

# INFORMATION ASYMMETRY, GMOs AND STRICT LIABILITY UNDER THE *GENE TECHNOLOGY ACT 2000 (CTH)*

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## ABSTRACT

The significance of this article is to review the important place of information asymmetry in justifying the *Gene Technology Act 2000 (Cth)* (the Act) and the ‘gaps’ in the current liability arrangements under the Act. A possible resolution to these ‘gaps’ is to reinforce the existing liability arrangements under the Act by imposing a general statutory strict liability scheme for any loss or damage resulting from dealings with GMOs covered by the Act. A possible amendment to the Act is set out to illustrate how a more broadly applicable strict liability scheme might be achieved under the current regulatory arrangements.

## I INTRODUCTION

Neo-liberal economics has generally considered that the parties to a bargain are perfectly informed about the quality of the goods or services being transacted in the market. However, in practice, in many markets it may be very costly, or even impossible, to gain accurate information about the quality of the goods or services being transacted. As a consequence, consumers may be reluctant to conclude a bargain because of their uncertain information about the quality of goods (information asymmetry), but might be assured by an institution that provides some quality standard, contributing positively to market efficiency and promoting economic welfare.<sup>1</sup> This article considers strict liability as a possible resolution, at least in part, to the problems of information asymmetry in regulating genetically modified (GM) organisms (GMOs)<sup>2</sup> under the Act.<sup>3</sup>

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<sup>1</sup> For the classical statement of this concept see G Akerlof, ‘The Market for “Lemons”: Quality, Uncertainty and the Market Mechanism’ (1970) 84 *Quarterly Journal of Economics* 488; for a recent statement in the context of consumer protection policy see, for example, G Hadfield, R Howse and M Trebilcock, ‘Information-Based Principles for Rethinking Consumer Protection Policy’ (1998) 21 *Journal of Consumer Policy* 131.

<sup>2</sup> *Gene Technology Act 2000 (Cth)* s 10 defines ‘GMO’ to mean a ‘genetically modified organism’,

Applying information asymmetry considerations to GMOs assumes that consumers (and the community) may be uncertain about the quality of GMOs, and in particular their possible detrimental health and safety and environmental consequences.<sup>4</sup> A further assumption is that through regulatory intervention under the Act to regulate some GMOs, consumers (and the broader community) can be provided with the necessary health and safety and environmental assurances to conclude bargains involving GMOs.<sup>5</sup> While it is accepted that these assumptions are open to question and that there are other factors in determining consumer choices,<sup>6</sup> the purpose of the article is to illustrate that a strict liability scheme is possible under the Act and that it is consistent with the purpose of dealing with the market failure of information asymmetry that the Act was intended to address.

The article is structured as follows: Part II sets out the information asymmetry theory as it might be applied to GMOs; Part III reviews the central place of asymmetric information in justifying the Act; Part IV examines the existing responsibilities under the Act in circumstances likely to result in loss or damage; while Part V considers the 'gaps' in the current regulatory arrangements; and the following Part VI concludes the article and sets out a discussion about imposing a strict liability scheme for any loss or damage resulting from dealings with GMOs covered by the Act as a possible resolution to these 'gaps', and reinforcing the existing institutional assurance arrangements under the Act. A draft amendment which illustrates how strict liability might be introduced into the Act as an amendment is appended to the end of the article.

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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). However, 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.

<sup>3</sup> Noting that some limited liability arrangements have been implemented by State and Territory governments according to the Gene Technology (Recognition of Designated Areas) Principle 2003, *Commonwealth Government Special Gazette No S340* (5 September 2003) requiring the Gene Technology Regulator to recognise a States' and Territories' rights to designate under State law special areas that are for either GM or non-GM crops for marketing purposes: see K Ludlow, 'Cultivating Chaos: State Responses to Releasing Genetically Modified Organisms' (2004) 9 *Deakin Law Review* 1, 21-36.

<sup>4</sup> Noting that *Gene Technology Act 2000* (Cth) provides that '[t]he object of this 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'.

<sup>5</sup> See for example S James and M Burton, 'Consumer Preference for GM food and other Attributes of the Food System' (2003) 47 *Australian Journal of Agricultural and Resource Economics* 501, and the references therein.

<sup>6</sup> For example, price discounting might be a significant factor in consumer preferences for some GMOs: see *ibid*.

## II INFORMATION ASYMMETRY THEORY AND STRICT LIABILITY

The significant advance in the economics of information asymmetry was the recognition that the information available to purchasers, in a market for goods and services, about those goods and services, was important in ensuring the quality of those goods and services and the ongoing viability of the market.<sup>7</sup> The traditional conception of the problem and its solution is usually illustrated by the market for new and used cars, primarily 'for its concreteness and the ease in understanding rather than for its importance or realism'.<sup>8</sup> According to this conception, the quality of a new or used car may be difficult for a purchaser to assess, there being some probability that the car is either of satisfactory quality ('good quality') or unsatisfactory quality ('bad quality' or 'a lemon').<sup>9</sup> However, the seller is more likely to be aware of the quality, and because the purchaser does not have this information, the seller will be able to sell the unsatisfactory quality cars at a price at or approaching that of satisfactory quality cars.<sup>10</sup> The consequence is that purchasers, unable to tell the difference between satisfactory quality and unsatisfactory quality, will drive down the price, paying less for satisfactory quality as they are concerned about paying too much for unsatisfactory quality, with the consequence of ever decreasing market price, market quality and market size.<sup>11</sup>

The information asymmetry between the seller and the purchaser can be addressed, at least in part, through an institution that provides some kind of guarantee about the quality.<sup>12</sup> For example, licensing doctors, lawyers and barbers provides some form of independent assessment about basic quality standards and an assurance about a level of proficiency necessary to have obtained the license.<sup>13</sup> Thus, governmental intervention in the market may also be desirable to increase the welfare of all parties in the market, through providing some form of quality assurance for purchasers.<sup>14</sup> The expected consequence of governmental intervention will be to maintain the price and quality, and also avoid the decline in market size (and perhaps even market extinction).<sup>15</sup>

Applying information asymmetry conceptions to GMOs and GMO regulation might be characterised as:

- (a) The potential purchasers of GMOs might be uncertain about the 'quality' of the GMO, be uncertain about the possible detrimental health and safety effects of GMOs on people (whether valid or not), and the possible detrimental effects of GMOs on the environment (whether valid or not).

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<sup>7</sup> There is an extensive literature on the application of information asymmetry theory, the foundation author considering insurance, the employment of minorities, the costs of dishonesty, and credit markets in under-developed countries: Akerlof, above n 1, 492-499; for another examination of the theory as it might apply to GMOs, see K Donat, 'Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Market Intervention in the Genetically Modified Food Market' (2003) 12 *Minnesota Journal of Global Trade* 417, 437-439.

<sup>8</sup> Akerlof, above n 1, 489.

<sup>9</sup> Ibid.

<sup>10</sup> Ibid.

<sup>11</sup> Ibid 488.

<sup>12</sup> Ibid 499-500.

<sup>13</sup> Ibid 500.

<sup>14</sup> Ibid 488.

<sup>15</sup> Ibid.

