



COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

STANDING COMMITTEE ON COMMUNITY AFFAIRS

Reference: Gene Technology Amendment Bill 2007

MONDAY, 23 APRIL 2007

CANBERRA

BY AUTHORITY OF THE SENATE

INTERNET

The Proof and Official Hansard transcripts of Senate committee hearings, some House of Representatives committee hearings and some joint committee hearings are available on the Internet. Some House of Representatives committees and some joint committees make available only Official Hansard transcripts.

The Internet address is: **<http://www.aph.gov.au/hansard>**

To search the parliamentary database, go to:
<http://parlinfoweb.aph.gov.au>

**SENATE STANDING COMMITTEE ON
COMMUNITY AFFAIRS
Monday, 23 April 2007**

Members: Senator Humphries (*Chair*), Senator Moore (*Deputy Chair*), Senators Adams, Allison, Carol Brown, Fierravanti-Wells, Patterson and Polley

Participating members: Senators Barnett, Bartlett, Bernardi, Mark Bishop, Boswell, Bob Brown, George Campbell, Carr, Chapman, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Ferris, Fielding, Forshaw, Heffernan, Hogg, Hurley, Hutchins, Joyce, Kemp, Kirk, Lightfoot, Ludwig, Lundy, Marshall, McEwen, McGauran, McLucas, Milne, Nash, Nettle, O'Brien, Parry, Payne, Robert Ray, Siewert, Stephens, Stott Despoja, Watson, Webber, Wong and Wortley

Senators in attendance: Senators Adams, Humphries, Moore and Siewert

Terms of reference for the inquiry:

To inquire into and report on: Gene Technology Amendment Bill 2007

WITNESSES

**ADDISON, Ms Linda, First Assistant Secretary, Regulatory Policy and Governance
Division, Department of Health and Ageing..... 38**

**BETZNER, Dr Andreas, Manager, Gene Discovery, Varieties LOB, Grains Research
and Development Corporation 11**

**HARVEY, Mr John, Executive Manager, Varieties, Grains Research and
Development Corporation..... 11**

**KHOO, Mr Kay, Regulatory, Public and Government Affairs Manager, Bayer
CropScience Australia 27**

**MEEK, Dr Sue, Gene Technology Regulator, Office of the Gene Technology
Regulator 38**

MURNANE, Ms Mary, Deputy Secretary, Department of Health and Ageing 38

**PENNA, Mr David John, Regulatory Affairs Lead—Australia/New Zealand,
Monsanto Australia Ltd 27**

PHELPS, Mr Robert Errol, Executive Director, Gene Ethics..... 16

**SALES, Ms Louise, Community Organiser, Genetic Engineering, Greenpeace
Australia Pacific..... 1**

TAGER, Mr Jeremy, Campaigner, Genetic Engineering, Greenpeace International 1

Committee met at 1.33 pm**SALES, Ms Louise, Community Organiser, Genetic Engineering, Greenpeace Australia Pacific****TAGER, Mr Jeremy, Campaigner, Genetic Engineering, Greenpeace International***Evidence was taken via teleconference—*

CHAIR (Senator Humphries)—The committee is taking evidence in its inquiry into the Gene Technology Amendment Bill 2007. I welcome Ms Louise Sales and Mr Jeremy Tager from Greenpeace.

Mr Tager—I am currently a campaigner with Greenpeace International on global rice but was previously with Greenpeace Australia Pacific working on issues of canola and the gene tech actors.

CHAIR—I think information has been provided to both of you on parliamentary privilege and the protection of witnesses. We also have a submission from Greenpeace on the bill. We would like to ask you some questions about that, but I invite you first of all to make an opening statement. If you could keep it to no more than 10 minutes, that would help us very much. Please go ahead.

Ms Sales—I am going to talk to the submission that we put in so it might be helpful if people have that in front of them. On looking at the bill, there were a few major concerns that we had. Most of these concerns were around part 5A of the amendment, which basically gives the minister unilateral powers to approve the release of GMOs. We also had concerns about the curtailing of certain public consultation. There was another part of the act that removed the requirement for public consultation in dealings that may pose significant risks to the health and safety of people or the environment and also removed the requirement to consult the states and other parties regarding the field testing of genetically engineered crops. We are also concerned about the proposed merger of the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee because we thought that would further limit the ability for public consultation on the act.

I will start with our particular concerns with part 5A. One major concern we have with this is that we think part 5A actually falls out with the object of the Gene Technology Act. The object of the act is defined as:

... 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.

However, part 5A of the bill as it currently stands is not intended to protect against risks posed by or as a result of gene technology but rather to bypass the regulatory process and to approve GMOs in cases where the minister is satisfied that there is an imminent threat. We also have some concerns about the defining of imminent threat. Basically, part 5A gives a broad discretion to the minister and almost no criteria that must be followed. For example, a threat can include pests and diseases even if the threat is constant and chronic. There is no requirement that the threat be of a particular severity or scope and nor is the term 'threat' explicitly defined. It is basically left open to ministerial discretion without the need to prove

that a threat actually exists—it is simply that the minister is satisfied that a threat is imminent. In making a decision under part 5A of the act the minister is merely required to take advice from one of his advisers and to consult with the states but not explicitly to get consensus on whether it is a threat.

I noticed in the actual review of the act itself there was concern raised about the lack of ability for the minister to fast-track vaccines—for example, for bird flu, cholera and things like that. We believe that part 5A as it currently stands has a much wider scope than that which is needed to deal with the emergency fast-tracking of vaccines and the like. If that is the intention then it should be explicitly stated in the act. One possible mechanism we discussed is that perhaps the TGA should make a request to the OGTR when such vaccines do need to be fast-tracked to speed up the process. We believe that, whenever any genetically-engineered product is released into the environment, there needs to be a full safety assessment and that that should never be compromised. So we think that, basically, the OGTR should only ever fast-track something if the risk of not doing anything far outweighs the risk of actually releasing a GMO. We think it falls out with the scope of the act as it currently stands so it needs to be either scraped completely or severely curtailed to reflect the original intent, if the providing of vaccines was the original intent.

Our other major concern with the amendment is the complete omission from the act of section 49, which deals with things that may pose significant risks to the health and safety of people or the environment. This omission basically removes the requirement for public consultation when a proposed dealing may pose significant risks to health and safety of people or the environment. This would basically remove the need for the federal government to consult with not only the state government but also local councils and members of the public whenever there is a controlled release into the environment, which we think is against the public interest.

Another attack on what we believe to be the check and balance system of the original act is the merger of the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee to create the Ethics and Community Committee. We basically think that this eliminates a 12-person committee intended to advise the ministerial council, further reducing the potential for public consultation regarding the government's policy on GMOs. Amongst people we spoke to there seemed to be consensus that these committees are rather ineffectual, but we think there is a need for a reform of the committees to give them more teeth rather than to scrap them altogether. They should provide an important function.

Another flaw in the amendments is section 35A, which says that a person must not breach conditions of an emergency dealing determination. With the current broad scope of section 5A, we are concerned about the ramifications if an emergency dealing is made as a result of pest attack and what this could mean for individual farmers who fail to carry out federal government recommendations. We are concerned that section 5A in particular will be used by the federal government to override the state moratoria on gene—

CHAIR—Do you mean part 5A?

Ms Sales—Part 5A, I am sorry. Do you have anything to add to that, Jeremy?

Mr Tager—No, not at this point. I think that really covers in a general way the concerns we have.

CHAIR—Thank you for that opening statement. That covered the issues that have been raised I think pretty comprehensively. I will start off with a couple of questions. You certainly, I think validly, draw attention to the width of powers that are available under part 5A to a minister to make a number of decisions that cut across the existing arrangements in the legislation that deal with consultation, due process, appeal rights and so forth.

