2007

Providing "Thoughtful Feedback": Public Participation in the Regulation of Australia's First GM Food Crop

Kerry Ross
University of Wollongong, kross@uow.edu.au

Publication Details

Kerry Ross, Providing "Thoughtful Feedback": Public Participation in the Regulation of Australia's First GM Food Crop, Science and Public Policy, 34(3), 2007, 213-225.

Providing "Thoughtful Feedback": Public Participation in the Regulation of Australia's First GM Food Crop.

The introduction of genetically modified (GM) food crops has generated considerable debate in many countries over the role of public participation in science and technology decision-making. In 2002 and 2003 the newly established Office of the Gene Technology Regulator (OGTR) considered the first application for the commercial release of a GM food crop in Australia. Despite rhetorical statements from government in support of public participation, and the provision of various avenues for public views or knowledge to enter the decision-making process, public input proved to be minimal. This paper offers two explanations for this: one, the inherent limitations of public participation in a risk assessment setting, and two, the inordinate level of discretion extended to the OGTR by the legislative framework that guides it.

Kerry Ross is a PhD candidate in the Science, Technology and Society Program at the University of Wollongong, Northfields Avenue, Gwynneville NSW 2522, Australia. Telephone: +61 2 42214408; Email ***kross@uow.edu.au***.

The author would like to thank Associate Professor David Mercer for his ongoing support and expertise during the writing of this paper. I am also indebted to two anonymous referees who provided valuable comments on previous drafts of this paper and to Professor Susan Dodds and Dr Stewart Russell.

> Insufficient stakeholder consultation in the development and commercialization of GMOs in the past has resulted in considerable questioning and public distrust, arising from ethical, political and scientific worries…The last year has seen a realization by governments, industry bodies, scientists and farmers that viewpoints beyond their own require accommodation, and, not to do so is to be out of step with community expectations about how decisions about our society should be reached. (Commonwealth of Australia, 2000-01: page 46)

This statement was contained in a 2000-2001 Australian parliamentary report that sought to summarize some of the major issues in the development of Australia's regulatory response to innovations in biotechnology. Subsequent legislation, the *Gene Technology Act 2000* (GTA) and the *Gene Technology Regulations 2000* (GTR) came into effect on June 21 2001 and in doing so

established the national Office of the Gene Technology Regulator (OGTR) to administer the new regulatory regime. In late 2001 the newly appointed Gene Technology Regulator reaffirmed the importance of public participation with the following statement

> Science and technology are major drivers of change in our society and economy. It is important that we increase public participation in decision making regarding their use. The Gene Technology Act 2000, with its extensive provisions for community input, is an important forum for such debate. (OGTR, 2001a)

In general terms the issue of public participation within the OGTR regulatory process has drawn attention from various commentators (Chin, 2000; Hain *et al*, 2002; Risely, 2003; Tranter, 2003; Schibeci *et al*, 2006). This paper provides a more detailed analysis by exploring the extent to which the Australian public participated in the successful licensing process for Bayer CropScience's InVigor® GM canola in 2002 and 2003. The Bayer application was the first to undergo the OGTR regulatory process for the commercial release of a GM food crop in Australia[i] and thus provided the first opportunity for the Australian public to participate in such a decision.

In this case study I focus on two key issues. One is the legislative framework that guides the OGTR and requires the Regulator to consider applications within a risk assessment setting. The other is the extent to which the provisions for public participation under the GTA were exercised by the OGTR. Of particular importance here is the degree to which the OGTR engaged with community advisory groups, stakeholders and the general public throughout the Bayer decision-making process. The legislation and select documents that guide the OGTR clearly demonstrate the capacity for the OGTR to have undertaken a broader and more rigorous approach to public participation than was the case. This paper finds the OGTR adopted a minimalist approach to public participation by way of what could be described as 'discretionary slack' embedded within the regulatory framework. The role of the public in this decision is examined through a discussion of public submissions to the Bayer process and the results of a Questionnaire distributed to key stakeholder groups in 2004.

Public Participation

Commentators argue that, to some extent, efforts to implement participatory practices are obstructed by difficulties in defining a normative concept of 'public participation' in the first place. In response to this, Rowe & Frewer (2005) note that public education and public consultation can be defined in terms of one-way communication and information flows, that is, from decision-makers to the public or from the public to decision-makers - whereas public participation involves a two-way exchange of information between decision-makers and the public. Sherry Arnstein's classic essay on public participation argues further; that participation is inadequate unless public input is genuinely considered in the decision-making process

> There is a critical difference between going through the empty ritual of participation and having the real power needed to affect the outcome of the process (Arnstein, 1969: page 217)

Arnstein constructs a typology of public participation where levels of participation correspond with eight rungs of a ladder. Arnstein rightly notes that limiting the 'ladder of participation' to eight rungs is a 'simplification' of real world variances, however, this simplification helps make clear the reality of 'gradations' of participation. Rungs one and two are recognized as 'nonparticipation'; with rungs six through eight denoting a shift to 'citizen power'. Rungs three through to five detail the middle ground of participation, that is, the area known by Arnstein as 'tokenism'. Level three (Informing), level four (Consultation), and level five (Placation) allow the public varying degrees of input into decision-making processes but do not entail a shift in power such that this public input necessarily impacts on the process. In Arnstein's words, it is at this level that "citizens may indeed hear and be heard" but significantly, "they lack the power to ensure that their views will be heeded". The shift from tokenism to citizen power begins at rung six (Partnership) where there is some 'redistribution' of power such that decision-makers and the public "agree to share planning and decision-making responsibilities" through the mutual establishment of decision-making 'groundrules' that are not then "subject to unilateral change" (Arnstein, 1969: page 221).

For some decades now science studies scholars have turned their attention to the issue of public participation, in most cases by focusing on how power is, or might be, redistributed in some way or another. Nelkin & Pollak emphasise the importance of decision-makers engaging with public

understandings early in the decision-making process; in order to ensure that public views are included in the decision-making agenda and not merely as a response to it (Nelkin & Pollak,1979). Efforts to 'democratize' science and technology range from a focus on how the *process* of science and technology deliberation might empower the public (Sclove, 1995); to a re-understanding of what constitutes meaningful knowledge in science and technology decision-making (Irwin, 1995). Whilst the former is consistent with the development of a range of deliberative public forums, these are often disconnected from the formal decision-making process and so there is little opportunity for a redistribution of power (Anderson & Jaeger, 1999; Eisendel *et al*, 2001). The latter argument is part of an ongoing effort to overcome the 'deficit' model of the public understanding of science;[ii] a central feature of ongoing controversies in science and technology decision-making, particularly in relation to the introduction of novel technologies with a high degree of scientific uncertainty, and more particularly when the decision-making framework is reduced to a risk assessment/risk management model.

