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3. Signed (Not for Publication)

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Signature of the witness

W. M. Insdale

Signed

Date

(For Publication)

4. Name of Witness

1. My name is Dr Mark Lonsdale and I currently hold the position of Program Leader, Weed Management Program, Commonwealth Scientific and Industrial Research Organisation (CSIRO) Entomology. I have held this position since the beginning of 1999.
2. Prior to this I held the position of Officer in Charge of the CSIRO European Laboratory in Montpellier, France.
3. In my current position I am responsible for directing research into integrated management of plant invasions in tropical and temporal Australia; co-ordinating CSIRO's research on ecological implications of genetically modified organisms (GMOs); co-ordinating the business plan for a National Co-operative Research Centre for Weeds in the July 2000 round; and managing the financial, capital and human resources, and intellectual property of all programs.
4. I have had 16 years experience researching a wide range of ecological impacts issues (e.g. fire, invading species) and associated invasion prediction and decision theory.
5. I have degrees in biology and population ecology and have lectured in biology. My particular research interests are biological invasions, ecological implications of GMOs, environmental risk assessments, control of weeds, and plant population ecology.
6. I have been a member of the Editorial Board of the Journal of Applied Ecology since 1996, and the Editorial Board, Biological Invasions since 1998. I am also involved in the SCOPE Global Invasive Species Program and the Global Change in Terrestrial Ecosystems Program.

5. Name of "Interested Person" (on behalf of whom the Witness will appear)

Parliamentary Commissioner for the Environment

6. Witness Brief Executive Summary

Executive Summary

Provide an overarching summary of the evidence and recommendations made [in respect of items (1) and (2) of the Warrant]. The Executive Summary should be no more than **3** pages in length

Please note that individual section summaries will be required and therefore the Executive Summary should focus on summarising the issues addressed in the brief and provide cross references to the sections in which the issues are covered rather than summarising the substantive content

1. Communities worldwide are early in the development of the science of risk analysis as it applies to Genetically Modified Organisms (GMOs). Actual data of the impacts of GMOs on biodiversity and sustainability are scarce. There is an increasingly urgent need for systems thinking to identify the range of risks that will be pertinent to a particular GMO once it is on general release.
2. This witness brief outlines a new Australian Commonwealth Scientific and Industrial Research Organisation (CSIRO) research program, which aims to expand the knowledge of the range of risks and benefits GMOs pose for the Australian environment.

3. Investigations will involve multi-disciplinary research teams carrying out ecological field work and data-mining exercises to study the impacts of GMOs on the Australian environment and farming systems at a larger scale than has been previously attempted anywhere in the world. (See **sections B(b) and B(j)(ii)** of this witness brief.) Field studies will include Bt cotton effects on beneficial arthropods at a landscape scale and the impacts of GM cotton and canola on soil processes such as nutrient cycling.
4. The potential impacts of future GMOs will focus on efforts to improve the digestion performance of rumen biota (e.g. risks of potential gene transfer to other microbes); the risks of faulty sterile-feral technology being developed for use with pacific oysters; potential risks of Bt eucalypts, including gene flows to non-modified eucalypt populations and effects on soil nutrient cycling; risks associated with viral vectoral immunocontraceptives for mice, including those to introduced and indigenous fauna and resistance selection. (See **sections B(b) and B(j)(ii)** of this witness brief.)
5. The results of these studies will be used to test and refine risk assessment models (see **sections B(b) and B(j)(ii)** of this witness brief), and will be communicated to regulators and other stakeholders via a range of mechanisms including technical-policy workshops. There will also be substantial engagement with the media to ensure that the activity is well publicised, and to engender public debate and discussion. The aim will be to deliver robust environmental risk assessment tools for GMOs to improve biotechnology investment decisions, and to help ensure that the use of GMOs in Australia is ecologically sustainable.

7. Evidence by Section (as specified in the matters set out in the Warrant)

Evidence by Section

Witness briefs are to be structured in line with the matters specified in the Warrant and the sections numbered accordingly

Each section should stand alone, and include a section summary, identifying the issues addressed in the section

Witness briefs may address **all** or only **some** of the sections (as specified in the Warrant). However section numbers should be retained, for example, if a brief addresses matters (a), (c) and (e), the sections shall be numbered (a), (c), and (e), rather than a, b, and c

Witness briefs may, within each section, adopt a sub-section approach using different headings; however, each paragraph should be consecutively numbered

Section B Relevant Matters

The Warrant has set the Commission the task of receiving representations upon, inquiring into, and investigating, the matters set out in Section B (a) – (n) below

Section B (b)

B (b) the evidence (including the scientific evidence), and the level of uncertainty, about the present and possible future use, in New Zealand, of genetic modification, genetically modified organisms, and products

Section B (b) Summary

See the **Executive Summary** of this witness brief set out above.

