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## RISK ASSESSMENT AND MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS UNDER AUSTRALIA'S GENE TECHNOLOGY ACT

Nicholas Linacre, Jose Falck-Zepeda, John Komen, and Donald MacLaren

2033 K Street, NW, Washington, DC 20006-1002 USA • Tel.: +1-202-862-5600 • Fax: +1-202-467-4439  
ifpri@cgiar.org www.ifpri.org

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## **Abstract**

Compared to both Canada and the United States, Australia has been slow to approve commercial planting of transgenic crops. Two probable reasons exist for the slow approval rate of transgenic crops in Australia. The first reason is community perceptions about the risks associated with transgenic technologies. The second is the regulatory framework currently employed to approve commercial releases. This paper examines some of the potential regulatory issues that may be affecting the review process and approval of transgenic technologies. First we provide a brief introduction to the regulatory structure in Australia, second we consider the impact of regional, national and state jurisdictions, third we argue that the regulator needs to consider the use of benefits analysis in decision making, fourth we argue for the use of probabilistic risk assessments in certain circumstances, and fifth we look at potential problems inherent in majority voting in a committee and recommend alternatives.

Keywords: GMOs, Risk Assessment, Regulation, Australia

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# RISK ASSESSMENT AND MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS UNDER AUSTRALIA'S GENE TECHNOLOGY ACT

Nicholas Linacre,<sup>1</sup> Jose Falck-Zepeda,<sup>2</sup> John Komen,<sup>3</sup> and Donald MacLaren<sup>4</sup>

## INTRODUCTION

Compared to both Canada and the United States, with 4.4 and 42.8 million hectares respectively of transgenic crops under cultivation,<sup>5</sup> Australia has been slow to approve commercial planting of transgenic crops. To date Australia has planted only 0.2 million hectares of transgenic crops, principally of GM insect-resistant cotton but also a small area of carnations modified for color.<sup>6</sup> In 2003, approval was given for the release of a third crop, herbicide tolerant canola.<sup>7</sup> However, despite national regulatory approval, a number of Australian State governments imposed moratoriums on commercial plantings. Currently, there are several crop transgene combinations awaiting regulatory approval.

Two probable reasons exist for the slow approval rate of transgenic crops in Australia. The first reason is Australian community perceptions about the risks associated with transgenic technologies<sup>8</sup> and the second is the regulatory framework

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<sup>1</sup> International Food Policy Research Institute (IFPRI), Washington D.C., USA. Email: n.linacre@cgiar.org.

<sup>2</sup> International Food Policy Research Institute (IFPRI), Washington D.C., USA. Email: j.falck-zepeda@cgiar.org

<sup>3</sup> International Food Policy Research Institute (IFPRI), Washington D.C., USA. Email: j.komen@cgiar.org

<sup>4</sup> Department of Economics, The University of Melbourne, Australia. Email: d.maclaren@unimelb.edu.au

<sup>5</sup> James (2003).

<sup>6</sup> Glover (2002).

<sup>7</sup> OGTR (2002a).

<sup>8</sup> Public attitude studies suggest that approximately 66 percent of the population believe that genetic engineering applications, of the type surveyed, could present serious risks. For details see Biotechnology Public Awareness Survey Final Report (2003).

currently employed to approve commercial releases. This paper examines some of the potential regulatory issues that may be affecting the approval of transgenic technologies. Two principal regulatory issues potentially affecting the adoption of transgenic crops are the failure of the regulatory system to include appropriate benefits assessments; and, ambiguity in the division of power between national and state governments. Two additional issues are discussed in this paper, relating to risk assessment approaches and voting systems. Neither of the two issues appears to be a major cause of regulatory paralysis, but may be important to address in order to encourage public confidence in decision-making.<sup>9</sup>

## **REGULATORY STRUCTURE IN AUSTRALIA**

The Australian Parliament passed the Gene Technology Act in the year 2000. The Act established a new single permanent national regulator, reporting to the National Parliament, an individual who is responsible for licensing and releases of genetically modified organisms. To assist the single Regulator, the Act also established a new regulatory agency, the Office of the Gene Technology Regulator (OGTR). The OGTR is the primary agency responsible for national regulation of genetically modified organisms. However, as the need arises because of multiple disciplines involved in the analysis a number of other agencies remain involved in the approval process as shown in Table 1. The Annex 1 provides the details of the institutions.