The adoption of a risk assessment/risk management approach to decision-making is problematic for a number of reasons. In general terms this approach tends to privilege scientific expertise with its narrow interpretation of risk; and thus overlook more complex public understandings of risk and the realization that *notions* of risk, both expert and public, are socially constructed - and not necessarily confined to issues of 'risk' in any case (Levidow, 1998; Slovic, 1999; Wynne, 2001; Robins, 2001; Mayer, 2003). As Wynne points out, this problem is self-reinforcing as scientists and decision-makers continue to see themselves as purveyors of objective risk assessment, and continue to view public concerns as subjective perceptions of risk that are thus marginal to the decision-making process.

Poor risk communication is a central issue for Powell and Leis who argue that language differences tend to reinforce the dichotomy between expert views of risk and public perceptions of risk by constituting "barriers to mutual understanding" (1997: page 27). In contrast, good risk communication is that which fosters a *mutual exchange* of information between experts and the public in order to help "manage the tension between these two profoundly different ways of representing risk" (Powell & Leis, 1997: page 29). This is consistent with the arguments of Rehmann-Sutter & Vatter who go further, suggesting that the identification of significant risk issues

may require participants who display a special type of knowledge, essentially local and contextual knowledge they label "the competence of the specifically affected" (1996: page 220). Rehmann-Sutter & Vatter also make a distinction between those who are undertaking the risk and those who are having the risk imposed upon them. They argue that this provides justification for public participation in identifying risk as those imposing a risk do not "have moral authority if those highly affected by the risks were not allowed to participate in the deciding procedure" (1996: page 217). These arguments echo the suggestion put forward by Slovic that risk assessment practices would benefit greatly from increased public participation in three key ways; a more competent analysis, increased public legitimacy, and a stronger democratic process (1999: page 689).

The OGTR and Public Participation

The OGTR was established to oversee the research and development (R&D) and the commercial release of GMOs in Australia. It was not, however, authorized to regulate aspects of GMO use that are administered by other agencies. For instance, Food Standards Australia New Zealand (FSANZ) continues to oversee the safety and labeling of GM foodstuffs, and the Australian Pesticides and Veterinary Medicines Authority (APVMA) continues to review the safety and ongoing use of agricultural chemicals such as herbicides. This type of GMO regulation is commonly referred to as a 'gap filler' approach in that the new regulatory body is only responsible for administering functions that are not covered by existing agencies. According to a briefing paper commissioned by the Australian government this type of fragmented regulatory regime has the potential for regulatory "mishaps or oversights" (Commonwealth of Australia, 2000-2001: page 15). The Australian experience is similar to that of the EU where Levidow *et al* found that the UK "played a key role in fragmenting the risk problem into separate administrative procedures – environmental safety, food safety and herbicide usage" (1996: page 97). Such fragmentation resulted in an EU wide regulatory regime for the environmental release of GMOs (Deliberate Release Directive 90/220) that in a UK test case "left no one officially responsible for a range of undesirable effects which lay beyond or spanned the existing administrative boundaries" (Levidow *et al*, 1996: page 98).

Fragmented approaches to GMO regulation are also significant in terms of public participation. In 2002 Bayer CropScience lodged an application with the OGTR to release 7 lines of InVigor®

herbicide resistant GM canola for commercial cropping in Australia (InVigor® Canola is genetically modified to resist the application of resistant to Bayer CropScience Liberty™ herbicide). Notably, the Australian New Zealand Food Authority (ANZFA), (now known as Food Standards Australia New Zealand or FSANZ), had previously approved all 7 lines for human consumption. Consequently, the OGTR did not independently consider any consumer health issues in relation to the Bayer application, it simply appealed to previous decisions made by ANZFA. Similarly, public concerns over increased herbicide use on InVigor® crops or subsequent volunteer growth were not open to public debate as the OGTR directed public concerns to APVMA.[iii] ANZFA and APVMA do not have participatory mechanisms in place, so in effect the public was excluded from participating in a range of decisions directly related to the Bayer application. The decision to provide a 'gap filler' approach to GMO regulation in Australia thereby limited public participation by reducing the scope of the OGTR decision-making process to a narrow range of very specific issues.

According to the GTA there are four distinct categories of 'dealings' with GMOs for which the OGTR is responsible.[iv] The Bayer decision, and thus the discussion here, is concerned with the most regulated category, that of dealings involving the intentional release of GMOs into the environment (known as DIR). For this category the OGTR base their licensing decision on a *Risk Assessment and Risk Management Plan* (RARMP) that is prepared for each application (OGTR, 2003a). The best indication of how the OGTR determines the content of the RARMP is documented in the *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (RAF), which is guided by the GTA and from general risk assessment principles (OGTR, 2002a). Summarized in Table 1 is the 9-stage process that is prescribed by the GTA, outlined in the RAF, and which formed the basis of the OGTR decision-making process in the Bayer case.[v]

Table 1

OGTR licensing process for the intentional release of GMOs

Stage 1

The applicant must prepare 'comprehensive' information about all possible hazards and consequent risks. Where possible quantitative data should be provided from contained work and early trials.

Stage 2

An 'Institutional Biosafety Committee' (IBC) within the organization applying for a license must undertake a review of the information from stage 1. This internal body must assure the Regulator of the completeness of the proponent's hazard identification and proposed risk management.

Stage 3

The Regulator considers whether the dealings pose 'significant' risk to human health or the environment.

Stage 4

If the Regulator considers that the dealings will have 'significant' impact on human health and the environment submissions must be sought from the public.

Stage 5

Irrespective of the level of risk posed the Regulator must 'seek advice' from the Commonwealth Environment Minister, the Gene Technology Technical Advisory Committee (GTTAC), the States and Territories, other Commonwealth Agencies, and appropriate local councils.

Stage 6

The Regulator 'may' take any other action that he or she considers necessary. This includes literature reviews, public hearings, independent research etc.

Stage 7

The Regulator must prepare a draft Risk Assessment and Risk Management Plan (RARMP). This is based on hazards that 'may' be posed, the level of risk, the likelihood and consequences of the hazard, and how any risk posed can be managed to 'ensure that unacceptable risks are not realized'.

Stage 8

The Regulator must notify the public of the draft RARMP and call for submissions from the public and the agencies listed in Stage 5.

Stage 9

The Regulator must consider the draft RARMP and the submissions in order to make a determination on the application and release the final RARMP.

(OGTR, 2002: 8-11)

Embedded in the 9 Stage licensing process are key terms that enable flexibility in setting the boundaries of public participation. For instance, the measure of 'significant' at stage 3 and 4 is a value judgment undertaken by the Regulator; and the use of 'may' at stage 6 hardly indicates at which point these actions should be undertaken. Thus the OGTR has a substantial level of discretion in determining the extent of public participation in the licensing process. This degree of 'discretionary slack' in the licensing process was critical in allowing the OGTR to limit and control the conduct of public participation in the Bayer decision.

