GTEC Discussion Paper

Managing Risk Ethically

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This paper was drafted by the authors as a GTEC submission to the review of the Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator (OGTR, 2002). The Risk Analysis Framework (RAF) is an OGTR document that outlines the process of risk analysis undertaken by the Regulator and provides a source of information and guidance for researchers and the public. In our submission we considered whether there were ethical or social factors inherent in the risk analysis process and how if at all they might be reasonably acknowledged in the RAF. It is our view that the acknowledgement of such factors is an important aspect of risk analysis and essential for building trust in the regulatory system. These factors include the nature of scientific inquiry as value-laden claims made for the benefits which are said to flow from gene technology, the reliability of scientific assessments of risk and the capacity of scientists to build and maintain trust, and decisions made about acceptable levels of risk. Recommendations are proposed for improvements to risk analysis to more fully comply with the requirements of transparency and the need to build community trust and confidence in the regulatory system. The revised edition of the Risk Analysis Framework was published in 2005 (OGTR, 2005) and incorporated several of the recommendations made in this submission.

Rosemary Robins & John Fleming, November 2007

Contents:

1. Introduction

The object of the *Gene Technology Act* "is to protect the health and safety of people and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs".[1] To this end, the Regulator issues licences to applicants proposing to work with GMOs either in contained facilities or as intentional releases into the environment unless the dealing is a Notifiable Low Risk Dealing or Exempt. Before issuing a licence the Regulator prepares a risk assessment and risk management plan. In the document Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator (January 2002) the OGTR provides a detailed account of the framework it uses when undertaking risk analysis for licence applications. It is important to note that this Risk Analysis Framework is a working document that is reviewed regularly and amended where necessary. The current version is due for review in 2004. It is therefore timely for GTEC to consider whether there are any ethical issues relevant to the analysis and management of risk that may be taken into consideration or proposed as recommendations in the review of the Framework. The aim of this paper, therefore, is to examine the OGTR's Risk Analysis Framework and to consider whether there are ethical or social factors inherent in the risk assessment and risk management process, and if so, how if at all they might be reasonably acknowledged so as to build trust in the regulatory system. To this end, therefore, the paper:

- Outlines some definitional parameters within the Risk Analysis Framework currently;
- Raises a number of questions and issues in relation to this framework. In particular, problems that may arise with differing concepts or perceptions of risk;
- Examines the charge that all scientific inquiry is inherently value-laden;
- Considers how assumptions about the benefits of gene technology might influence the risk assessment and risk management process;
- Considers the reliability of expert scientific assessments of risk and their capacity to build and maintain trust in the regulatory system; and
- Examines some of the social and ethical dimensions of decisions about acceptable levels of risk.

In conclusion, several modest recommendations are made for ways to improve risk communication that take account of the issues raised in the paper and which are intended to help build trust in the regulatory system and its processes.

The current paper incorporates and extends earlier drafts of this paper that were prepared by this GTEC working group and presented at previous GTEC meetings.[2]

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1 *Gene Technology Act 2000*, Part 1, Section 3

2 GTEC meetings May 15 & 16, 2002, 23 & 24 October 2002, 9 & 10 April 2003, 10 & 11 November 2003, and March 25 & 26 2004. GTEC working group members: R. Robins, J. Fleming and N. Hicks. This paper written by R. Robins and J. Fleming.

2. Key terms in the OGTR Risk Analysis Framework

The OGTR Risk Analysis Framework defines risk and the process of risk analysis in strictly 'scientific' terms. It outlines four main stages in the risk analysis process: Hazard identification, risk assessment, risk management and risk communication.

> **Hazard** is the capacity of a GMO to produce a particular type of adverse health or environmental effect, directly or indirectly; or an event, sequence of events or combination of circumstances that could potentially have adverse consequences.[3]
>
> **Risk** is the probability that in an identified timeframe (eg, duration of project including the post trial monitoring periods and until the Regulator is satisfied that there are no more risks to human health and safety or the environment that need to be managed), an adverse outcome will occur in a person, group of people, plants, animals and/or the ecology of a specified area that is exposed to a particular GMO. Typically risk depends on the level of hazard of the agent and the level of exposure to the receptor (human, animal, plant etc) and both have to be assessed to ascertain the level of risk.[4]

According to the framework "risk has two dimensions the probability (likelihood) of an event and its consequence (impact of the event when it happens)".[5]

> **Risk assessment** is the process of estimating the potential impact of a hazard on a specified human population or the environment under a specific set of conditions within an identifiable timeframe. It is the process of determining as accurately as possible both the actual likelihood and the consequences (should that risk occur) of the risks presented by exposure to identified hazards.