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[http://www.biotechnology.gov.au/content/controlfiles/display\\_details.cfm?objectid=443164A1-7F7B-410C-BD068DA14499A560](http://www.biotechnology.gov.au/content/controlfiles/display_details.cfm?objectid=443164A1-7F7B-410C-BD068DA14499A560)

<sup>9</sup> The Commonwealth Scientific and Industrial Research Organisation (CSIRO), not the Office of the Gene Technology Regulator (OGTR), is the organisation most respondents (40 percent) believe is likely to provide reliable information. For details see Biotechnology Public Awareness Survey Final Report (2003). [http://www.biotechnology.gov.au/content/controlfiles/display\\_details.cfm?objectid=443164A1-7F7B-410C-BD068DA14499A560](http://www.biotechnology.gov.au/content/controlfiles/display_details.cfm?objectid=443164A1-7F7B-410C-BD068DA14499A560)

**Table 1--Responsible agencies for genetically modified organisms in Australia and the United States.**

Subject	Responsible Agency	
	Australia	USA
Food and Food Additives	OGTR, FSANZ, AQIS	FDA, FSIS
Pesticides	OGTR, NRA, EA	EPA, APHIS
Biologics	OGTR, TGA, EA	FDA
Animals and Plants	OGTR, EA, FSANZ	APHIS, FSIS, FDA

**Source:** Compiled by Authors

The Act is consistent with the precautionary principle that, where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation. The Act directs the Regulator to take account of human health and safety and environmental risks in the Regulator's deliberations on the environmental release of new genetically modified organisms (GMOs). The Act does not direct the Regulator to consider the environmental or socio-economic benefits of such releases (Government of Australia 2000).

The Act also established a policy committee and three advisory committees that have different roles (Figure 1). The policy committee, the Gene Technology Ministerial Council, issues policy principles, policy guidelines and codes of practice that govern the activities of the Regulator. The Committee has powers to appoint or dismiss the Regulator, and the chairpersons of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee, and the Gene Technology Ethics Committee. The Gene Technology Community Consultative Committee (GTCCC) advises the Regulator and the Ministerial Council on community views on issues surrounding the regulation of gene technology and allows for community input into the development of the policy guidelines and codes of practice. The Gene



Technology Ethics Committee (GTEC) provides advice to the Regulator and the Ministerial Council on ethical issues relating to gene technology.

The Gene Technology Technical Advisory Committee (GTTAC) plays a central role in peer review of the risk assessment and management plans developed by staff in the OGTR. The Regulator must seek input from the GTTAC on the risk assessment and risk management plans developed by the OGTR (OGTR 2002b). A negative finding by this Committee would condemn any license proposal. From this perspective the Committee, while advisory, is pivotal in the decision making process because it is unlikely that the Regulator would ignore a safety recommendation by the committee. The Committee is composed of 18 expert members drawn from a range of disciplines. Regulations to the Act specify the use of majority voting for decision-making by the GTTAC (Box 1).