As noted in Table 1 the RAF provides avenues for general public participation, including stakeholder groups, throughout the process. The OGTR can engage with the public at Stage 4, Stage 6, and Stage 8, although Stage 8 is the only point at which the OGTR must call for public submissions. Moreover, the OGTR has the capacity to undertake public hearings and commission independent research at Stage 6 in which case there is scope for deliberative type procedures or non-industry knowledge to enter the process. In the Bayer case, despite this being the first GM food crop to come before the OGTR and the first opportunity for the public to engage with this new decision-making process, Stage 8 was the only point at which the OGTR engaged with the public by undertaking the mandatory public submission process. Moreover, the OGTR did not commission any independent studies as per Stage 6 of the process[vi] to investigate the background of either the applicant or the particular GM crops under review.

As the public submissions were not called for until the final stage of the decision-making process the framing of the assessment had already been decided upon - in which case any new issues raised by the public could not be addressed. This is made clear in the OGTR *'Summary of Public Submissions'* which forms appendix 10 in the final RARMP (OGTR, 2003a: pages 150-6). The appendix lists eleven 'types of issue' that were raised in the public submissions. Issues deemed "Outside the Scope of Assessment" were identified as; 'Agricultural practices', 'Economic/market issues', and 'Other general issues'. In relation to these the RARMP states

> Public submissions raised a number of issues, such as impacts on domestic and export markets, costs and adequacy of segregation protocols, liability and impacts on organic

> status, that are outside the scope of the evaluations conducted under the Act and therefore could not be considered as part of the assessment process. (OGTR, 2003a: page 151

"Issues which are the responsibility of other agencies" included; 'Safety and labeling of GM foods' and 'Herbicide use and resistance management' (OGTR, 2003a: page 151) in which case the public was directed to FSANZ and AVPMA for more information. Those issues that fell within the framing of the assessment: 'General Health concerns'; 'Precaution and general safety'; 'General environmental concerns'; 'Pollen flow and contamination'; 'Herbicide resistant weeds'; and 'Applicant suitability' were noted and the OGTR referred to amendments in the final RARMP that provided more information on these issues. The OGTR did not engage with the public regarding these latter issues as such, but adopted a 'deficit model' by assuming that giving the public more information was an adequate response.

This deficit model of the public understanding of science is indicative of the general relationship between the OGTR and the public. For example, a Fact Sheet on the OGTR website entitled, *Public Participation in the Assessment of Gene Technology* illustrates the extent to which the OGTR 'informs' the public regarding GMO applications. According to the Fact Sheet, the public can; receive notification of an application, the public can 'comment' on the draft RARMP, the public can access the OGTR website, the public can read a licensing application in the OGTR office, or the public can nominate to be on the OGTR mailing list. In other words, apart from the restrictive submission process outlined above, the flow of information is from the OGTR to the public.

This continues after the OGTR has handed down its decision. The GTA defines reviewable decisions as those that refuse a license, suspend a license, or otherwise restrict or impose conditions upon a license (Gene Technology Act, Section 179, *Review of decisions*). There is no review process in the case of a license being granted. Moreover, only the license holder can call for a review. This effectively cuts off any exchange between the OGTR and the public once a decision has been made. This not only limits the capacity for the public, including neighboring landowners,

to challenge a decision that they have legitimate concerns about, but restricts the capacity for new information to flow to the Regulator should unknown affects be discovered in the future.

In addition to the public submission process the OGTR can also draw information from two public advisory bodies, the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).[vii] A third advisory body, the Gene Technology Technical Advisory Committee (GTTAC) essentially provides scientific advice to the OGTR. What is notable here is that according to the GTA and the RAF the OGTR *must* consult with the GTTAC, however, whilst it *may* consult with the GTEC or the GTCCC, it is not obliged to do so. (GTA, section 112 and section 107). Although the GTTAC must include one member each from the GTEC and the GTCCC, the role of ethics or community concerns are nonetheless marginalized unless the OGTR chooses to consult with them. In the Bayer decision the final 185 page RARMP does not contain any reference to either the GTEC or the GTCCC, nor do they appear in the list of acronyms of institutions participating in the process, suggesting that the OGTR did not consult them in this particular decision. Indeed, following a meeting on February 20 2003, in response to the Bayer application but some five months before the final decision, the GTCCC had released the following statement:

> The GTCCC expresses concern that a state of community unreadiness exists concerning the risks to the environment of the commercial release of GM canola, so significant that the applications should be denied at this time. (GeneEthics, 2003: page 1)

Given the lack of input from the public and non-technical advisory bodies in the Bayer decision it becomes evident that the process was predominantly informed by industry expertise. The significance of this situation can be found in the Explanatory Memo that accompanied the *Gene Technology Bill 2000*. This document notes that the reliance on industry to fully disclose issues regarding GMOs was a major inadequacy of the previous voluntary system (GMAC) that preceded the OGTR:

> There are difficulties in relying upon industry to provide the necessary information and make appropriate risk assessment and management decisions. This is because, in an objective aggregate sense, it may not be in their best interests to draw the possibility of risk to the attention of prospective consumers and the community more generally. (Commonwealth of Australia, 2000: page 12)

Clearly, although industry no longer make risk assessment and risk management decisions, in considering Stage 1 and 2 of the licensing process, they continue to 'provide the necessary information' in the early framing stages of the OGTR process and thus continue to inform the basis of subsequent risk assessment and risk management decisions.[viii]

The primary objective of the OGTR is to establish a national regulatory system:

> 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 (Gene Technology Act, Section 2, *Object of Act*).

This concern with identifying and minimizing the risks associated with biotechnology is to be expected, however, in practice, the OGTR interprets its role in such a way as to resist engaging with public views by insisting that a scientific understanding of specific risk issues is the *only* way this objective can be realized:

> It should be noted that risk assessment is a scientific process that does not take political or other non-scientific aspects of an application to a GMO into account (OGTR, 2002a: page 12)

This statement contradicts the procedural intent of the Gene Technology Regulations though, which directs the OGTR to pursue a regulatory process that:

- Continue[s] a science based approach to the assessment of risks but including capacity for formal consideration of broader issues such as ethics.

- Be more responsive to stakeholders and community views consistent with the legislation. (OGTR, 2001b: page 4)

On announcing the decision to issue a license for Bayer InVigor® canola the Regulator paid tribute to the "input" from experts in this decision, suggesting that these experts contributed to the decision in some way. In the same sentence, the Regulator also paid tribute to the public for their "thoughtful feedback", a strong indication that the Regulator saw public participation as a *reaction to* the risk assessment process, rather than a contributing factor (OGTR, 2003b).