The framework emphasises that "risk assessment is a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account." [6]

The regulator uses 'best practice' risk assessment methodologies and these may change over time and with new information and in light of experience. Best practice risk assessment methodologies are the best currently available. The Regulator will review its own risk assessment processes in the light of experience, modifying procedures and practices if required.[7]

"Risk management is the process of evaluating alternative actions, selecting options and implementing them in response to risk assessments. The decision making will incorporate scientific, technological and any other relevant considerations" such as for instance the capacity of the applicant to observe risk management conditions.[8]

Finally

> **Risk communication** is the process of ensuring that:

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3 OGTR *Risk Analysis Framework* p.12

4 *Ibid*.

5 *Ibid*.

6 *Ibid*.

7 *Ibid.*

8 *Ibid*.

- an open and transparent process of identification of risks associated with gene technology and GMOs has been rigorously followed, and;
- the community is adequately informed about what risks there are and how they are being managed;
- public confidence in the regulatory system is maximised.[9]

For applications involving the intentional release of a GMO into the environment the risk assessment and risk management plan is made available to the public. The consultation process seeks input from government, non-government organisations and the community.

Currently, ethics may be factored into this process in the following way:

> Where the Regulator identifies an ethical issue in relation to a dealing which is not covered by a policy principle or by ethical guidelines issued by other organisations (eg: the National Health and Medical Research Council) the Regulator may also seek advice on a particular issue from the Gene Technology Ethics Committee.[10]

3. Questions raised by the OGTR Risk Analysis Framework

3.1 The key terms in the Risk Analysis Framework – what do they mean?

> Following the *Gene Technology Act 2000* the Risk Analysis Framework commits itself when examining risks to the health and safety of people and the environment" to consider "risks and potential risks to all living organisms and relevant ecosystems … for both long and short term effects.[11]

How are we to understand "health", "safety", "ecosystems" and "the environment"?

The environment is defined in the *Gene Technology Act 2000* in very broad terms.[12] However, no definition is provided for "ecosystems" "health" and "safety". These terms, too, may be read in a very broad sense and, depending upon the operational definition used, may well have an influence on risk assessment.

For example, The World Health Organisation (WHO) defines health in these terms:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.[13]

On this definition account would have to be taken of the way in which human beings are affected psychologically and socially by developments in gene technology. This would require attention

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9 *Ibid*., p.13.

10 *Ibid*., p. 25.

11 OGTR *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*, p. 16

12 *Gene Technology Act 2000*, section 10

13 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. The Definition has not been amended since 1948.

to the way in which human beings perceive the risks as well as the way a scientist might perceive risk when he or she is representing risk in purely scientific terms.

Where "safety" is concerned the Oxford Concise dictionary defines it broadly as "being safe, freedom from danger or risks". Its second definition is "safeness, being sure or likely to bring no danger." Such definitions may well explain why it is that there is a mismatch between what scientists may think is "safe" and what people generally might think is conveyed by the word "safe".

Risk analysis usually provides an assurance of relative not absolute safety because uncertainty is an inherent component of risk expressed as the probability of a hazard occurring.

3.2 What is risk?

Risk is conceptualised in the Risk Analysis Framework as hazards and the probability and magnitude of their occurrence once risk management strategies have been taken into consideration. There is now a vast literature on concepts of risk[14] and it is clear from this literature that there is more than one way to conceptualise risk[15] and moreover, that this is why risk is such a contentious issue.

Hansson has identified two categories: 'risk' (based upon known probabilities) and 'uncertainty' (epistemic – based upon what cannot be clearly identified). While life typically contains a measure of uncertainty, certain probabilities can be quantified, much like the tossing of a coin or the roll of a dice[16]. For each individual, even though they live with quantifiable 'risk', life is always risky, and generally, people have difficulty resolving risk-benefit conflicts. "People's perceptions frequently fail to match up with the actual dangers risks pose. Few people have a 'feel' for what a chance of dying, say a chance of one in a million, really means… We tend to emphasize low probabilities and underestimate those that are high"[17]. The use of statistics is one way to overcome this judgement bias; however, denial and overconfidence are more common ways that people deal with it[18].

On the other hand, Thompson and Dean[19] discuss the conceptualisation of risk by identifying two extreme types: probabilists on the one hand and contextualists on the other. At the extreme probabilist end, the conception of risk is characterised by the probability of events and their consequences. One understands risk only if one understands probabilities and risk assessment is a value free process. This view has also been referred to as that of the 'naïve positivist'.[20] At the opposite extreme is the contextualist conception. It sees all risk as characterised by subjective attributes that come into play depending upon the context in which the risk is being

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14 For a recent compilation of such literature see: Slovic, P., *The Perception of Risk*, Earthscan, London, 2000.