- (b) The differences between non-GMOs and GMOs are not readily discernable by potential purchasers (in the absence of clear and meaningful labelling), so that:
  - (i) Purchasers are faced with the potential risks of detrimental health and safety effects from GMOs (such as allergenic reactions, and so on).
  - (ii) Purchasers might be promoting detrimental environmental effects from GMOs by providing a market for GMOs that have detrimental consequences for the environment (such as contamination, weediness, and so on).
- (c) The producers and marketers (including the supply chain handlers) of GMOs may not recognise, or may discount, a purchaser's concerns (whether valid or not) about the possible health and safety and environmental effects.
- (d) Governmental intervention through regulating GMOs provides an independent assurance for purchasers about the likely health and safety effects and effects on the environment through an assessment of risk, and imposing of penalties that operate to ameliorate a purchaser's concerns about the possible health and safety and environmental effects.
- (e) Without governmental intervention, information asymmetry theory suggests that:
  - (i) The prices of GMOs (and possibly non-GMOs equivalents) will decline as sceptical purchasers are unwilling to pay for satisfactory quality (that is non-GMOs and GMOs with *no* detrimental health and safety and environmental effects) when they can not distinguish them from unsatisfactory quality (that is GMOs with detrimental health and safety and environmental effects).
  - (ii) The quality of GMOs will decline as producers and marketers (including the supply chain handlers) do not have the price premium signals to favour satisfactory quality that purchasers might otherwise desire from unsatisfactory quality.
  - (iii) The size of the market for GMOs will reduce and possibly extinguish as GMOs with increasingly detrimental health and safety and environmental effects (whether valid or not) are placed onto the market.

Among the legal liability regimes, strict liability is one of the ways of imposing liability for damage and internalising the costs of an activity.<sup>16</sup> Strict liability provides a means of compensating third parties that suffer damage in the future, by including those likely future costs in the price of the GMO (internalises the costs), as well as providing an

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<sup>16</sup> Other statutory and common law liability schemes (such as negligence laws, and so on) may also apply, although their application to internalise the costs of damage is by no means certain: see, for example, M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 529-535; N Rogers, 'Seeds, Weeds and Greed: An Analysis of the *Gene Technology Act 2000* (Cth), Its Effect on Property Rights, and the Legal and Policy Dimensions of a Constitutional Challenge' (2002) 2 *Macquarie Law Journal* 1, 3-6.

incentive for producers and marketers (including the supply chain handlers) to avoid or minimise those likely risks and prospects of future damage.<sup>17</sup> Thus, strict liability may reinforce the existing institutional arrangements by assuring purchasers that with the prospect of bearing all the costs of liability, producers and marketers (including the supply chain handlers) of GMOs, will *only* bring quality products to market. Without a reassuring legal liability regime in some form, information asymmetry theory suggests that purchasers will pay a *lower price* for GMOs as they take on the burden of the risk or prospect of damage (some of it non-financial), and further reduce the quality and size of the market.

### III INFORMATION ASYMMETRY AND REGULATING GMOs

The Act formally regulates dealings with certain organisms that have been modified through 'gene technology'.<sup>18</sup> The Act was considered necessary because 'GMOs and GM products present a range of possible health and environmental risks to the community'.<sup>19</sup> The key concern appears to have been that consumers and the community lacked the relevant knowledge and information to be able to assess those risks.<sup>20</sup>

While the level of knowledge about possible risks is growing in the community, there remains inadequate information available to the community and consumers;<sup>21</sup>

Individuals may also have difficulty in assessing and processing available information to help them make informed choices about what levels of possible risk they consider to be acceptable to their health and safety;<sup>22</sup>

[T]here are possible risks to public health and the environment that may not be properly taken into account by either the industry involved with GMOs or GM products, or the consumers, or users of GMOs or GM products;<sup>23</sup> and

There are difficulties in relying upon industry to provide the necessary information and make appropriate risk assessment and management decisions.<sup>24</sup>

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<sup>17</sup> There is an extensive economic literature on this issue: see, for examples, M Polinsky, 'Strict Liability versus Negligence in a Market Setting' (1980) 70 *American Economic Review* 363; S Shavell, 'Strict Liability versus Negligence' (1980) 9 *Journal of Legal Studies* 1.

<sup>18</sup> Where 'gene technology' means 'any technique for the modification of genes or other 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': *Gene Technology Act 2000* (Cth) s 10.

<sup>19</sup> Explanatory Memorandum, Gene Technology Bill 2000 (Cth) 12.

<sup>20</sup> Although this sentiment was not reflected in the second reading speech: see Commonwealth, *House of Representatives Hansard*, 22 June 2000, 18105-18106 (Minister for Health and Aged Care).

<sup>21</sup> Explanatory Memorandum, above n 19, 12.

<sup>22</sup> *Ibid.*

<sup>23</sup> *Ibid.*

<sup>24</sup> *Ibid.*; 'because, in an objective aggregate sense, it may not be in their [industries'] best interests to draw the possibility of risk to the attention of prospective consumers and the community generally. Equally, consumers might discount the usefulness of industry provided information on that basis' (12).

On this basis, there was considered to be ‘a case for government intervention to assess and manage the risks and to provide information to consumers and the community’.<sup>25</sup> Perhaps most significantly, however, 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’,<sup>26</sup> with a consequence that might ‘harm the ability of industry to market GMOs and GM products assessed as safe’.<sup>27</sup> Then in assessing the costs and benefits of a regulatory scheme,<sup>28</sup> the benefit for the community that outweighed any costs was:

Assurances that all GMOs used in Australia have been comprehensively assessed by an independent Regulator as being safe in terms of the health of people and the impact on the environment. Public confidence in the regulation of GMOs also has positive downstream effects for industry, manifesting in increased consumer acceptance of GMOs assessed to be safe.<sup>29</sup>

In other words, the Act’s purpose was to promote the quality (or legitimacy) of GMOs (and GM products) through a governmental institution making an independent risk assessment about the likely risks posed by GMOs.<sup>30</sup> The intended consequence was to promote commercial transactions in GMOs and GM products as safe for consumers and the broader community.<sup>31</sup>

#### IV THE ACT’S PROHIBITORY SCHEME AND ITS REACH

Essentially the Act prohibits all ‘dealings with’ GMOs,<sup>32</sup> unless they are allowed, either because they satisfy defined criteria,<sup>33</sup> or they are licensed by the Gene Technology

<sup>25</sup> Ibid.

<sup>26</sup> For a review of the early developments eventually leading to the *Gene Technology Act 2000* (Cth) see generally R Hindmarsh, *Genetic Manoeuvres: Bio-utopian Visions* (Curtain University Books 2005).

<sup>27</sup> Explanatory Memorandum, above n 19, 13.

<sup>28</sup> This was the founding principle articulated in the *Independent Committee of Inquiry into Competition Policy in Australia* (see Independent Committee of Inquiry into Competition Policy in Australia, *National Competition Policy* (1993) 206-208) and the subsequent codification of this principle in the *Competition Principles Agreement* binding the Commonwealth, States and Territories to facilitate effective competition to promote economic efficiency and benefits for consumers (*Competition Principles Agreement* cl 5(1)), as part of the *National Competition Policy*: see National Competition Council, *Compendium of National Competition Policy Agreements* (1997).

<sup>29</sup> Explanatory Memorandum, above n 19, 42.