Brief Summary of the OGTR Risk Assessment and Risk Management Plan for InVigor® Canola

The following summary and critique of this process provides a basic understanding of the InVigor® canola Risk Assessment and Risk Management Plan in order to provide a foundation on which to discuss the public response to this document. Reflecting stage 7 outlined above, the final RARMP assessed the following hazards:

- Human health and Safety – Toxicity and Allergenicity
- Environmental Safety – Toxicity to other organism
- Environmental Safety – Weediness
- Environmental Safety – Transfer of introduced genes to other organisms
- Herbicide Resistance

The risk assessment process carried out in regards to InVigor® canola looked at the likelihood of these hazards to pose a risk to human health or the environment. The risks to human health and the environment are assessed as being either: 'negligible', 'very low', 'low', 'moderate', 'high', or 'very high'. The process considered the hazards according to; 'the likelihood of the hazard

occurring', or the 'likely consequences of the hazard, were it realized', it also canvassed the risk management options to 'mitigate any significant hazards' (OGTR, 2003a: page 27).

Human health and Safety – Toxicity and Allergenicity

The OGTR used a range of studies to identify the likelihood and consequences of toxic or allergenic hazards posed by InVigor® canola to human health. These included; traditional toxicology tests in animals and analysis of any changes to proteins expressed or levels of toxicants or allergenics as compared to conventional canola. The assessment found: the proteins expressed by InVigor® canola are not 'similar' to known toxins and are 'rapidly degenerated by mammalian digestive systems'[ix] and that allergenic risks were 'unlikely' because humans are already exposed to the proteins in InVigor® in the environment. As a result of these studies and other evidence the OGTR assessment concluded that the toxicological or allergenic risks of InVigor® canola to human health were 'very low' and as a result "risks are considered negligible and it not considered necessary to impose any management conditions" (OGTR, 2003a: *Executive Summary*).

Environmental Safety – Toxicity to other organism

In this section the RARMP considered the risks posed by InVigor® canola to: grazing animals, native animals, animal feed safety, insects, and soil bacteria. This assessment again looked at: the toxicity of novel proteins expressed by InVigor®, and the toxicity of herbicide metabolites. The OGTR listed a large number of findings that "strongly supports the conclusion that the GM canola…will not present a toxicity or allergenicity hazard to any organism" (OGTR, 2003a: page 76). These included that the: 'the composition of the 7 GM canola lines does not differ significantly from non-GM canola', 'proteins produced are rapidly degraded by mammalian digestion', no 'anti-nutritional' effects noted in sheep or pigs, 'no adverse impacts on foraging bees, and 'there are no reports of adverse effects…on native animals or birds in Australia or commercial production in North America.' The OGTR again concluded that "the risks are considered negligible and it is not considered necessary to impose any management conditions" (OGTR, 2003a: *Executive Summary*).

Environmental Safety – Weediness

This element of the risk assessment looked at whether InVigor® canola had the potential to be more invasive or persistent than non-GM canola in the environment. ('Volounteer' plants, or weeds, both on the farm and in surrounding areas, are seen as a normal function of farming) The RARMP states that InVigor® is no more likely to invade the environment than non-GM canola as it can be controlled by alternate herbicides and farm management practices (alternate to applications of Liberty™ herbicide). The RARMP 'recommends' that a farmer growing InVigor® 'notify' the adjoining landowner. However, the *recommendation* to notify adjoining farmers is problematic – if for any reason they are not notified they will be ignorant of the need to take alternate management steps to address the issue of weediness. Despite this the assessment concludes

> As the risk that the GM canola lines will be more likely than conventional canola to spread in the environment, and result in more detrimental environmental impact is negligible, no management conditions are required. (OGTR, 2003a: page 94)

Environmental Safety – Transfer of introduced genes to other organisms

In this section the OGTR identifies two hazards that are of particular concern, the transfer of genes to other plants related to canola, and the transfer of genes to other organisms including humans. (This is known as horizontal transfer.) The assessment acknowledges that there will be varying levels of gene transfer between InVigor® canola and other canola and canola related species. However, it dismisses this concern by arguing that the same safety conclusions and management practices proposed for InVigor® will apply. The assessment does however, address the critical issue of multiple herbicide resistant plants. This has been documented in Canada with GM crops transferring herbicide resistant genes to other GM crops with different herbicide resistance.[x] The RARMP admits that multiple herbicide resistance is 'inevitable' but that it can be managed through the use of 2,4-D and with strict adherence to Bayer's 'Crop Management Plan.' (CMP). The Bayer

CMP recommends that farmers minimize the risk of multiple herbicide tolerance in volounteers by creating buffer zones and notifying neighbouring landowners of crop details. In the end, the prevention or control of multiple herbicide resistant canola may prove difficult as genes do not respect farm boundaries and again the Bayer CMP only 'recommends' that GM farmers notify their neighbours in this regard, it does not insist they do. The assessment concludes that risk posed to human health and the environment by gene transfer to related species is 'negligible' to 'very low'.

In assessing the risk of genes being transferred to unrelated organisms, including humans, the OGTR makes a number of crucial assumptions. It states for instance that

> there are no known mechanisms whereby horizontal gene transfer could occur between plant and mammalian cells, therefore primary consideration will be given to the possibility of transfer from GM plants to microorganisms[xi]

The RARMP does go on to state however, that:

> Theoretically, horizontal gene transfer from GM canola to other organisms, including humans and microorganisms is possible, but it is extremely unlikely. (OGTR, 2003a: page128)

Another assumption is made soon after when the possibility of gene transfer from GM crops to grazing animals, via gut bacteria, is said to have, "received little attention, largely because free DNA has been considered unlikely to survive." (OGTR, 2003a: page 129) In the end the conclusion is that the 'likelihood' of gene transfer to other organisms, including humans, is 'considered negligible' because: there is 'limited probability of occurrence', 'natural events of horizontal gene transfer to distantly related organisms are extremely rare' and 'horizontal gene transfer has generally been achieved only under highly controlled experimental conditions and with related gene

sequences' (OGTR, 2003a: page 132-3) Once again, there are no 'management conditions' imposed by the OGTR in relation to these risks.

Herbicide Resistance

In this section of the Assessment the OGTR acknowledges that there is potential for herbicide resistant weeds to develop. However, according to the RARMP this will only occur if Liberty herbicide is used 'inappropriately'. As herbicide use is administered by APVMA, 'no specific conditions are imposed in the licence in relation to management of herbicide resistance' other than adherence to APVMA protocols (OGTR, 2003a: page 134). In turn, the APVMA is satisfied that implementation of Bayer's CMP "will provide effective management of the development of herbicide resistance" (OGTR, 2003a: page 134).