I put it to you, however, that the arrangements here with emergency determinations would reflect the kinds of powers that would accrue to a minister or some other authority in the event of equivalent emergencies in other areas of community life. For example, powers would certainly be available to certain appointed officers where there are civil emergencies or climatic catastrophes such as the cyclone in Innisfail last year. For example, there would be the power to take and use property that belonged to somebody else or the power to close down certain activities or functions that might impede emergency operations. There would be limited appeal rights in those circumstances against the designated authority to take those steps.

Can you indicate to the committee why you feel that the emergency powers here, which would replicate, broadly speaking, the sorts of emergency powers available in other equivalent circumstances, are not appropriate for some kind of emergency dealing with an issue relating to gene technology?

Mr Tager—I will try and reply to that first. The first thing to note is that the emergency provisions that are being provided here are not within the ambit of the expertise of the regulator. In fact, the kind of emergency that is suggested here is a medical emergency. This is what is contained in the review of the Gene Technology Act and, in private or public discussions regarding the act, it has been suggested that the reason that we need this particular provision relates to emergencies such as bird flu. In the event of a medical emergency, this is well outside the ambit of the Gene Technology Regulator, whose expertise would be in assessing the risks of releasing a GMO without proper assessment. But that should be contingent on a request coming from the medical community that there is a risk of that nature that is imminent and is something that may be able to be dealt with through a genetically engineered organism.

The way the provisions are currently worded, firstly, does not require an emergency and, secondly, gives the minister scope to act in an area where there isn't expertise within the ambit of the act, so the act is not about determining medical emergencies. Why we argue that this is outside the ambit of the act is that it relates to circumstances and risks associated with non-genetically engineered emergencies. So, for instance, if you have bird flu as the emergency that is the subject of that particular notification, that is not the way the act sees the regulator acting. I can see, for instance, that where there is contamination occurring as a result of genetic engineering in fields and there is a health risk associated with that, the emergency provisions relating to that would be entirely appropriate where they could recall and make all sorts of emergency provisions relating to the risks associated with GE. Here we are not talking about the risks associated with GE; we are talking about the risks associated with a

medical emergency that does not have anything to do directly with genetically engineered organisms.

CHAIR—I suppose the question is whether a response to a medical emergency involving some areas of control or power exercised under the Gene Technology Act would be appropriate in such an emergency. Obviously, when we get to the department and the Gene Technology Regulator later today, we will be able to ask what kinds of emergencies might be envisaged in that situation, and I am not clear what kinds of powers could be exercised in that scenario. Isn't it possible, say, that with an outbreak of bird flu, some determination, which is within the purview of this act, might be an appropriate response? If that were the case, it need not matter that the regulator's expertise is not in the area of medical issues. The minister is the one that has the power to make the determination and he or she would take advice, presumably from medical authorities, about an appropriate response. So wouldn't that scenario give rise to an appropriate power of the kind that is outlined in the bill?

Ms Sales—We think that, as the bill is currently drafted, far too broad and sweeping powers are given to the minister. What is then implied in the review of the act is that the problems are just confined to one emergency such as bird flu, but this is not explicitly defined in the act; in fact, it is quite a broad scope and it talks about risks from pests and disease. The minister only has to be satisfied that there is an imminent threat, so there does not even have to be an emergency as such. So we think the powers given to the minister are far beyond the scope of what is necessary to fast-track, for example, a vaccine.

CHAIR—Let us assume that there is an emergency of some kind. You take issue, for example, with proposed section 35A. You say that there should not be a power for a determination to be made that requires a person to take an action specified in the determination or omit to take an action specified in the determination. Again, wouldn't that be the equivalent of emergency provisions available to, say, an administrator appointed in an Innisfail type of situation, where he instructs public transport authorities to bring in public transport to take survivors out or instructs people to open the doors of public buildings to allow people to come in to shelter, or something of that sort? What is the difference between the kind of power in that situation and the kind of power which the minister is to accrue under this legislation?

Mr Tager—I think there are two big differences. The first is that the provisions themselves do not require an emergency. They simply require a finding of an imminent threat with virtually no criteria that would necessarily support that.

CHAIR—Okay.

Mr Tager—So there is both the lack of criteria and the ministerial discretion in terms of being satisfied that an imminent threat exists. If you look at the threats that are provided in section 5 provisions, those are not emergencies necessarily—for instance, threats of pests and diseases. Blackleg is a common problem in canola fields. Is there anything in the current provisions that would prevent that from being an imminent threat that would justify the release of a GMO, overriding both individual objections to that at a farmer level and state moratoria, at the same time?

The other thing is that when you look at emergency provisions that relate to things such as hurricanes you are looking at provisions that relate to dealing with circumstances in ways that are well accepted and understood. The release of a GMO into the environment is not necessarily one of those. And the notion of trying to deal with an emergency with a GMO that has not been tested has the potential to be an even worse cure. I think there is ample evidence and ample concern, even in the Gene Technology Act, that one of the reasons for having a regulatory regime is that the risks associated with GMOs are not well understood and need to be fully assessed.

If I can throw in a personal note here, I remember that my father was working for the National Institute of Health in the 1950s when they rushed through a polio vaccine with the notion that this was an emergency that needed dealing with. They ended up killing more people than they saved with that particular vaccine. I think it is a highly risky activity to put that in the hands of a regulator, particularly a regulator that is, in our view, so politicised, and has tended to be very in favour of genetically engineered organisms, as has the current government.

CHAIR—Can I interrupt there for a minute, Mr Tager, to clarify something?

Mr Tager—Sure.

CHAIR—The power that has been granted here is not to the regulator, is it? It is to the minister.

Mr Tager—No, that is true. I suggest that the advice relating to whether to declare an imminent threat would probably come from the regulator, but you are right; I stand corrected on that.

CHAIR—The criteria for there to be a triggering of this emergency event obviously needs to be clear in the legislation, but you said that you took issue with the idea of pests or diseases being an appropriate trigger. Wouldn't bird flu fall under that category of a disease? Why wouldn't that be the kind of event that might appropriately trigger an emergency response?

Mr Tager—Certainly bird flu would, as perhaps would Ebola virus. The question isn't whether there are legitimate emergencies that would need responding to with some kind of emergency provisions. Leaving aside what those are, I think the question is that the current wording is that the nature of the threats that are described are so broad that they could include the kinds of pests and diseases that you currently see in agricultural cropping systems all over the country.

Ms Sales—There is also a big difference between GMOs and vaccines—for example, vaccines that are developed in the lab, and genetically engineered crops that are released into the environment. We do not think the distinction is drawn between these two different sorts of GMOs in the act. If the intention is solely to confine part 5A to GMO vaccines that are developed in the lab, then that should be explicitly defined in the legislation.

CHAIR—You have raised, legitimately, the question of how such powers might be abused. Certainly they are broad and sweeping powers, and in the wrong hands they could certainly be abused—there is no question. You would accept that there would have to be emergency powers of some sort, would you not, to deal with a crisis such as bird flu?

Mr Tager—I think our view would be that that should be limited to medical emergencies. I think that, if you are talking about agricultural emergencies, that is clearly not justified by the current state of knowledge. I think that, as Louise pointed out, having a GMO vaccine developed in a laboratory that is used in a limited way—in other words, it is not a broad environmental release but used for specific treatment without, for instance, being planted in the ground—is very different from saying to a particular state or a particular group of farmers that they need to plant a disease-resistant GMO variety to respond to an existing problem with a variety of pests and diseases. I think a medical emergency is one that you could legitimately include in there, but that should be in conjunction with the powers that rest with the TGA and it should be specified in the legislation that it is intended for dealing with medical emergencies, not general agricultural problems.

Ms Sales—And we do not think there should ever be justification for releasing a GMO of any sort without a full safety assessment.

CHAIR—Well, let's take a non-medical emergency situation. I am not sure if the calicivirus that was used to control rabbits would count as a matter that was governed by the gene technology legislation, but let's assume for the moment that it was. We had a situation a few years ago where, because the virus had escaped from a site in South Australia where it was being tested and had started to spread, it was decided that on an emergency basis it should be released generally across the country in order to maximise its effectiveness. That would be an example of a non-medical emergency where you might argue that an appropriate authority, say a minister, should have the power to control, in this case, a pest—namely, rabbits—to deal with that particular problem. Would you accept that that is an example of a situation where you might need appropriate emergency powers like that?