<sup>30</sup> House of Representatives Hansard, above n 20, 18104; see also M Hain, C Cocklin and D Gibbs, ‘Regulating Biosciences: The Gene Technology Act 2000’ (2002) 19 *Environmental and Planning Law Journal* 163, 165.

<sup>31</sup> There is a considerable literature on this issue, see for example P Newell, *Biotechnology and the Politics of Regulation*, IDS Working Paper 146 (2002) 5-7.

<sup>32</sup> *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)’.

<sup>33</sup> See *Gene Technology Act 2000* (Cth) s 78 (declared to be a GMO) and *Gene Technology Regulations 2001* (Cth) rr 5 (organisms that are not genetically modified organisms), 6 (dealings

Regulator ('the Regulator'), under the Act.<sup>34</sup> The allowable dealings are those dealings that are exempt from licensing,<sup>35</sup> a notifiable low risk dealing,<sup>36</sup> a licensed dealing,<sup>37</sup> a dealing on the GMO Register,<sup>38</sup> or a dealing with an organism, or class of organisms declared to be outside the definition of a GMO.<sup>39</sup> However, in considering information asymmetries and liability arrangements, the Act makes an important distinction between those GMOs outside the Act's prohibitory scheme and those within the Act's prohibitory scheme, the Act *only* applies to the latter.

### A *GMOs Outside the Prohibitory Scheme*

The Act does not deal with an organism, or class of organisms, declared to be outside the definition of a GMO.<sup>40</sup> This is potentially a large class and could capture some significant dealings, noting that the Regulator may have no knowledge of such dealings as they are outside the scope of the Acts obligations. For example, the *Gene Technology Regulations 2001* (Cth) provides that 'an organism mentioned in Schedule 1 is not a genetically modified organism',<sup>41</sup> that includes:

A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).<sup>42</sup>

This will include a GMO that has been subjected to any form of mutation that does 'not involve the introduction of any foreign nucleic acid', such as chemical, radiation, and so on, mutation, and potentially extend to genetic modification with its own nucleic acid (such as the introduction of multiple gene copies) and possible even homologous DNA from the same species.<sup>43</sup>

Further, the potential class of organisms excluded from being GMOs for the purposes of the Act may be expanded by the definition of the term 'gene technology'.<sup>44</sup> Under the current arrangements this 'does not include' organisms that are modified through the

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exempt from licensing) and 12 and 13 (notifiable low risk dealings).

<sup>34</sup> See *Gene Technology Act 2000* (Cth) pt 5.

<sup>35</sup> See *Gene Technology Act 2000* (Cth) ss 32(1) and 32(4) and *Gene Technology Regulations 2001* (Cth) r 6.

<sup>36</sup> See *Gene Technology Act 2000* (Cth) ss 32(1) and 76 and *ibid* rr 12 and 13.

<sup>37</sup> See *Gene Technology Act 2000* (Cth) s 32(1) and pt 5 and *ibid* rr 7-11.

<sup>38</sup> See *Gene Technology Act 2000* (Cth) s 32(1) and s 76.

<sup>39</sup> See *Gene Technology Act 2000* (Cth) s 10 and *Gene Technology Regulations 2001* (Cth) r 5.

<sup>40</sup> See *Gene Technology Act 2000* (Cth).

<sup>41</sup> See *Gene Technology Act 2000* (Cth) r 5.

<sup>42</sup> *Gene Technology Regulations 2001* (Cth) sch 1 pt 1 (item 1).

<sup>43</sup> Another example is the exemption from licensing of '[a] plant formed by: (a) embryo rescue; or (b) in vitro fertilisation; or (c) zygote implantation; or (d) protoplast fusion': *Gene Technology Act 2000* (Cth) sch 1 pt 1 (item 5). This could include a plant that was 'modified by gene technology' and as a final step relied on the technique of embryo rescue or protoplast fusion, thereupon ceasing to be a GMO for the purposes of the Act.

<sup>44</sup> See *Gene Technology Act 2000* (Cth) s 10 (definition of 'gene technology') and *Gene Technology Act 2000* (Cth) r 4.

techniques of 'sexual reproduction',<sup>45</sup> 'homologous recombination',<sup>46</sup> and 'somatic cell nuclear transfer if the transfer does not involve genetically modified material'.<sup>47</sup>

### B *GMOs Within the Prohibitory Scheme*

For those GMOs within the scope of the Act, the Act does not seek to avoid *all* risks posed by GMOs, but rather to identify and evaluate risks (hazards) and manage them, acknowledging that a certain amount of risk is acceptable.<sup>48</sup> The assessment of risk is built into the regulatory framework imposed by the Act that classifies different dealings according to their perceived risks,<sup>49</sup> and consideration of a 'checklist' of possible hazards.<sup>50</sup> For the dealings not requiring a license, the risks are considered to be 'negligible' or 'not present any significant risks'.<sup>51</sup> For the licensed dealings (so-called Dealings Not involving Intentional Release (DNIR)<sup>52</sup> and Dealings involving Intentional Release (DIR)<sup>53</sup> of the GMO into the environment), a methodology for identifying, evaluating and managing risks according to a *Risk Analysis Framework* is applied.<sup>54</sup>

Risk assessment involves identifying sources of harm, and assessing the likelihood that harm will occur and the consequences if it does occur. Risk management refers to evaluating which risks require management and selecting and implementing the plans or actions that may be taken to ensure that those risks are controlled. Risk communication involves an interactive dialogue between stakeholders and risk assessors and risk managers.<sup>55</sup>

<sup>45</sup> *Gene Technology Act 2000* (Cth) s 10 (para (a) of the definition of 'gene technology').

<sup>46</sup> *Gene Technology Act 2000* (Cth) s 10 (para (b) of the definition of 'gene technology').

<sup>47</sup> *Gene Technology Regulations 2001* (Cth) r 4.

<sup>48</sup> See Explanatory Memorandum, above n 19, 39.

<sup>49</sup> *Gene Technology Act 2000* (Cth) s 32(1) providing for exempt from licensing dealings (ss 32(1) and 32(4) and *Gene Technology Regulations 2001* (Cth) rr 6-11), notifiable low risk dealings (s 32(1) and pt 6 div 2 and rr 12-13), licensed dealings (s 32(1) and pt 5 and rr 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 r 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 J Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution' (1998) 61 *Modern Law Review* 621, 621.

<sup>50</sup> *Gene Technology Act 2000* (Cth) ss 49(2) and 51(1) and *Gene Technology Act 2000* (Cth) r 10; noting that other risks may also be identified through the consultation process (ss 50, 52 and 56), and in considering the application and preparing the risk assessment according; see also K Hayes, *Robust Methodologies for Ecological Risk Assessment: Best Practice and Current Practice in Ecological Risk Assessment for Genetically Modified Organisms* (2004) 32.

<sup>51</sup> Explanatory Memorandum, above n 19, 22.

<sup>52</sup> See *Gene Technology Act 2000* (Cth) pt 5 div 3.

<sup>53</sup> See *Gene Technology Act 2000* (Cth) pt 5 div 4.

<sup>54</sup> See Office of the Gene Technology Regulator, *Risk Analysis Framework* (2005); this is a methodology of 'risk analysis', being 'risk analysis = risk assessment + risk management + risk communication'.

<sup>55</sup> *Ibid* 5.