The public and the OGTR process

The public submission process to the draft Bayer RARMP (Stage 8) began on April 1 2003 and ended on May 26 2003. Appendix 10 of the final RARMP lists and summarizes a total of 256 public submissions. Contained within this number are 5 petitions and 8 campaign letters that represent more than 1000 additional signatures however, these are not listed separately and so their impact is lost. Assessing the content of public submissions to the Bayer application proved extremely difficult as the OGTR did not publish the submissions (this also raises concern about how the OGTR may have categorized the submissions in Appendix 10 of the final RARMP). The OGTR was contacted in relation to this matter and replied that:

> The OGTR is not in the practice of releasing submissions on RARMPs as they contain personal names and addresses. Hence for privacy reasons submissions are not released…In addition, and from a logistical perspective, any one RARMP may receive a significant of submissions, sometimes as many as several hundred.[xii]

This statement is at odds with a number of similar public submission processes in which the identity and/or content of submissions have been released. Indeed there is a history of public disclosure in a number of related debates suggesting that it is commonplace for government agencies in Australia to publish submissions and/or the identity of those who participated.[xiii]

Keeping these limitations in mind, the analysis presented here draws on the submissions of 5 key stakeholder groups that were accessed via an internet search: Greenpeace; Network of Concerned Farmers (NCF); GeneEthics; the Public Health Association of Australia (PHAA); and the Australian Consumers Association (ACA). This was complemented by an online Questionnaire sent to each of these groups in mid 2004. (See Appendix 1 for list of questions) All of the groups listed here responded to the 15 questions and the results are detailed at the conclusion of this discussion. The 5 submissions can be seen as a representative sample of views within the broader public as a recent study by the Australia Institute argues that NGOs such as these play an important role in representing public views in Australia (Maddison *et al*, 2004). Moreover, it is evident from the OGTR's categorization of the submissions that in most instances the concerns raised by the submissions of individual members of the public were the same concerns expressed by environmental, consumer and public interest groups such as those examined here (OGTR, 2003a: page 150-6). It is beyond the scope of this paper to comment on whether the views expressed in the submissions are sound, rather, I briefly present the key themes from the submissions in order to indicate the types of concerns raised by the public in response to the Bayer RARMP.

The submissions detailed below are briefly summarized in Table 2 with URLs for each submission listed among the references.

Table 2

Summary of stakeholder submissions

- **Greenpeace** - A very comprehensive submission that addresses all of the major issues raised in the draft RARMP in detail; the submission is particularly critical of poor scientific practices in

the OGTR assessment. This submission was based, in large part, on peer reviewed scientific studies that conflicted with the studies used by the OGTR.

- **Network of Concerned Farmers (NCF)** – Primarily concerned with the impact of GM crops on conventional farming this submission also addresses a broad range of GM issues raised in the RARMP. NCF essentially argued that the GM risk to human health and the environment cannot be assessed in isolation from social, political, and economic issues.
- **GeneEthics –** This submission criticizes a number of key shortcomings by the OGTR decision-making process and details Bayer's history of non-compliance in Australia, arguing they are not fit to hold a license.
- **The Institute of Health and Environmental Research** – under the auspices of the **Public Health Association of Australia (PHAA) –** A well researched submission that does not limit itself to human health issues but also addresses environmental concerns as raised in the draft RARMP, and is critical of the lack of scientific rigor in the assessment. This submission is similar to that of Greenpeace in that it counters the industry basis of the OGTR risk assessment with peer reviewed scientific studies.
- **Australian Consumer Association (ACA)** – Claiming a neutral stance on GM, this submission is critical of the narrow scope of the OGTR assessment and its failure to protect consumers through a more comprehensive, independent process.

The public submissions challenged the narrow framing of the issues by the OGTR and put forward their own understandings of the Bayer application by appealing to counter-expertise and lay knowledge and understandings.[xiv] In most cases the public submissions were concerned with the Regulator's narrow definition of the terms 'human health' and 'environment'. The Regulator's definition of environment is reflected in a Senate Estimate Report that detailed questioning between the Regulator and Senator Cherry in late 2003.[xv]

> **Senator Cherry** – Coming back to the issue of the environment, are you operating under any policy instructions from government as to what is and is not the environment for the purposes of the act?
>
> **Regulator** – No, the definition of the environment that we use is the one that is in the Gene Technology Act

> **Senator Cherry** – But that does not exclude the notion of a neighboring farm environment, for example?
>
> **Regulator** – It would only include a neighbouring farm environment in the context of whether or not there was a risk to human health and safety in the environment. (Commonwealth of Australia, 2003: page 151)

The Regulator appears to have framed the environment in terms of whether there is risk to human health *in* the environment rather than that which is the objective of the GTA, that is, a consideration of human health *and* the environment. For the purposes of regulation the GTA defines the environment in much broader terms than does the OGTR:

(a) Ecosystems and their constituent parts; and

(b) Natural and physical resources; and

(c) The qualities and characteristics of locations, places and areas. (GTA, section 10, *Definitions*, (1) *environment*)

The narrow interpretation of the 'environment' by the OGTR was commented on in most of the submissions, with the PHAA stating:

> To the OGTR, "the environment" seems to be just natural, undisturbed ecosystems, of which there is very little remaining in Australia. The rest of Australia, including agricultural lands, disturbed lands, or roadside verges do not seem to be included in the definition, despite being parts of the Australian environment. (PHAA, 2003: page 1)

The Greenpeace submission challenged the scientific basis of the OGTR claims by pointing out many of the studies in the RARMP were industry funded and/or unpublished, and countering these with independent peer reviewed research. Additionally, Greenpeace identified a number of instances in which the RARMP quoted studies that did not support the particular claim for which they were cited. Moreover, although Greenpeace recognised APVMA as the appropriate body to licence the use of herbicides, it argued that the human health and environmental impact of herbicide

use on GM crops was the concern of the OGTR and should therefore have been independently assessed by the OGTR.

The NCF submission was also concerned about the tendency for the Regulator to take a very narrow view of the environment. An OGTR study cited in the Bayer RARMP showed that GM contamination of canola type plants could occur up to 2.6 km from a GM crop (OGTR, 2002b: page 13). Therefore, if GM canola were to be introduced in Australia it may become impossible for surrounding farmers to claim GM free status and could also lead to liability issues between the biotechnology industry and individual farmers[xvi]. In this case the OGTR considered the contamination of conventional or organic canola crops an economic imposition rather than an environmental risk and therefore simply stated that it was beyond the scope of its assessment. Greenpeace and the NCF on the other hand, argued that this scenario is an environmental issue that leads to an economic imposition.

In the same way the definition of 'human health' according to the Regulator was extremely limited. In the same Senate Estimates hearing as detailed above the Regulator was asked:

> **Senator Cherry** – What research have you commissioned in the issue of human health effects of GM crops?
>
> **Regulator** – Directly, we have not commissioned research. Obviously FSANZ does a lot of work in assessing food products.
>
> **Senator Cherry** – But they have commissioned no research either.
>
> **Regulator** – I am not aware of what they have done, but there is obviously a great deal of data.

Following further discussion:

> **Senator Cherry** – What does human health mean under your Act then?
>
> **Regulator** – It can be things to do with occupational health and safety issues. For example, as I said earlier, exposure to the crop…it is human health outside the food side of things.[xvii]

With a focus then on occupational exposure the PHAA submission was particularly critical of studies cited in the RARMP that were either weak or not designed to inform human health matters.