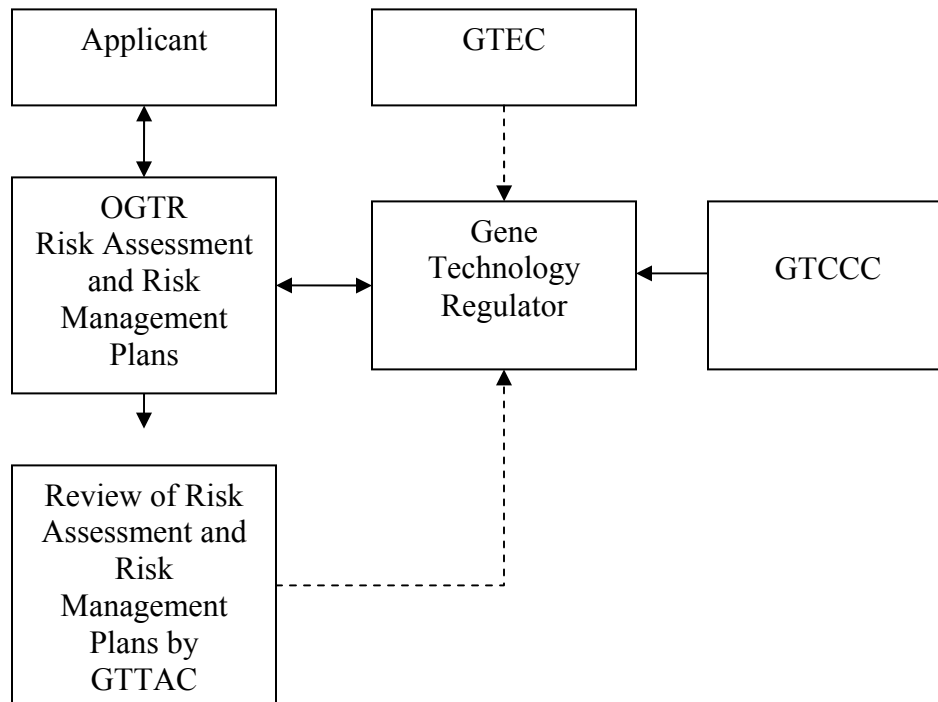
#### **Box 1--Provision for Voting in GTA**

Division 2 section 28 of the Gene Technology Regulations 2001 specify following decisions by majority voting.

- (1) A decision of the Gene Technology Technical Advisory Committee is made by a majority of the members present, and voting for the decision, at a Committee meeting.
- (2) The member presiding at a Committee meeting has a deliberative vote and also has a casting vote in the event of an equality of votes by members present.

Source: GTA (2001).

**Figure 1--Interrelationship between the Gene Technology Regulator, the agency and various committees (GTTAC, GTEC, and GTCCC)**



### **Impact of regional, national, state jurisdictions**

Existing regional structures are in place to develop coordinated standards for the approval of foods. Food Standards Australia New Zealand (FSANZ) is a bi-national independent statutory authority that develops food standards for composition, labeling and contaminants, including microbiological limits, that apply to all foods produced or imported for sale in Australia and New Zealand. In Australia FSANZ is involved in the approval process for transgenic crops destined for human consumption (Table 1). Despite the success of the FSANZ regional approach, no coordinated approach exists for the approval of environmental releases of transgenic crops between Australia and New

Zealand. A regional approach to the environmental approval of transgenic crops may be difficult to develop due to difference in ecological systems between Australia and New Zealand.

The issue is also complicated at a domestic level in Australia. In 2003, approval was given by the OGTR for the release of a third crop, herbicide tolerant canola.<sup>10</sup> GM canola is a contentious issue with some interest groups because of the possibility of gene flow. Oil seed rape (*Brassica napus*) comprises 45-50 percent of Australia's canola crop. The pollen from *B. napus* is heavy and sticky but may become airborne due to its small size. The pollen is primarily dispersed by wind with the honeybee being an important dispersal vector over longer distances. The majority of pollen travels less than 10 meters. However, long distance dispersal events can occur due to wind (1.5 km) and insects (4 km). The proposed release was for canola modified to be tolerant to glufosate, replacing low yielding conventionally derived triazine tolerant canola. The GM variety was expected to provide environmental benefits, replacing triazine compounds, which remain persistent in both soils and water, with glufosate, which breaks down more rapidly.<sup>11</sup>

However, despite national regulatory approval that GM canola is safe for commercial release, a number of Australian State governments imposed moratoriums on commercial plantings. In Australia state governments are responsible for land management issues. This demarcation of responsibilities between the national and state level allows state governments to impose moratoria.