The Act then proscribes various offences for the prohibited dealings,<sup>56</sup> with the elements of the offence being detailed in the *Criminal Code Act 1995* (Cth).<sup>57</sup> This essentially distinguishes between ‘physical elements’,<sup>58</sup> and ‘fault elements’.<sup>59</sup> An offence, consisting of physical elements and fault elements,<sup>60</sup> is established by proving:<sup>61</sup> ‘the existence of such physical elements as are, under the law creating the offence, relevant to establishing guilt’,<sup>62</sup> and ‘in respect of each such physical element for which a fault element is required, one of the fault elements for the physical element’.<sup>63</sup> The elements of the prohibited dealing offences and maximum penalties are:

- (a) Dealing with a GMO without a licence – A person ‘is guilty of an offence’ if they deal with a GMO covered by the Act,<sup>64</sup> and either ‘knows’ or ‘is reckless as to whether or not the dealing’ is not exempt from licensing,<sup>65</sup> not a notifiable low risk dealing,<sup>66</sup> not authorised by a GMO licence,<sup>67</sup> and not on the GMO Register.<sup>68</sup> The maximum penalties for an ‘aggravated offence’ are: <sup>69</sup> ‘imprisonment for 5 years or 2,000 penalty units’;<sup>70</sup> and in other cases ‘imprisonment for 2 years or 500 penalty units’;<sup>71</sup>
- (b) Breaching conditions of a GMO licence – A person ‘is guilty of an offence’<sup>72</sup> if they hold a GMO licence,<sup>73</sup> or they are ‘covered by a GMO licence’,<sup>74</sup> and ‘intentionally takes an action or omits to take an action’,<sup>75</sup> and either ‘knows’ or ‘is reckless as to whether or not the action or omission contravenes the licence’.<sup>76</sup> The maximum penalties for an ‘aggravated offence’<sup>77</sup> are

<sup>56</sup> *Gene Technology Act 2000* (Cth) ss 32-37; except the Crown (s 6(2)); noting that there is provision for no doubling-up of liabilities (s 18) and conduct by directors, employees and agents (s 188).

<sup>57</sup> *Gene Technology Act 2000* (Cth) s 8(1); see *Criminal Code Act 1995* (Cth) sch (ch 2) setting out the general principles of criminal responsibility with effect on and after 15 December 2001 (s 2.2).

<sup>58</sup> *Criminal Code Act 1995* (Cth) sch (s 4.1); ‘[a] physical element of an offence may be: (a) conduct; or (b) a result of conduct; or (c) a circumstance in which conduct, or a result of conduct, occurs’ (s 4.1(1)).

<sup>59</sup> *Criminal Code Act 1995* (Cth) sch (s 5.1); ‘[a] fault element for a particular physical element may be intention, knowledge, recklessness or negligence’ (s 5.1(1)).

<sup>60</sup> *Criminal Code Act 1995* (Cth) sch (s 3.1(1)).

<sup>61</sup> *Criminal Code Act 1995* (Cth) sch requires that the prosecution prove the existence of the matter (s 13.1(1)) beyond reasonable doubt (s 13.2(1)).

<sup>62</sup> *Criminal Code Act 1995* (Cth) sch (s 3.2(a)).

<sup>63</sup> *Criminal Code Act 1995* (Cth) sch (s 3.2(b)).

<sup>64</sup> *Gene Technology Act 2000* (Cth) s 32(1).

<sup>65</sup> *Gene Technology Act 2000* (Cth) s 32(1)(d).

<sup>66</sup> *Gene Technology Act 2000* (Cth) s 32(1)(c).

<sup>67</sup> *Gene Technology Act 2000* (Cth) s 32(1)(b).

<sup>68</sup> *Gene Technology Act 2000* (Cth) s 32(1)(e).

<sup>69</sup> *Gene Technology Act 2000* (Cth) s 38; where ‘the commission of the offence causes significant damage, or is likely to cause significant damage, to the health and safety of people or to the environment’ (s 38(1)).

<sup>70</sup> *Gene Technology Act 2000* (Cth) s 32(2)(a); noting that ‘penalty units’ are defined in the *Crimes Act 1914* (Cth) s 4AA(1) where ‘penalty unit means \$110’.

<sup>71</sup> *Gene Technology Act 2000* (Cth) s 32(2)(b).

<sup>72</sup> *Gene Technology Act 2000* (Cth) ss 34(1) and (2).

<sup>73</sup> *Gene Technology Act 2000* (Cth) s 34(1).

<sup>74</sup> *Gene Technology Act 2000* (Cth) s 34(2); and additional requirement is that the person ‘has knowledge of the conditions of the licence’ (s 34(2)(c)).

<sup>75</sup> *Gene Technology Act 2000* (Cth) ss 34(1)(a) and (2)(a).

<sup>76</sup> *Gene Technology Act 2000* (Cth) ss 34(1)(b) and (2)(b).

‘imprisonment for 5 years or 2,000 penalty units’,<sup>78</sup> and in other cases ‘imprisonment for 2 years or 500 penalty units’,<sup>79</sup> with there being a separate offence for ‘each day (including the day of a conviction for the offence or any later day) on which the person is guilty of the offence’;<sup>80</sup>

- (c) Breaching conditions on GMO Register – A person ‘is guilty of an offence’<sup>81</sup> if they deal with a GMO on the GMO Register,<sup>82</sup> ‘knowing that it is a GMO’,<sup>83</sup> and the dealing contravenes a condition specified in the GMO Register.<sup>84</sup> The maximum penalty is ‘50 penalty units’;<sup>85</sup> and
- (d) Dealing with a notifiable low risk dealing not according to the *Gene Technology Regulations 2000* (Cth) – A person ‘is guilty of an offence’<sup>86</sup> if they deal with a notifiable low risk dealing GMO,<sup>87</sup> ‘knowing’ that it is a GMO,<sup>88</sup> and the dealing is ‘not undertaken in accordance with the Regulations’.<sup>89</sup> The maximum penalty is ‘50 penalty units’.<sup>90</sup>

In addition to these offences, the Act also proscribes limited strict liability offences.<sup>91</sup> The *Criminal Code Act 1995* (Cth) sets out that where there is an offence of strict liability,<sup>92</sup> then ‘there are no fault elements’ for either ‘any of the physical elements of the offence’,<sup>93</sup> or ‘that physical element’.<sup>94</sup> The ‘defence of mistake of fact’<sup>95</sup> is available,<sup>96</sup> together with ‘any other defence’.<sup>97</sup> Essentially the strict liability offences are:

- (a) Dealing with a GMO without a licence – A person ‘is guilty of an offence’<sup>98</sup> if they deal with a GMO and they are ‘not authorised by a GMO licence’,<sup>99</sup> ‘the dealing is not a notifiable low risk dealing’,<sup>100</sup> ‘the dealing is not an exempt

<sup>77</sup> *Gene Technology Act 2000* (Cth) s 38.

<sup>78</sup> *Gene Technology Act 2000* (Cth) s 34(3)(a).

<sup>79</sup> *Gene Technology Act 2000* (Cth) s 34(3)(b).

<sup>80</sup> *Gene Technology Act 2000* (Cth) s 34(4).

<sup>81</sup> *Gene Technology Act 2000* (Cth) s 36(1).

<sup>82</sup> *Gene Technology Act 2000* (Cth) s 36(1)(b).