15 For example, the definitions committee set up in 1985 by the United States Society of Risk Analysts, reviewed the literature and came up with thirteen possible definitions of risk (Beer T. and Ziolkowski, F., *Environmental Risk Assessment: An Australian Perspective*, Commonwealth of Australia, Canberra, ACT, 1995.

16 Hansson S E, "What is Philosophy of Risk?" *Theoria* 62 (1996) pp 169-86

17 Teuber A. "Justifying Risk" *Daedalus* 119 (1990) 235-253

18 Slovic P, Fischhoff B and Lichtenstein S. "Cognitive Processes and Societal Risk Taking", in Slovic P (ed.) *The Perception of Risk*, Earthscan London 2000, pp 32-50

19 Paul B. Thompson and Wesley Dean, "Competing Conceptions of Risk", *Risk Health, Safety and Environment*, Vol. 7, (Fall, 1996).

20 K.S. Shrader-Frechette, Risk and Rationality: Philosophical Foundations for Populist Reforms, Berkeley, University of California Press, 1991.

assessed. This view has also been referred to as 'social constructivist'[21] and 'relativist'[22]. Thompson and Dean argue that most conceptions of risk lie somewhere between these two extremes.

3.2.1 How does risk perception influence the conceptualisation of risk?

Trust in the Regulator will depend at least partially on how members of the public conceptualise risk: some individuals may be more risk averse than others. The literature on risk perception suggests that a clear separation between 'actual' and 'perceived' risks cannot be maintained. All assessments of risk, whether they are based on data provided by applicants, the expertise of the OGTR and GTTAC, an individual's experience and perceptions, or broader cultural factors, depend upon human judgement and involve some degree of subjectivity and values.[23]

Much research into the public's 'perceptions of risk' has been and is being conducted. For example, a comparison of rival theories of risk perception considers the following[24]:

1. *knowledge:* people perceive things to be dangerous because they know them to be dangerous.

2. *personality theory:* some love risk-taking, others are averse.

3. *economic theory:* (a) the rich are more willing to take risks because they benefit more and are shielded from the consequences, while the poor feel the opposite; (b) "post-materialist" – living standards have improved so the rich are more interested in social relations and better health.

4. *political theory:* struggles over interests, i.e. explanatory power in social and demographic characteristics.

5. *cultural theory:* individuals choose what to fear (and how much to fear it) in order to support their way of life.[25]

Teuber concludes that "we are not only end-oriented; we are also ideal-oriented. We do not care just about where we end up; we care about the kind of people we have to become in order to end up in one place or another"[26].

Slovic *et al*. have identified several subjective heuristics that people deploy when making judgements about risk:

- whether or not the risk is undertaken voluntarily,

- the immediacy of the effect if things go wrong,

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21 Ortwin Renn, Concepts of Risk: A Calssification, in Sheldon Krimsky and Dominic Golding, (eds.), *Social Theories or Risk*, Wesport Connecticut, Praeger, 1992, pp.53-79.

22 Schrader-Frechette, *op. cit.*

23 Royal Society Study Group, *Risk Analysis, Perception and Management*, London, Royal Society, 1992: 89-90

24 Wildavsky A and Dake K, "Theories of risk perception: who fears what and why?" *Daedalus* 119 (1990) pp 41-60

25 Mary Douglas and Aaron Wildavsky, *Risk and Culture*, Berkeley, University of California, 1982

26 Teuber (1990) *op cit*

- knowledge about the risk by persons exposed,
- to what extent the risks are known to science,
- the degree of control that can be exercised over the risk,
- whether the risk is new and novel or old and familiar,
- whether the effect is chronic acting gradually over time or catastrophic producing a large degree of harm in one instance,
- whether the risk is something we have learned to live with and can think about calmly or dreaded, and
- the severity of the consequences.[27]

Early work in this area attempted to explain why lay perceptions of risk differed from expert judgements. It showed that lay people relied heavily on subjective heuristics in judging risk. More recent work has examined the way experts judge risk and asked whether or not they operate with heuristics of any kind. Typically experts have data and maybe a trustworthy model for only part of the problem. The final steps towards a decision must encompass or allow for uncertainty and be traversed by speculation, estimates and judgements. There is no particular reason to believe that the thought processes experts use are appreciably different from those used by lay people. When forced, as they are, to go beyond the limits of the available data, they fall back on intuitive processes like everybody else.[28]

The Risk Analysis Framework refers to risk communication in terms of following the process rigorously, and ensuring that "the community is adequately informed about what these risks are and how they are being managed" and that "public confidence in the regulatory system is maximised."[29] If the process of risk assessment is not an interactive one with the community's broader understanding of what constitutes risk being taken fully into account, it may be difficult to achieve the maximization of public confidence in the regulatory system.

