *Risk Society: Towards a New Modernity* (Sage Publications, 1992) pp 53-55.

[198] Noting further that "probability" itself is a "mental and social creation" subject to contentious debate: see, for example, Smithson M, *Ignorance and Uncertainty: Emerging Paradigms* (Springer Verlag, 1989) p 41; see also Gigerenzer G, *Calculated Risks: How to Know When Numbers Deceive You* (Simon & Schuster, 2002).

[199] See Lawson, n 23 at 201-202; see also Carman J, "Is GM Food Safe to Eat" in Hindmarsh and Lawrence, n 184, pp 82-93.

assessments have been attempted for simply-constructed GMOs (such as the "Farm-Scale Evaluations" study in the UK),[200] they have proven to be costly, have limited predictive utility for other GMOs (including closely related lines), and do not address all the possible hazards (however characterised) to changes to the wider environment (such as gene flow to wild relatives).[201] This approach therefore considers unimportant, or insignificant, low probability adverse events accepting that there is a level of risk that can be managed.[202] Thus, an adverse event is acceptable below a certain probability threshold.[203] This poses two immediate problems, first, the assumption that low probability can be counted as zero, and secondly, the threshold of the low level probability[204] which ignores the consequences of any adverse event (albeit very unlikely).[205] Entirely outside this assessment are the unknown, unintended effects that are tacitly accepted or considered manageable.[206]

While there is no doubt that a regulatory measure is necessary in some form to address the Act's objective of establishing legitimacy about the safety of GMOs (and GM products), the challenge is to "make visible the non-scientific elements that are always behind risk-influenced decisions regarding who will be allowed to do what to the environment".[207] Moreover, to acknowledge the uncertainty inherent in the methodology of "science" as an approach to understanding nature,[208] including definitive information about how much of an activity poses "no risk" or "an insignificant risk".[209] The problem with the current Act's approach is that it allows for the Regulator, assisted by the Office of the Gene Technology Regulator, to selectively adopt often highly uncertain and contested knowledge about scientific theories and measurement techniques under the guise of consensus expert knowledge. Further, these can then be changed, minimised, magnified or dramatised within that knowledge and subject to the Regulator's particular preferences, social definitions and construction about the acceptability of possible and unknowable adverse outcomes.[210]

The Regulator's authority to define the risks within the framework of the Act according to the methodology set out in the *Risk Analysis Framework* is perhaps tempered by the requirement that the Regulator seek advice about the risk assessment and risk management plan[211] and comply with

[200] The results are presented in six articles in (2003) 358 *Philosophical Transactions of the Royal Society B* at 1779-1913; see also Giles J, "Biosafety Trials Darken Outlook for Transgenic Crops in Europe" (2003) 425 *Nature* 751; Gura T, "The Battlefields of Britain" (2001) 412 *Nature* 760; notably the CSIRO has concluded that "while the UK experiment can inform our future research in this area, its findings cannot be extrapolated directly to Australia and are therefore of quite limited relevance to Australian farming systems. The results cannot be applied to Australian GM crops in general": Lonsdale M, Baker G, Godfree B, Hirsch M, Williams K and Yeates D, *Findings from the UK Farm Scale Evaluation of Genetically Modified Herbicide Tolerant crops – An Appraisal of their Implications for Australia* (CSIRO Entomology, 2003) p 3.

[201] Wilkinson M, "Abandoning "Responsive" GM Risk Assessment" (2004) 22 *Trends in Biotechnology* 438 at 439; the author suggests such intensive and expensive studies might become impractical as the diversity and complexity of constructs introduced into GM crops expands (at 439); see also Davies P, "Gene Flow and Genetically Engineered Crops" in Hindmarsh and Lawrence, n 184.

[202] For example, the Regulator considers risks categorised as "very low" and "negligible" as acceptable and requiring limited management: see Bayer CropScience Pty Ltd, n 29, pp 29-36; see also Monsanto Australia Ltd, *General Release of Roundup Ready canola (Brassica napus) in Australia*, DIR 020/2002 (Office of the Gene Technology Regulator, 2003) pp 26-34.

[203] See Okrent D, "Comment on Societal Risk" (1980) 208 *Science* 372; for example, a 10^{-6} or lower probability of a human fatality was considered negligible for commercial nuclear reactor safety in the United States: see United States Nuclear Regulatory Commission, *Reactor Safety Study: An Assessment of Accident Risks in US Commercial Nuclear Power Plants* (United States Nuclear Regulatory Commission, 1975) p 38.

[204] See Shrader-Frechette K, *Risk Analysis and Scientific Method: Methodological and Ethical Problems with Evaluating Societal Risks* (Kluwer, 1985) pp 134-140 for an analysis of the problems of this "decision theory".

[205] See Shrader-Frechette, n 204, p 142.

[206] See Levidow, n 188, p 181; see also York G, "Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agricultural Trade" (2001) 7 Colum J Eur L 423 at 433.

[207] O'Brian M, *Making Better Environmental Decisions: An Alternative to Risk Assessment* (MIT Press, 2000) p 243.

[208] See generally Kuhn, n 193; for example, "we must recognise how very limited in both scope and precision a paradigm can be at the time of its appearance. Paradigms gain their status because they are more successful than their competitors in solving a few problems that the group of practitioners has come to recognise as acute" (p 23); see also Latour, n 192.

[209] O'Brian, n 207, pp 59-60; see also Wynne B and Mayer S, "How Science Fails the Environment" (1993) 138 *New Scientist* 33 (5 June 1993).

[210] See Beck, n 197, pp 22-23; Levidow, n 188, p 181.

[211] Preparation of the risk assessment and risk management plan – from the States, the Gene Technology Technical Advisory Committee, prescribed Commonwealth agencies, the Environment Minister and any local council the Regulator considers

various policy instruments (although there is only one presently in place).[212] There is, however, *no* requirement that the Regulator comply with any of these sources of advice. The effect of the Act, therefore, is to empower the Regulator to construct and then assess the risks of GMOs (and GM products) through a reliance on the rhetoric of science-based objectivity to promote legitimacy in GMOs (and GM products) and generally to promote commercial transactions in GMOs (and GM products). The question is therefore, whether the Regulator's decision promotes legitimacy or undermines legitimacy.