Ms Sales—You talked about the calicivirus, but equally you could have referred to cane toads as an example of biological control gone wrong. I think that emphasises the importance of doing a full safety assessment when any living organisms are released into the environment. I think there is seldom justification for releasing any living organisms into the environment without a full safety assessment.

Mr Tager—A few years ago, CSIRO was actually involved in research into a genetically engineered virus for dealing with mouse plagues, which at the time were certainly seen as emergencies. But, as a result of, I think, intervention by a virologist at ANU, it was pointed out that the release of a genetically engineered virus into the environment had the potential to be far more dangerous than any mouse plague. I think the notion of an emergency such as you have outlined has to be tempered by recognition of how real the threats are from GMOs and from genetic modifications that have never before been seen in nature. The risk of something like the cane toads occurring but being invisible and untouchable in that sense is one that certainly Greenpeace believe is very real. We see so many emergencies that are real emergencies in terms of the lives that are affected by them on a day-to-day basis but that, at a national level, in terms of the kind of policy that should underpin the release of GMOs, certainly does not justify their release.

CHAIR—Thank you. Senator Moore?

Senator MOORE—I want to ask about the consultation process. Have you seen the explanatory memorandum that the department has put out with this bill?

Ms Sales—No, I do not believe we have.

Senator MOORE—It is a relatively short one, but it begins by saying that the vast majority of people support the legislation and talks about the extensive consultation. In terms of the issues you raised in your submission and in your evidence, I am interested in what feedback you got if and when you raised these issues with the department during that consultation.

Mr Tager—I was actually involved in some of the consultations on the Gene Technology Act initially, with the review process—not the subsequent consultations and the explanatory memorandum. That issue, this question of emergency provisions, was certainly never raised with Greenpeace. I am aware that Gene Ethics did note that, during the consultation that took place in relation to part 5, those who were making the presentation indicated that this was only about things such as bird flu vaccine. As a result of that, Gene Ethics indicated to us initially that they were not that concerned with the provisions. I have to say that I did start reading the explanatory memorandum but I found that it so poorly reflected the actual provisions in the act in terms of their scope that it was not a very valuable document.

Senator MOORE—Was there any particular gap in it that you would like to put on record?

Mr Tager—Absolutely. The indication in the explanatory memorandum is that these emergency provisions relate solely to medical emergencies such as bird flu.

Senator MOORE—Yes, it does say that.

Mr Tager—As we have said, from the current reading of the act, you could not possibly see that as being limited to that kind of emergency.

Senator MOORE—Did I hear you correctly when you said that was the impression in the review consultations and that statement was made?

Mr Tager—Yes. The explanatory memorandum downplayed the significance of all of the provisions by simply saying that these were administrative changes that were made as a result of the review. There is little doubt that the potential scope of part 5 is neither administrative nor minor; it is actually really large and it potentially puts this act in a completely different area in terms of its capacity to release GMOs into the environment contrary to either state or individual wishes.

Senator SIEWERT—In relation to part 5A, let us say that we are in a drought, like the one we are in at the moment, and various elements of industry put forward a proposal which says, ‘Okay, we need to release some genetically modified plants into the environment to start dealing with the drought.’ My understanding of your interpretation of the amendment is that it would enable that to happen. A situation such as a drought could be deemed an emergency and drought tolerant GMOs could then be released. Is that a correct understanding of your interpretation of part 5A?

Mr Tager—It is not actually an emergency that is needed, though. It is simply advice that is taken by the minister, who needs to be satisfied as to its correctness, that there is an

imminent threat of a kind mentioned. This is referred to in subparagraph (3). That is not a limiting clause because it includes the possibility of drought. Yes, they could say that there is an imminent threat related to drought and agricultural production in a particular area, potentially even on a particular farm as far as we can tell from the provisions, and it would allow the minister, if the minister were satisfied that this was an imminent threat, to require the planting of that GMO.

Senator SIEWERT—So, in the future, if a minister—and I am not reflecting on any current ministers—decided that they were frustrated because of the extensive testing and consultation periods et cetera required under the current act, they could use the proposed provision to override them to start getting GMOs into the agricultural system? Is that what you are afraid of?

Mr Tager—Absolutely.

Senator SIEWERT—I notice that you do not specifically make recommendations in your submission; you mainly talk about your concerns. Would you suggest that, if this part is about emergency medical situations in particular, the definition of an emergency would need to be much more specifically defined to say that it is actually about medical emergencies?

Ms Sales—That is right. Each emergency needs to be specifically defined or that whole part should be struck out, because we think it is beyond the objects of the act as it stands.

Senator SIEWERT—I have two other questions. One relates to section 35A, which talks about strict liability. What you are concerned about there is that, if an emergency were declared and these organisms were released, people would be required to plant them.

Ms Sales—Yes. Certainly under the provisions of the act as it currently stands, it could be interpreted to mean that.

Senator SIEWERT—If I understand your submission and the Gene Ethics submission, you do not believe that this is accurately reflecting the outcomes of the review of the act. What we are being told is that this is actually implementing some of the reviews of the act and that—

Mr Tager—The way it reads is that the Office of the Gene Technology Regulator noted that they did not have emergency provisions. They use the example of, I believe, bird flu. I think that the notion of emergencies is absolutely correct but that these provisions have it the wrong way around. It should be dealing with emergencies associated with release of GMOs that are not approved and are potentially or actually dangerous—in other words, an imminent threat themselves. This is asking the minister, via either the regulator or another adviser, to declare that a non-GMO threat exists, and this is where we think it is beyond the ambit of the act and that the Office of the Gene Technology Regulator or other advisers to the minister simply bypass the assessment provisions. It seems well beyond what was in the review document and what the regulator pointed out in her submission.

Senator SIEWERT—Thank you.

Ms Sales—The regulator in her submission pointed out that she was unable to fast-track an approval in an emergency. She specifically spoke about genetically modified cholera vaccine for release into the environment in conjunction with the relevant approval from the TGA. Obviously part 5A goes well beyond that limited scope. We do not think it adequately reflects the findings of the review.

Senator ADAMS—I have a question on your concern about the proposed merger of the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee. Would you like to elaborate on that for me?

Ms Sales—Basically, one of the recommendations that we are concerned about relates to where we think there is already limited scope for public participation in the act and in the regulation of GMOs generally. That just removes another opportunity for the public to feed into the process. There have been concerns raised about the effectiveness of these committees and we think that is an issue that needs to be looked at. Certainly the process as it stands needs to be reviewed. We think that the ineffectiveness of the committees is not an argument for scrapping them altogether. We think they need to be strengthened and made more effective.

Mr Tager—There has been real concern within those committees that the regulator has relied unduly on technical advice to the exclusion of ethical and community advice. Rather than responding to ineffectual committees by either merging them or abolishing them, it would seem that it would be far more valuable to strengthen the kind of community and ethical input that goes into decisions that are being made. There is currently very little advice being given by those committees and even less of that advice being taken in the decisions that have been made.

Senator ADAMS—I would think that, by combining them and having the same information coming through, it would be a lot easier to cope with than having two individual committees.

Mr Tager—That is actually limiting. One is confusing two very different roles. An ethics committee is one role that relates to a very specific part of the assessment of GMOs and community input is another. I also think that, if you are going to combine them, you need to change the kinds of powers and roles that they have so that they can become effectual. I cannot see that there is any rationale for combining them in the current circumstances or anything in the combining of them that would lead to them being more effective.

Senator ADAMS—I would think that by having both committees represented you would be able to argue that out rather than coming back to two separate committees. You would have members from both sides being able to come to a conclusion and taking that forward jointly rather than having one on each side and trying to come to some consensus.