3.3 In what way is the current risk assessment process 'scientific'?

The OGTR's conceptualisation of risk, as described in the Risk Analysis Framework[30] leans heavily toward the probabilistic end of the risk concept spectrum, and indeed the risk assessment

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27 P. Slovic, B. Fischhoff, and S. Lichtenstein, "Facts and Fears: Understanding Perceived Risk" in R. Schwing and W.A. Albers, (eds*.), Societal Risk Assessment: How Safe is Safe Enough?*, New York, Plenum Press; P. Slovic, "Perceptions of Risk: Reflections on the Psychometric Paradigm", in Sheldon Krimsky and Dominic Golding, (eds.), *Social Theories or Risk*, Wesport Connecticut, Praeger, 1992, 117-152.

28 P. Slovic, B. Fischhoff, and S Lichtenstein, "Rating the Risks", in Theodore S. Glickman and Michael Gough, (eds.), *Readings in Risk*, Washington D.C., Resources for the Future, 1990, pp.61-70; Slovic *et al*. *Perceptions of Risk*, 2002

29 OGTR, *Risk analysis and Risk Management Framework*, p. 13

30 OGTR, Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator, January 2002 , p.20.

phase expressly eschews subjective factors.[31] Does the claim to be 'scientific' mean that the process is value-free?

A recent United States National Research Council report noted that:

> Ethical considerations are generally normative and cannot be resolved scientifically. Yet to ignore ethical concerns is to assume that science can and should be value-free, an obvious contradiction, since this is a normative assertion in itself (Thompson, 2001). Moreover, values can influence both the design of scientific inquiry and the interpretation of data and certainly motivate much of the pressure bought to bear on regulatory agencies and other government bodies to address impacts of biotechnology beyond those directly affecting health and the environment.[32]

According to the OGTR:

> The Risk Analysis Framework involves evaluating the impacts of potential risks and their significance before considering management plans. This analysis will lead to a science-based conclusion about the overall or composite level of risk, taking into account risk management measures (ie net risk). Either the risk will be too great to permit the dealing to proceed, or the risk will be manageable through imposed licence conditions, or there will be no risk that requires management. If there is a single (or more) significant risk (or risks) that cannot be managed, the overall risk will be regarded as unacceptable and the proposal will not be allowed to proceed.[33]

The level of acceptable risk is therefore contingent upon its manageability. Evaluating the impacts of potential risks and their significance requires a simultaneous judgement about the feasibility and appropriateness of risk management options.

Thus, when we consider assessment of risk as 'scientific', consideration needs to be given as to what we think science can achieve. Science attempts to provide answers and explanations and frequently provides answers that are close to correct. But the *questions* are of infinite importance since the questions reveal the values and priorities of the one who asks those questions. Who decides which questions must be asked, and why? What about the questions which are *not* asked? For example, which health effects should be measured in relation to GM products – toxicity, allergies or maybe anxiety – and how are they measured?

Then, when the questions have been asked and the data collected, the data needs to be interpreted. However, data interpretation can also be riddled with value judgments. For example, making decisions about removing outliers, or setting confidence intervals and levels of significance. If scientists, public policy regulators, and the community at large are unaware of their own philosophical and ideological commitments they may well find themselves 'forcing' the data to support conclusions to which they are committed on quite other grounds.

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31 Ibid., p.12

32 Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology; Committee on Agricultural Biotechnology,, Health, and the Environment; Board on Agricultural and Natural Resources, Board on Life Sciences, Division on Earth and Life Studies National Research Council, *Animal Biotechnology: Science-Based Concerns*, Washington D.C., National Academy Press, (prepublication 2002), p.121. Also available at http://www.nap.edu/catalog/10418.html?se_side. The reference to Thompson 2001 is to P.B. Thompson (2001) Food Animal Productivity and Welfare, paper presented to a National Academy of Sciences Workshop.

33 OGTR *Risk Analysis Framework* p. 17

Philip Regal puts it this way:

> Philosophers of science could do a great deal to improve the quality of risk assessment by helping regulators and the public to further identify and understand the differences between judgments based on credible scientific information and theory, and judgments based on world-views that include theory reductionism, essentialism, idealism, Greek cosmology, and utilitarianism masking as objective science … [S]ome environmentalists … also mistake Platonic or Aristotelian models of the balance and perfection of nature for hard science. They may strongly oppose any modifications of nature and may make the false claim that the science of ecology warns that any disturbance of nature is unsafe.[34]

The appeal here is to make sure that the facts are not made to support conclusions which individuals or the many have an interest in defending but which may not be, on a more sober assessment, really supportable on the facts as they are known. Of course we all see 'facts' from our own personal point of view and through the prism of our own philosophical commitments. There is no counsel of perfection here. But at the least we can do our best to see to it that we treat the data as honestly and impartially as we can.