<sup>83</sup> *Gene Technology Act 2000* (Cth) s 36(1)(a).

<sup>84</sup> *Gene Technology Act 2000* (Cth) s 36(1)(c).

<sup>85</sup> *Gene Technology Act 2000* (Cth) s 36(1).

<sup>86</sup> *Gene Technology Act 2000* (Cth) s 37(1).

<sup>87</sup> *Gene Technology Act 2000* (Cth) s 37(1)(b).

<sup>88</sup> *Gene Technology Act 2000* (Cth) s 37(1)(a).

<sup>89</sup> *Gene Technology Act 2000* (Cth) s 37(1)(c).

<sup>90</sup> *Gene Technology Act 2000* (Cth) s 37(1).

<sup>91</sup> *Gene Technology Act 2000* (Cth) ss 33, 35, 36(2) and 37(2).

<sup>92</sup> *Criminal Code Act 1995* (Cth) sch (ss 6.1(1) and (2)).

<sup>93</sup> *Criminal Code Act 1995* (Cth) sch (s 6.1(1)(a)).

<sup>94</sup> *Criminal Code Act 1995* (Cth) sch (s 6.1(2)(a)).

<sup>95</sup> Being the defence that ‘(a) at or before the time of the conduct constituting the physical element, the person considered whether or not facts existed, and is under a mistaken but reasonable belief about those facts; and (b) had those facts existed, the conduct would not have constituted an offence’: *Criminal Code Act 1995* (Cth) sch (s 9.2(1)).

<sup>96</sup> *Criminal Code Act 1995* (Cth) sch (ss 6.1(1)(b) and 6.1(2)(b)).

<sup>97</sup> *Criminal Code Act 1995* (Cth) sch (s 6.1(3)).

<sup>98</sup> *Gene Technology Act 2000* (Cth) s 33(1).

<sup>99</sup> *Gene Technology Act 2000* (Cth) s 33(1)(b).

<sup>100</sup> *Gene Technology Act 2000* (Cth) s 33(1)(c).

[from licensing] dealing’,<sup>101</sup> and ‘the dealing is not included on the GMO Register’.<sup>102</sup> The maximum penalties for an ‘aggravated offence’<sup>103</sup> is ‘200 penalty units’,<sup>104</sup> and in other cases ‘50 penalty units’;<sup>105</sup>

- (b) Breaching conditions of a GMO licence – A person ‘is guilty of an offence’<sup>106</sup> if they hold a GMO licence,<sup>107</sup> or they are ‘covered by a GMO licence’,<sup>108</sup> and ‘takes an action or omits to take an action’,<sup>109</sup> and the ‘action or omission contravenes the licence’.<sup>110</sup> The maximum penalties for an ‘aggravated offence’<sup>111</sup> is ‘200 penalty units’,<sup>112</sup> and in other cases ‘50 penalty units’;<sup>113</sup>
- (c) Breaching conditions on GMO Register – A person ‘is guilty of an offence’<sup>114</sup> if they deal with a GMO on the GMO Register and the dealing contravenes a condition specified in the GMO Register.<sup>115</sup> The maximum penalty is ‘50 penalty units’;<sup>116</sup> and
- (d) Dealing with a notifiable low risk dealing not according to the *Gene Technology Regulations 2000* (Cth) – A person ‘is guilty of an offence’<sup>117</sup> if they deal with a notifiable low risk dealing GMO and the dealing is ‘not undertaken in accordance with the Regulations’.<sup>118</sup> The maximum penalty is ‘50 penalty units’.<sup>119</sup>

The Act also provides the Regulator with express power to ‘give directions’ to a current licence holder or to a person covered by a current licence where the Regulator ‘believes on reasonable grounds’ that the licence holder or person covered by the licence is ‘not complying with this Act or the regulations in respect of a thing’,<sup>120</sup> and that the exercise of the power is necessary ‘in order to protect the health and safety of people or to protect the environment’.<sup>121</sup> However, the directions are limited to ‘requiring the person, within the time specified in the notice, to take such steps in relation to the thing as are reasonable in the circumstances for the person to comply with this Act or the

<sup>101</sup> *Gene Technology Act 2000* (Cth) s 33(1)(d).

<sup>102</sup> *Gene Technology Act 2000* (Cth) s 33(1)(e).

<sup>103</sup> *Gene Technology Act 2000* (Cth) s 38.

<sup>104</sup> *Gene Technology Act 2000* (Cth) s 33(3)(a).

<sup>105</sup> *Gene Technology Act 2000* (Cth) s 33(3)(b).

<sup>106</sup> *Gene Technology Act 2000* (Cth) s 35(1) and (2).

<sup>107</sup> *Gene Technology Act 2000* (Cth) s 35(1).

<sup>108</sup> *Gene Technology Act 2000* (Cth) s 35(2); and additional requirement is that the person ‘has knowledge of the conditions of the licence’ (s 32(2)(c)).

<sup>109</sup> *Gene Technology Act 2000* (Cth) ss 35(1)(a) and (2)(a).

<sup>110</sup> *Gene Technology Act 2000* (Cth) ss 35(1)(b) and (2)(b).

<sup>111</sup> *Gene Technology Act 2000* (Cth) s 38.

<sup>112</sup> *Gene Technology Act 2000* (Cth) s 35(4)(a).

<sup>113</sup> *Gene Technology Act 2000* (Cth) s 35(4)(b).

<sup>114</sup> *Gene Technology Act 2000* (Cth) s 36(1).

<sup>115</sup> *Gene Technology Act 2000* (Cth) s 36(2).

<sup>116</sup> *Gene Technology Act 2000* (Cth) s 36(1).

<sup>117</sup> *Gene Technology Act 2000* (Cth) s 37(1).

<sup>118</sup> *Gene Technology Act 2000* (Cth) s 37(2).

<sup>119</sup> *Gene Technology Act 2000* (Cth) s 37(1).

<sup>120</sup> *Gene Technology Act 2000* (Cth) ss 146(1)(a) and (2)(a).

<sup>121</sup> *Gene Technology Act 2000* (Cth) ss 146(1)(b) and (2)(b).

regulations'.<sup>122</sup> Failure by the licence holder or person covered by the licence to comply with the directions is an offence,<sup>123</sup> and the Regulator may arrange for the steps specified in the notice to be taken,<sup>124</sup> and recover an amount equal to the cost as a debt due to the Commonwealth.<sup>125</sup> Significantly, the directions power was expressly intended to deal with containment:

This provision effectively enables a 'clean-up' or remediation to be undertaken, either by the Regulator or via the direction of the Regulator, where, for example, a condition of licence has been breached resulting in the accidental release of a GMO, and there is a need to re-contain the GMO.<sup>126</sup>

Further offences arise under the Act where a current licence holder fails to comply with directions given by the Regulator,<sup>127</sup> a person unlawfully discloses 'confidential commercial information',<sup>128</sup> or another person unlawfully discloses 'confidential commercial information' knowing it is 'confidential commercial information',<sup>129</sup> submission of false or misleading information or documents,<sup>130</sup> interference with dealings with GMOs,<sup>131</sup> refuse or fail to answer a question about the import or export of goods,<sup>132</sup> the return of identity cards,<sup>133</sup> and the application and use of warrants.<sup>134</sup>

The Regulator may also suspend or cancel a current licence by notice in writing given to the holder of a GMO licence, if she 'believes on reasonable grounds that the licence holder, or a person covered by the licence, has committed an offence against this Act or the regulations'.<sup>135</sup> In these circumstances any dealing with a GMO will be prohibited because it is 'not authorised by a GMO licence'.<sup>136</sup>

The significance of the Act's prohibitory approach is that it reaches *all* GMOs, including those non-GMOs defined to be GMOs for the purposes of the Act,<sup>137</sup> but excluding those GMOs defined not to be GMOs for the purposes of the Act,<sup>138</sup> and then provides:

<sup>122</sup> *Gene Technology Act 2000* (Cth) ss 146(1) and (2).