Mr Tager—I would agree with that if these were not two marginalised committees already. I would suggest that a merger that should perhaps take place is to put the community committee in with the technological committee and the advice that is given there. You would perhaps then see very different kinds of results and recommendations coming out. I think at the moment combining two ineffectual committees is just creating one ineffectual committee and nothing more.

CHAIR—Thank you very much for your evidence this afternoon. We appreciate the difficulties of giving us evidence on the telephone. We appreciate the time you spent with us this afternoon and the submission which Greenpeace has made to the committee.

Mr Tager—Thanks for your time.

[2.11 pm]

BETZNER, Dr Andreas, Manager, Gene Discovery, Varieties LOB, Grains Research and Development Corporation

HARVEY, Mr John, Executive Manager, Varieties, Grains Research and Development Corporation

CHAIR—Welcome. We have provided you with information about parliamentary privilege and the protection of witnesses. I hope you understand the rules in that area. We have a submission, No. 9, from you to the committee. We would like to ask you questions about that, but I first of all invite you, if you wish, to make a short opening statement.

Mr Harvey—In this opening statement I will briefly outline who the GRDC, the Grains Research and Development Corporation, are and our interest in new technologies relevant to the grains industry, including biotechnologies. I will also outline our interest in the amendment to the bill and clarify aspects of our written submission to the committee.

The Grains Research and Development Corporation is a statutory corporation with a mandate to plan and invest in R&D for the Australian grains industry. Our primary business activity is the allocation and management of investments in R&D. The reason we exist is to enable Australian grain growers to effectively compete in ever-changing global markets. The pressure on Australian grain growers to be at the leading edge of new technology has never been greater. The harsh Australian environment and the rapidly changing global market is putting enormous pressure on the economics of grain production. The continuous decline in trade, which has been compounded by the emergence of China and India as major producers and potential exporters; increasing production capabilities in eastern Europe, Russia and Brazil; and now the pressure of the rising Australian dollar highlight the need for new technologies that will not only sustain on-farm productivity but also create new uses for grains, in particular specialised functional foods, and thereby create new markets.

The harsh reality in the grains industry is: you innovate or you die. The Australian grains industry has an excellent track record when it comes to innovation. Since GRDC's establishment back in 1991, investment in R&D has contributed to an 86 per cent increase in average annual production to about 43 million tonnes. This has been derived from a 64 per cent increase in the area planted to about 23 million hectares. Over this period the total factor productivity of the grains farms has continued to grow at an impressive 3.2 per cent. The industry has quadrupled from a \$2 billion industry to a \$9 billion industry, while at the same time growers have overcome numerous environmental and economic challenges.

However, recent evidence reported by ABARE suggests that the rate of gain in total factor productivity is dropping off. As a leading grower in New South Wales put it recently: 'We have adopted the newest management practices, like controlled traffic, like reduced tillage, like zero tillage, like precision agriculture. What we need now is innovation in the seed—better varieties.' Growers in other countries have had access to GM canola, maize and soybeans for almost 15 years. In Canada, over 80 per cent of the canola grown is GM. On a visit I made to Canada last year I was impressed by the advantages that GM hybrid canola offered Canadian growers in terms of yield, cost savings, weed control and convenience.

The GRDC has a policy on GMs which states that the GRDC invests in the development and use of gene technologies and genetically modified crops where this will provide substantial agronomic, environmental or economic benefit to our stakeholders. For these investments to succeed we require a strong, credible, national legal and regulatory framework. The GRDC believes that the Gene Technology Act 2004 fulfils this requirement. The act has been extensively reviewed and the GRDC endorses the finding of the review and supports its recommendations. We understand that these recommendations are now reflected in the amendment bill. The GRDC welcomes the opportunity to lend its support to the existing bill and the proposed amendments.

In its submission to the Senate committee the GRDC specifically referred to parts 3 and 6 of the amendment bill. The GRDC recognises that the amendment outlined in part 6 on inadvertent dealings will close a gap in the existing legislation. Part 3 of the amendment bill acknowledges that a majority of licence applications to the Gene Technology Regulator are for proof of concept research. The amendment bill will allow the regulator to deal with these applications under one new class of licence application for limited and controlled release and impose strict controls on the dissemination and persistence of GMOs. The GRDC supports this new licence category and the corresponding amendments described in section 3 of the bill.

The GRDC also believes that the consultation process around risk assessment and risk management plans forms an essential part of the existing act; in particular, the corporation believes that it is critical that excellent scientific and technical input be sought through this process.

In its written submission, the GRDC expressed concerns about item 38. Our concern was that the amendment would waive the obligation of the regulator to consult with the Gene Technology Technical Advisory Committee over the risk assessment and risk management plan for limited and controlled release applications. Hence the inclusion of the suggestion in our written submission that item 38 be modified to retain the requirement to consult the Gene Technology Technical Advisory Committee when dealing with the limited and controlled release applications.

However, we have become aware that section 50(3) of the original act survives the amendment bill unchanged. This clause requires the regulator to consult with the GTTAC and others after the risk assessment and risk management plan have been prepared. This addresses our concern in full and we no longer have any concerns with item 38. There are no other matters that we wish to raise in relation to the amendment bill.

In conclusion, the reason GRDC exists is to enable Australian grain growers to compete effectively in ever-changing global markets. Our competitors have access to GM technologies and are reaping the benefits. Australian grain growers must continue to adopt new technologies to remain competitive. The GRDC sees the changes proposed in the amendment bill as a step in the right direction. Thank you for the opportunity to be able to make this opening statement, which I trust has clarified GRDC's position.

CHAIR—Do you have an opening statement, Mr Betzner?

Dr Betzner—I fully endorse the statement just made.

CHAIR—Thank you for that opening statement.

Senator MOORE—Mr Harvey, you said in your submission that it was a step in the right direction. Are there more steps that should happen?

Mr Harvey—That is a good question but I have not given it a lot of thought. At the moment the key thing that we are raising here is the ability to effectively and efficiently explore new technologies, in particular the biotechnologies, in Australia. The changes that are suggested here, we believe, will take us a good step towards making that a lot more efficient within Australia, and that is important. So we see it very positively.

Senator MOORE—You said you are now satisfied that the later section addresses your concerns.

Mr Harvey—That was in relation to part 3.

Senator MOORE—But part 6 still remains an issue for you?

Mr Harvey—We did not raise an issue with part 6. We simply welcomed that being included in the bill. We saw it as an oversight and an important loop to close.

Senator MOORE—That it was an oversight that had been addressed?

Mr Harvey—Yes, exactly.

Senator MOORE—And you raised that before this process had gone through?

Mr Harvey—Not as far as I am aware, no.

Senator MOORE—So at this stage you have no problems at all with the bill before you?

Mr Harvey—Given that clarification about section 52(3) remaining unchanged and that, even though it may be after the risk assessment and management plan has been developed, the requirement still exists for the regulator to consult with the technical committee as well as with other committees, we believe it really does address our concerns.

Senator ADAMS—I have a question that I asked the last group regarding the committees being combined. Do you have any feeling about that? Do you think it will improve it or will it be worse?

Dr Betzner—We did not offer a comment in our submission on this because it was not an issue for the GRDC. We do not see a problem in combining those two committees as proposed.

Senator SIEWERT—Have you looked at the submissions by Gene Ethics and Greenpeace about the emergency provisions?

Mr Harvey—We looked briefly at their submissions this morning. That is a part of the legislation that we do not particularly feel we are in the right position to comment on. Our main issue is around being able to make sure that we can research, trial and develop potential technologies for Australian grain growers, so we did not comment on that part of the legislation.

Senator SIEWERT—Now that you have read it, do you have any comments?

Mr Harvey—I would prefer not to comment on that.

Dr Betzner—At the time we made the submission we thought that we were not in a position to comment on this particular issue. We commented on those issues that we believed we were competent to comment on from the GRDC point of view, which is part 6 and part 3 and the issues we raised.