3.4 How sufficient is reliance only on the 'scientific' process of risk assessment?

There are a number of avenues where values enter the OGTR's risk analysis process. The object of the Act refers to the health and safety of people and the environment. In assessing the risks of a particular license application the parameters of 'health' 'safety' and 'environment' need to be interpreted. (The definitions of 'health', 'safety', and 'environment' are considered at 3.1) How they are interpreted will be contingent upon what questions are asked of the applicant. To a large extent these are pre-determined by the Risk Analysis Framework, although this is not set in concrete. The answers to the questions are provided by the applicant and need to be as accurate, complete and honest as possible. The data then needs to be interpreted by the experts involved in the risk analysis process (the Regulator, staff of the OGTR and GTTAC members). The adequacy of the data needs to be judged and any areas of uncertainty or ignorance acknowledged. A decision then needs to be made about what types of risk management are suitable and whether the risk is acceptable. The decision about when a risk is acceptable is particularly difficult from an ethical and social perspective and more will be said about this shortly.

When the community are informed about "what the risks are and how they are being managed" they are also being presented with a risk analysis outcome that has particular values embedded in it. If they are to accept statements such as "the risk is minimal" or "the risk is extremely low" they by implication also accept the conceptualisation of risk adopted by the OGTR Risk Analysis Framework and the values that either frame or are inherently part of the process.

'Scientific' risk assessment cannot be separated from values. Analysis cannot replace process, only inform it.[35] And science cannot pretend to be 'objective'.[36] What is studied, how the

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34 Regal P J "Metaphysics in Genetic Engineering: Cryptic Philosophy and Ideology in the 'Science' of Risk Assessment", appears in Ad Van Dommelen (ed.) *Coping with Deliberate Release: The Limits of Risk Assessment*, International Center for Human and Public Affairs, Tilburg/Beunos Aires 1996: 15-32. Find also at www.psrast.org/pjrbiosafety.htm

35 Fischhoff B "Acceptable Risk: A Conceptual Proposal", *Risk: Health, Safety and the Environment* vol 5 (1): 1994

research is designed, how it is interpreted and reported are all value-laden.[37] This leads to three corollaries:

- Disagreement about risk will not disappear in the face of 'scientific evidence'.[38]
- 'Public education' is not the sole answer.[39]
- We don't only need improved risk assessment techniques; we also need greater participation in decision-making[40] and processes that acknowledge public 'non-scientific', cultural/symbolic concerns.[41]

3.5 What difficulties underlie GM risk assessment?

The Risk Analysis Framework provides a list of general parameters within which the risk analysis will be conducted. Here it is asserted 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."[42]

There clearly are philosophical difficulties in making any sense of a balance of risk and benefit, yet the potential benefits of gene technology form the backdrop to gene technology research and development and this expectation of benefit may even condition the way in which risks are assessed. Just as the benefits are expressed in a way that is hardly value free, so any risk assessment may, in the end, be conditioned by an expectation of generous benefits to the community as a whole. Put another way, would the risks currently regarded as tolerable still be regarded as tolerable absent the benefits? And does the community believe that risk assessment will not be significantly influenced by the expected benefits? Is there any way in which the expected benefits can be quarantined from risk assessment, and if there is, how can that be shown to be the case?

The benefits of gene technology are promoted by a range of stakeholders and conveyed to the community via the media, in promotional literature, on websites etc. Moreover, surveys confirm that public acceptance of gene technology depends significantly on acceptance of the benefits. For instance, Biotechnology Australia's research indicates that the Australian public more

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36 Thompson P B "Risk Objectivism and Risk Subjectivism: When are Risks Real?" *Risk: Health, Safety and the Environment* 1: 3 (1989) Also find at www.fplc.edu/risk/vol1/winter/thompson.htm

37 For example see Cranor C. "Scientific Conventions, Ethics and Legal Institutions", *Risk: Health, Safety and the Environment* 1 (1989):155. Presentation given at Symposium on Public Participation in Risk Management. www.fplc.edu/risk/vol1/spring/cranor.htm; the ethics of confidence and type I and II errors.

38 Slovic, Fischhoff and Lichtenstein (2000) *op cit*

39 Freudenberg W R and Rursch J A, "The risks of 'putting the numbers in context': a cautionary tale", in Löfstedt R and Frewer L, *The Earthscan Reader in Risk and Modern Society*, Earthscan London 1998, pp 77-90

40 Teuber (1990) *op cit*

41 PABE study "Public Perceptions of Agricultural Biotechnologies in Europe" (2001). In this study 11 focus groups were conducted in 5 European countries (UK, Germany, France, Italy, Spain): 55 focus groups total. The groups consisted of citizens not engaged in the GMO debate. In addition, stakeholders (groups and individuals engaged in the GMO controversy) were interviewed for their perceptions of the public response to GMOs.; This was also one of the conclusions in Wellcome Trust, *Public Perspectives on Human Cloning*, www.wellcome.ac.uk

