A system under strain: The Regulation of Gene Technology

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Introduction

The Gene Technology Act 2000 Cth (the Act) was intended to establish a nationally consistent scheme for enabling the use of gene technology[1]. However in its short life of approaching two years[2], five of the States have indicated they would not allow the commercial release of any new genetically modified (GM) food crops despite licences granted under the Act[3].

The Act establishes the independent position of Regulator[4]. It is the responsibility of the Regulator to determine applications for dealings with genetically modified organisms (GMOs)[5]. Dealings are defined widely under the Act to include:

(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 paragraphs (a) to (g)[6].

Thus the Regulator is responsible for the sanction or oversight of a large spectrum of dealings from experiments contained within a laboratory to the wholesale commercial release of GM crops. The final approval for the release of food, pharmaceutical drugs and agricultural and veterinary chemicals lies with other agencies after approval by the Regulator[7]. A hefty penalty applies to engaging in a dealing without an authorisation under the Act[8]. There are various authorisations available under the Act. These are:

- The dealing is included in the GMO Register[9];
- The dealing is an exempt dealing[10];
- The dealing is a notifiable low risk dealing[11];
- The dealing is licensed[12].

1 *Gene Technology Act 2000* s5.

2 The Act commenced on 22 June 2001.

3 Queensland is the only State which has not committed itself to a moratorium of any sort.

4 *Gene Technology Act 2000* s 26. The present incumbent is Dr Sue Meeks.

5 *Gene Technology Act 2000* s55.

6 *Gene Technology Act 2000* s10 "deal with".

7 Food Standards Australia and New Zealand, Therapeutic Goods Administration and Australian Pesticides and VeterinaryMedicines Authority.

8 *Gene Technology Act 2000* s 32 the penalty being 2,000 penalty units or five years imprisonment.

9 *Gene Technology Act 2000* s76 and following.

10 *Gene Technology Act 2000* s32(3).

11 *Gene Technology Act 2000* s74.

12 *Gene Technology Act 2000* Part 5.

GM Canola Applications

The authorisations which have attracted the most recent attention are licence applications for the commercial release of GM canola. The applications are by two global food science companies, Bayer CropScience Pty Ltd[13] and Monsanto Australia Ltd[14]. The Regulator, as she is required to do as part of the assessment process under the Act[15], has recently released the Risk Assessment and Risk Management Plan (RARMP) in connection with the Bayer application indicating an intention to issue a licence[16]. RARMPs are open to public submissions before the Regulator makes a final determination[17].

The use of GMOs generally, and these two canola applications in particular, have provoked much controversy. The Office of the Gene Technology Regulator lists the general arguments in relation to the use of GMOs. The arguments in favour for the rural sector being increased productivity and reduced use of chemicals, whereas arguments against include potential health risks, unknown long term consequences and risk to the integrity of non-genetically modified crops through the spread of GM crops[18]. It is this last aspect which has raised most concern amongst those opposed to the release of GM canola. There is the claim that because of the nature of the pollination of canola over a great distance, then non-GM crops will be contaminated and markets will be lost as a result of producers being unable to retain their non-GM status. There is judicial recognition of the unintentional spread of GM canola to non-GM crops in the Canadian case of *Monsanto Canada Inc v Schmeiser* 2001 FCT 258. Although Schmeiser grew non-GM canola, his crop was found to contain a proportion of Monsanto's patented Roundup Ready canola (a GM variety resistant to the Monasanto brand of glyphosate herbicide). Schmeiser was found liable for breaching Monsanto's patent although it was accepted that the plants had appeared on the Schmeiser farm through cross-pollination or spillage from passing trucks and not through deliberate planting. This decision was confirmed on appeal[19]. It is against this background that the Regulator has indicated that the Bayer licence is likely to be granted.

The object 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[20].

It should be noted that implicit in this object is that the risks posed by gene technology can be managed rather than the technology be rejected. This is reinforced by the statement of the Minister at the time in the second reading speech that:

> This bill demonstrates that it is possible to effectively regulate risks associated with technology. For Australia to lose the benefits of this technology when we are able to manage those risks would be an irresponsible and insupportable step for government to take[21].

The conclusion has been drawn that this legislation favours the introduction of gene technology[22].

13 Office of Gene Technology Regulator, DIR021/2002 at http://ogtr.gov.au.ir/index.htm viewed 7 February 2003.

14 Office of Gene Technology Regulator, DIR020/2002 at http://ogtr.gov.au.ir/index.htm viewed 7 February 2003.

15 *Gene Technology Act 2000* s50.