The assessment in this article so far suggests a very limited objective "science" supporting the Regulator's assessments; marked by a failure to acknowledge value judgments in framing the hazards, assessing the risks, and accepting that the identified risks are objectively acceptable. This could be seen to undermine the legitimacy of the Act. A deeper analysis of the Bayer license for the general or commercial release of GM canola highlights the sorts of contentions that are likely to undermine that legitimacy. These include four aspects: framing the GMO "problem"; selecting risk issues; making decisions without acknowledging uncertainty; and framing decisions that avoid recognition of who frames them.

Framing the GMO "problem"

This is where the Regulator frames the GMO "problem" that requires the risk assessment by:

> Confining considerations about the GMO to those that are not substantially equivalent to the "conventional canola".[213] Applying the principles of substantial equivalence (and familiarity) avoids detailed assessments of GMOs by recognising only those risks posed by the "novel" GMO, while at the same time promoting biotechnology as an innovative and competitive technology and downplaying potential environmental hazards.[214] Perhaps more importantly, however, the substantial equivalence approach avoids some critical assessments. For example, canola is a relatively recently domesticated crop with the potential to outcross with its weedy relatives. This raises concerns about the potential invasiveness of GM canola transgenes into the broader environment.[215]

Applying the substantial equivalence standard to releasing GM herbicide-tolerant canola into the environment then is a question of whether the invasiveness of the herbicide tolerance transgene will be different to traditional canola, there being a documented history of herbicide tolerance entering weedy populations related to the crop.[216] The invasiveness of releasing the herbicide tolerance transgene is unlikely to be any different to the impact of releasing a non-GM herbicide tolerant variety, although the consequences of the GM canola might be significantly different.[217]

Thus the Regulator considered the inherent weediness of conventional and GM canola in various environments (see Table 2C) and concluded, "that the GM canola lines will be more likely than conventional (non-GM) canola to spread in the environment, and result in more detrimental

appropriate: *Gene Technology Act 2000* (Cth), s 50(3); after preparing the risk assessment and risk management plan – to seek written submissions from the public, and again seek the advice of the States, the Gene Technology Technical Advisory Committee, prescribed Commonwealth agencies, the Environment Minister and any local council the Regulator considers appropriate (s 52).

[212] The Regulator is also required to "have regard to" any policy guidelines issued by the Ministerial Council relating to risks and ways to manage risks (*Gene Technology Act 2000* (Cth), ss 23 and 56(2)(d)) and be consistent with any policy principles issued by the Ministerial Council (ss 21 and 57(1)); see the only policy principle in force is the Gene Technology (Recognition of Designated Areas) Principle 2003, Commonwealth of Australia Special Gazette No S340 (5 September 2003).

[213] Bayer CropScience Pty Ltd, n 29, p 10; see also Organisation for Economic Co-operation and Development, "Biological Resource Management in Agriculture Challenges and Risks of Genetically Engineered Organisms: Scientific Challenges for Risk Assessment" (2004) 11 *SourceOECD Science & Information Technology* 328.

[214] See Barrett K and Abergel E, "Breeding Familiarity: Environmental Risk Assessment for Genetically Engineered Crops in Canada" (2000) 27 *Science and Public Policy* 2; although the merits of "substantial equivalence" remain hotly contested, compare for example, Miller H, "Substantial Equivalence: Its Uses and Abuses" (1999) 17 *Nature Biotechnology* 1042; and Millstone E, Brunner E and Mayer S, "Beyond "Substantial Equivalence"" (1999) 401 *Nature* 525; see generally McGarity T, "Seeds of Distrust: Federal Regulation of Genetically Modified Foods" (2002) 35 U Mich J L Reform 403.

[215] See Conner A, Glare T and Nap J-P, "The Release of Genetically Modified Crops into the Environment" (2003) 33 *The Plant Journal* 19 at 25-26 and the references therein.

[216] See Conner et al, n 215 at 24.

[217] See Conner et al, n 215 at 26 and the references therein.

environmental impact is negligible",[218] although the crosses MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3 were not considered.[219]

This, however, is more broadly an issue about the costs and benefits of a particular agricultural strategy of managing herbicide tolerance. It avoids the question about the particular herbicide tolerance transgene and its specific effects, with there being no agreed threshold for where a GMO (or GM product) ceases to be acceptably "equivalent".[220] This threshold is also a particular problem in assessing the potential toxicity of GMOs. For example, the Regulator was able to conclude that risks to humans of the toxicity and allergenicity of the expressed proteins (PAT, Barnase, Barstar and NPTII) compared to conventional canola was "very low",[221] even though the only data available was either undisclosed or correlated with mostly unpublished data (see Table 2A(i)). Further, there are no benchmarks for compositional and other tangible characteristics in making the substantial equivalence determination.[222] By using the standard of substantial equivalence, the Regulator thus leaves open the challenge of not taking relevant matters into consideration and applying a threshold standard that does not reflect a consensus of views about what is, and what is not, a "novel" or (un)safe organism.

Accepting that the only way to gain experience with general or commercial releases is to allow them, promotes releases as the best route to gain familiarity with any likely problem and requires the reporting of "[i]nformation about any adverse impacts, unintended effects, or new information relating to risks".[223] The consequence of this approach is to tacitly accept or consider manageable the unknown unintended effects of GMOs.