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<sup>10</sup> OGTR (2002a).

<sup>11</sup> Salisbury (2002a; 2002b).

In Victoria, the State Government commissioned a study to help it determine whether or not the moratorium should be extended beyond the initial one year.<sup>12</sup> Despite sound economic analysis, and a recommendation that the State government should allow commercial plantings for a limited period, in order to establish the magnitude of the risks involved, political considerations took precedence and the moratorium was extended for a further four years based on the perceived concerns of the community about GM crops.

### **Cost benefit analysis**

The risk assessment framework used by the OGTR does not explicitly allow any consideration of the human health or environmental benefits that might accrue from the release of a GM organism.<sup>13</sup> It is stated in the risk analysis framework that, “the risk assessment will be transparent, objective and scientifically based. It is purely based on risk, not on a balance of risk and benefit” (emphasis added).<sup>14</sup> It is also stated that: “[e]ither the risk will be too great to permit the dealing to proceed, or the risk will be manageable, or there will be no risk that requires management.”<sup>15</sup> The natural question to ask is: at what level is the risk too high? For example, in the risk assessment and management plans, words such as low, negligible, and manageable are used (e.g. OGTR 2002d, 2002e). However, if the *status quo* is presumed safe, then any technological change creates some risk no matter how small and a justification is required for undertaking the risk. This justification is missing from GM crop risk assessments under

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<sup>12</sup> This report is available at [http://www.dpi.vic.gov.au/dpi/nrensr.nsf/93a98744f6ec41bd4a256c8e00013aa9/7ffecb5f7229f0bca256eca0028583b/\\$FILE/Lloyd%20Part%203.pdf](http://www.dpi.vic.gov.au/dpi/nrensr.nsf/93a98744f6ec41bd4a256c8e00013aa9/7ffecb5f7229f0bca256eca0028583b/$FILE/Lloyd%20Part%203.pdf). Subsequent to the Government’s decision, Monsanto decided to cease its research on this crop in Victoria.

<sup>13</sup> OGTR (2002b).

<sup>14</sup> OGTR (2002b), p15.

<sup>15</sup> OGTR (2002b).

the Australian system (e.g. OGTR 2002d, 2002e). More comprehensive analyses should also consider the *risks of not approving* novel GM products, which may imply the continued use of, for example, triazine.

Without explicit consideration in the conduct of a risk assessment of any benefits, it is difficult to understand how any decision, no matter how inconsequential the incremental increase in the risk, could be made in favor of the release of a GMO. In other words, the underlying philosophy of the Act is risk minimization rather than the more comprehensive philosophy of balancing the overall social costs and benefits of licensing a particular GM crop.<sup>16</sup>

To illustrate this deficiency in the current approach taken in the Act, suppose that a genetically modified virus that targets the reproductive system of foxes, makes them infertile. The fox is an introduced species in Australia that is thought to be responsible for the decline of many small, endangered, marsupial populations. The risk is that the virus could mutate and spread to the native dog (the dingo) and to dogs kept as domestic pets. On a purely risk basis such a proposal is unlikely to be approved because no recognized benefit is calculated against which to compare the cost. However, a decision to accept the risk to dingoes and domestic dogs can only be made sensibly in relation to the conservation benefits derived from a reduction in fox numbers.

Another deficiency in the current approach is that the Australian Gene Technology Regulator ignores the economic behavioural response of individuals towards the environmental management rules set by the regulator and excludes consideration of economic benefits and costs. Such a position ignores the important role economics plays

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<sup>16</sup> By contrast, in the report to the Victorian Government, the expert (Lloyd P.) used a social costs and benefits framework to arrive at his recommendations.

in shaping the decisions individuals make. Behavioral analysis is essential because if an economic incentive exists for non-compliance, then the rules set by the Regulator are unlikely to be followed unless adequately enforced. This is a well-documented problem in the United States, where concern about the emergence of insect resistance in the European corn borer, prompted the establishment of refugia (areas set aside for planting non-genetically modified crops). Such areas may or may not be effective in managing the emergence of insect resistance, much depends on the economic behavioral response of farmers to this added cost and the ability of the United States EPA to enforce the rules.<sup>17</sup>