Senator SIEWERT—The concerns that Greenpeace and Gene Ethics have raised seem to me to be fairly significant concerns that I would have thought would have been of concern to the industry, if in fact they are interpreting the legislation correctly—and I am going to be asking the department about that. They could have some significant implications for industry. You have not thought of looking at them from that perspective?

Mr Harvey—We iterate the point that we made that we were concerned that there was a requirement to consult, particularly with the technical committee but also with the other committees. That is relevant to what you are saying, that they are consulted in the process. We are saying that that is important. We believe that is covered and addressed to our satisfaction in other aspects of the bill because there is still a requirement, even under the limited and controlled release, for the technical committee and the other committees to be consulted.

Senator ADAMS—I have a fairly basic question regarding areas in the world where we are currently marketing our grain. Would we lose any of those markets because of going into GM?

Dr Betzner—The only market where there are potential consequences for us going into GM would be in Europe. Indications, especially through ABARE reports last year, were that the European market is going to import canola grain over the forthcoming years. There is also some indication that to allow that grain to be imported into the European Community, the European Community may be looking at relaxing their requirements in relation to GM. If there is a current disadvantage for GM in Europe for the European market, the expectation is that that situation may reverse.

CHAIR—Could I ask you a related question about the emergency powers in the legislation. You may have seen part 5A, which has been discussed with previous witnesses. This might not be an area you can comment on. Presumably it is one that affects grain growers. We were struggling, as you might have heard, to envisage circumstances where it might be appropriate for civil authorities to exercise emergency powers with respect to the release into the community of genetically modified organisms. I suppose it is hard to ask whether you can envisage such circumstances if none have actually arisen, but do you believe it is appropriate to have a power of that kind available to deal with situations that might conceivably arise? In particular, do you think that the availability of such a power would be supported and understood by grain growers as a community? To postulate a possible scenario: let us suppose that a new strain of rust suddenly emerges in Australia and starts to sweep across our wheat belts and there is some genetically modified organism that counters that but needs to be released quickly in order to counter this wave of rust. I could be talking through my hat here with these sorts of scenarios, but assuming that to be the case, do you think there would be—

Senator SIEWERT—In that circumstance, I would rather lose a year's worth of crop than bear the potential costs of emergency release.

CHAIR—You could be right, but I suppose I am asking: do you think there would be support among grain growers for that kind of emergency power to exist? Would they accept that it is better to lose a year's crop to a disease and not risk the release of a new organism that is not fully tested yet, or do you think those powers would be accepted as appropriate by grain growers?

Mr Harvey—It is probably a question that you need to address much more to the regulator this afternoon. Andreas can comment more on this from a technical point of view, but when you take an example of a rust, the time frames often involved are a little bit longer than that. You need to back-cross, for example, the resistance, be it GMO or natural, into adapted varieties. In the example you gave, there tends to be a longer time frame required to do what you are suggesting. I am struggling to see a situation where you might suddenly have a problem and suddenly be able to implement a solution in the same season, but I really do think that is a question that you probably should direct much more to the regulator. I must admit, in putting the submission together, we very much focused on the impact on our business which is around doing research and development. Our responses and our investigation of the act were to satisfy ourselves that it would work okay from that point of view. So that is where we put our thoughts.

CHAIR—Do you have any comments, Dr Betzner?

Dr Betzner—We believe that anyone who would use emergency powers would most certainly try to get very solid advice before exerting that power and that power would not be used light-heartedly. There are political reasons and a lot of other reasons involved in that. Clearly, there are risks or emergencies and that was discussed previously with Greenpeace. There are emergencies which can be defined as situations where you require a very fast response and then those, as John alerted to, where you have a longer lead time, in fact. It is for the minister to make the call as to whether or not he or she uses those emergency powers, but in any case that power would not be taken light-heartedly by the minister. We are very sure of that. It would always involve solid advice, including from the scientific community and the regulator. Taking this together, we do not see a problem so much with these emergency power provisions. We trust that the system with which we currently live is working.

Senator SIEWERT—You have more trust than I have.

CHAIR—We won't have any editorial comments from the committee on that! Thank you for that evidence and for the submission you have made to the committee.

[2.32 pm]

PHELPS, Mr Robert Errol, Executive Director, Gene Ethics

Evidence was taken via teleconference—

CHAIR—Thank you for being available to give us evidence today. I think you are a veteran of these sorts of appearances so you know all about parliamentary privilege and the protection of witnesses.

Mr Phelps—Yes.

CHAIR—We have the submission which Gene Ethics has provided to the committee; it is No. 7. Thank you for that. Would you like to make a short opening statement about that before we proceed to ask you some questions?

Mr Phelps—Yes, thank you. I would like to ask the committee to recommend that all jurisdictions are again consulted about the Gene Technology Amendment Bill 2007 as we do not consider that it fairly and fully reflects the Gene Technology Ministerial Council's decisions in response to the Timbs review of the Gene Technology Act. There are four particular points I would like to make.

The first point is that the bill proposes the complete omission of section 49, entitled 'Dealings that may pose significant risks to the health and safety of people or the environment'. This omission removes the requirement that the Gene Technology Regulator tell the public that proposed dealings may pose significant threat to the health and safety of people or the environment, sidelining the public and increasing the OGTR's powers. We find this unacceptable. We believe this section should be retained in the act.

The second point is that the proposed amendment designated as 5A, 'Emergency dealing determinations', in our view falls outside the scope of the act. The proposal envisages emergencies unrelated to genetically manipulated organisms such as a pandemic of bird flu or an oil spill. That is not a dealing with a genetically manipulated organism and therefore, in our view, does not fall under the act, although the explanatory note says:

An emergency is when there is an actual or imminent threat to the health and safety of people or to the environment. The licence would be in relation to an activity for a GMO which is intended to address the threat; including activities to minimise or eradicate the problem organism, its vectors, or to convey immunity in humans and/or animals.

What may fall under the act is any proposal to license a GMO for release if it were envisaged that such a release would be a possible solution to an emergency, such as the bird flu. But this is an invitation for an experimental organism or perhaps even more than one organism that has probably never been released into the environment before and probably has not been assessed by the regulator at that point to be unleashed on the public and the environment without any assessment processes or public notice at all. We find that totally unacceptable as well.

We believe that any GMO proposed for release must go through the same notification, assessment and licensing processes as any other GMO. If bird flu or any other viruses really are the threat that we are told they are, preparing to prevent or ameliorate those threats in a

measured, timely and precautionary way makes a lot of sense. But we do not consider that being stampeded into giving certain officials and the minister too much power is wise. We think it is dangerous and against the public interest.

If the bill proceeds, it should be amended to ensure that the states at least have to approve any emergency proposal and not merely be consulted. The notes claim that the emergency powers proposed by the bill are comparable to emergency provisions in other regulatory regimes, but we highly dispute that. For instance, if an industrial chemical regulated by NICNAS were identified as a hazard to human health or the environment in an emergency, the emergency dealing would be exclusively with the licensed chemical, not with some other unlicensed chemical or living organism. We do not see that the emergency powers in other regulatory regimes are at all parallel or comparable to the one proposed by the bill.

Thirdly, we generally object to the bill giving relatively unfettered powers to the minister, selected officials and the Office of the Gene Technology Regulator. Those checks and balances were put there for very good reasons when the act was first established. We consider that they should remain. Without a full OGTR assessment of a GMO proposed for release in emergency or other situations, we do not believe that the federal officials are likely to be able to offer reliable advice to the minister in that situation. It is highly inadequate to merely say, as the explanatory document says:

The minister must not issue the licence unless the Regulator is satisfied that any risks posed by the dealing proposed by the licence are able to be managed.

Even the OGTR is unlikely to be sufficiently well informed to advise on the impacts of any proposed emergency GMO release if the organism has never previously been the subject of an application or a full assessment.