Failing to address the broader ecological concerns (such as community studies, succession studies, ecosystem analysis, population dynamics or organism-environment relationships)[224] about "ecosystems and their constituent parts" and "the qualities and characteristics of locations, places and areas", required by the Act's definition of the term "environment",[225] and its incorporation of the concepts of ecologically sustainable development.[226] This is particularly relevant as ecological sustainability involves a consideration of the long term ecological consequences of releasing GMOs,[227] including a "need to consider, in an integrated way, the wider economic, social and environmental implications of our decisions and actions for Australia, the international community

[218] Bayer CropScience Pty Ltd, n 29, p 94.
[219] See Bayer CropScience Pty Ltd, n 29, p 78.
[220] See Millstone et al, n 214 at 525; see also Rowland I, "Genetically Modified Foods, Science, Consumers and the Media" (2002) 61 *Proceedings of the Nutrition Society* 25 at 27.
[221] Bayer CropScience Pty Ltd, n 29, p 66.
[222] Rowland, n 220 at 27; the recent difference of opinion between the United States Food and Drug Administration (FDA) and the Environment Protection Agency (EPA) over the "substantial equivalence" of the Cry9C protein illustrates the variable standards that might apply, in this example, the EPA found that the Cry9C protein was resistant to protease breakdown, remained stable at high temperatures, and remained intact following four hours in simulated mammalian gastric juices and on this basis concluded that the applicant had failed to show the GMO was "substantially equivalent in all essential respects to its unmodified parent", while the FDA had approved the application finding "substantial equivalence": see Bratspies R, "Myths of Voluntary Compliance: Lessons from the Starlink Corn Fiasco" (2003) 27 Wm & Mary Envtl L & Pol'y Rev 593 at 616-619; other problems arise in determining who is qualified to make this assessment and whether the standard should be applied to individuals or classes: see McGarity, n 214 at 428; Pryme I and Lembcke R, "In Vivo Studies on Possible Health Consequences of Genetically Modified Food and Feed – With Particular Regard to Ingredients Consisting of Genetically Modified Plant Materials" (2003) 17 *Nutrition and Health* 1.
[223] Bayer CropScience Pty Ltd, n 29, p 141.
[224] For further commentary see generally, Rissler J and Mellon M, *The Ecological Risks of Engineered Crops* (MIT Press, 1996).
[225] *Gene Technology Act 2000* (Cth), s 10; for an analysis of the term "environment" see Trantor, n 10, pp 253-254; McGrath, n 64 at 35.
[226] Attempts to include these sorts of measures in the *Gene Technology Act 2000* (Cth) were expressly rejected (for example, an amendment "to promote ecological sustainability": Australia, Senate, *Debates*, (7 December 2000) pp 21181-21182 (Senator Natasha Stott Despoja)); on the basis that: "[w]e do not consider a separate definition [of ecological sustainability] is required, because ecological sustainability is not separate and distinct from the environment", see Australia, Senate, *Debates* (7 December 2000) p 21204 (Parliamentary Secretary to the Minister for Health and Aged Care).
[227] Described as "costs" that the *Gene Technology Act 2000* (Cth) was intended to address: *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, n 5, p 6.

and the biosphere" and with a "long term view".[228] The prepared risk assessment and risk management plan show that this has not happened, with no long term (such as 50 or 100 year)[229] hazards considered or identified. Further, there was no evaluation of the likely tillage and herbicide regimes' effects on weed populations as a consequence of using GMO canola resistance to the herbicide glyphosate. Instead the Regulator merely asserted that, "[t]here is potential for development of herbicide-resistant weeds if the InVigor crop-Liberty herbicide combination is used inappropriately".[230] This was a surprising omission because the widespread adoption of herbicide-resistant GMOs will effect weed communities towards naturally resistant species, species with inherent characteristics (such as delayed emergence), and herbicide resistant bio-types, each with potentially significant environmental and economic consequences irrespective of the herbicide regime.[231]

Selecting risk issues

This is where the Regulator then selectively addresses risk issues by:

- Overlooking the absence of quantitative data about the GMOs (and GM products) about which the license was sought. Instead the Regulator relies on correlations and assertions from a variety of sources to find that the risks are low or negligible, and in particular the views and opinions of experts without acknowledging the epistemic cultures from which those views and opinions originate (see Table 2).[232] For example, the lack of toxicity for humans of the PAT protein from the pat and bar genes was correlated from unpublished mice and rat feeding studies over 14 days where purified PAT protein (including a recombinant PAT protein) was administered over a period of time where "no gross internal findings were observed" and "[n]o significant differences were observed".[233] The use of the terms "no gross" and "no significant" reflect an assessment that there were some differences between the rats fed with purified PAT protein and an acceptance by the Regulator that these difference were of no consequence (and particularly of no consequence for humans). This then required no further consideration of the consequences of any adverse event (in effect, probability zero for human health and safety).[234] The problem with this approach is that it considers unimportant, or insignificant, what are assessed in the Regulator's view – based on limited data and assertions from a particular epistemic culture – to be the likelihood of low probability adverse events. This tends to ignore the consequences of any adverse event that may be significantly detrimental (even fatal) for particular individuals.[235]
- Failing to identify, acknowledge or address inherent value judgments in the assessment of the risks. For example, the Regulator finds the risk of the GM canola being more invasive or persistent than conventional canola is "negligible" and decides that this is a risk worth taking.[236] While this might be a valid and appropriate value judgment, it is still a judgment that accepts some risks that might eventuate, especially over the long term, where the consequences might be considerable. For example, stochastic modeling of the impacts of feral populations of crops on wild relatives suggests over a long period of time (100 years) the invasiveness and persistence of crop species may not be "negligible".[237] Perhaps more importantly, however, the Regulator

[228] Council of Australian Governments, *National Strategy for Ecologically Sustainable Development* (Commonwealth of Australia, 1992) p 6.
[229] See, for example, Burgmann, n 25 at 131-132.
[230] Bayer CropScience Pty Ltd, n 29, p 134.
[231] See for an overview, Owen M and Zelaya I, "Herbicide-Resistant Crops and Weed Resistance to Herbicides" (2005) 61 *Pest Management Science* 301.
[232] See generally Knorr-Cetina, n 190.
[233] Bayer CropScience Pty Ltd, n 29, p 56.
[234] See Rescher N, *Risk: A Philosophical Introduction to the Theory of Risk Evaluation and Management* (University Press of America, 1983) p 36.
[235] See Shrader-Frechette, n 204, p 142.
[236] Bayer CropScience Pty Ltd, n 29, pp 11 and 94; perhaps surprisingly, the line or variety of GM and conventional canola investigated and reported by the Regulator were not disclosed either by the Regulator or the cited authority (p 93).
[237] Burgmann, n 25 at 131-132 showing that a 0.5% and 5% escape rate of a competitively inferior crop on wild populations will fall to 1% of their initial population size with a probability of 20% and 100% respectively (p 132).