B (b)

6. This witness brief outlines a new Australian Commonwealth Scientific and Industrial Research Organisation (CSIRO) research program that is embarking on a study of the impacts of Genetically Modified Organisms (GMOs) on the Australian environment and farming systems at a larger scale than has previously been attempted anywhere in the world.
7. Given the biotic nature of New Zealand's economy (in farming, forestry and fishing) and its unique biodiversity, this research initiative provides valuable insight into the GMO ecological impacts questions NZ researchers should be asking and obtaining data on, in order to investigate the level of uncertainty that exists and manage the risks involved.
8. CSIRO considers gene technologies have the potential to improve our health, create a safer and more secure food supply, generate greater prosperity and attain a more sustainable environment. Some may also carry the risk of unwanted side effects on both production systems and on the environment. In response, Australia has developed a surveillance network to assess transgenic organisms from development to general release. Genetic Manipulation Advisory Committee (GMAC), in particular, poses a rigorous scientific framework to address a wide range of issues concerned with biosafety: specifically, risk to human health and hazards to the environment.

9. Despite this, there are a number of places in the regulatory environment that could be made more efficient and more reassuring to the community:
- * Despite advances in the area of environmental risk assessment in recent years, much remains to be done in risk quantification and the application of risk assessment theory to introductions, both for GMOs and new organisms generally. Limited information about key aspects of a species' biology, or of the ecosystems into which the GMO is to be introduced, means delays while hazards or risks are estimated.
 - * GMAC's involvement in risk assessment continues only up to the point of general release, and it has been seeking to address this limitation. Unless another authority, such as the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), requires it, no post-release impact studies are required (e.g. with herbicide resistant crops). Thus, in the absence of detailed research after general release, predictions from the regulatory process about biosafety and the environment remain untested. Not only does the community desire independent evidence that the regulatory system is working effectively, such studies can in themselves make the regulatory process more effective, by identifying areas in which the process is too conservative, or not comprehensive enough.
 - * The current regulatory system is severely taxed in trying to focus on biosafety of GMOs as well as issues associated with large scale, landscape impacts that affect efficiency and sustainability of land management systems e.g. impact on integrated crop management practices; risks associated with rotations of crops with different GMOs; movement of new toxins through soil and water; movement of microorganisms between livestock under grazing conditions. Indeed, Standing Committee on Agriculture and Resource Management (SCARM) noted: *'...the deployment of genetically modified organisms (GMOs) in agricultural systems raises broader issues and risks relating to the sustainability of the technology and of agricultural systems than the safety issues considered by GMAC.'* (SCARM Guidelines for Good Agricultural Practice for the Use of Genetically Modified Plants', March 1999).
10. In the community at large, there is considerable debate about the merits of GMOs. On the one hand, there are concerns about food safety, environmental impacts and market access issues while on the other, Australia needs to have access to the new technologies, and our agriculture is desperate for new solutions to intractable problems.

Research areas to address ecological impacts

11. Ecological research is the appropriate framework in which to address key scientific issues about risk assessment, sustainability and landscape impacts of GMOs. Some of the ecological framework can be built upon theories and data available for the impact of biological invasions of exotic organisms. Other research will fall within the broader framework of landscape studies of changes in management systems. While CSIRO has some significant research capability in these two major areas, it lacks the capacity to undertake the studies at the necessary scale

or in the new strategic directions. Synergies between projects in biological invasion and landscape scale studies, on the one hand, and the research program on GMOs will lead to significant advances in both non-GMO and GMO research.