We are concerned that this is an ad hoc approach to decision making, particularly in an emergency situation. We think it is highly dangerous. We have concerns even about the OGTR's existing assessments as a matter of routine required under the law and regulations since they do not establish any objective scientific criteria or standards in advance by which the issues of health, safety and the environment are judged by the Office of the Gene Technology Regulator. This lack of objectivity would be even more dangerous if the sorts of emergencies that are envisaged did happen to arise.

Fourthly, I would again just reiterate and expand that the bill would remove important consultations, advice and, particularly, other public procedures that generally create the checks and balances in the act. For instance, the OGTR would be able to bypass the advice from the states that is now required, particularly on field trials. While we agree with field trials being separated conceptually from the commercial releases, we do not agree at all that the procedures for publicising and consulting on such releases should be watered down by the proposed bill.

The bill proposes that if the GTR is satisfied that the controls and limits on field trials are appropriate then the GTR need not seek advice. But those controls and limits are generally decided by applicants—not by government bodies and not by the OGTR. So we therefore reiterate our view that the act should continue to require the regulator to consult, firstly, the state governments; secondly, the Gene Technology Technical Advisory Committee, which

would otherwise be bypassed as well; thirdly, relevant Commonwealth authorities and agencies; fourthly, the environment minister; and, finally, local councils and the public. We think that those consultation processes are important in relation both to field trials and to commercial releases, and we urge that the act not be amended to remove those checks and balances.

In summary, we think that all genetically manipulated organisms under all circumstances must be required to undergo a full risk assessment, and that this process must not be compromised by the passage of this bill. We think that full scientific risk assessments are necessary to the orderly and trouble-free introduction of any and all novel organisms into the Australian environment, and that should be taken to include not only GMOs but also any other foreign organisms.

CHAIR—Thank you very much for that opening statement, Mr Phelps. I ask you to clarify the first page of your submission. In it you refer to the Timbs review of the act and you quote from the communique of the Gene Technology Ministerial Council. You then go on to say that the bill does not fully reflect the GTMC's intention. In what way does it not reflect the council's intention?

Mr Phelps—It seems to me that there is a disjunction between the communique which was issued by the Gene Technology Ministerial Council and the terms of the bill. Some of the matters that I have raised do not seem to be reflected in the GTMC's intentions. I think the GTMC has gone along rather misguidedly, for example, with the notion that something like bird flu would call for an emergency response by the regulator. But, as we have pointed out, the emergency is not about genetically manipulated organisms at all; it is actually about a completely separate matter for which the solution is thought to be the release of a genetically manipulated organisms—and that is a much different matter. Personally, I think the GTMC were stampeded into accepting the proposal without realising that the act would not directly cover the sorts of scenarios envisaged with the bird flu or the oil spill. Does that answer your question?

CHAIR—Sort of. I am wondering if there is any specific part of the communique, which is the only evidence I suppose we have of what the council intended, that you would say is in contradiction to or at odds with what is actually in the bill. I assume that the principles behind the bill have already been aired to the state and territory governments since, as I understand it, they have a cooperative arrangement in place to underpin the basis for it being enacted. So I assume—and we can test this when we get evidence later on from the department—that the states and territories have signed off on this. So I am curious about where we might say that there was a failure to reflect the council's intention.

Mr Phelps—I am just quickly trying to take a look at their statement to remind myself. There is so much documentation and I am afraid the time frame has been a bit short for us to—

CHAIR—That is the problem. If you wanted to take that on notice I am quite happy for you to do that.

Mr Phelps—Thank you and I would be happy to write to the committee about where I see the disjunction as being. Is that by tomorrow?

CHAIR—We would appreciate it fairly quickly because we have to report in one week. I am sorry, I did not realise it was that soon. We do have a time frame problem, so tomorrow would be great.

Mr Phelps—Okay.

CHAIR—We do not have time to go back to ask the states and territories what they think, so we would appreciate any advice that you can give us on that.

Mr Phelps—Okay, thank you.

CHAIR—You made the point, which was made by Greenpeace as well, that it is inappropriate for the emergency powers in the legislation to provide that there should be a gene technology type of response to a non-gene technology or GMO based emergency. You cited the example that the release of an unlicensed chemical into the community would not be responded to by the release of another chemical of some kind to counter it necessarily.

Mr Phelps—Probably not, no.

CHAIR—That analogy may be correct, but I wonder whether there would not be situations where a particular kind of threat to human, crop or organism safety, or environmental safety, might not be responded to by the release of a GMO in emergency situations. The example that we were talking about earlier today was the emergency release of the calicivirus a few years ago across Australia when early experiments on an island in South Australia were released, accidentally or on purpose, and they started to spread and so the virus was then released on a planned basis across the rest of Australia. I am not sure if a virus counts as an organism, but let's assume for a moment it does. Would not that be an example where you might appropriately, for the control in this case of pests, as an emergency measure actually approve the release of a GMO that was not fully tested?

Mr Phelps—In the calicivirus case I think it would have been much better to have taken a more measured approach. Despite the unauthorised release from the island—which should have been foreseen, and had been put to the committee by us—they should have waited and considered a plan to actually release it in a much more rational and less ad hoc fashion as a response. I am not sure that that goes to the heart of this matter. I concede that you might want to release a GMO to deal with something like the bird flu, but the bird flu is not here now. There have been 140 deaths in Asia. We can envisage it as an item on the ABC news; a show on the ABC last night proposed that this might go worldwide. But if indeed it is that kind of threat, then we should be planning now in a precautionary way the options for dealing with that and not saying at the last minute that we have this GMO in the cupboard somewhere and we will just let it go and see if it cures the problem when it has not been assessed and has not been the subject of the kinds of processes that the regulator quite properly goes through in order to assess those impacts before releasing anything.

This does appear to envisage that the GMO proposed for emergency release will not have been the subject of an application or an assessment. Its behaviour in the environment and its impacts on public and animal health may be completely unknown. That is, I think from a public perspective, totally unacceptable that the thing would be let go under those circumstances.

CHAIR—Could not there be a scenario though where, let's say in the case of bird flu, some kind of GMO was developed in the United States, for argument's sake, which appeared to be able to counter the bird flu. Suddenly there is an outbreak in Australia and it is proposed that this organism is released here to counter it. I suppose I am getting to the question here: is there any circumstance you could foresee where such a power might conceivably be useful and efficacious to public health and safety?

Mr Phelps—No, quite the contrary. If something had been trialled in the USA and there were good information about its behaviour and in the environment and its efficacy for heading off the bird flu, it would be appropriate that an application were made here, even by public health authorities, so that the assessment process could go on in a timely and measured way rather than waiting until the emergency arose.

CHAIR—Let's suppose that that was happening, that there was an application being made—as we know, these things take some time—and that in the meantime the flu breaks out before it has had a chance to be fully assessed; wouldn't that be a circumstance where you would authorise its early release?

Mr Phelps—It depends what the evidence showed, but I think it would be an invitation to make bad matters worse, personally.

CHAIR—Senator Moore?

Senator MOORE—I have been busy floating around the internet site here trying to find various statements that were made. I am interested, Mr Phelps, that your submission recommends that the state and territory governments be provided to critique the Commonwealth bill as part of the present process.

Mr Phelps—Yes.

Senator MOORE—Yet the website of the ministerial council shows that they welcomed it and accepted it. It does interest me, having just had a look at this—and I will ask the department when they come in later—that the discussion we have had today on emergency powers, which seems to be the thing that people have been raising, did not get a guernsey in that public comment that came out on the website. It is interesting to see what happened between October last year, when this joint communiqué was released, and now, with the focus on the ministerial powers. You said earlier—and I would just like you to restate it, if you will, because it is quite a strong word—that you felt that the ministerial council members may have been 'stampeded' into their agreement.

Mr Phelps—Yes.

Senator MOORE—Would you like to add to that?