accepts conclusively that GM canola will not persist in undisturbed natural environment by relying on a published study showing GM canola became extinct in such environments after two years.[238] This does not acknowledge that there was considerable debate about the merits of the study, its design and the generality of its conclusions.[239] Further, even where quantitative risk assessments are available (probability-based inferences), they rely on statistical models with considerable judgment lying in the choice of model and its underlying assumption.[240] What might be considered "not significant" (or "negligible") overlooks potentially contested conclusions about the methodology and its assessment (climate change modelling provides a current example,[241] as does the safety testing of GM foods).[242]

- Avoiding any assessment of the understanding of knowledge or the values involved in acquiring and producing knowledge (and in particular scientific uncertainty).[243] For example, the consequences of unintended or pleotropic effects were assessed in part according to feeding studies of the MS1 x RF1 cross seeds fed to canaries having "no differences in food consumption, behavior and body weight between the GM and non-GM diets".[244] This study did not disclose how this data was derived or the experimental design, both involving value judgments about how to conduct the experiment (such as how to measure behavior) and then assumptions in the statistical model that revealed "no difference" (assuming the data was subjected to a statistical analysis).[245] A similar criticism applies to the Regulator's reliance on assessing human toxicity and allergenicity based on unpublished mice and rat feeding studies,[246] and upon an undisclosed line or variety of canola.[247]
- Avoiding any long-term or intergenerational assessment of potential impacts, especially the degree of environmental risks,[248] even though this is an express requirement of the Act[249] and an identified community concern that was "scientific".[250] For example, in assessing the risk of GM

[238] Bayer CropScience Pty Ltd, n 29, p 93; see also OGTR, n 107, p 11.
[239] Reviewed in Metz P and Nap J-P, "A Transgene-Centred Approach to the Biosafey of Transgenic Plants: Overview of Selection and Reporter Genes" (1997) 46 *Acta Botanica Neerlandica* 25.
[240] See Hayes, n 17, p 38; see also Harding R, *Environmental Decision-making* (Federation Press, 1998).
[241] For an overview of the contested modelling debate See for example, Murphy J, Sexton D, Barnett D, Jones G, Webb M, Collins M, Stainforth D, "Quantification of Modelling Uncertainties in a Large Ensemble of Climate Change Simulations" (2004) 430 *Nature* 768.
[242] See Carman, n 199, pp 82-93.
[243] Bayer CropScience Pty Ltd, n 29, p 147; by way of example, recognised experts may contest the interpretation of data where the risks are uncertain: see Von Krauss MK, Casman E and Small M, "Elicitation of Expert Judgements of Uncertainty in the Risk Assessment of Herbicide-Tolerant Oilseed Crops" (2004) 24 *Risk Analysis* 1515; see also Walker V, "The Siren Songs of Science: Towards a Taxonomy of Scientific Uncertainty for Decision Makers" (1991) *Connecticut Law Review* 567.
[244] Bayer CropScience Pty Ltd, n 29, p 59; a recent report suggests that these effects, where they are examined, may be significant: see Prescott V, Campbell P, Moore A, Mattes J, Rothenberg M, Foster P, Higgins T and Hogan S, 'Transgenic Expression of Bean α-Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity' (2005) 53 *Journal of Agricultural and Food Chemistry* 9023; see also Schubert D, "A different perspective on GM food" (2002) 20 *Nature Biotechnology* 969.
[245] See Bayer CropScience Pty Ltd, n 29, p 59; the cited reference merely provides: "[a]n avian dietary test was performed with the seed eating canary bird (Serinus canaria domestica), and a feeding study was performed with the domesticated rabbit (Oryctolagus cuniculus); these studies showed no differences in food consumption, behaviour and body weight between birds or rabbits fed with the transgenics or counterparts": see Canadian Food Inspection Agency, *Determination of Environmental Safety of Plant Genetic Systems Inc. (PGS) Novel Hybridization System for Canola* (Brassica napus L.), Decision Document DD95-04 (Canadian Food Inspection Agency, 1995) para 24.
[246] Bayer CropScience Pty Ltd, n 29, pp 58-59.
[247] Bayer CropScience Pty Ltd, n 29, p 61.
[248] Despite ongoing criticism that there is insufficient monitoring and testing to reliably assess the degree of environmental risks: See for example, Ervin D, Welsh R, Batie S and Carpentier CL, "Towards an Ecological Systems Approach in Public Research for Environmental Regulation of Transgenic Crops" (2003) 99 *Agriculture, Ecosystems and Environment* 1.
[249] See *Gene Technology Regulations 2000* (Cth), Reg 10(2); notably there is some reference and consideration of a "long-term ecological study" of weed invasiveness and persistence over "a 10 year period", although this seems a relatively short period when models often consider 100 years; See for example, Burgmann, n 25 at 132.
[250] See *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, n 5, p 6; see also Okrent D and Pidgeon N, "Introduction: Dilemmas in Intergenerational Versus Intragenerational Equity and Risk Policy" (2000) 20 *Risk Analysis* 759 and the other

canola entering "undisturbed natural habitats", the Regulator considers "[c]anola having been bred as a cultivated crop *can only* germinate and establish under optimal growing conditions within a well managed agronomic system" (emphasis added).[251] But then the Regulator reviews the results of a "long-term ecological study conducted at 12 sites in 8 different habitats over a 10 year period", which concluded that "[o]ur results do not mean that other genetic modifications could not increase weediness or invasiveness of crop plants, but they do indicate that arable crops are *unlikely* to survive for long outside cultivation" (emphasis added).[252] Further, the study only examined an undisclosed line of oilseed rape with a kanamycin resistance and kanamycin resistance plus tolerance to glufosinate herbicide modification in English habitats.[253] It expressly cautioned that other GM traits would require an assessment of their ecological impacts.[254] Perhaps significantly, in this study the oilseed rape did not persist beyond the second year.[255] The question of what happened to conventional and GM canola that does persist was thus not addressed by the experiment, although the study did note, "[t]he survival of [non-study site] sea beet on open ground elsewhere in Silwood Park, where potted plants had stood in 1992, sounds the cautionary note that perennial plants can persist for extended periods in extremely odd places".[256]