16 Office of the Gene Technology Regulator, *Risk Assessment and Risk Management Plan, Commercial Release of Genetically Modified Canola (DIR 021/2002) Consultation Version*, (April 2003) p10.

17 *Gene Technology Act 2000* s52.

18 Office of the Gene Technology Regulator, *General Information*, at www.health.gov.au/ogtr/about/index.htm viewed 7 February 2003.

19 *Schmeiser v Monsanto Canada Inc* 2002 FCA 309 at http://decisions.fct-cf.gc.ca/fct/2002/2002fca309.html viewed 25 November 2002.

20 *Gene Technology Act 2000* s3.

21 Dr M Wooldridge, Minister for Health and Aged Care, *Hansard: House of Representatives*, 22 June 2000, p18105.

22 M Hain, C Cocklin & D Gibbs, "Regulating Biosciences: The Gene Technology Act 2000" (2002) 19 EPLJ 179.

Bearing in mind this background, it is necessary to look at the task of the Regulator when assessing such applications as the canola application. Her assessment is rightfully guided by the objects of the Act, thus she is assessing the canola applications against the risk to human health and safety and the risk to the environment[23]. In the Bayer application, the RARMP concludes that:

> the risks posed by the proposed commercial release of these GM canola lines to human health, safety and the environment are no greater than those posed by conventional (non-GM) canola[24].

Thus the assessment of risk is in comparison with the non-GM canola. There is consideration given in the RARMP of the likely effect of the spread of GM canola to non-GM varieties:

> the likelihood of some gene transfer from the GM canola to other cultivated canola is high, but the overall frequency of out-crossing will be very low. If gene transfer to other canola did occur, it would not pose any risks other than those posed by non-GM canola or require any additional management[25].

Thus there is recognition that there will be "some gene transfer" to non-GM canola. In the course of the risk assessment the Regulator acknowledges that current research indicates that there is the possibility of cross pollination of canola up to 2.6 kilometres[26] but citing other research, the independence of which has recently been called into question, the Regulator indicates that the rates are quite low, less that 0.2 per cent[27]. The Regulator gives no consideration to the economic or market impact of this risk. The reason for this is that the Regulator has interpreted the Act as excluding those considerations:

> Evaluation of trade, marketing and cost–benefit issues have been intentionally excluded from the *Gene Technology Act 2000* assessment process[28].

Despite this conclusion, the Regulator's own *Risk Analysis Framework for Licence Applications* defines 'Risk management" as incorporating "scientific, technological, social and economic information and community values"[29] (emphasis added). At least one Government draughtsperson believes that the issue of buffer zones is an appropriate matter for conditioning by the Regulator:

Conditions can be placed on the dealings where the Regulator believes these are necessary to protect the health and safety of people and the environment. For example, conditions may be placed on where and how GM crops can be grown, how close they can be grown to non GM crops…..[30]

23 *Gene Technology Act 2000* s3.

24 Office of the Gene Technology Regulator, *Risk Assessment and Risk Management Plan, Commercial Release of Genetically Modified Canola (DIR 021/2002) Consultation Version,* (April 2003) p9.

25 Office of the Gene Technology Regulator, n24, p9.

26 Office of the Gene Technology Regulator, n24, p101.

27 Office of the Gene Technology Regulator, n24, p100 citing: Rieger, M.A., Lamond, M., Preston, C., Powles, S.B., Roush, R. "Pollen-mediated movement of herbicide resistance between commercial canola fields" (2002) 296 *Science* 2386; SBS Television *Insight: Coming Ready or Not*, 15 May 2003, one of the authors, Dr C Preston admitted the research was funded by Monsanto and Bayer.

28 Office of the Gene Technology Regulator, n24, p8.

29 Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Gene Technology Regulator,* (January 2002), Appendix 1, p70.

30 Therapeutic Goods Administration, *Draft Regulatory Impact Statement: Policy Principle to Recognise GM/Non-GM Designated Areas* (2 May 2003) at http://www.health.gov.au/tga/gene/gtrdap_a.htm viewed 19 May 2003.

Nevertheless, the conclusion in the RARMP is that the issue of the degree of cross-pollination between GM and non-GM canola does not pose a risk to human health or the environment and so the crucial issue of buffer zones between these crops is not a matter for a specific licence conditions. The Regulator leaves the matter of buffer zones to industry standard which is currently 5 metres between crops[31].