42 OGTR *Risk Analysis Framework*, p. 15 There is currently a legislative obligation imposed on the Regulator and OGTR to consider risk only and exclude benefit.

readily accept gene technology where they perceive a benefit that is useful and not merely cosmetic.[43]

3.5.1 What general goods are assumed?

Risk analysis may not explicitly weigh benefits and risks but nevertheless benefits are implicit in risk analysis and risk management and important to community acceptance of the need to manage the risks. As Langdon Winner points out, the concept of risk differs from that of hazard. If something is a hazard one seeks to avoid or eliminate it whereas if we consider taking a risk, or a chance of harm, we would usually only do so because there is something to be gained.[44]

The benefits of gene technology to Australia formed part of the background to the regulation of gene technology. In the Explanatory Memorandum that accompanied the Gene Technology Bill "the potential benefits of gene technology to Australia" were outlined as follows:

> *Proponents of gene technology identify a range of benefits to be derived from the various applications of gene technologies in relation to agriculture, health and the environment.*
>
> ***Agricultural benefits***
>
> *Proponents of gene technology believe that gene technology advances in primary production will allow Australia to maintain or improve existing production efficiency and thus maintain Australia's share of world markets, through:*
>
> - *increased productivity and yield leading to reduced or stable prices for consumers;*
> - *more efficient use of agricultural and veterinary chemicals;*
> - *savings in energy inputs to farm production;*
> - *recovery of degraded land; and*
> - *reduced chemical sprays, with less exposure of farm workers.*
>
> *While some of these benefits can be derived from the application of other technologies, gene technology is more precise than other conventional techniques (such as mutagenesis and some conventional cross breeding) and produces results more quickly than can be achieved through, for example, selective breeding. Gene technology therefore holds the potential to realise benefits more quickly and cost effectively than other techniques.*
>
> *Gene technology also produces changes to the characteristics of agricultural products that are not possible through other techniques.*
>
> ***Health benefits***
>
> *The Australian health sector is already utilising gene technology as a diagnostic tool and for disease prevention and treatment as well as to conduct research into the cause of disease.*
>
> *Biopharmaceuticals already in use in Australia, include cytokines, enzymes, hormones, monoclonal antibodies, blood coagulation factors, and a Hepatitis B vaccine. These GM*

43 Biotechnology Australia, Community has new concerns about Gene Technology, Press release, 31 July 2001.

44 Langdon Winner, *The Whale and the Reactor: A Search for Limits in the Age of High Technology*, Chicago, Chicago U.P. Press, 1986, p.145.

products have advantages such as improved efficacy, greater availability, cheaper production, reduced allergenicity and reduced risks of transmission of infectious agents.

Biotechnology can also provide safer food. An example includes the reduction of food contaminants, allergens and natural toxic compounds in foods, minimising adverse health effects such as allergic reactions and food poisoning.

Environmental benefits

Gene technology also promises benefits for the environment including:

- *reduced use of chemicals/pesticides, reduced ground water contamination, reclaiming of polluted or salt-affected land;*
- *increased agricultural productivity reducing the need for land clearing, thus protecting biodiversity;*
- *production of biodegradable plastics and biodiesel; and*
- *bio-remediation*.[45]

3.5.2 How reliable is 'expert scientific' assessment?

Currently most of the OGTR's risk assessment is qualitative. It relies heavily on data supplied by the applicant which is then assessed by scientific staff at the OGTR, members of GTTAC, the Regulator and any other experts or sources of expertise consulted.[46] However, there is often uncertainty and this may be especially the case with a new technology like gene technology. The report by the United States National Research Council[47] suggests that many issues arising from gene technology are better characterised as concerns rather than risks. They identified five overarching concerns:

- Can anything go wrong theoretically?
- Is gene technology substantially different to traditional techniques?
- Are there completely novel environmental hazards?
- Animal health and welfare issues
- Have ethical and policy issues emerging from gene technology been adequately addressed?

In addition to the five concerns the NRC Report points out that gene technology is characterised by "fundamental uncertainty":

Fundamental uncertainty results from indeterminacy, ignorance, and ignorance of ignorance. In the case of novel technologies, existing models might not apply.[48]

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45 The Parliament of the Commonwealth of Australia House of Representatives, *Gene Technology Bill 2000 Explanatory Memorandum 2000*, pp.5-6.