- Excluding some information as "confidential commercial information",[257] and not disclosing data and information about the earlier trials of GM canola.[258] While this may not be significant, failure to disclose the "confidential commercial information" diminishes transparency and accountability in the Regulator's decision. Moreover, failure to disclose data and information about the earlier trials of GM canola leaves open the possibility that those "trials" may not have been addressing risk issues, but rather agronomic performance and other practical issues (such as seed multiplication).[259]
- Accepting some of the data supporting the application that was provided by the applicant (Bayer), and some that was unpublished materials (not peer reviewed).[260] While the applicant and its paid researchers may be well placed to provide data and information about the GM canola, their contributions are open to undermine the Act's scheme. This is because "it may not be in their best interests to draw the possibility of a risk to the attention of prospective consumers and the community generally", and "consumers might discount the usefulness of industry provided information on that basis".[261]

articles in that issue; notably, this was also a significant community concern in assessing the Bayer GMOs: see Bayer CropScience Pty Ltd, n 29, pp 152-156 ("General environmental concerns").

[251] Bayer CropScience Pty Ltd, n 29, p 93.

[252] Crawley M, Brown S, Hails R, Kohn D and Rees M, "Biotechnology: Transgenic Crops in Natural Habitats" (2001) 409 *Nature* 682 at 683.

[253] See also Crawley M, Hails R, Rees M, Kohn D and Buxton J, "Ecology of Transgenic Oilseed Rape in Natural Habitats" (1993) 363 *Nature* 620.

[254] Crawley et al, n 252 at 683 and in particular traits "such as drought tolerance or pest resistance that might be expected to enhance performance under field conditions" (at 683); a similar view has been expressed about the particularities of the Australian environment: see Lonsdale et al, n 200 at 3.

[255] See Crawley et al, n 252 at 683; see also Crawley et al, n 253 at 620.

[256] Crawley et al, n 252 at 683.

[257] See Bayer CropScience Pty Ltd, n 29, p 8.

[258] See Bayer CropScience Pty Ltd, n 29, pp 18-19.

[259] Significantly, the previous Aventis limited or field trial release of GM canola appears to have been directed to these agronomic performance and practical issues: see Aventis CropScience Pty Ltd, n 30, p 7 providing, "[t]he purpose of this release is to conduct plant breeding (including agronomic assessments) and seed production trials for the development of canola cultivars for the Australian, North American and European cropping systems".

[260] See, for example, Bayer CropScience Pty Ltd, n 29, pp 62 (allergenicity of PAT protein data provided by Bayer) and 56 (toxicity of PAT protein from DeKalb Genetics Corporation (a Monsanto Company related entity)).

[261] *Gene Technology Bill 2000* (Cth), Explanatory Memorandum, n 5, p 10; see also the allegations of undisclosed and overlooked industry provided data often in the form of "summary data" sets: Shubert D and Freese W, "Safety Testing and Regulation of Genetically Engineered Foods" (2004) 21 *Biotechnology & Genetic Engineering Reviews* 299.

Making decisions without acknowledging uncertainty

This is where the Regulator makes apparently conclusive decisions without acknowledging the uncertainty by:

- Accepting that the identified risks are "negligible" or "very low"[262] after considering "the likelihood of the hazard occurring"; "the likely consequences (impact) of the hazard, were it to be realised"; and, "risk management options to mitigate any significant hazards";[263] without acknowledging that the "science" cannot provide definitive information about how much of an activity poses "an insignificant risk",[264] or the likely consequences of an adverse event (albeit a very unlikely event).[265] For example, studies of hybridisation between canola (B. napus) and wild turnip (B. rapa) in Denmark found between 9% and 93% of seeds produced were hybrids of the two plants.[266] In contradistinction, a study in England of wild turnips in disturbed ground near canola fields found hybridisation in only 0.4% and 1.5% of seeds.[267] The risk of canola outcrossing with a wild relative based on these results is not definitive (probably somewhere between 0.4% and 93%). More importantly, the results provide no indication of how much outcrossing is a risk that is not worth taking. Perhaps most importantly, however, is that horizontal (or lateral) gene transfer into other organisms in the environment is uncontrolled but predictable (and inevitable),[268] but there is no consideration of the likely consequences of such an eventuation.
- Accepting that certain genetic modifications to the glufosinate ammonium tolerance structural gene (the transit peptide nucleotides in MS1, RF1 and RF2 and the codon substitution in MS8 and RF3) and relic sequences from the Agrobacterium-mediated transformation did not require specific consideration or assessment (see Table 1).[269] Thus, eg the genetic construction of MS1 and MS 8 might be considered different, even though they both express the bar gene, as the BAR proteins are unlikely to be the same in all respects and therefore require a possibly different comparison. By ignoring these minor genetic modifications and not requiring a separate assessment of each transformation event T45, Topas 19/2, RF1, RF2, RF3, MS1 and MS8 (and their crosses) the Regulator failed to make an assessment that each GMO has satisfied the Act's requirements. This leaves uncertainty about the risks of those GMOs. Further, in making the assessments about human health and safety, the Regulator took into account the particular components of the genetic modification construction, but in the assessment of the weediness of the different lines and crosses no such detail was required (compare Tables 2A(i) and 2C).[270]
- Accepting the available data without waiting for the completion of the Aventis field trials that might have been expected to have addressed uncertainties in the available data, and provided further confirmation about the presumptive risks identified in the Aventis application.[271] Further, accepting an application where some of the GMOs have never been subjected to limited or field trial release in Australia (notably T45, Topas 19/2, RF1, RF2, and MS1, and some of the crosses)[272] accepts that there was no or incomplete Australian data about their character in the