<sup>123</sup> *Gene Technology Act 2000* (Cth) s 146(3); the maximum penalties for an 'aggravated offence' is '2000 penalty units' and in other cases '500 penalty units', although the *Crimes Act 1914* (Cth) s 4K (dealing with continuing and multiple offences) does not apply so this is not a daily offence committed until the requirement is complied with (s 146(6)).

<sup>124</sup> *Gene Technology Act 2000* (Cth) s 146(4).

<sup>125</sup> *Gene Technology Act 2000* (Cth) s 146(5).

<sup>126</sup> Explanatory Memorandum, above n 19, 90.

<sup>127</sup> *Gene Technology Act 2000* (Cth) ss 53(4) and 146(3).

<sup>128</sup> *Gene Technology Act 2000* (Cth) s 187(1).

<sup>129</sup> *Gene Technology Act 2000* (Cth) s 187(2).

<sup>130</sup> *Gene Technology Act 2000* (Cth) s 192.

<sup>131</sup> *Gene Technology Act 2000* (Cth) s 192A.

<sup>132</sup> *Gene Technology Act 2000* (Cth) s 164(4).

<sup>133</sup> *Gene Technology Act 2000* (Cth) s 151.

<sup>134</sup> *Gene Technology Act 2000* (Cth) ss 175(1) and (2).

<sup>135</sup> *Gene Technology Act 2000* (Cth) s 68(b).

<sup>136</sup> See *Gene Technology Act 2000* (Cth) ss 32(1)(b), 33(1)(b) and 60.

<sup>137</sup> *Gene Technology Act 2000* (Cth) s 10 (para (c) of 'genetically modified organism' definition).

<sup>138</sup> *Gene Technology Act 2000* (Cth) (para (e) of 'genetically modified organism' definition) and *Gene Technology Regulations 2001* (Cth) r 5.

- (a) A blanket assessment of ‘negligible’ or ‘no significant’ risk for exempt from licensing dealings, notifiable low risk dealings and dealings on the GMO Register; and
- (b) A tailored risk assessment for those dealings requiring a licence (so-called Dealings Not involving Intentional Release (DNIR) and Dealings involving Intentional Release (DIR) of the GMO into the environment).

Importantly, the Regulator applying the Act makes *no* claims that dealings with GMOs pose no risks. Inherent in the Act as a regulatory scheme is that it accepts that some identified and some unidentified risks may occur. As a consequence, some loss or damage might be expected, albeit that the Regulator may be minimising or moderating such an eventuality.

## V THE ‘GAPS’ IN THE LIABILITY ARRANGEMENTS

The Act addresses some issues of liability by providing for criminal sanction for breach of the Act,<sup>139</sup> and gives the Regulator some powers to require that a problem be rectified when the legislation has been breached.<sup>140</sup> However, the Act makes no comprehensive provision for a statutory right of action for a remedy for those affected by economic, health or environmental loss or damage resulting from GMOs. Further the loss or damage is not affected by whether the dealing is either authorised by the Act or not authorised by, and breaches the Act. In other words, the Act may minimise the likely risks posed by GMOs by identifying some risks and seeking to minimise their impact through appropriate management, but the Act *does not* establish a cause of action for any third parties affected by economic, health or environmental loss or damage resulting from GMOs.<sup>141</sup> The recourse in these circumstances would be through the common law and other existing statutory schemes:<sup>142</sup>

Specific legislation relating to liability for the risks posed by gene technology does not exist, nor has liability been tested in the courts. Common law provides a means for redressing problems arising from GMOs. Remedies might also be sought through environmental protection and pollution control legislation, and legislation relating to wild animals and abnormally dangerous activities. Liability in relation to food would be caught under the Trade Practices Act.<sup>143</sup>

As a consequence of this approach, there remain ‘gaps’ in the Act’s liability scheme:

- (a) The Act’s prohibitions against exempt from licensing dealings,<sup>144</sup> notifiable low risk dealing,<sup>145</sup> licensed dealings,<sup>146</sup> and dealings on the GMO Register,<sup>147</sup> relate

<sup>139</sup> *Gene Technology Act 2000* (Cth) ss 32(1), 33(1), 33(2), 34(1), 34(2), 35(1), 35(2), 36(1), 36(2) and 37.

<sup>140</sup> *Gene Technology Act 2000* (Cth) s 146.

<sup>141</sup> Notably, the Australian Government asserts the view that ‘[l]iability for environmental damage (such as loss of biodiversity) and personal injury (eg allergenicity, toxicity) has been excluded as a regulatory system has been implemented to avoid such dangers and thus the risk to those in the agricultural community is minimal’: Department of Agriculture, Fisheries and Forestry, *Liability Issues Associated with GM Crops in Australia* (2003) 1.

<sup>142</sup> See also Department of Agriculture, Fisheries and Forestry, *ibid* 6-14.

<sup>143</sup> House of Representative Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution – Primary Producer Access to Gene Technology* (2000) 159.

<sup>144</sup> *Gene Technology Act 2000* (Cth) s 32(1) and s 32(4) and *Gene Technology Regulations 2001* (Cth) r 6.

to ‘physical elements’<sup>148</sup> and ‘fault elements’<sup>149</sup> of the statutory offence. Any amounts paid as a penalty will be ‘public money’ for the purposes of the *Financial Management and Accountability Act 1997* (Cth),<sup>150</sup> and form part of the Consolidated Revenue Fund.<sup>151</sup> Further, amounts recovered from the license holder, or a person covered by a GMO licence, by the Regulator from ‘clean-up’, remediation, and so on, to comply with the Act,<sup>152</sup> is merely the amount to repay an amount expended by the Regulator.<sup>153</sup> These prohibitions:

- (i) *Do not* address the loss, damage or injury as a result of the conduct that is prohibited, or for amounts to be paid to those suffering loss, damage or injury as a result of the offence.
  - (ii) *Do not* address activities that are not identified as a risk (hazard) that can be managed in authorising the dealing at the time it is assessed by the Regulator. As an inherently risky product, GMOs and identified and unidentified risks, and the prohibitions only relate to the conditions and other limits placed on them as a result of known risks to the Regulator. Thus, risks unknown to the Regulator, but potentially known to the person dealing with the GMO,<sup>154</sup> that eventuate are not prohibited.
  - (iii) *Do not* address GMOs, or classes of GMOs, that are declared to be outside the definition of a GMO.<sup>155</sup>
- (b) The Regulator has power to require ‘clean-up’, remediation, and so on, as part of the general power to require compliance with the Act during the period of a licence.<sup>156</sup> However, this power:

<sup>145</sup> *Gene Technology Act 2000* (Cth) s 32(1) and pt 6 div 2 and *Gene Technology Regulations 2001* (Cth) pt 3 div 2.