Risk assessment of GMOs

12. Ecological risk assessment is characterised by a multiplicity of techniques and methods, partly because of the relative immaturity of the discipline and partly due to the complexity of ecological management issues and the variety of possible stressors and endpoints. A common, albeit simplistic, framework specifies three steps: (1) hazard identification (identifying the type of harm that can be caused), (2) the relation between the degree of injury and the amount of hazard, and (3) the probability of exposure to the hazard. (2) and (3) can then be combined to estimate the amount of damage that might be caused (risk characterisation).
13. Although risk assessment of GMOs has been carried out in Australia and overseas, it largely remains at stage (1), the rather unquantitative stage of hazard identification. Because the current regulatory system essentially permits only low risks, it rarely moves onto stages (2), (3) or further, though CSIRO's work on Bt cotton is something of an exception. These latter stages require knowledge of how organisms interact with the environment, and which environments are more vulnerable. Building capacity in ecological risk assessment and strengthening linkages between groups working in the area of ecological modelling, climate matching, and studies of resilience of different ecosystems, is an important objective. The aim would be to be able to carry out much more quantitative, probabilistic risk assessments than have proved possible in the past, which should facilitate a more rational approach to decision-making.

Landscape impacts – the environment and issues of scaling up

14. The potential benefits of GMOs for sustainable agriculture will depend largely on the rate at which they are adopted by farmers, and farmers' willingness and ability to comply with the necessary changed practices (SCARM 1999). The knock-on, or indirect, consequences for farm management and for the natural environment are difficult to predict (e.g. minimum tillage is beneficial for soil structure, but it also has been associated with some declines in productivity of wheat with increases in previously unimportant pest, weed and disease problems). These consequences could arise from (1) changes in ecosystem function, either above or below ground, if carbon- or nutrient-cycling species, or pathogens, are affected; (2) evolution of resistance in target and non-target species, with or without gene transfer. Either of these reduces the value of the GMO to agriculture and could potentially reduce productivity. Alternatively, (3) there could be changes in management, behaviour or markets that could produce higher order effects, less easy to predict, but which may have powerful impacts at the landscape level.

Specific proposals

15. CSIRO proposes to build an ecological risk assessment group that networks ecological modellers, risk analysts, ecologists working in systems ecology and on

the ecology of pests and weeds, and climate matching specialists. Their tasks will be to:

1. Develop a robust risk assessment framework for GMOs that considers effects at a wider, landscape scale, and at the longer time-frames at which environmental interactions occur.
2. Initiate a number of case studies to follow through each stage of introduction of a GMO and the possible consequences. This will provide data and insights that will be used to test and refine the risk assessment framework.

Interaction between these two activities will be assured by frequent technical/policy workshops that bring together the researchers and regulators, so that results inform the regulatory process at a rapid rate.

16. The following outlines the background and proposal research to develop a robust risk assessment framework and investigate the potential impacts of GMOs at a landscape level.

RISK ASSESSMENT OF GMOs

Kinds of GMO hazards perceived by the public

17. Research by CSIRO has shown that the proportion of the public “very concerned” about genetic engineering (GE) has risen from roughly 53% in 1998 to 64% in 1999 (data of Dr Katrine Baghurst, CSIRO Health Science and Nutrition and Food Science Australia; henceforth indicated by KB). The community perceives two kinds of dangers from GMOs:
 - Human health hazards; and
 - Environmental hazards such as:
 - Spread of introduced genes (e.g. for herbicide resistance) to wild relatives
 - Loss of insecticide resistance in non-target species through ubiquity of insecticide in plant/soil system
 - Invasion by the GMO itself (weediness etc).
18. However the level of information amongst the public is even now quite low – 50% of those questioned had heard little or nothing about GE before answering the CSIRO 1999 survey (KB). Thus, these perceptions of hazard are not the result of a highly informed discussion. In reality, the risks of the hazards above may well be generally low. Instead, the hazards that seem more real, and were identified by a group of ecologists at a multidivisional workshop organised by Joanne Daly at Entomology in August 1999, are what may be termed the higher order and landscape scale risks, such as:

- Promised reductions in inputs (herbicides, insecticides, fertilizer etc) not achieved (see <http://www.econ.ag.gov/whatsnew/issues/gmo/index.htm>, which shows the effect of GM crops on pesticide use in the US at a regional scale where promised reductions in inputs were not always attained), or even reversed;
- changes to land management practise reducing biodiversity; and
- land degradation through GMOs allowing use of marginal land.

These hazards are also at the scale at which the *benefits* of input traits will also be felt.

The five pillars of risk analysis

19. Not every environmental problem can be addressed, and priorities need to be set by agencies and land managers. In recognition of this, risk analysis has forced itself onto the agenda for governments around the world over the last twenty years. Risk is the likelihood that damage can be caused some behaviour or action (including no action). Hazard is the agent that causes damage. When describing risk-based disciplines, risk analysis is the most general term, and comprises the following four components, referred to as the “four pillars of risk analysis” by Davies (1996).