For instance, the OGTR relied on a statement by Bayer that employees and contractors in daily contact with GE canola plants, "have not shown changed allergic reactions (as compared to the non-GM canola) in annual medical examinations." (OGTR, 2003a: page 66) The PHAA noted that there was no pre-employment measurement with which to compare these findings, nor was there any indication of what tests were conducted during the medical examinations. The PHAA went on to state:

> Only a properly conducted epidemiological study on a large number of people can determine the relationship between exposure to InVigor® canola and adverse health. (PHAA, 2003: page 8)

The Public Response to the Bayer Decision-Making Process – the Questionaire

As noted earlier, one of the problems in assessing the impact of public views in the Bayer decision was the failure of the OGTR to make the submissions publicly available. In response to the Questionnaire (see Appendix 1) all of the groups agreed that the submissions should be publicly available, with one group arguing that industry submissions should also be released (the question of anonymity bought a mixed response). In replying to the Questionnaire the groups also made a number of suggestions toward improving the decision-making process. These included: the need for more accountability in the process; the need for public views to be valued; the need for the GTCCC to engage more with the public; and the need for public hearings and forums to be a mandatory part of the decision-making process. Furthermore, the Questionnaire also raised the problematic nature of reducing decisions to a risk assessment. The suggestions made by the groups in response to this included: the need to assess 'real world' risk; the importance of quantifying the desire/need for GM crops; the idea that the decision-making process should be more than an avenue for voicing concerns; and the lack of debate over the benefits of GM crops, and whether they outweigh the risks. In the end none of the groups discussed here received a substantive reply to the concerns raised in their submission, although two claimed to have received a 'standard' reply.

There was a belief among some of those who responded to the Questionnaire that the Regulator had already made a decision prior to the call for public submissions. Moreover, one group suggested

that the submission process was a mechanism for dispersing the energy of those who have concerns about GM crops, with another group agreeing that it was a way of channeling public views without recognizing them. The negative views of these groups toward the OGTR process could well be understood as a reflection of their opposition to the Bayer decision. Yet given the minimal way in which the OGTR engaged with the public, and the understanding of the issues evident in the submissions, one could also argue that there is a reasonable basis to these views.

The actions of the OGTR in relation to public participation in the Bayer decision are not restricted to this decision alone, but have implications for the future of public participation in the OGTR process. All of the respondents to the questionnaire sent out in mid 2004 indicated that they did not believe that their participation in the Bayer decision was worthwhile – and each group was convinced that the OGTR ignored all of their concerns. When asked whether they felt their experience or expertise was valued in the OGTR process, again the response from all was an emphatic no. Despite this, a number of the groups planned to continue to engage with the OGTR, albeit in a reduced capacity, simply to maintain contact with the process. The remainder felt that as their submissions did not appear to have impacted on the process they would not make future submissions but would direct their activities into other areas that engage with the GM crop debate. A number of those who responded to the Questionnaire also expressed concern about the need to submit separate submissions for each application to the OGTR as the submissions are quite detailed and take some time to prepare.

Certainly the public has its own expectations of what participation should look like in biotechnology decision-making. In March of 1999 the Australian Consumer's Association initiated Australia's first Consensus Conference on '*Gene Technology in the Food Chain'* (Report). One of the key recommendations in the Lay Report was contained in Section 2, *Processes of Decision-making*:

> Government should establish a mechanism similar to the model of the Consensus Conference, to bring together consisting of industry, consumer groups, critics, other experts and Australian lay people. This would ensure that dialogue between all of these groups would lead to better government decisions. (Australian Museum, 1999)

This is consistent with the views expressed both by commentators such as Chin (2000: page 535) and those who, in responding to the Questionnaire, proposed the conduct of 'public hearings and forums to be a mandatory part of the decision-making process'. Indeed, it was claimed that the GTCCC was generated in response to this recommendation from the Consensus Conference (IOGTR 2000). There are two problems with this though: one, the GTCCC is not a 'mechanism similar to the model of the Consensus Conference' as the public does not determine, or engage in, discussion as in the Consensus Conference model; and two, as detailed above, the GTCCC is marginalised in the OGTR process and so fails in its function to promote dialogue between public groups and decision-makers in any case.

Conclusion

Returning to Arnstein's model as a measure of public participation this paper clearly shows that the Australian public did not engage with the OGTR decision-making process in the Bayer decision beyond the level of tokenism. In other words, the public submission process allowed the public to 'hear and be heard' but did not involve a redistribution of power such that public views were necessarily included or heeded throughout the process, or indeed, in response to it. This is, to some extent, consistent with criticisms of decision-making within a risk setting as it is evident that the OGTR engaged with expert views throughout the process but tended to adopt a deficit model when communicating with the public. Moreover, there did not appear to be any middle ground in relation to the communication of risk as the decision-makers and the public displayed very different views on the range and complexity of risks associated with the commercial release of InVigor® canola. The contribution to this paper from those who responded to the Questionaire confirm Slovic's argument that more rigorous public participation would increase public acceptance and legitimacy of decisions and make for a stronger democratic process; arguably, it could also have led to a more competent analysis in this case. The Australian government has recently (2005) undertaken a public review of the operations of the Gene Technology Act 2000, including the efficacy of public participation in the OGTR decision-making process. This review was an important opportunity to improve public participation under the GTA and it is hoped that its outcome will be the subject of future studies into the role of the Australian public in science and technology decision-making.

Notes

[i] The governance of GMOs in Australia underwent major changes in 2001. The previous voluntary systems, the Interim Office of the Gene Technology Regulator (IOGTR) and its predecessor, the Gene Manipulation Advisory Committee (GMAC) were replaced by a nationally consistent, compulsory process administered by the OGTR. The role of the OGTR is to regulate GMO dealings under the Gene Technology Act 2000 (GTA), and according to the Gene Technology Regulations 2001 (GTR), and to provide information to other regulatory agencies and the public. The OGTR does not determine decisions as such, but supports the Gene Technology Regulator (Regulator) in making decisions according to the GTA. Prior to the Bayer decision the only GM crops released into the Australian environment were GM cotton and GM carnations.

[ii] For example, see the large body of ongoing work by Alan Irwin and Brian Wynne.

[iii] For example, at some points in the RARMP the OGTR does identify risk hazards and yet as they do not pose a direct threat to human health or the environment they are not considered risks for the purposes of regulation and are thus passed on to these other agencies. In this regard there is much criticism of the fact that FSANZ does not have an adequate process in place to conduct rigorous assessment of the risks of GMOs in the food chain. See Hain et al, page 177. See also NSW Hansard, *Interim Report: Genetically Modified Food*, Standing Committee on State Development, p 1, which notes that rather than develop an innovative approach to regulation, "ANZFA [previous title for FSANZ] merely assesses GE foods from data supplied by corporations promoting the technology."