<sup>146</sup> *Gene Technology Act 2000* (Cth) s 32(1) and pt 5 and *Gene Technology Act 2000* (Cth) rr 7-11.

<sup>147</sup> *Gene Technology Act 2000* (Cth) s 32(1) and s 76.

<sup>148</sup> *Criminal Code Act 1995* (Cth) sch (s 4.1); ‘[a] physical element of an offence may be: (a) conduct; or (b) a result of conduct; or (c) a circumstance in which conduct, or a result of conduct, occurs’ (s 4.1(1)).

<sup>149</sup> *Criminal Code Act 1995* (Cth) sch (s 5.1); ‘[a] fault element for a particular physical element may be intention, knowledge, recklessness or negligence’ (s 5.1(1)).

<sup>150</sup> *Financial Management and Accountability Act 1997* (Cth) s 5 provides ‘public money means: (a) money in the custody or under the control of the Commonwealth; or (b) money in the custody or under the control of any person acting for or on behalf of the Commonwealth in respect of the custody or control of the money; including such money that is held on trust for, or otherwise for the benefit of, a person other than the Commonwealth’.

<sup>151</sup> *Australian Constitution* s 81 provides ‘all revenues or moneys raised or received by the Executive Government of the Commonwealth shall form one Consolidated Revenue Fund, to be appropriated for the purposes of the Commonwealth in the manner and subject to the charges and liabilities imposed by this *Constitution*’.

<sup>152</sup> See *Gene Technology Act 2000* (Cth) ss 146(1) and (2).

<sup>153</sup> See *Gene Technology Act 2000* (Cth) s 146(5).

<sup>154</sup> Noting that *Gene Technology Act 2000* (Cth) s 192 a person must not, in an application or complying with the Act, give or produce false or misleading information or document, subject to a criminal sanction for the offence; there is not, however, any positive requirement to give or produce information or documents that is known to the person and might materially affect the application or compliance with the Act.

<sup>155</sup> *Gene Technology Act 2000* (Cth) s 10 and *Gene Technology Regulations 2001* (Cth) r 5.

<sup>156</sup> See *Gene Technology Act 2000* (Cth) ss 146(1) and (2).

- (i) *Only* extends to the current licence holder, or a person covered by the licence, and so will not apply to an expired, suspended, surrendered or cancelled licence.<sup>157</sup>
- (ii) *Only* deals with contamination where the licence holder or a person covered by the licence is not complying with the Act, and will not address contamination that has been sanctioned by the Act. For example, a contamination event that has been assessed as a reasonable risk.
- (iii) *Only* addresses the licence holder, or a person covered by the licence, and does not address any dealing with a GMO declared not to be GMOs for the purposes of the Act,<sup>158</sup> exempt from licensing dealings,<sup>159</sup> or notifiable low risk dealings, or other persons covered by any of these dealings.
- (iv) *Only* addresses ‘such steps in relation to the thing as are reasonable in the circumstances for the licence holder [or the person covered by a GMO licence] to comply with this Act or the regulations’.<sup>160</sup>
- (v) *Only*, where the licence holder or a person covered by the licence does not comply with the Regulator’s direction, liability for a one-off penalty of up to a maximum of ‘2,000 penalty units’ (\$220,000).<sup>161</sup>

The directions power expressly *does not* require the licence holder, or a person covered by the licence, to address the loss, damage or injury caused to a third person or the public good.

- (c) Where a person suffers loss or damage resulting from GMOs the Act *does not* establish a cause of action, instead leaving the person to find recourse through a range of statutory and common law liability arrangements. While these arrangements may provide an adequate and effective resolution, in some circumstances they may not. For example, the determination of liability for simple common law negligence only addresses the loss or damage resulting from GMOs if the GMO producers and marketers (including the supply chain handlers) do not meet or exceed the legal standard of care (defined by the Court), and if this standard is met the injurer’s liability for the loss or damage is zero. In the case of a statutory liability scheme, the injurer will only be liable if the particular elements of the statutory scheme have been satisfied. Consumers (and the community) will be unsure whether their particular circumstances will necessarily be protected against loss or damage, the assessment only being possible after the event.

<sup>157</sup> *Gene Technology Act 2000* (Cth) s 60.

<sup>158</sup> See *Gene Technology Act 2000* (Cth) s 10 (para (e) of ‘genetically modified organism’ definition).

<sup>159</sup> See *Gene Technology Regulations 2001* (Cth) r 6.

<sup>160</sup> *Gene Technology Act 2000* (Cth) ss 146(1) and (2).

<sup>161</sup> See *Gene Technology Act 2000* (Cth) ss 146(3) and (6); see also *Crimes Act 1914* (Cth) s 4AA(1).

## VI DISCUSSION

This article assumed that consumers (and the community) might be uncertain about the quality of GMOs (and GM products), and that regulatory intervention under the Act might provide consumers and the broader community with the necessary health and safety and environmental assurances to conclude bargains involving GMOs and GM products. The analysis in this article suggests that the Act was implemented, at least in part, to address the information asymmetry faced by consumers and the community to the introduction of GMOs. The expectation from imposing regulation on some dealings with GMOs was that the benefits from assurances that GMOs had been independently and comprehensively assessed as safe for health and the environment would be consumer and the community confidence, and a positive downstream effect for industry manifest as acceptance of GMOs as safe.<sup>162</sup>

The response in the Act was to create a separate and independent institution in the Regulator capable of providing an assessment about the likely risks, with the power to control various uses of some GMOs in a way that minimised the potential loss or damage. Included in this scheme are criminal sanctions (including strict liability) for some conduct and a power for the regulator to clean-up or remediate some contaminations. However, the analysis in this article also suggests that significant ‘gaps’ exist in the statutory liability scheme, leaving other common law and statutory schemes to provide an uncertain remedy for any economic, health and safety or environmental loss or damage resulting from GMOs.

Importantly, the Regulator in applying the Act makes *no* claims that dealings with GMOs pose no risks. Further, in applying the Act and assessing risk under the *Risk Analysis Framework*, the Regulator relies on a standard of substantial equivalence and familiarity to the non-GMO parental organism:

The Regulator can only consider risk posed by or as a result of gene technology. Therefore risks posed by a particular GMO need to be considered in the context of the risks posed by the unmodified parental organism in the receiving environment. For DIRs this might be considered by examining whether the GMO would cause an adverse outcome over and above that which would occur if the status quo were maintained, that is, if the GMO was not deployed in the environment. For DNIRs the contained facilities prevent exposure to the environment although the potential for unintended release must be considered.<sup>163</sup>

The effect of applying this standard of substantial equivalence and familiarity is to avoid a detailed assessment 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.<sup>164</sup> For

<sup>162</sup> See Explanatory Memorandum, above n 19, 42.

<sup>163</sup> Office of the Gene Technology Regulator, above n 54, 31.