- (i) Comparative risk analysis consists of comparing two or more types of risk, principally a tool for policy makers to decide on resource allocation.
- (ii) Risk assessment is a set of analytical techniques for estimating the frequency of undesired events and their consequences (damage or injury), and is properly accompanied by a description of uncertainty in the assessment process.
- (iii) Risk management, in contrast to risk assessment, considers social, economic and political factors to determine the acceptability of damage and what action can be taken to mitigate it.
- (iv) Risk communication is about conveying information about risk.

To these four terms CSIRO would add

- (v) Monitoring, to detect the impact of hazards at an early stage (although purists might include such monitoring under the heading of risk management) or to provide data to refine future risk assessments.

20. This witness brief now goes on to expand on each of these terms in turn, as they apply to GMOs, and will finish by synthesizing the insights for gene technology from this rich field, in order to draw out strategies for the future.

(i) Comparative Risk Analysis

21. This has two forms. The first (also termed risk ranking) consists of comparing two types of risk. This approach might involve comparing the risks of an insect

resistant crop with those of insecticidal control of pests. The second type of CRA is of a larger scale. It is also known as programmatic CRA and is used for setting government priorities amongst a large number of risks. It involves more value judgements than risk ranking and is “as much a philosophical as a scientific effort” (Davies 1996). It is “a process that generally uses a professional judgement approach to evaluate the relative magnitude of effects and set priorities among a wide range of environmental problems” (US EPA 1998). Our recent establishment (NWS 1999) of a list of its top twenty weeds of national significance from amongst its 2200 or so (Hnatiuk 1990) naturalized species is a limited example of this kind of approach.

22. We need also to be able to capture philosophical and value-based differences in appraisal of risk. Techniques such as multi-criteria mapping, used for public policy debates on new developments in northern Europe since the Second World War, may provide a mechanism for mapping the debate around biotechnology amongst policy makers and interest groups (see report on this technique by Stirling and Mayer, accessible as a supporting document from the main report on “The Politics of GMO Food” by the Economic & Social Research Council at <http://www.susx.ac.uk/Units/gec/gecko/gm-brief.htm>). Australia needs to build capacity and increase activity in the area of CRA.

(ii) Risk Assessment

23. The phrase “ecological risk assessment” has been widely interpreted by many different agencies. The most notable attempt to date to develop a unified framework for ecological risk assessment, that can be applied to all stressors – physical, chemical and biological (including GMOs) – has been made by the United States Environmental Protection Agency. The USEPA framework (US EPA 1992), evolved from the National Academy of Science’s human-health risk assessment process. The latter was developed for chemical pollutants and consists of a four step procedure:
 1. Hazard identification – what type of damage can a substance cause?
 2. Exposure assessment – how long will a target population be exposed to how much substance?
 3. Dose-response assessment – how does the target population respond to this exposure?
 4. Risk characterisation – combines information from the steps above to estimate the likelihood and magnitude of damage.
24. The USEPA framework is conceptually similar to this consisting of a problem formulation phase, an analysis phase (divided into characterisation of exposure and characterisation of ecological effects) and a risk characterisation phase. The framework acknowledges, however, that:

1. species vary widely in their response to hazards – the NAS model was developed for a single species – humans – but ecological risk assessment must address risks to a wide variety of species;
 2. there is no single set of ecological values, analogous to human fatality or injury that can serve as the endpoint for an ecological risk assessment. Ecological endpoints are much more diverse, including for example population increase or decrease, changes in the physical or chemical characteristics of habitat (Suter, 1990; 1993), or genetic impacts (Adam *et al*, 1993);
 3. the NAS model considers risks to the individual, whereas ecological effects may occur at the population, community or ecosystem level. For a rare species one lost individual may be too much; for a common species, the population may be able to compensate for the loss of individuals up to a point. Ecological risk assessment must therefore identify the level at which the endpoints of the assessment are specified;
 4. biological stressors (including GMOs) can reproduce and multiply, and potentially evolve, in stark contrast to chemical stressors; and
 5. human health risk assessments commonly assume that there are no external feedback loops from the damage to undamaged portion of the target population. Ecological risk assessment, however, must consider such interactions, especially where species are important determinants of community structure and function.
25. A number of workers noticed deficiencies in the framework originally developed by the USEPA (Simberloff and Alexander, 1994). Lipton *et al* (1996) suggested three additional stages to the original NAS model to accommodate some of these problems (**Table 1** see the end of this section). The USEPA, however, has since modified its original framework to accommodate each of these problems (United States Environmental Protection Agency, 1998).
26. The USEPA framework, however, is not necessarily the ideal model for GMO risk assessment. For example the framework ignores the quantitative approach to biological risk assessment developed by the Office International des Epizooties (Office International des Epizooties, 1996; Morley, 1993), and the rigorous hazard identification procedures developed with the Quantitative Risk Assessment paradigm (Hope *et al*, 1982). Other models specifically developed for GMOs are listed in **Table 2** (see the end of this section).
27. Clearly, a thorough risk assessment is a very involved process. We are early in the development of this science as it applies to GMOs. Even for small-scale releases, there is a feeling amongst proponents that they are being asked to address endless questions to no purpose, and a counter-view amongst regulators that they may be missing something. This is in part because of the newness of the technology, but there is also a need for systems thinking that will identify the range of risks that are pertinent to a particular GMO. In particular, CSIRO should aim to