[iv] The four dealings are as follows: 1) 'Exempt dealings with GMOs' – that is GMOs that are exempt from licensing due to their known negligible risk; 2) 'Notifiable low risk dealings with GMOs' (NLRD) – GMOs that are deemed low risk provided they are contained within certified facilities, they must also be listed on the GMO register; 3) 'Licensed dealings with GMOs' – includes all dealings with GMOs that do not fit the above categories and require a case by case consideration by the Gene Technology Regulator. These dealings are licensed in two ways, a) Dealings not involving intentional release of GMOs (DNIR) includes those dealings where the risks are less understood and where the GMOs must be confined to a contained system, and b) Dealings involving intentional release of GMOs (DIR) includes those dealings where the intention is to release the GMO into the environment. This category must undergo a more rigorous licensing process than DNIR dealings and thus requires more data to be submitted for assessment.

[v] This was the decision-making process at the time of the Bayer decision. As will be noted in the conclusion, a review of the GTA was held in 2005 however, this study does not comment on the changes to the decision-making process since this time.

[vi] The reference list in the final RARMP for Bayer InVigor® GM canola does contain three studies commissioned by the OGTR, however, these were not commissioned in response to the Bayer application and so cannot be said to address the particular concerns raised by this application. For detail see OGTR, 2003a, Reference list – Agronico (2002), OGTR (2002a) & Rieger (2002).

[vii] The GTEC and the GTCCC are made up of representatives from: environmental groups, consumer groups, farmers, industry stakeholders, local council representatives, social scientists, media representatives, ethicists, ecologists, law academics, and philosophers.

[viii] Bayer or the biotechnology industry undertook many studies cited in the RARMP. Moreover, a number of studies were either unpublished or had not undergone peer review. For more detail see the following submissions, Greenpeace, Network of Concerned Farmers, and the Public Health Association of Australia.

[ix] OGTR, RARMP:56. This was not based on human testing but on a 14 day mouse study and a 10 day rat study that was criticised in at least four of the submissions made to the OGTR.

[x] OGTR, *RARMP*:96-8. In this instance the assessment states that the risk of gene transfer between cultivated canola crops is 'high'. See also *Op Cit*, OGTR RARMP Executive Summary. This phenomenon is well documented in scientific and lay literature. See for instance, Huxham M., and Sumner, D., Science and Environmental Decision Making, Prentice Hall, London, 2000, who outline the impact of gene transfer and mutation on the function of GM crops.
[xi] OGTR, *RARMP*:126. By microorganisms the RARMP is referring to bacteria.
[xii] Email correspondence between the author and the OGTR, 3 February 2004.
[xiii] There are many examples of public submissions being released into the public domain, including those listed in the Senate Committee Report on the Gene Technology Bill. In this case all organizations and individuals who made written submissions as well as all witnesses who appeared at public hearings were listed in Appendix 1 and 2 of the Senate Committee Report, *A Cautionary Tale: Fish Don't Lay Tomatoes*.
[xiv] In general, the submissions challenged the scientific basis of the claims made by the OGTR in the RARMP, in large part by noting that much of the OGTR analysis was based on industry funded or non-published data rather than independent peer reviewed research.
[xv] In 2003 Senator Cherry was a Democrat Senator for Queensland.
[xvi] A 2002 study details that since the introduction of GM crops in Canada the organic industry has disappeared in some areas and many conventional canola growers have been forced to grow GM canola in order to protect themselves against legal challenges from the biotech industry for breach of intellectual property rights (Warwick and Meziani, 2002).
[xvii] Commonwealth of Australia, 2003, p 159.The act is ambiguous in relation to human health and does not provide a tangible definition. Gene Technology Act, section 51, *Matters Regulator Must Take Into Account In Preparing Risk Assessment and Risk Management Plan,* (1a) states that in preparing the risk assessment the Regulator must 'take into account' "the risks posed by those dealings, including any risks to the health and safety of people". The Regulator must also 'take into account' (1b) "any submission made under Section 49 (3c) in relation to such risks." Section 49 (3c) is that which relates to "written submissions on whether the license should be issued, being submissions about matters that the Regulator is required to take into account". Those matters the Regulator must take into account are Section 51 (1a) above and also Section 51 (2a), "the means of managing any risks posed by those dealings in such a way as to protect: (2a) (i) the health and safety of people." These circular guidelines under the Act gives no clear indication of what should be considered in assessing the risk to human health, rather, it is left to the Regulator to interpret the definition of Human Health according to these guidelines.

References

Anderson, I, and B Jaeger 1999. Scenario workshops and consensus conferences: Towards more democratic decision-making. *Science and Public Policy*, **26**(5), October, 331-340.

Arnstein, s 1969. A Ladder of Citizen Participation. *Journal of the American Planning Association*, **35**(4), 216-224.

Australian Consumers Association 2003. *ACA's response to the Office of the Gene Technology Regulator on the Risk Assessment and Risk Management Plan for the commercial release of Bayer genetically modified canola*, May 26. Available at <http://www.choice.com.au>, last accessed 15 January 2004.

Australian Museum 1999. *First Australian consensus conference: Gene technology in the food chain – Lay Panel Report*, Canberra, Old Parliament House, March 10-12.

Chin, G 2000. The role of public participation in the genetically modified organisms debate. *Environmental and Planning Law Journal*, **17**(6), December, 519-535.

Commonwealth of Australia (2003) *Senate Estimates*. Community Affairs Legislation Committee, Çanberra, 5 November.

Commonwealth of Australia (2000) *Explanatory guide to the Commonwealth Gene Technology Bill 2000*. Available at <www.ogtr.gov.au>, last accessed 15 May 2004.

Commonwealth of Australia (2000-2001) *Genetically Modified Governance Issues*, Research Paper No 17, Department of the Parliamentary Library.

Eisendel, E, E Jelsoe, and T Breack 2001. Publics at the technology table: the consensus conference in Denmark, Canada and Australia. *Public Understanding of Science*, **10**, 83-98.

GeneEthics (2003) *Submission to the Office of the Gene Technology Regulator for the Risk Assessment and Risk Management Plan for DIR021*, GeneEthics Network, May. Available at <http://geneethics.org/community/modules.php?name=Sections&op=viewarticle&artid=64> last accessed 13 January 2004.

Gene Technology Act 2000. Available at <www.ogtr.gov.au>, last accessed 15 June 2005.

Greenpeace (2003) *Submission to the Office of Gene Technology Regulator: Response to the Risk Assessment and Risk Management Plan for DIR021/2002*, Greenpeace Australia Pacific, 26 May. Available at <http://www.greenpeace.org.au>, last accessed 20 May 2004.

Hain, M, C Cocklin, and D Gibbs 2002. Regulating biosciences: the Gene Technology Act 2000. *Environment and Planning Law Journal*, **19**(1), February, 163-179.

IOGTR 1999 *Discussion Paper: Proposed national regulatory system for genetically modified organisms – How should it work?* Available at <www.health.gov.au/tga/gene/genetech/consult.htm>, last accessed 13 June 2004.

Irwin, A 1995. *Citizen Science: A study of people, expertise, and sustainable development*, London: Routledge.