<sup>164</sup> See K Barrett and E Abergel, ‘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 examples, H Miller, ‘Substantial Equivalence: Its Uses and Abuses’ (1999) 17 *Nature Biotechnology* 1042 and E Millstone, E Brunner and S Mayer, ‘Beyond “Substantial Equivalence”’ (1999) 401 *Nature* 525; see generally T McGarity, ‘Seeds of Distrust: Federal Regulation of Genetically Modified Foods’



example, in assessing the risks of releasing GM canola into the environment 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 seven GM canola lines are no greater than those posed by non-GM canola i.e. they are as safe as conventional canola’.<sup>165</sup> As a consequence, the Regulator’s decisions might be interpreted as making no legitimate claims about the health and environmental safety of the products.<sup>166</sup>

This means that GMOs (and GM products) do pose risks and that some of those risks may eventuate, possibly causing loss or damage to third persons and the public good. In considering information asymmetries and how these apply to consumers (and the community) in a way that overcomes the uncertainty about the quality of GMOs, the ‘gaps’ are likely to undermine the consumer’s (and the community’s) acceptance of the assurances that the Act does provide an adequate assurance. Thus, the question is not whether GMOs pose a novel threat that the current liability arrangements can satisfy,<sup>167</sup> but rather, whether consumers (and the community) would be better assured by a different liability arrangement. It is in this context that a statutory scheme of strict liability for any economic, health or environmental loss or damage resulting from GMOs is one possible solution.

Essentially, the argument is that the producers and marketers (including the supply chain handlers) of GMOs are best placed to know and be aware of the potential and scope of the possible risks of GMOs and their consequences. Without this information consumers (and the community) are unlikely to conclude bargains with GMOs because they are uncertain about the potential health and safety and environmental consequences. With a more robust assurance through a strict liability scheme about the health and environmental safety of GMOs, consumers (and the community) might be provided with more confidence about the quality of GMOs and so conclude more bargains involving GMOs and GM products.

Further, the costs of providing the best information should be internalised by the producers and marketers (including the supply chain handlers), rather than externalised to the broader community and unfortunate individual consumers. One way to achieve this is through a statutory strict liability scheme that avoids the uncertainties about liability from reliance on the common law and existing statutory schemes. Where producers and marketers (including the supply chain handlers) know that they will be strictly liable for any loss or damage, they will factor these costs (and risks of being exposed to those costs) into their considerations about producing and marketing GMOs and GM products. Perhaps significantly, without such an effective incentive to disclose the best information to consumers, to the community and to the Regulator under the Act, individual producers and marketers (including the supply chain handlers) of GMOs will favour poorer quality goods (some with risks of adverse health and safety and

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(2002) 35 *University of Michigan Journal of Law Reform* 403.

<sup>165</sup> Bayer CropScience Pty Ltd, *Commercial Release of Genetically Modified (InVigor hybrid) Canola: Risk Assessment and Risk Management Plan*, DIR 021/2002 (2003) 10; see also C Lawson, ‘Risk Assessment in the Regulation of Gene Technology under the *Gene Technology Act 2000* (Cth) and the *Gene Technology Regulations 2001* (Cth)’ (2002) 19 *Environmental and Planning Law Journal* 195.

<sup>166</sup> See Millstone *et al*, above n 164.

<sup>167</sup> This appears to have been the principal conclusion of various reviews: see Department of Agriculture, Fisheries and Forestry, above n 141, 2-6 and the references therein.

environmental outcomes), with a consequential reduction in the size of the market that will follow.<sup>168</sup>

A possible amendment to the Act that imposes strict liability so that liability rests with the person, being the producers and marketers (including the supply chain handlers) dealing with the GMO that causes the loss or damage, including financial loss or damage is appended at the end of this article. The remaining parts address vesting of a cause of action, joint and several liability, survival of the cause of action, avoidance and consistency requirements, and co-existence with State and Territory laws and other laws. This possible amendment is consistent with the Act maintaining the defined terms and the limitations inherent in those terms,<sup>169</sup> the Act's existing '[n]o doubling-up of liabilities' arrangements,<sup>170</sup> and the intergovernmental *Gene Technology Agreement*.<sup>171</sup>

While a comprehensive strict liability scheme under the Act is only one possible solution, this article shows that it is consistent with the Act's purpose of addressing the information asymmetry market failure. The benefit of a strict liability scheme will be to address the existing 'gaps' in the Act's liability arrangements and reinforce the Regulator's assurances about the quality of GMOs and GM products for the benefit of consumers and the community.

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<sup>168</sup> See, for example, Akerlof, above n 1, 488.

<sup>169</sup> For example, the term 'GMO' would not include GMOs that have been declared not to be GMOs for the purposes of the Act and would include GMOs that have been declared to be GMOs for the purposes of the Act: see *Gene Technology Act 2000* (Cth) s 10 (para (c) and (e) of 'genetically modified organism' definition).

<sup>170</sup> *Gene Technology Act 2000* (Cth) s 18(1); further provision is also made for a 'a pecuniary penalty under a corresponding State law' (s 18(2)).

<sup>171</sup> The *Gene Technology Act 2000* (Cth) is the Commonwealth's component of this regulatory scheme; mirror legislation is required in each State and Territory for a comprehensive regulatory scheme (s 5); see also *Gene Technology Act 2001* (Vic), *Gene Technology Act 2001* (SA) and *Gene Technology Act 2001* (Qld); see also 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* (2003) 22-24.

ATTACHMENT 1  
*Gene Technology (Strict Liability) Amendment Bill 2005*

*Long Title*

An Act to amend the *Gene Technology Act 2000* and impose strict liability for activities involving gene technology, and for related purposes.

1 *Short Title*

This Act may be cited as the *Gene Technology Amendment (Strict Liability) Act 2005*.

2 *Commencement*

This Act commences on the day on which it receives Royal Assent.

3 *Schedule*

Each item that is specified in the Schedule to this Act has effect according to its terms.

*Schedule — Amendments to the Gene Technology Act 2000*

1 At the end of s 8

Add:

8A *Strict liability for loss or damage*

- (1) If a person (the first person) deals with a GMO, and another person (the second person) suffers loss or damage, including financial loss or damage, then the first person is liable to compensate the second person for the amount of the second person's loss or damage.
- (2) A law of a State or Territory about the survival of causes of action vested in persons who die applies.
- (3) If 2 or more persons are liable for the same loss or damage they are jointly and severally liable.
- (4) If the loss or damage in a liability action was caused by an act or omission of the person who suffers the loss or damage concerned then the amount of the loss is to be reduced to such extent (which may be to nil) as the court thinks fit having regard to that person's share in causing the loss or damage. [font size?]
- (5) A person may commence a liability action at any time within 20 years after the time the person became aware, or ought reasonably to have become aware, of the alleged loss or damage.
- (6) Any term of a contract, arrangement or understanding that purports to exclude, restrict or modify, or has the effect of excluding, restricting or modifying:
  - (a) the exercise of a right conferred by this section; or
  - (b) any liability under this section;

is void.

(7) This section:

- (a) is not intended to exclude or limit the concurrent operation of any law, whether written or unwritten, in force in a State or Territory; and
- (b) is not to be taken to limit, restrict or otherwise affect any right or remedy a person would have had if this section had not been enacted.

(8) In this section:

- (a) a reference to loss or damage, other than a reference to the amount of any loss or damage, includes a reference to injury; and
- (b) a reference to loss or damage includes an amount necessary to restore the health and safety of humans or the environment after the release of a GMO into the environment.