refine and develop risk assessment frameworks for GMOs in Australia that streamline the assessment process and highlight the information that is essential, desirable, and unnecessary if the process is to achieve a satisfactory outcome.

(iii) Risk management

28. In the field of risk analysis, risk management is what is done to minimize harm when a hazard is realised, and is commonly practised where hazardous events are difficult to predict. For earthquakes, it involves placing greater emphasis on building earthquake-resistant buildings, and de-emphasizing prediction (Matthews 1997). Risk management reduces risk by:
1. reducing the potential impact of the hazard (e.g. earthquake proofing a building);
 2. reducing the probability of the hazard occurring (e.g. installation of dual controls in a driving-school car); or
 3. reducing exposure (e.g. through the use of containment facilities in laboratories where radioactive materials are handled).
29. All of these strategies can be applied to GMOs. For example, the potential for off-target impact by insect-resistant cotton has been reduced by inserting a gene for a toxin (Bt toxins) that affects insects rather than animals generally. (Better still would be a toxin against only the target insect, heliothis). Similarly, the probability of unforeseen effects is reduced by ensuring that only the desired gene is inserted, with minimal other material. Lastly, potential exposure is reduced by staged releases that allow any unforeseen effects to be seen before the organism is released more widely.

Risks and benefits

30. Weighing up the risks and benefits of an action is the domain of decision theory. Smith *et al.* (1999) adapted a decision theoretic analysis of the value of earthquake prediction to explore the basis for heeding predictions about damage resulting from introduced organisms. They showed that the decision on whether to heed a recommendation to exclude a new crop plant depended on:
1. the damage that would be caused if a useful plant was excluded;
 2. the damage that would be caused if a weed was allowed in;
 3. the background probability (also called base-rate or prevalence) that a plant would be come a weed; and
 4. the accuracy of the system that predicts whether the plant will be a weed.
31. This simple but powerful analysis deserves further exploration. It may turn out to be too simplistic, but it certainly suggests aspects of the risk/benefit research

agenda for CSIRO. We should be carrying out economic evaluations of the costs of different types of pests and weeds and the benefits of differing types of agricultural animals and plants, meta-analyses of the rate at which different kinds of organisms become pests or weeds, and aiming to increase the accuracy of our predictions of harm (see Risk Assessment). Note that the estimate of harm could also embody social perceptions of the degree of harm – what risk analysts call “dread” – and policy initiatives such as the Precautionary Principle (see below).

Methods of control

32. Not only do we need systems for detecting adverse impacts on human health and the environment, risk management implies that we mitigate their impacts should they occur. CSIRO needs to apply its thinking on pest and weed ecology and management to the control of GMOs in the event that they have negative consequences. This would involve recommending best-bet management packages as part of the implementation plan for a new GMO.

(iv) Risk Communication

Background

33. The old model for risk communication involved experts speaking from on high to a credulous and accepting audience. This situation no longer pertains. Experts are now more likely to be listened to very critically, or even distrusted, and we increasingly find that a model involving dialogue with regulators, stakeholders, and the public is likely to be more fruitful. For GMOs, much of our risk communication centres on an interchange with regulatory authorities to arrive at a decision on whether to release the organism.

Precautionary principle

34. In 1992, governments (Federal, States and Local Governments) in Australia agreed to follow the precautionary principle (PP) as part of a commitment to ecologically sustainable development. There are many formulations of the principle, but that adopted by these governments was:

Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. In the application of the precautionary principle, public and private decisions should be guided by: (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and (ii) an assessment of risk-weighted consequences of various options.