Levidow, L 1998. Democratizing technology – or technologizing democracy? Regulating agricultural biotechnology in Europe, *Technology in Society*, **20**, 211-226.

Levidow, L, S Carr, R von Schomberg, and D Wield 1996. Bounding the risk assessment of a herbicide-tolerant crop, In van Dommelen, A., (ed.) *Coping with Deliberate Release: the Limits of Risk Assessment*, The Netherlands: International Centre for Human and Public Affairs.

Lowrance, W. 1976. *Of Acceptable Risk*, California: William Kaufmann Inc.

Maddison, S, R Denniss, and C Hamilton 2004. *Silencing Dissent: Non-Government Organizations and Australian Democracy*, Discussion Paper 65, The Australia Institute. Available at <www.tai.org.au>, last accessed 8 May 2005.

Mayer, S 2003. Science out of step with the public: The need for accountability of science in the UK. *Science and Public Policy*, **30(**3), June, 177-181.

Nelkin, D and M Pollak 1979. Public Participation in Technical Decisions, *Technology Review*, **81**, 55-64.

Network of Concerned Farmers, 2003. *InVigor® Canola Submission OGTR*, Non-GM_Farmers.com, 16 May, Available at <http://www.non-gm-farmers.com/news_details.asp?ID=375>, last accessed 15 January 2004.

OGTR *Public Participation in the Assessment of Gene Technology*, Fact Sheet. Available at <http://www.ogtr.gov.au>, last accessed 9 April 2005.

OGTR 2002b. *The Biology and Ecology of Canola (Brassica napus).* Available at <http://www.ogtr.gov.au>, last accessed 9 April 2005.

OGTR 2001a. *New Gene Technology Regulator Takes Up Position*, Media Release, 6 December. Available at <http://www.ogtr.gov.au>, last accessed 10 May 2004.

OGTR 2001b. *Regulation Impact Statement for the Gene Technology Regulations 2001*. Available at <http://www.ogtr.gov.au>, last accessed 10 May 2004.

OGTR 2003b. *Rigorous Assessment Confirms GM InVigor® Canola Safe as Non_GM Canola*, 25 July. Available at <http://www.ogtr.gov.au>, last accessed 10 May 2004.

OGTR 2002a. *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (RAF), January. Available at <http://www.ogtr.gov.au>, last accessed 10 May 2004.

OGTR 2003a. *Risk Assessment and Risk Management Plan (RARMP): Commercial Release of Genetically Modified (InVigor® Hybrid) Canola, DIR021/2002*. Available at <http://www.ogtr.gov.au>, last accessed 10 May 2004.

Powell, D and W Leiss 1997. *Mad Cows and Mothers Milk: The Perils of Poor Risk Communication*, Montreal: McGill-Queen's University Press.

Public Health Association of Australia 2003. *Submission to the OGTR on the Commercial Release of InVigor® Canola (DIR 021/2002)*, The Institute of Health and Environmental Research Inc. Available at <http://www.phaa.net.au?Advocacy_Issues/OGTR2.htm>, last accessed 9 April 2004.

Rehmann-Sutter, C and A Vatter 1996. Risk communication and the ethics of democracy. In van Dommelen, A. (ed.) *Coping with Deliberate Release: the Limits of Risk Assessment*, The Netherlands: International Centre for Human and Public Affairs.

Risely, M. 2003. *The Politics of Precaution: An Eco-Political Investigation of Agricultural Gene Technology Policy in Australia, 1992-2000*. University of Adelaide: Dissertation.

Robins, R 2001. Overburdening risk: policy frameworks and the public uptake of biotechnology. *Public Understanding of Science*, **10**, 19-36.

Rowe, G and L Frewer 2005. A typology of public engagement mechanisms. *Science, Technology and Human Values*, **30**(2), Spring, 251-290.

Schibeci, R, Harwood, J, Dietrich, H 2006. Community Involvement in Biotechnology Policy?: The Australian Experience, *Science Communication*, **27**(3), 429-445.

Sclove, R 1995. *Democracy and Technology*, New York: Guilford Press.

Slovic, P 1999. Trust, emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield, *Risk Analysis*, **19(**4), 689-701.

Tranter, M 2003. A question of confidence: an appraisal of the operation of the Gene Technology Act 2000, *Environmental and Planning Law Journal*, **20**, 245-259.

Wynne, B 2001. Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs. *Science as Culture*, **10**(4), 445-481.

Appendix 1

Questionaire Regarding the OGTR and DIR 021/2002 (Bayer InVigor® canola)

Question 1

At what point did you or your organisation actively engage with the OGTR process in regards to DIR 021/2002? Did you participate prior to the release of the draft RARMP, or was the submission you made regarding this document the first opportunity for you to participate in the OGTR decision-making process?

Question 2

Did the OGTR fail to identify or address any issues of importance to you or your organisation in the DIR 021/2002 decision-making process? If so, what were they.

Question 3

Do you consider that your participation in the OGTR decision-making process regarding DIR 021/2002 was worthwhile? Please elaborate.

Question 4

Do you believe the public participation model adopted by the OGTR in regards to DIR 021/2002 was adequate? If not, how do you think public participation in the OGTR decision-making process could be improved?

Question 5

Will you or your organization continue to take part in the formal OGTR decision-making process regarding the release of GMOs into the environment? Why or why not?

Question 6

Did you receive a reply from the OGTR to your submission regarding DIR 021/2002? If so, did the reply specifically address the issues raised in your submission?

Question 7

Do you think that submissions made to the OGTR by the public should be publicly available? If so, should those making the submission have the option of remaining anonymous?

Question 8

What types of scientific evidence or expertise did you or your organisation rely on to support your submission?

Question 9

What types of experience or expertise did you or your organisation bring to the debate in relation to DIR 021/2002?

Question 10

Do you think your experience or expertise was valued in the OGTR decision-making process regarding DIR 021/2002?

Question 11

Having taken part in the formal OGTR decision-making process regarding DIR 021/2002 have you or your organisation reviewed your actions? If so, what will you do differently in the future?

Question 12

Are there any other issues in relation to public participation in the OGTR decision-making process that you wish to raise here?

Question 13

Other than the submission you made to the OGTR regarding DIR 021/2002, did you or your organisation participate in this debate in any other way? If so, please explain briefly the type of action you undertook and at what point in the debate you did so, and why. (ie were you already active in the general GMO debate or did you mobilise in response to this particular decision.)

Question 14

On a scale of 1 – 10, with 10 being the highest risk, where would you rate the risks associated with the commercial release of InVigor® GM canola? Why?

Question 15

The OGTR decision-making process is based on a Risk Assessment and Risk Management Plan. Do you think that this type of process is an adequate method for making decisions regarding the use of GMOs? If not, do you think that decision-making regarding the use of GMOs should be based on socially acceptable outcomes? For example, debate about whether or not Australia should adopt gene technologies in agriculture in general.