The Definition of environment under the Act

Thus the assessment by the Gene Technology Regulator is confined to those matters contained in the objects, being human health and safety and the environment, while the contamination of non-GM crops is classed as an economic or marketing consideration and beyond the scope of the *Gene Technology Act 2000* assessment. It is submitted that in not addressing this aspect more specifically in the proposed licence or conditions, the objects of the Act have not been fully complied with.

As previously indicated, the objects refer to protection of the environment. The environment is defined as including:

(a) ecosystems and their constituent parts; and

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas[32].

There is no mention in this definition of social, economic and cultural matters as there is in the *Environment Protection and Biodiversity Conservation Act 1999*[33]. While this confirms the Regulator's assertion that economic factors are excluded from consideration, and that is overtly the case, the argument is that by failing to set any conditions in relation to buffer zones the RARMP fails to consider the effect on the environment.

The argument is that the environment includes non-GM crops which might be grown in adjoining fields or kilometres away from a GM crop. These non-GM crops are part of the ecosystem which would be normally found in an agricultural area and such crops should be protected under a RARMP for GM canola. Thus a prescription of buffer should be made to protect this aspect of the environment. Furthermore, in considering the width of such a buffer zone, regard should be had to the industry accepted standards for non-GM and organic crops. Thus the Regulator's assessment of risk to non-GM crops should be based on accepted minimum levels of contamination to those crops, if any is allowed, not on an assessment of being "low to negligible"[34] without regard to any standards but simply a value judgement on the size of the predicted outcrossing.

A second reason why buffer zones should be specifically addressed relates to the reference in the definition of environment to "the qualities and characteristics of locations, places and areas."[35] The environment which the Regulator should consider protecting are the areas where non-GM crops may wish to be grown. The considerations relating to the issue of a licence and, if a licence is to be issued, the conditions of that licence, should be directed toward this aspect of the environment.

The failure of the RARMP to view the issue of non-GM crops and areas where they are grown as *part of the environment and take those into account* is a failure to carry out the object of the Act.

31 Gene Technology Grains Committee, *Canola Industry Stewardship Protocols*, (20 December 2002), p10.

32 *Gene Technology Act 2000* s10 "environment".

33 *Environment and Biodiversity Conservation Act 1999* s528 definition of "environment".

34 Office of the Gene Technology Regulator, n24, p24.

35 *Gene Technology Act 2000*, s10 "environment".

State Moratoriums and the Ministerial Council Policy Principle

As stated previously five of the six States have indicated that they will not allow the commercial release of canola. Only Tasmania has actually given statutory force to its moratorium through proclamation under the *Plant Quarantine Act 1997* (Tas) and there is a proposal to introduce further legislation on the issue. South Australia has a *Gene Technology (Temporary Prohibition) Bill 2002* which is in abeyance although the Government, with the acquiescence of the crops science companies, does not intend to sanction the commercial release of GMOs until a parliamentary select committee on the topic reports. The Western Australian government promised a five year moratorium and has a Bill before Parliament. The bill does not specify any time for a moratorium but gives the Minister responsible power to issue an order designating an area free of GM crops[36]. Victoria has just announced that with the agreement of the gene technology companies there would be no plantings of GM canola at least until the 2004 season[37]. New South Wales has introduced a *Gene Technology (GM Crop Moratorium) Bill 2003* into Parliament which allows the Minister to publish a moratorium order prohibiting the cultivation GM plants[38].

The constitutionality of any legislation purporting to implement these proposed moratoriums is the subject of some conjecture. The Gene Technology Act states as its sources of power the corporations power and the trade and commerce power[39]. Despite this quite broad basis for the legislative power of the Commonwealth, the Act is a co-operative arrangement as set out in the Commonwealth, State and Territory intergovernmental Gene Technology Agreement which commenced in September 2001. Under the Agreement each of the States and Territories were to pass co-operative legislation to implement the scheme[40]. Notwithstanding that some States have not yet passed this legislation, it would seem to be in only a narrow range of cases that the Commonwealth legislation would not be effective[41]. Thus because of the seemingly comprehensive nature of the Commonwealth legislation, any State or territory legislation purporting to impose a moratorium may be found to be invalid pursuant to section 109 of the Constitution.

The Gene Technology Act provides a mechanism whereby the Gene Technology Ministerial Council, established by the Gene Technology Agreement, may issue Policy Principles under the Act recognising areas designated under State law for marketing purposes as non-GM or GM[42]. Thus while that Act excludes economic or marketing issues from consideration by the Regulator, it countenances that those issues be dealt with by the States, if they see fit. The effect of such a policy principle is that the Regulator cannot issue a licence that is inconsistent with a Policy Principle[43].