Mr Phelps—It is in relation to what I see as the publicity, or media scare really, about the bird flu—like the item on the ABC last night which was at great pains to say what a threat this posed to the world; yet it seemed to me that the evidence was still quite weak that this was likely to happen. I was speaking particularly in relation to the emergency provisions, particularly the removal of the multiplicity of checks and balances which are already in the act. I do not see why those powers need to be removed. I think that consultation with other officials in the states and territories can be expedited quite quickly. I just think the more

people who are consulted the better, particularly when there is very poor information about a particular GMO if a GMO with no history of safe use in the environment were proposed for release. I was not quite sure which website you were actually referring to.

Senator MOORE—I was on the gene technology one, which actually listed all the various committees that met and looked at the media release that went around the joint communique.

Mr Phelps—Right.

Senator MOORE—It was very short, very sharp. There was one sentence at the end of it that said, 'Emergency provisions were also discussed.' That does interest me. I did not read that until today, which is my oversight; I was looking at the submissions and the act. So far the discussion we have had with a couple of witnesses has concentrated a great deal on that section 5 element of the whole process.

Mr Phelps—I would like to be reassured, if I have a moment, Senator Moore, just to be absolutely sure that the proposed amendments to the bill have been fully considered by state officials and that there is no disjunction between the quite detailed responses that they made at their last meeting—it was actually between meetings. This document I have is as a result of being a member of the Gene Technology Community Consultative Committee.

Senator MOORE—Yes.

Mr Phelps—That is the response to the recommendations. But, as far as I am aware, that document was never publicised to the public generally and I am not surprised that you have not had much response to it. The fact that I had it was only the result of getting it in the papers for that committee meeting, which was about six weeks ago, and then alerting Greenpeace to the fact that this document actually existed. So it has not been the subject of very much public discussion or debate, and I get the feeling—from talking to some officials in the states, which we do—that the emergency powers were at least one thing—and there were others—on which they might not have been fully consulted. I am saying that the ministers when they heard 'bird flu' may have responded, 'Yes, that's an emergency.' But I am not sure that the subtlety of it, that the emergency is not about a GMO—cleaning up some GMO spill or some unauthorised release of a GMO or dealing with a GMO—but is about having a novel GMO which had no history of safe use or proper assessment and about then proposing to release it, was entirely clear to them.

Senator MOORE—I was aware that you were on that particular consultative committee or community group. I am interested to know what kind of discussion was held at your meeting about these provisions.

Mr Phelps—At the Gene Technology Community Consultative Committee?

Senator MOORE—Yes. Your submission does touch on a few issues given your longstanding interest in this area. The point about the area of emergency powers seems to take up the bulk of your submission.

Mr Phelps—Yes, sorry; time was short as we had only a week and a half.

Senator MOORE—That is not a criticism. I am just saying it is a focus of your submission.

Mr Phelps—Yes, it is because I see it as the most important matter, to be honest.

Senator MOORE—At the community consultative forum, which is designed to actually discuss these issues, all issues to do with gene technology operations in this country, was there a great deal of discussion around how these provisions would operate?

Mr Phelps—No, I cannot say that there was a great deal. One or two of us asked a few questions and, no, there was not a long or heated discussion. Again, the papers came to us a very short time before the meeting and I think the full implications of all the detail and of the recommendations and so on were perhaps not fully appreciated. At that point, not having had a chance to read the act in conjunction with the decisions, I did not see the implications: what the removal of checks and balances and the introduction of emergency powers would actually mean in practice. So there was not a great deal of discussion with the regulator about it.

Senator MOORE—So the regulator may not be aware that there are these questions in that the information that they have based on the discussions they have had and so on may not lead them to be aware that people have these concerns.

Mr Phelps—I cannot be totally sure of that. The two people represented there were Elizabeth Flynn, who is in the secretariat, and Sue Meek. I do not know how aware they are of our concerns. It seems to me that one thing to say, however, is that it appreciably increases their powers and also clears the deck for them to—as they keep telling us—focus on things that are more dangerous and more important. We do not think that they always appreciate the extent that the public would like them to address the potential impacts of field trials as compared with commercial releases. We do appreciate that these two categories of things are now to be separated, but, as I mentioned in my paper, in the case of some releases to the environment purporting to be field trials the seed is actually bulked up for export overseas and ultimately for sale, yet they are called field trials. So I do not think that the distinction between field trials and commercial releases is as clear or clean as we may be led to believe.

Senator MOORE—By the terminology?

Mr Phelps—Yes, by the terminology. There is no clear definition. The definition is muddled because there is nothing in the act which mandates scientific criteria, standards or quality assurance to say what kind of evidence needs to be brought forward or even what constitutes an experiment. Most of the releases into the environment on a small scale in Australia are not experiments at all. They are actually releases to collect agronomic data about whether or not the crop will grow and whether or not it will do what it purports to do in our environment. It is not in any sense an experiment within the nomenclature of science. I think that is another problem with the bill.

Senator MOORE—So that delineation is not clear?

Mr Phelps—Not at all. Not in the slightest.

Senator MOORE—Have you raised that issue with the regulator?

Mr Phelps—Yes, constantly over a lot of years.

Senator MOORE—What has been the response from the regulator when you have raised that?

Mr Phelps—They say, as everybody does, that they run a science based system of assessment and licensing—and being science based is not scientific. So in our perception the regulator is willing to accept quite unscientific data usually generated by the applicants themselves as the basis for receiving an application and for issuing licenses when, in our view, the act and the regulation should actually mandate experimental protocols which would say, in a feeding trial for example, how many animals and for how long, with an intergenerational study and so on to establish the health and safety of the foodstuffs.

It is just not scientific in any meaningful sense. As a result the public and expert critics of particular applications are never in a position to argue effectively that an application not be approved and a release not be licensed because the regulator does not have any clear standards or benchmarks by which you can say, ‘This doesn’t qualify because it isn’t scientific enough or it is not large enough or long enough.’ For most things I do not think the regulator has ever rejected anything for licensing and as a result the public have lost a certain amount of confidence in the system and certainly are not making nearly as many submissions on releases as they used to because it is really a waste of breath and paper.

Senator MOORE—Is that your criticism of the original legislation and process as opposed to this amendment?

Mr Phelps—I think it is made weaker by the proposed bill than it was before. So, yes, it is a critique of the act itself but also of the proposals to remove the very significantly watered down checks and balances which are in there and do at least require the states, territories and local councils to be consulted and to bring their expertise to bear on the issue of whether or not GMOs should be released as well. I think more is better in this case.

Senator SIEWERT—I want to go on from where we have just left off. It relates to section 49. As I understand it, in your submission you point out that the community will no longer be told—this is as to limited and controlled release and consultation on significant risk—whether something poses a significant risk to the health and safety of people and the environment. I am going back to the point you were making about section 49.

Mr Phelps—Yes.

Senator SIEWERT—I presume that, with regard to your comments on the community being further restricted in its involvement in consultation, your argument is that section 49 also means that they do not get access to that information and therefore it restricts their access?

Mr Phelps—Section 49(1) requires a notice in the *Gazette*, which is not too helpful for the public but is important, in a newspaper circulating generally in all states and on the regulator’s website. So it seems that, if section 49 goes out altogether, there would be no such notice that appears. Subsection (2) then talks about the properties of the organism, its effects and so on. Subsection (3) says that the application has to be detailed, that we may request further information and they must invite written submissions et cetera. All of that, it appears, would go if section 49 goes. That is an important process.

It may seem troublesome to the regulator where the regulator considers that certain dealings are of no particular danger or consequence, but we do happen to think that these processes in a democratic society are important and that the regulator alone making a decision

on whether something is of significance to the community is not the benchmark. For example, it is thought that genetically engineered flowers may pose no particular concern to the environment or public health, but the people of Yarra Ranges, who declared themselves GE free several years ago, have certainly raised very serious objections to a current proposal to release genetically engineered flower plants on a trial basis in their shire on the outskirts of Melbourne. That would be only one example.