[262] See Bayer CropScience Pty Ltd, n 29, pp 29-36.
[263] Bayer CropScience Pty Ltd, n 29, p 27.
[264] O'Brian, n 207, pp 59-60.
[265] Shrader-Frechette, n 204, p 142; although the potential for future consequences exists as a result of, for example, preserved viable seeds in soil layers transferring the risk of gene flow to the future: see Gruber S, Pekrun C and Claupein W, "Life Cycle and Potential Gene Flow of Volunteer Oilseed Rape in Different Tillage Systems" (2005) 45 *Weed Research* 83.
[266] Jorgensen R, Andersen B, Landbo L and Mikkelsen T, "Spontaneous Hybridisation Between Oilseed Rape (Brassica napus) and Weedy Relatives" (1998) 407 *Acta Horticulturae* 193.
[267] Scott S and Wilkinson M, "Transgene Risk is Low" (1998) 393 *Nature* 320.
[268] See, for example, Panoff J-M and Chuiton C, "Horizontal Gene Transfer: A Universal Phenomenon" (2004) 10 *Human and Ecological Risk Assessment* 939, which describes a failure to take such horizontal transfers into account as "a denial of scientific knowledge" (at 942).
[269] See Bayer CropScience Pty Ltd, n 29, pp 46-52.
[270] See Bayer CropScience Pty Ltd, n 29, pp 54-56 and 79-94.
[271] See Aventis CropScience Pty Ltd, n 30, pp 64-65; Bayer CropScience Pty Ltd, n 29, pp 143-144.
[272] See Bayer CropScience Pty Ltd, n 29, pp 143-144.

Australian environment and that this is of no consequence.[273] In both instances uncertainty remains about the risks posed by the GMOs.

Framing decisions that avoid recognition of who frames them

This is where the Regulator frames her decision in a way that avoids her apparent role in deciding whether there are risks that can then be managed by:

- Deciding that the GM canola is "as safe as conventional canola"[274] applying the substantial equivalence standard. The Regulator's decision might be interpreted as making no legitimate claims about the health and environmental safety of the products.[275] Further, the substantial equivalence standard assumes the genetic modification itself is an inconsequential process that is of no concern to either regulators or consumers.[276]
- Issuing the license in uncertain terms to a trademark "InVigor hybrid canola", and for "canola" described as "containing" the transformation event T45, Topas 19/2, RF1, RF2, RF3, MS1 and MS8.[277] There is no clear statement about what "InVigor hybrid canola" constitutes (although presumably this will include at least "canola containing transformation event[s]" MS8 *and* RF3, but it might also include, for example, an MS1 x RF3 hybrid) and whether the license also extends to "other" varieties of *B. napus* (such as other cultivars in addition to AC EXCEL and Drakkar)[278] that contain the inserted construct T45, Topas 19/2, RF1, RF2, RF3, MS1 and MS8.[279]

CONCLUSIONS

The significance of the assessment in this article is the finding that the "science-based" decision making advocated by the Act in practice relies almost exclusively on qualitative assessments. While the inherent uncertainty posed by predicting likely future risks will always remain, the lack of quantitative data that is knowable is an obvious failing in the Regulator's decision. Significantly, such data could be required as part of the application process, as an essential element of licensing field trials (limited releases into the environment), and as part of the ongoing monitoring of general or commercial releases into the environment. Each of these data sources could significantly reduce uncertainty and enhance the legitimacy of the Regulator's decisions. Importantly, this study also shows the complexity involved in assessing GMOs (and GM products) and perhaps points to the increasing difficulty in requiring "science" to address each of the components of the genetic construction and the possible effects.

However, the authors' findings also challenge the suitability of "science" alone as a basis for regulatory decision-making to deliver a credible assurance (openness and transparency) about the safety of GMOs (and GM products). The reliance on standards, such as substantial equivalence, and the exercise of decision-making powers without acknowledging the preferences and values inherent in those judgements leaves decisions open to challenge. This is particularly so where the Regulator is in a position to both construct and assess the risks, and then decide that those risks are objectively acceptable. The solution, in the author's view, is to acknowledge the subjective judgments and

[273] Noting that Bayer has since been granted a license for a limited field trial release of other MS and RF lines: see Bayer CropScience Pty Ltd, *Field Trial - Seed Increase and Field Evaluation of Herbicide Tolerant Genetically Modified Canola Incorporating a Hybrid Breeding System: Risk Assessment and Risk Management Plan*, DIR 032/2002 (Office of the Gene Technology Regulator, 2004).
[274] Bayer CropScience Pty Ltd, n 29, p 10.
[275] Millstone et al, n 214.
[276] For a discussion of this contention see Kysar D, "Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice" (2004) 118 Harv L Rev 525 and 554-562.
[277] Bayer CropScience Pty Ltd, n 29, pp 7 and 143; for example (1) "InVigor hybrid canola" being *only* canola hybrids containing the MS8 and the RF3 transformation events; (2) "InVigor hybrid canola" being hybrids containing either the MS8 transformation event or the RF3 transformation event, or both the MS8 and the RF3 transformation events; and (3) "InVigor hybrid canola" being hybrid canola *some* of which are the hybrids containing the MS8 and RF3 transformation events.
[278] See Bayer CropScience Pty Ltd, n 29, p 39.
[279] Although this interpretation is likely to be limited in that Bayer has been granted a limited or field trial release license for other MS and RF lines with a different (confidential) herbicide tolerance gene: see Bayer DIR 032/2002, n 273.

construct the regulatory scheme in a way that adopts these broader considerations and that does not characterise community concerns about the risks of GMOs as a technical, scientific matter within the expertise of experts and free of political and other non-science concerns. This is vital for a legitimating regulatory scheme because of its role in balancing the imposition of a potentially adverse event against individuals and the broader community that they otherwise might have been able to individually reject. While *more* "science" will enhance the Regulator's decisions, "science" alone is not enough to avoid a further loss of legitimacy with regard to the current regulation of commercial and general releases of GMOs (and GM products) into the environment.