46 OGTR Risk Analysis Framework, Chapter 4.

47 Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, *op. cit.*

48 Ibid.

Currently the Gene Technology Act and the OGTR's Risk Analysis Framework do not require the Regulator to comment on areas of uncertainty or indeterminacy in the risk analysis of licence applications. In the Regulations there is mention of what must be acknowledged in cases where the applicant fails to supply relevant data and references but here the focus is on the applicant and the requirement that they explain why the data is incomplete and the significance of this for risk assessment.[49] The Risk Analysis Framework states that "where the level of risk is uncertain, but the consequences of the risk being realised would be significant, one might adopt conservative professional judgement in implementing management strategies".[50]

The level of uncertainty about the risk of a particular application surely has a bearing on the decision as to whether and under what circumstances risks posed by a proposed dealing are acceptable; a judgement about acceptable risk being the paramount aim of the risk analysis process. In the Gene Technology Act 2000 it states that the "Object of the Act" is to be achieved through a regulatory framework that:

"Provides 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"[51]

This precautionary approach is one means by which uncertainty may be incorporated into the OGTR's risk analysis and risk management decisions.

3.6 How can public trust in the Regulator be secured in risk assessment and risk management?

While realistically risk management must be undertaken by regulatory bodies (a certain amount of paternalism seems unavoidable), lack of trust is a critical factor underlying controversy over technological hazards[52]. The playing field is tilted towards distrust, and 'the system destroys trust'.[53] Even being honest is more difficult than it appears, and scientists and policy makers who point out the gamble often taken in assessing risk are frequently resented for the anxiety their frankness provokes.[54] In fact there has been a tendency for a 'Mexican stand-off' between companies involved in experiments with GMOs and large sections of the community that seem to distrust the safety and necessity for these developments.

Coming from the scientific and industry side, the developmental stages in risk management identified by Fischhoff seem to have been applied so far:

- All we have to do is get the numbers right
- All we have to do is tell the public the numbers
- All we have to do is explain what we mean by the numbers

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49 *Gene Technology Regulations* 2001 Part 3 Division 1 Regulation 7(4).

50 OGTR *Risk Analysis and Risk Management Framework*, p.20

51 Gene Technology Act 2000, Part I, Section 4 (aa)

52 Slovic P "Perceived Risk, Trust and Democracy", in Slovic P (ed.) *The Perception of Risk*, Earthscan London 2000, pp 316-326

53 *Ibid*

54 Slovic, Fischhoff, Lichtenstein (2000) *op cit*

- All we have to do is show the public that they have accepted similar risks in the past
- All we have to do is show the public that it's a good deal for them
- All we have to do is treat the public nicely
- All we have to do is make partners of the public
- All of the above[55]

Many sections of the community remain *sceptical* about the numbers. They are concerned that scientists cannot identify in advance all of the variables and then control for them, and that there may be catastrophic unforeseen consequences. Some argue that given there is no real necessity for these developments when the world already produces sufficient food for its populations (although we are nowhere near achieving equitable distribution), are these risks worth taking? Is it possible that the ones who are really running the agenda on risk assessment are those who stand to gain most financially and/or professionally from these developments? And if that is the case, is it possible that risks are, inadvertently or otherwise, being down-played? Moreover, many sections of the public simply do not trust "experts" where environmental issues are concerned.

That is, the attitudes one brings to a particular issue where risk assessment is concerned may well condition what one makes not only of the evidence that is available but who is interpreting the evidence.

Public confidence in the Regulator depends upon trust in the regulatory system and this, at least in part, depends upon public acceptance of the process and its outcomes. There is also a vast literature on trust. Like risk, trust can be conceptualised in different ways. Trust can involve a general expectancy that the word or promise of another individual or organisation can be relied upon. It may depend upon the degree of confidence placed in the relationship between the parties involved or on a general expectancy that the message received is true and reliable or that each party shares a set of expectations about the future.[56] Kasperson *et al*. define 'social trust' as "a person's expectation that other persons and institutions in a social relationship can be relied upon to act in ways that are competent, predictable, and caring".[57]

3.7 How might acceptable risk be determined and by whom?

The main concern for regulatory bodies such as the OGTR is to assess and manage risks to human health and safety and risks to the environment and to determine what risks are acceptable, both ethically and socially (what is ethically acceptable, and what the public will accept?). To some extent, governments must make paternalistic decisions of this kind on behalf of the public, because consultation of every interested or affected individual is simply not possible.

So how do regulatory bodies, charged with this daunting task, ethically determine acceptable levels of risk? Considerations of policy regarding risks are highly complex:

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55 Fischhoff, B (1994), *op. cit.*, 134

56 R.E. Kasperson, D. Golding, and S. Tuler, "Social Distrust as a Factor in Siting Hazardous Facilities and Communicating Risks", *Journal of Social Issues*, 48(4), 1992, pp.161 - 187.

57 *Ibid*., p.169.