The idea of explicit benefit calculations in risk management is not new. Kopp et al. (1997), Omenn et al. (1997), Farrow and Toman (1998), and Lutter (1999) all argue for the integration of benefit-cost analysis and risk assessment. The purpose of benefit-cost analysis is to assist social decision-making, the objective being the efficient allocation of society's resources.<sup>18</sup> Some authors consider that risk assessment is a subset of benefit analysis.<sup>19</sup> In the simplest cases expected utility theory may be used as the method of integrating benefit cost analysis and risk assessment.

However, cost benefit cost analysis may be criticized on a number of grounds. Of particular importance is the utilitarian assumption germane to cost-benefit analysis: the aggregation of individual utilities should be maximized, trading one person's utility gains against another person's utility losses.<sup>20</sup> Benefit-cost analysis also suffers from a number of practical problems that limit its value for decision making. For example, cost-benefit

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<sup>17</sup> US EPA (2000).

<sup>18</sup> Boardman et al. (1996).

<sup>19</sup> Kopp et al. (1997).

<sup>20</sup> Boardman et al. (1996).

analysis is also not “value free” and the usefulness of the analysis depends on the quality, training, and objectivity of the analysts undertaking the valuation.<sup>21</sup> The valuation of benefits and the choice of discount rates can be problematic, especially when non-market quantities are involved.<sup>22</sup>

Despite these problems with the measurement of expected social benefits, we believe that the framework of social benefit cost analysis is worth using because it provides a more balanced and comprehensive approach to social decision making, in this case, GMO regulation.

### **Probabilistic risk assessment**

The regulator in Australia uses qualitative risk assessments based on expert judgments about risk. These expert judgments are supported by empirical studies (e.g. Rieger et al. 2002).<sup>23</sup> However, this approach has problems. Psychological research on human perceptions of risk suggests that experts have difficulty in making objective assessments of risk because they are prone to a variety of perceptual biases known as information processing shortcuts which include: anchoring, framing, and hindsight bias.<sup>24</sup> The alternative to qualitative risk assessment is the use of probabilistic risk assessments, based on mathematical models, in which the assumptions and dependencies are made explicit and in which the effects of these assumptions can be measured and the most important ones identified.

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<sup>21</sup> Lave (1996).

<sup>22</sup> Lave (1996).

<sup>23</sup> OGTR (2002b).

<sup>24</sup> Various authors have discussed these issues at length, e.g. Slovic *et al.* 1974a, 1974b, Slovic *et al.* 1975, 1979, Fischhoff *et al.* 1982, Slovic *et al.* 1982, Kahneman and Tversky 1984.

The OGTR in Australia views probabilistic risk assessments as having limited value owing to a lack of the direct ecological information which is needed to build such models in the context of risks to the environment.<sup>25</sup> At least in some situations of importance, sufficient data are probably available for the development of basic decision models. For example, Rieger et al. (2002) and Salisbury (2002) provide data on canola gene flow, which could be used as a basis for model building and sensitivity analysis. The position of the OGTR only serves to highlight the weakness of its approach in which only qualitative assessments are used, because it fails to make explicit the vagueness of the probabilities involved, a vagueness which can be recognized and built into quantitative models and modeling processes by which, through alternative values, probabilities can be assessed. The significance of these probabilities for risk, and the consequent decision, can then be assessed through simulations.

The decision to approve the release of herbicide tolerant canola provides an example of the potential application of probabilistic risk assessments. In this situation the decision was based on a series of studies of gene flow, for example see Rieger et al. (2002). However, a probabilistic risk assessment (mathematical) model, in which the assumptions and dependencies were explicit, may have augmented expert opinion by better informing decision makers about the risks of gene flow by providing a tool to explore the effects of spatial scale on gene flow. Such models may also have provided the regulator with a defensible method for establishing isolation distances to limit gene flow.