Table 1: Summary of disclosed Bayer canola modifications.

Line	Glufosinate ammonium tolerance						Hybrid breeding system			Antibiotic resistance		
	5'	Structural gene				3'	5'	Structural gene	3'	5'	Structural gene	3'
T45	*P-35S CaMV*	*pat S. viridochromogenes*			Plant preferred codon usage	*T-35S CaMV*						
Topas 19/2*	*P-35S CaMV*	*pat S. viridochromogenes*			Plant preferred codon usage	*T-35S CaMV*				*P-nos A. tumefaciens*	*nptII Tn5 E. coli*	*3' cos A. tumefaciens*
MS1	*PSsuAra A. thaliana*	*bar S. hygroscopicus*	Transit peptide		Plant preferred codon usage	*3'g7 A. tumefaciens*	*PTA29 N. tabacum*	*barnase B. amylo-liquifaciens*	*3' nos A. tumefaciens*	*P-nos A. tumefaciens*	*nptII Tn5 E. coli*	*3' cos A. tumefaciens*
MS8	*PSsuAra A. thaliana*	*bar S. hygroscopicus*		Codon substit-ution	Plant preferred codon usage	*3'g7 A. tumefaciens*	*PTA29 N. tabacum*	*barnase B. amylo-liquifaciens*	*3' nos A. tumefaciens*			
RF1	*PSsuAra A. thaliana*	*bar S. hygroscopicus*	Transit peptide		Plant preferred codon usage	*3'g7 A. tumefaciens*	*PTA29 N. tabacum*	*barstar B. amylo-liquifaciens*	*3' nos A. tumefaciens*	*P-nos A. tumefaciens*	*nptII Tn5 E. coli*	*3' cos A. tumefaciens*
RF2	*PSsuAra A. thaliana*	*bar S. hygroscopicus*	Transit peptide		Plant preferred codon usage	*3'g7 A. tumefaciens*	*PTA29 N. tabacum*	*barstar B. amylo-liquifaciens*	*3' nos A. tumefaciens*	*P-nos A. tumefaciens*	*nptII Tn5 E. coli*	*3' cos A. tumefaciens*
RF3**	*PSsuAra A. thaliana*	*bar S. hygroscopicus*		Codon substit-ution	Plant preferred codon usage	*3'g7 A. tumefaciens*	*PTA29 N. tabacum*	*barstar B. amylo-liquifaciens*	*3' nos A. tumefaciens*			

* Topas 19/2 has two copies of the *pat* and *nptII* genes as head to head inverted repeats of the T-DNA.

** RF3 has two copies of the *barstar* gene, the second copy being part of an incomplete T-DNA being a functional *pTA29* promoter, a complete *barstar*, a complete *3' nos*, and truncated non-functioning *PssuAra*

Table 2: Data and information set out in the prepared risk assessment and risk management plan identifying "gaps" in the data and information

This analysis is presented in Parts A, B, C and D that correspond to the hazards identified by the Regulator in the prepared risk assessment and risk management plan.

A. Human health and safety:
   (i) Toxicity or allergenicity of the expressed proteins and other compounds, and in particular for humans;
   (ii) Toxicity or allergenicity of the GM lines, and in particular for humans; and
   (iii) Toxicity or allergenicity of the GM line crosses, and in particular for humans.

B. Environmental safety – toxicity or allergenicity of GM lines and crosses for other organisms;

C. Environmental safety – weediness of GM lines and crosses; and

D. Environmental safety – transfer of introduced genes to other organisms.

The Tables were constructed by taking each component identified by the Regulator relating to the possible hazards and identifying whether there was some data or information based on data collected from experimentation considered in the prepared risk assessment and risk management plan. Where some data or information based on data collected from experimentation was identified this is recorded in the Tables with a ✓. This analysis only identifies "gaps" in the data and information of hazards identified by the Regulator. Where the analysis for lines and crosses was the same then the lines and crosses have been pooled together.

Table 2A(i): Toxicity or allergenicity of the expressed proteins and other compounds, and in particular for humans

Lines and crosses	*Component*	*Data or information*
T45	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*pat* gene)	✓; correlation with unpublished mice and rat feeding studies
Topas 19/2	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*pat* gene)	✓; correlation with unpublished mice and rat feeding studies
	NPTII	✓; correlation with mice feeding studies
MS1	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	Barnase	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
MS8	Erucic acid	✓; data disclosed
	Glucosinolates	✓; data disclosed
	PAT (*bar* gene, codon)	✓; correlation with unpublished mice and rat feeding studies
	Barnase	
RF1	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	Barstar	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
RF2	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	Barstar	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
RF3	Erucic acid	✓; data disclosed
	Glucosinolates	✓; data disclosed
	PAT (*bar* gene, codon)	✓; correlation with unpublished mice and rat feeding studies
	Barstar	
MS1 x RF1 cross MS1 x RF2 cross	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed

Lines and crosses	*Component*	*Data or information*
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	Barnase	
	Barstar	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
MS1 x RF3 cross	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	PAT (*bar* gene, codon)	✓; correlation with unpublished mice and rat feeding studies
	Barnase	
	Barstar	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
MS8 x RF1 cross MS8 x RF2 cross	Erucic acid	✓; data not disclosed
	Glucosinolates	✓; data not disclosed
	PAT (*bar* gene)	✓; correlation with unpublished mice and rat feeding studies
	PAT (*bar* gene, codon)	
	Barnase	
	Barstar	
	NPTII	✓; correlation with mice feeding studies
	Transit peptide	
MS8 x RF3 cross	Erucic acid	✓; data disclosed
	Glucosinolates	✓; data disclosed
	PAT (*bar* gene, codon)	✓; correlation with unpublished mice and rat feeding studies
	Barnase	
	Barstar	
	Transit peptide	

Table 2A(ii): Toxicity or allergenicity of the GM lines, and in particular for humans