35. Other governments around the world have adopted the PP to a greater or lesser degree, and it is certainly a watchword for environmental groups who are stern critics of GMOs. In practise, a layered or tiered risk assessment that maintains conservative assumptions until such time as additional data allows a higher level

of assessment embodies the precautionary principle (Fairbrother and Bennet, 1999; Hayes, in press).

Good and bad risk communication

36. Failures in risk communication can be costly. The financial cost of the BSE crisis in the U.K. is estimated at around \$5 billion, a cost that could have been reduced with more effective risk management and communication procedures (Powell 1999). Good risk communication is probably just as important as risk assessment and risk management, and it is down to us scientists to take primary responsibility for it if our work is to be accepted by society. The message from the worlds of food safety and the chemical industry is that we must (i) establish credible, open and responsive regulatory systems, (ii) communicate effectively about the nature of risk, (iii) make demonstrable efforts to reduce levels of uncertainty and risk, and (iv) never make statements implying that very low probabilities mean no risk at all. We should be aware that there is always more to a risk issue than just the science. "Educating the public" about the mysteries of scientific research is no substitute for sound risk communication practise (Powell 1999). Given that risk perception changes with culture, gender, and degree of education, it will be essential for us to research how the risks of our actions are perceived by different sections of society, the better to formulate our risk communication practises.

"SNAGs": sensitive new age GMOs

37. The market for GMOs is shifting globally towards output traits rather than input. CSIRO's own research has shown that some kinds of GMOs are more appealing than others. For example, the prospect of vegetables with animal genes is acceptable to 9% of respondents (KB), while that of leaner meat with genes from another animal is 19%. Novel foods are highly acceptable to only 9% of the populace, but GM foods with health benefits are highly acceptable to 33%, and with medicinal or pharmaceutical benefits, the figure rises to 55% or more.

(v) Monitoring

38. GMAC's involvement in risk assessment continues only up to the point of general release. Unless another authority, such as the NRA, requires it, no post-release impact studies are needed (e.g. with herbicide resistant crops). Thus, in absence of a research agenda, assumptions about biosafety and the environment remain untested or unvalidated.
39. The focus on biosafety of GMOs ignores issues associated with large scale, landscape impacts e.g. impact on integrated crop management practices; risks associated with rotations of crops with different GMOs; movement of new toxins through soil and water; movement of micro-organisms between livestock under grazing conditions. Indeed, SCARM noted '*...the deployment of genetically modified organisms (GMOs) in agricultural systems raises broader issues and risks relating to the sustainability of the technology and of agricultural systems than the safety issues considered by GMAC.*' (SCARM Guidelines for Good Agricultural Practice for the Use of Genetically Modified Plants', March 1999).

The wider implications of the deployment of GMOs will require a broad scale national monitoring program, in the design and execution of which CSIRO should be involved.

Synthesis

40. What risk analysis initiatives should CSIRO should have in place in 5 years' time, to ensure that the use of biotechnology in Australia is sustainable in the longer term? It is critical that CSIRO, as the national research agency, address national research needs, particularly those of the regulatory authorities. The national biotechnology strategy under development by Biotechnology Australia is attempting to map out the landscape into the future and shows good parallels with the ideas canvassed here. In particular, the draft national strategy advocates the funding of a program of risk-based research including research on risk assessment, risk management, environmental monitoring and risk-benefit analysis.
41. The following paragraphs outline the various case studies that CSIRO intends to carry out as part of its program.

CASE STUDIES

(a) Ecological Impacts of Current or Imminent Plant Improvements

Outline of proposed activity

42. The project examines the non-target impacts of genetically modified plants to take into account landscape scale interactions that will occur after commercial release. Regulatory requirements for GMOs require ecological studies only on a small (field) scale and cannot fully test underlying assumptions about broader impacts on the pest and beneficial complexes in the ecosystem. This project tests for both positive and negative consequences of widespread GMO adoption. It focuses on those processes that could disrupt ecosystem structure (distribution and abundance of non-target species, particularly beneficial species) and ecosystem function (e.g. nutrient cycling/decomposition) in three key systems: Bt cotton, herbicide tolerant canola (derived using mutagenesis) and in GM pasture legumes. All three plant types are released commercially or expected to be within 3 years.