The Ministerial Council has issued a draft Policy Principle, which at the time of writing was open for consultation. This proposed Principle recognises an area under a State law:

> ….. that is designated for the purpose of preserving the identity of GM crops, non-GM crops or both GM crops and non-GM crops, for marketing purposes….[44].

Although the Policy Principle talks of "areas" it should be noted that the various legislative instruments under consideration or enacted by the States envisage that the "areas" would be the whole of the State[45].

36 *Genetically Modified Crops Free Areas Bill 2003* s4.

37 Bob Cameron, Minister for Agriculture, *Media Release: No Commercial GM Canola This Year,* 8 May 2003.

38 *Gene Technology (GM Crop Moratorium) Bill* 2003 (NSW), s6.

39 *Gene Technology Act 2000* s13 and Commonwealth Constitution s51(i) & (xx).

40 Commonwealth, State and Territory intergovernmental Gene Technology Agreement, section 9.

41 Unincorporated entities not involved in interstate trade, for example.

42 *Gene Technology Act 2000* s21(1).

43 *Gene Technology Act 2000* s57(1).

44 Draft *Gene Technology (Recognition of Designated Areas) Principle 2003*, section 5, available at http://www.health.gov.au/tga/gene/gtrdap.htm.

While this Policy Principle will clarify the constitutional issue, it makes the assessment system of the Gene Technology Regulator established under the *Gene Technology Act 2000* irrelevant for the time being. The return of authority to the States and Territories to make a determination to allow the commercial release of GM crops seriously undermines the national system.

However, there are signs that the anti-GM stance of some of the States may only be a temporary measure. In New South Wales, the proposed three year ban has become a proposal for "moratorium orders" with no prescribed minimum or maximum time limit under the Bill which itself is stated to expire in 2006[46]. The Western Australian proposal of a five year moratorium has been dealt with in a similar fashion with a Ministerial designation also available under that State's proposed legislation[47]. The Proclamation under the Tasmania's *Plant Quarantine Act 1997* does not specify a time but a five year ban has been the stated intention. The public statements of the Victorian Government clearly indicate that its ban is only until the end of the year. The indications are that at least some States may be reserving their options as far as the commercial release of GM crops.

Conclusion

The area of assessment and licensing of gene technology under the *Gene Technology Act 2000* was intended to be efficient, effective, seamless and consistent[48]. However, the controversial issue of the licensing of GM canola for commercial release has highlighted shortcomings in the system and its implementation.

The omission of economic or marketing considerations from the legislation fails to take account of the highly contentious issue of segregation of GM and non-GM crops and the related issue of public acceptance of GM foods. This issue is a highly complex and uncertain matter. Excluding these matters from the Act may have simplified the task of the gene technology Regulator by confining the assessment of the effect of gene technology to purely the scientific issues of protection of human health and safety and the environment, but this has not enhanced the credibility of the assessment process in the eyes of a significant section of the community.

A wider reading of the term "environment" in the objects of the Act could have seen the Regulator address the issue of buffer zones in greater detail. An assessment of the width of the zones necessary to protect the integrity of non-GM crops as part of the environment should have been undertaken. This would be done, not on the basis of small percentages of outcrossing, but against the manner in which the non-GM market assesses contamination of non-GM crops.

The failure of the Act to assess these market issues has meant the disintegration for the time being of the nationally consistent scheme. The proposed Policy Principle will entrench the ability of the States and territories to maintain unilateral approaches to the utilisation of GM crops.

Besides the strains in the legislative scheme for gene technology which have exhibited themselves as a result of the canola applications, there are other inadequacies in the scheme which have not been canvassed here. Issues such as limited appeal rights for third parties, lack of emphasis on the precautionary principle in favour of management of risks and some issues about the administration of the Act also cause the system to be under strain. The canola applications have focussed attention on the Act. If the nationally consistent scheme enabling the use of gene technology is to regain some credibility a review of the Act should be commenced before the statutory date of June 2005[49].

45 *Gene Technology (GM Crop Moratorium) Bill 2003* (NSW), s6; *Genetically Modified Crops Free Areas Bill 2003* (WA) s4; Revocation and Declaration of Protected Area 2003, *Plant Quarantine Act 1997* (Tas), Schedule 1; *Gene Technology Temporary Prohibitation) Bill 2002* (SA) s4.

46 *Gene Technology (GM Crop Moratorium) Bill 2003* (NSW), s6 & s42.

47 *Genetically Modified Crops Free Areas Bill 2003 s4.*

48 Commonwealth, State and Territory intergovernmental Gene Technology Agreement, Recital B.

49 *Gene Technology Act 2000* s194