Line	*Characteristic*		*Data or information*
T45	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*pat*)	✓; correlation with unpublished rat feeding study
	Occupational exposure		
Topas 19/2	Pleotropic (feeding studies)		✓; unpublished broiler chicken feeding studies
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*pat*)	✓; correlation with unpublished rat feeding study
		NPTII	
	Occupational exposure		
MS1	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		NPTII	
	Occupational exposure		
MS8	Pleotropic (feeding studies)		
	Composition		✓; data disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
	Occupational exposure		
RF1	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barstar	
		NPTII	
	Occupational exposure		
RF2	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study

Line	*Characteristic*		*Data or information*
		Barstar	
		NPTII	
	Occupational exposure		
RF3	Pleotropic (feeding studies)		
	Composition		✓; data disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barstar	
	Occupational exposure		

Table 2A(iii): Toxicity or allergenicity of the GM line crosses, and in particular for humans

Crosses	*Component*		*Data or information*
MS1 x RF1 cross	Pleotropic (feeding studies)		✓; unpublished rabbit and published canary feeding studies
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
		NPTII	
	Occupational exposure		
MS1 x RF2 cross	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
		NPTII	
	Occupational exposure		
MS1 x RF3 cross	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
		NPTII	
	Occupational exposure		
MS8 x RF1 cross	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
		NPTII	
	Occupational exposure		

Crosses	*Component*		*Data or information*
MS8 x RF2 cross	Pleotropic (feeding studies)		
	Composition		✓; data not disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
		NPTII	
	Occupational exposure		
MS8 x RF3 cross	Pleotropic (feeding studies)		✓; rabbit feeding studies
	Composition		✓; data disclosed
	Herbicide metabolites		✓; correlation with undisclosed line or variety
	Allergenicity	PAT (*bar*)	✓; correlation with unpublished rat feeding study
		Barnase	
		Barstar	
	Occupational exposure		

Table 2B: Toxicity of the GM lines and crosses to other organisms

Line and crosses	*Characteristic*		*Data or information*
T45	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	✓; data not disclosed
		Genetic modifications	✓; unpublished rabbit/chicken and published canary feeding studies
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; no effect on bee foraging or brooding behavior
Topas 19/2	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	✓; data not disclosed
		Genetic modifications	✓; unpublished rabbit/chicken and published canary feeding studies
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; no effect on bee foraging or brooding behavior
MS1, RF1 and RF2	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	✓; data not disclosed
		Genetic modifications	✓; unpublished rabbit/chicken and published canary feeding studies
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; correlation with different line or variety
MS8 and RF3	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	✓; data disclosed
		Genetic modifications	✓; unpublished rabbit/chicken and published canary feeding studies
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; no effect on bee foraging or brooding behavior
MS1 x RF1 cross	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	

Line and crosses	*Characteristic*		*Data or information*
		Genetic modifications	
	Soil invertebrates (including insects)		✓; significant differences not attributed to GM line
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; no effect on bee foraging behavior
MS1 x RF2 and MS1 x RF3 crosses	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	
		Genetic modifications	
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		✓; correlation with different line or variety
MS8 x RF1, MS8 x RF2 and MS8 x RF3 crosses	Grazing and native animals		✓; unpublished rabbit/chicken and published canary feeding studies
	Feed safety	Erucic acid and glucosinolates	
		Genetic modifications	
	Soil invertebrates (including insects)		✓; correlation with different line or variety
	Soil microbes		✓; differences attributed to GM line (different line or variety)
	Insects		

Table 2C: Weediness of GM lines and crosses.

Lines and crosses	*Characteristic*		*Data or information*
T45, Topas 19/2, MS1 (no anthers), MS8 (no anthers), RF1, RF2 and RF3	Glufosinate ammonium tolerance		✓; correlation with different lines or varieties
	Hybrid breeding system		
	Antibiotic resistance		
	Disease characteristics		✓; data not disclosed
	Environmental stresses (eg light)		✓; data not disclosed
	Seed persistence		✓; eg 17.5% sites had volunteers after 3 years (line or variety uncertain)
	Seed dissemination	Animals and birds	✓; eg 0.1% daily seed intake of sheep excreted (line or variety uncertain)
		Transport	✓; eg roadside canola weeds not eradicated (line or variety uncertain)
	Long term weediness		✓; correlation with equivalent to non-GM (line or variety uncertain)
MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3 crosses	Glufosinate ammonium tolerance		
	Hybrid breeding system		
	Antibiotic resistance		
	Disease characteristics		
	Environmental stresses (eg light)		
	Seed persistence		
	Seed dissemination	Animals and birds	
		Transport	
	Long term weediness		

Table 2D: Gene transfer from GM lines and their crosses to other canola, other plants and other organisms

Lines and crosses	*Characteristic*		*Data or information*
T45, Topas 19/2, MS1 (no anthers), MS8 (no anthers), RF1, RF2 and RF3	Gene transfer to other canola	Outcrossing within conventional canola	✓; correlation with different lines or varieties
		Outcrossing within GM canola	✓; correlation with different lines or varieties
	Gene transfer to other plants	*B. napus* vegetables and forage rape	✓; correlation with different lines or varieties

Lines and crosses	*Characteristic*		*Data or information*
		Other *Brassica* species	✓; correlation with different lines or varieties
		Brassicaceous weeds	✓; correlation with different lines or varieties
	Gene transfer to other organisms	Humans	
		Animals	
		Micro-organisms	
		Bacteria	
		Fungi	
		Plant viruses	
MS1 x RF1, MS1 x RF2, MS1 x RF3, MS8 x RF1, MS8 x RF2 and MS8 x RF3 crosses	Gene transfer to other canola	Outcrossing within conventional canola	✓; correlation with different lines or varieties
		Outcrossing within GM canola	✓; correlation with different lines or varieties
	Gene transfer to other plants	*B. napus* vegetables and forage rape	
		Other *Brassica* species	
		Brassicaceous weeds	
	Gene transfer to other organisms	Humans	
		Animals	
		Micro-organisms	
		Bacteria	
		Fungi	
		Plant viruses	