Ecosystem Structure

43. *Impact of Bt cotton on beneficial arthropods (pollinators, predators, parasitoids) or other non-target pest species.* This work will provide rigorous data on the impacts of current technology and establish clear protocols for future impact assessments of new gene constructs. Laboratory experiments will measure the indirect effects of Bt cotton on fitness of key predators and parasitoids. Landscape scale field studies will document the abundance and diversity of the beneficial fauna in commercial fields, farms and surrounding crop and non-crop habitat. The data will feed into systems modelling that will explore the long term potential consequences of the GM crop. This work will extend the work undertaken for GMAC that was more limited in time, in geographic scope (to single fields) and in the level of impact on non-target species.

44. *Impact of GM clover pasture legumes on their rhizobial symbionts and herbivorous pasture insect pests (Redlegged earth mite).* Legumes are a key component of pastures and nitrogen to the soil for cropping rotations. Changes in the protein composition of subclovers, designed to improve wool production, and insertion of herbicide tolerance (subclover) and virus resistance (white clover) have the potential to alter the rate of spread, competitiveness and invasiveness of GM legumes in both farming and native plant communities in southern Australia. The core activity in this work will examine the impact of the new, high sulphur legumes on rhizobial symbiotic associations, the composition of pastures, and on the abundance and feeding damage caused by pest species that limit the distribution and abundance of the legumes. Specific questions regarding virus-plant interactions in white clover will be achieved with industry support.

Ecosystem Function

45. *Impacts of GM cotton / canola on key soil processes.* Changes in plant quality and input of new gene products in agricultural soils may have consequences on essential processes such as nutrient cycling. This work will determine the ecological impacts of Bt cotton and herbicide tolerant canola on key soil processes, including evaluation of the persistence of GMO and/or gene products in the soil environment. The structure and specific outline for experimental work will be based on highest risk categories and the case study will be carried out according to standard risk assessment framework. Landscape level effects will be assessed using models developed and refined in parallel.

(b) Contrasting case studies of GMOs of long term interest

Outline of proposed activity

46. Five CSIRO Divisions will collaborate in studies of potential ecological impacts and social and regulatory risks and benefits of diverse GMOs. The organisms, listed below, are ones for which diverse genetic technologies are being developed for benefit to Australian primary industries and the environment. These contrasting studies will provide a spectrum of issues and a broad foundation for developing a robust framework for pro-actively identifying and assessing landscape scale risks and benefits of new genetic technologies.
47. The case studies were chosen specifically to maximise the breadth of the robust risk assessment framework. The four case studies were selected to be as diverse as possible among current research projects in order that the proposed risk assessment framework will embrace as far as possible all ecological risks inherent in future applications of gene technology to all types of organisms. Thereby, the four component studies will identify and assess many ecological risks from different applications of gene technology to a wide range of organisms with different ecological roles in different environments. The organisms were selected primarily on the basis of their potential to contribute to the risk assessment framework. In addition, the studies of risks of individual GM organisms are relevant to sustaining biodiversity as follows:

Eucalypts:

48. Protecting the genetic integrity of natural populations of eucalypts is essential for sustaining the functions, services and the biodiversity of eucalypt ecosystems, the dominant tree association of the Australian landscape. Australian populations of eucalypts are the original source of eucalypt plantations that supply the world's main hardwood product. Expansion of Australian plantations is to be based on eucalypts. To use these natural assets sustainably, it is essential that the genetic resources of the native species are maintained free of genes from exotic eucalypts or other species. Pure native populations are the base line for plantations worldwide, and are essential for maintenance of our biodiversity. The core research addresses the ecological implications or risks of applying gene technology to eucalypts.

Rumen biota:

49. On two occasions GMAC has indicated concern about lack of information on environmental risks of specific GM rumen microorganisms, and release approval was withheld. The proposed research has implications for potential changes to the grazing behaviour of ruminants including feral populations and their impact on floral biodiversity. A report from the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) shows regulatory and public concern on resistance to antibiotics. Feeding agricultural by products to stock could become uneconomic if GM crops were to be restricted for this purpose. Such crops are available now, but the implication for transfer of transgenes to gut micro-organisms is little known.

Oysters:

50. The project will assist regulators of gene technology and fauna with decisions on introduction or release of GM exotic species for commercial purposes. It will provide an assessment of whether the current concepts for sterile-feral technology potentially provide an option for genetic containment of exotic populations and protection of the environment from further feral species. The risk assessment study also is pertinent to prospects for further opportunity for industry.