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<sup>25</sup> OGTR (2002b).



## Group decision making

The method enshrined in the regulations to the Act is that the GTTAC use majority voting to arrive at its recommendation to the Regulator to grant or to refuse a license. Now majority voting is only one possible way of aggregating the preferences of individuals in a group in order to arrive at the optimal choice for the group and, as will be shown below, it is not necessarily the best way. Before discussing the optimal choice for a group, it is necessary to outline elements of the theory of individual choice. The remaining material in this sub-section draws heavily from Allingham (2002).

In order to characterize an individual's choices over a closed set of a finite number of mutually exclusive choices, it is necessary to make certain assumptions. The concept of a preference relation is a useful way of imposing some basic structure on such choices. It involves being able to specify for any pair-wise choices amongst alternatives, such as  $A$  and  $B$ , that either  $A$  is at least as good as  $B$  ( $A \succeq B$ ) or  $B$  is at least as good as  $A$  ( $B \succeq A$ ). If  $A \succeq B$  and  $B \succeq A$ , then the individual is indifferent between the two ( $A \sim B$ ). A second assumption is made which imposes certain consistency on choices. If there were three objectives of choice,  $A$ ,  $B$  and  $C$ , then if for the individual,  $A \succeq B$  and  $B \succeq C$ , then  $A \succeq C$ . With this second assumption, that of transitivity, the preference relation becomes a preference ordering which allows a ranking of the objects of choice from best to worst. If the individual makes choices consistent with these two conditions, then the choices are said to be rational.

In order to investigate the choices of a group of rational individuals, some further concepts are required. First, a group is a collection of at least three individuals. The rules for aggregating the individuals' preferences into a group decision is called a

constitution. There are two issues with respect to constitutions which are important for this paper: the first is the way in which individuals' preferences are used to arrive at a group decision, i.e., the rule of aggregation; and the second is whether the rule will generate a group choice.

One of the most commonly used rules is the majority rule. It appears to combine the preferences of the individual members of the group in a reasonable way, if the conditions of neutrality, responsiveness and anonymity are imposed. However, the actual choice made may not be satisfactory because this rule may lead to no choice at all. The latter unsatisfactory situation arises when the individuals' preferences are cyclic.<sup>26</sup> In an attempt to overcome the non-existence of the group's choice when that choice is made using majority voting, a variation is sometime advocated, namely, voting in two rounds. In this situation control of the order of voting can pre-determine the group's choice.<sup>27</sup> This creates the possibility of controlling the agenda and influencing the outcome, which raises the issue of strategic voting, if the members of the group realize what is going on.<sup>28</sup>

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<sup>26</sup> For example suppose that there are three members of a group,  $M1$ ,  $M2$  and  $M3$ , and there are three choices available, namely,  $A$ ,  $B$  and  $C$ . The preference orderings of the members are:  $M1 A \succ B \succ C$ ;  $M2 B \succ C \succ A$ ;  $M3 C \succ A \succ B$ . Majority voting will fail.  $M1$  and  $M3$  rank  $A$  above  $B$  and, therefore,  $B$  cannot be chosen;  $M1$  and  $M2$  rank  $B$  above  $C$  and, therefore,  $C$  cannot be chosen; and  $M2$  and  $M3$  rank  $C$  above  $A$  and so  $A$  cannot be chosen. Another feature of this example is that the outcome does not satisfy the condition of transitivity. In choosing between  $A$  and  $B$ ,  $A$  gets two votes; in choosing between  $B$  and  $C$ ,  $B$  gets two votes; and because  $A \succ B$  and  $B \succ C$ , then by transitivity,  $A \succ C$ . Yet majority voting reveals that  $C \succ A$ . This example illustrates the case that there may not exist any group choice based on the majority voting rule.