> The acceptability of risk is a relative concept and involves consideration of different factors. Considerations in these judgments may include: The certainty and severity of the risk; the reversibility of the health effect; the knowledge or familiarity of the risk; whether the risk is voluntarily accepted or involuntarily imposed; whether individuals are compensated for their exposure to the risk; the advantages of the activity; and the risks and advantages for any alternatives.[58]

There are a variety of ways to answer the question "which risks are acceptable?", and Slovic *et al*. recommend the last of the following options which unfortunately provides no formula for decision-making[59]:

a) cost-benefit analysis

b) revealed preferences based on behaviour (assumes people have information and can use it optimally)

c) expressed preferences by directly asking people what they prefer (considered more democratic)

d) natural standards ('biological wisdom', that is, assuming that the optimal level of exposure is that under which the species evolved is acceptable)

e) multiple hazards (considering many hazards at once, and therefore needing to prioritise)

f) facing political realities (can't please everyone at once)

g) muddling through intelligently (no approach is clearly superior, so careful consideration should be given to all aspects, and good analysis should be insightful but not necessarily conclusive)

h) a combined approach (using the various approaches well enough in combination so that they complement one another's strengths rather than compound each other's weaknesses).

Teuber considers that muddling through may be the only ethical way to make choices about public risk.[60] Fischhoff presents a detailed description of 'orderly muddling' risk regulation[61]. He and others suggest that the *reasonable person standard* could be used to determine generally acceptable tradeoffs, and that acceptable tradeoffs must be ones that citizens endorse in principle (rather than actual or hypothetical consent).[62]

One question of great importance here is "acceptable to whom?". In deciding if and when a risk is acceptable, what standard of acceptableness is being applied? This is a dilemma that confronts all risk assessment and risk management decisions and it is not unique to decisions about gene technology. Presumably the Regulator would consider an acceptable risk to be one that does not

58 53 Fed. Reg., at 28,513. cited in Fischhoff (1994) *op cit*

59 Slovic, Fischhoff, Lichtenstein (2000) *op cit*

60 Teuber (1990) *op cit*

61 Fischhoff (1994) *op cit*

62 Fischhoff (1994) *op cit*, Thompson (1989) *op cit*

threaten the health and safety of people or the environment. However, the decision on acceptable risk should also be acceptable to the community. By necessity this judgment must be a generalisation. So who in the community is the 'reasonable person' to whom the standard of acceptability is pitched?[63] If this is indeed a necessary assessment to make, should it be explained in risk assessment and risk management reports?

Most writers suggest that ethical guidelines, or values, should be established first. The process of risk regulation should be, at least to some extent, democratic, because the *procedure* of decision-making is as important as the *outcome*.[64]

In conclusion:

> Ethical concerns cannot be completely resolved through scientific debate. Yet the nature, scope, and direction of scientific research and scientific practice are influenced by ethical considerations. Inasmuch as ethical concerns cannot be cleanly separated from scientific concerns, a strong case can be made that the ethical assumptions that underlie a research initiative or the application of a technology should be made explicit.[65]

At the moment, public disquiet on the risks involved with GMOs is unlikely to be allayed by bland assurances of safety from business, government, and scientific authorities. That is, "just trust us" doesn't quite cut it. Therefore with regards to the process of risk assessment, (a) the ethical foundations of the entire endeavour must be clarified at the outset and (b) the process itself must be transparent and thorough, with no pretence of being 'value-free'.

Recommendations

In the interests of transparency and to serve the common good, risk communication should include, where applicable, the following elements:

1. Where there is identifiable uncertainty or where noticeable gaps exist in the data used for the risk analysis of applications for a license, these must be clearly identified and acknowledged by the applicant and the OGTR and expressly acknowledged in the RARMPs. Moreover, the significance of such uncertainty or gaps in the data for risk management must also be clearly identified and stated together with the strategies that have been developed for accommodating or resolving the uncertainty.
2. An explanation of whether and how, in the process of risk analysis and/or risk management, the precautionary approach has been applied and its relevance to the conclusions that have been drawn.
3. A clear and precise statement must be provided on how judgments about the acceptability of risk have been made in a particular case.

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63 B. Fischhoff, "Acceptable Risk: A Conceptual Proposal", *Risk, Health, Safety and Environment*, Vol. 5, (Winter 1996).

64 Renn O. (1992) *op cit;* Fischhoff (1994) *op cit*

65 Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, *op. cit.*, p.122.

4. A statement must be provided revealing awareness of any specific community concerns about risk that are relevant to the application under consideration, whether these have been obtained via OGTR community consultation processes or from other sources, and an explanation of how these concerns have been addressed.

Implementation of these four recommendations will require consideration as to which of them could be implemented within the current regulatory framework, and which would require a change in policy via one of the mechanisms available currently to the OGTR or Ministerial Council (Policy Principle, Guideline, Code of Practice), or legislative amendment.