Mouse cytomegalovirus:

51. The potential for a comprehensive assessment of risks of IC MCMV to contribute to the development of a robust risk assessment framework was demonstrated recently. Progressive development of virus vectored immunocontraception, including IC MCMV, caused GMAC to revise its categories of risk and specify genetic manipulation that may induce auto-immune responses. IC MCMV has the potential to sustain biodiversity by diminishing harmful non-target impact of some current mouse management strategies on flora and fauna on-farm and fauna off-farm. Conversely, the prospective technology has the potential to disrupt the application of existing mouse management strategies. More importantly, IC MCMV represents a technology that is keenly sought, but seen to be potentially

risky to other mammals (WHO Informal Consultation on “Reproductive Control of Carnivores”). IC MCMV, being the most advanced of current immunocontraception projects, is pioneering the application of virus vectored immunocontraception to the control of many species of feral mammal pests that affect biodiversity in Australia and worldwide, such as rabbits and foxes.

Tables

Table 1. The ecological risk assessment framework of Lipton *et al.* 1996, which builds on the NAS (1983) framework. Components additional to the original NAS (1983) framework are asterisked.

1. **Receptor identification:* here we characterize the biotic components and organization of the system, and the components most vulnerable to disturbance of the system. This could involve drawing up a flow chart of the whole system under study, including higher trophic levels potentially affected.
2. *Hazard identification:* here one identifies hazards for the species listed in the receptor identification stage, and the system level (individual, population, or community) at which those hazards will be expressed.
3. **Endpoint selection:* here one chooses species and system levels that will be sensitive to the hazard, and relevant to ecological concerns. These will become the indicators that will be monitored. For a very rare threatened plant, one may decide to monitor all individuals to quantify any undesirable effect. For one that is less endangered, population level monitoring may be acceptable, while damage to individuals may be compensated by the rest of the population.
4. **Relationship assessment:* using a knowledge of the ecology of the system, the presence of feedback loops to identify secondary and tertiary risks is evaluated. If new receptors are identified, that may be affected by the GMO, it is necessary to repeat stages 2 and 3. Thus, stages 2-4 are an iterative process to identify the potential risks.
5. *Exposure assessment:* here we attempt to predict where the GMO will go, perhaps using climate modelling, and the extent to which it will overlap in space and time with the receptors.
6. *Response assessment:* the dose-response curve approach of the original NAS framework implies a level of data collection that is generally unavailable for the impact of one organism on another. Rather, in GMO risk assessment one would perhaps explore the consequences of a low, medium or high density of the organism.
7. *Risk characterization / uncertainty analysis:* This last stage combines all the information above to evaluate and encapsulate the degree of risk posed to ecological end points. The stage is modified from the last stage of the NAS framework in that it also includes an analysis to identify uncertainties in each stage of the analysis, quantitatively if possible.

Table 2. List of some GMO risk assessment models. See Hayes (1997) for a brief comparison of each.

Model	Reference
NRC Risk assessment model for genetically modified plants and micro-organisms	NRC 1989
Cornell/ICET Risk assessment schema for release of biotechnology products	Strauss 1991
Population dynamics model for assessing the risks of invasion for genetically engineered plants	Parker and Kareiva 1996
GENHAZ –a system for critically evaluating genetically modified organism hazards	RCEP 1991

Abbreviations

ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine Inspection Service
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
GRDC	Grains Research and Development Corporation
IOGTR	Interim Office of the Gene Technology Regulator
KRA	Key Research Area
LWRRDC	Land and Water Resources Research and Development Corporation
NAP	National Awareness Program (CSIRO)
NME	New Molecular Entity
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
RIRDC	Rural Industries Research and Development Corporation
SCARM	Standing Committee on Agriculture and Resource Management

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Section B (j)

B (j) the main areas of public interest in genetic modification, genetically modified organisms, and products, including those related to:

- (i) human health (including biomedical, food safety, and consumer choice)
- (ii) environmental matters (including biodiversity, biosecurity issues, and the health of ecosystems)
- (iii) economic matters (including research and innovation, business development, primary production, and exports)
- (iv) cultural and ethical concerns

Section B (j) Summary

The matters discussed in section B(b) of this witness brief are also relevant to subsection (ii) of this section in that the studies to be carried out by CSIRO under its new research program relate to the impacts of GMOs on biodiversity and the health of ecosystems. Section B(b) has included a section on the public interest in this area. (See **section B(b)** of this witness brief.)

B (j)(ii)

See **section B(b)** of this witness brief.