<sup>27</sup> To see this possibility, assume that in the first round it is decided by the agenda setter that a vote will be taken of  $A$  against  $B$  with the winner facing  $C$  in the second round. Using the members of the group above and their preferences, in the first round  $A$  will win and in the second round  $C$  will beat  $A$  to be the overall choice. However, had the controller decided that the first round should involve a choice between  $B$  and  $C$ , then the first-round winner would be  $B$  and, in the second round,  $A$  would be the group's choice. Finally, if the choice in the first round involved  $A$  against  $C$ , then  $C$  would win and go into the second round against  $B$  and would lose to  $B$ .

<sup>28</sup> For example,  $M1$  might decide on the first round of a vote between  $A$  and  $B$  to vote for  $B$ , even although  $A$  is preferred to  $B$ , because in the second round, the individual knows that  $B$  will beat  $C$  and, for this individual,  $B$  is preferred to  $C$ . However, in a group of several individuals, and with secret ballots, it is unlikely that individuals in the group will have sufficient common knowledge to vote in this way.

There exist a few alternatives to the majority voting rule. The extent to which these rules are useful depends upon the conditions which they impose on the aggregation rule. If completeness and transitivity are imposed, then the majority rule may fail to provide a group choice, as shown in the example above. However, these are not the only possible conditions. Others include the weaker conditions of independence and unanimity.<sup>29</sup> With only these two conditions imposed upon the aggregation of the individuals' preferences, the only rational outcome for the group, i.e., one arrived at through a preference ordering, is to have a dictator make the decision for the group. This famous, but destructive, result is known as Arrow's Impossibility theorem (Arrow 1963).<sup>30</sup>

In the context of decision making under uncertainty it is probable that individuals will have different intensities of preferences over the objects of choice. So far, the rules explored do not take account of this possibility nor can they because they are based implicitly on an ordinal scale. In order to incorporate intensity of preferences, it would be necessary to measure utility on a cardinal scale and also to allow interpersonal comparisons to be made amongst members of the group. This is what is done in a utilitarian framework in which the group's choice is the one which maximizes the group's utility.

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<sup>29</sup> The independence condition means that the group's choice between  $A$  and  $B$  does not change in response to a re-ordering of an individual's preferences which leaves the alternatives  $A$  and  $B$  ranked as before. The unanimity condition means that if everyone in the group prefers  $A$  to  $B$ , then the group will choose  $A$  alone.

<sup>30</sup> As an alternative, if the condition known as anonymity is also imposed, then a slightly better result may be achieved by the group, although at the cost of its decisions not being transitive. This result is known as the Pareto rule: if there is no other choice which every individual in the group ranks above a specific one, then that specific one is the group's choice. However, this rule in practice is not particularly helpful because, unless every member of the group happens to agree, there is no single, group choice possible by the Pareto rule. Other rules for group decision making include Borda's rule and the patriarch rule (see Allingham 2002, ch. 6)

## Limitations of analysis

The simplicity of our analysis may be criticized on a number of grounds. Much debate surrounds the various assumptions of utility theory when used to represent a group of individuals.

For a variety of reasons people find it difficult to optimize their decisions. Simon (1956) argues that in practice individuals have a limited range of alternatives, i.e. we do not know all the decision options available to us, and, even if we do, our conceptual limitations and time prevent us from comparing all of the options available. It is argued that cognitive limitations of the decision-makers force them to construct simplified models of the world to deal with decisions.<sup>31</sup> The result is that decision makers strive to attain some level of satisfaction within constraints that we do not necessarily optimize.<sup>32</sup> For example, it is unlikely in practice that preferences of committee members could be known at such a detailed level, suggested in our analysis, i.e., they each may not know the possible states of nature let alone the probabilities associated with each state.

Research in psychology also suggests that the way in which two options are framed or described can affect the preferences that individuals have for different options, although the options are in fact identical. The consequence of this is that people do not necessarily show transitive preferences.<sup>33</sup>

Another important limitation of our analysis is that if cycling is as pervasive as suggested, then it would be expected that the GTTAC's decisions would gyrate from meeting to meeting (e.g Mueller 1989:p89). The fact that this does not happen suggests that other processes are occurring that convey some stability. Although regulations to the

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<sup>31</sup> Slovic et al. (1974b).

<sup>32</sup> Simon (1956).

<sup>33</sup>(Slovic et al. (1982), Tversky and Kahneman (1982), Kahneman and Tversky (1984).

Act require the expert committee (GTTAC) to use majority voting,<sup>34</sup> it is likely that the Committee works by consensus most of the time. However, when critical disagreements do arise, majority voting is used.

## **CONCLUSION**

We have attempted to show: first, that division of powers between the national government and state governments has led to regulatory paralysis over GM canola; second that cost benefit analysis has a role in societal decision making; third that qualitative risk assessment have some deficiencies when used to guide public policy and probabilistic risk assessments may be more useful in guiding decisions; and fourth, that even if the preferences of the individuals who comprise a committee are well-defined, it is no simple matter to aggregate these preferences in a meaningful way, i.e., a way which leads to a reasonable outcome from the group. It is certainly not necessarily the case, as our example shows, that majority voting will lead to a reasonable outcome. Control of the agenda can pre-determine the outcome of a committee voting process and that process does not weight the strength of belief that each member has about the correctness of that belief.

We have attempted to contrast the decision-making process of the OGTR, which involves qualitative risk assessment, a cost-only approach and majority voting (based on an ordinal scale of preferences), with the feasible alternative of probabilistic risk assessment, the measurement of both costs and benefits and the use of monetary values to measure them (a cardinal scale). It is important for the quality of public policy making in

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<sup>34</sup> Commonwealth of Australia(2001)

the area of risk assessment and the release of GM crops that these distinctions were more widely debated.<sup>35</sup>

There are a number of simple alternative voting procedures that the Committee could follow, such as exhaustive ballots (e.g. Mueller 1989:p112). However, none of these approaches provides the Regulator with any information on the range of views expressed by the Committee. Since the aim of the Regulator is to make decisions based on an assessment of risk and, where there are different views about the size of the risk, it is essential that a range of views be expressed. A useful alternative procedure that reports a range of views is the Delphi system (Linstone 1999), first used by RAND, which provides a structured way to elicit judgments from expert panels using questionnaires with feedback to panel members. In this way the Regulator could obtain knowledge of the uncertainty (i.e., the vagueness of the relevant probabilities) associated with a particular recommendation.

Even given all these changes: resolving Federal State jurisdictional conflicts, incorporating benefits within a probabilistic risk assessment framework, and introducing the Delphi system for eliciting views instead of voting, approvals for transgenic crops will still depend on resolving the political situation.

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<sup>35</sup> A similar call has been made to incorporate economics into the Agreement on the Application of Sanitary and Phytosanitary Barriers of the World Trade Organization (see Anderson, et al. 2001)

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**Annex 1—List of abbreviations, descriptions, and URL**

Abbreviation	Description	URL
OGTR	Office of the Gene Technology Regulator	<a href="http://www.ogtr.gov.au">www.ogtr.gov.au</a>
FSANZ	Food Standards Australia and New Zealand	<a href="http://www.foodstandards.gov.au">www.foodstandards.gov.au</a>
AQIS	Australian Quarantine Inspection Service responsible for food imports	<a href="http://www.aqis.gov.au">www.aqis.gov.au</a>
NRA	National Registration Authority	<a href="http://www.nra.gov.au">www.nra.gov.au</a>
TGA	Therapeutic Goods Administration	<a href="http://www.health.gov.au">www.health.gov.au</a>
EA	Environment Australia	<a href="http://www.ea.gov.au">www.ea.gov.au</a>
FDA	Federal Drug Administration	<a href="http://www.fda.gov">www.fda.gov</a>
FSIS	Food Safety Inspection Service	<a href="http://www.fsis.usda.gov">www.fsis.usda.gov</a>
EPA	Environment Protection Agency	<a href="http://www.epa.gov">www.epa.gov</a>
APHIS	Animal and Plant Health Inspection Service	<a href="http://www.aphis.usda.gov">www.aphis.usda.gov</a>

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