What I am thinking about, though, more importantly, is the future. We might just be talking about crop plants at the moment, but in the wings are things like crop plants that contain human genes for the purpose of producing pharmaceuticals or human proteins. They are now being both field trialled and generally released in the USA. We just need to be looking to the future and taking a precautionary approach to anything that might be coming along through this pipeline and ensuring that, even if people do not respond to every application and every proposal to license a release, they do at least have it within their knowledge that something is happening in their local area that they may be concerned about and can respond. Also, those of us who are taking a more general interest can monitor what the regulator is considering in a timely way, find the relevant evidence and make a contribution to those deliberations.

Senator SIEWERT—Can I go back to the emergency dealing determinations. I asked Greenpeace earlier what recommendations they would actually suggest. They said they thought it would be best to delete that section. But, if not, I asked them whether it would be better to define more clearly what is meant by ‘emergency’—for example, relating it to a medical emergency. Would that in some way address your concerns?

Mr Phelps—I think it is somewhat defined. It mentions impacts on public health and safety and animal health and safety and the environment. So I do not think it is just a definitional matter. I think the core problem is that the people who have thought about this and decided on the current bill have not seen that this is actually a different sort of ballgame from the emergency powers given to other regulators, as I tried to point out in my opening remarks.

Senator SIEWERT—I understand what you are saying. The point is—if something were around bird flu—to define it as closely as possible to that form of emergency. As I raised with Greenpeace, if, for example, they decided that the drought were an emergency, the minister at some future date, under another government, could say, ‘We have decided this is an emergency and we need to get on and stop mucking around with consultation over genetically modified organisms, so we are going to decide that this is an emergency and release a particular organism.’ My understanding of what both you and Greenpeace are saying is that they are interpreting the act to mean that they could do that.

Mr Phelps—That is one potential outcome, yes. For example, a drought tolerant crop plant could conceivably be a candidate. The drought is more of a present than a future reality and we certainly do need to respond to it. We would still say, even if there were now, say, a drought tolerant wheat, a GMO available, that the organism should go through the proper processes. We have serious questions that I have raised already about the actual process, and I do not know that you can do anything about that, but I think that it is making it worse by enabling these emergencies to be declared and to fast-track organisms into the environment which have not been properly assessed and where there may be very little known about their

behaviour or their potential impacts in the environment or on public health. I think they should not be fast-tracked out there on some pretext of doing good, because, as we know, when you try to do good you can easily end up doing worse, and I think that this is a good example of that.

The bird flu would undoubtedly be a terrible disaster, but being aware now that that disaster is possible and potential, some decent planning needs to be done for it. The same is true of something like drought. Simply, on an ad hoc and emergency basis, letting an organism go that has not gone through the processes of review is likely to end up making matters worse, as indeed it did in the calicivirus case. Because it was not strategically released, it has proved ineffective, and that was for reasons that were known prior to the release: for example, if the kittens were exposed to calicivirus before they were six or eight weeks old, they became permanently immune. This is what I mean by being stampeded. We must not put power into the hands of our regulator, our senior officials or the minister that will at some future time, on the basis of who knows what scenario, allow them also to be stampeded into using those powers which they are going to be given now if this bill is passed.

Senator SIEWERT—Thank you. I have one final question. In GRDC's presentation and submission, they said that they supported part VI of the bill, dealing with those that are unintentionally holding a GMO. Do you support those provisions of the bill?

Mr Phelps—I think that is also still rather unclear, to be honest. I think that what was envisaged there was that if, for example, somebody had their crop contaminated and they wanted to talk to the regulator about disposing of it in a timely and safe fashion, a concession would be made to them to do that.

Senator SIEWERT—Yes, that is it.

Mr Phelps—But, again, it cannot be used to actually get around the law, and I think that, unfortunately, it can be. We have had instances already of substantial contamination around Mount Gambier by Bayer and its predecessor Aventis from field trials. We have also experienced canola contamination in Tasmania as a result of contaminated seed being sent by the Victorian department of agriculture.

These things need to be prevented, not fixed up afterwards by such a provision. I think the checks and balances to ensure that contaminated seed is not out there have simply been bypassed. For example, when a farmer out near the South Australian border was discovered to have his crop contaminated, all the ministers rushed to introduce thresholds of allowable contamination—0.9 per cent in harvested grain and 0.5 per cent in seed. Again, it seemed to me that they were stampeded into a very unwise response because, instead of it being that some concessions are allowed where you are accidentally contaminated, we are now in a position of some people thinking they can routinely contaminate and also get away with it. I think this is a very unsatisfactory place to move to. That is why I am not undividedly supportive of this particular provision. I am not quite sure what its implications are, given the way it is drawn at the moment.

Senator SIEWERT—Thanks.

CHAIR—Mr Phelps, thank you very much for your evidence today. You have given us a lot of time and it has been very useful. Thank you for talking to us this afternoon.

Mr Phelps—Thank you for your attention.

Proceedings suspended from 3.17 pm to 3.28 pm

KHOO, Mr Kay, Regulatory, Public and Government Affairs Manager, Bayer CropScience Australia

PENNA, Mr David John, Regulatory Affairs Lead—Australia/New Zealand, Monsanto Australia Ltd

CHAIR—Welcome. I think that information on parliamentary privilege and the protection of witnesses has been provided to you. We have submissions from Monsanto, Bayer CropScience and also Dow AgroSciences and CropLife. I understand that you gentlemen are representing both your own organisations and those other two organisations. Is that correct?

Mr Khoo—Yes, that is correct.

CHAIR—Does one of you represent one other organisation or do you both represent both organisations, as it were?

Mr Khoo—We represent both CropLife and our respective organisations.

CHAIR—That sounds good. Thank you very much. We have the submissions from all four of those organisations. We are going to ask you questions about those submissions, but would you like to start with a short opening statement to summarise the position of those four organisations?

Mr Penna—Sure. Thank you for the opportunity of addressing the committee this afternoon. I just point out to clarify our discussions that we each represent our own companies, who are providers of gene technology to Australian farmers, but we also represent CropLife who represent all the developers, registrants, manufacturers and formulators of plant site solutions for use in agriculture and the management of pests in other settings. As the industry's peak representative body, CropLife leads industry efforts to ensure a science based, efficient and effective regulatory and policy environment to support innovation and encourage high-quality products. On that basis, we are representing both ourselves and CropLife.

We note that the Gene Technology Act has been in operation for nearly six years. It is certainly one of the most stringent regulatory systems operating on a national basis in the world for assessing the safety of bio-tech crops, from both a human and an environmental perspective. We also note that the act has undergone extensive review through several rounds of public consultation, including written submissions, public hearings and meetings that the review panel conducted with key stakeholders to explore specific issues in much more detail. As such, with this extensive consultation, we largely support the adoption of the amendment bill intact. However, there are two areas in which we have specific concerns. The first is in relation to the amalgamation of the two committees. We support the amalgamation as proposed. However, we consider that it may be appropriate to have more criteria around the persons that may be selected for those committees. Specifically, to ensure the committees remain effective in their operation and balanced in the views they represent, we think that the participation of individuals and organisations that are actively campaigning for or against gene technology should not be eligible for inclusion on that committee, simply because their views tend to polarise the committee and the advice given to the regulator and, indeed, may

appear to be predetermined before such discussions. Therefore, we consider that those campaigning for or against the technology hamper the effectiveness of those committees.

The second point that we have raised in our submissions relates to section 3—in particular the inclusion of a type of dealing for limited and controlled release. We are supportive of inclusion of this nature of dealing in the act; however, we do have concerns around the definitions around the purpose of those dealings. Specifically, if you go back to the objectives of the act—that is, namely, to protect the health and safety of humans and the environment—we do not see a need to specify the purpose of limited and controlled release dealings. We see that the emphasis should be on the limits and controls placed on those dealings, not the purpose of the dealings. Indeed, if you look at most of the licences for such dealings that have been issued by the regulator, they very much relate to the controls—what happens during the growing of those dealings and during harvest, in relation to genetically modified crops during and after harvest. What happens and why it happens is immaterial to the protection of human health and the environment. Indeed, if the regulator identifies specific concerns in relation to the purpose of the dealing, it is within his or her capacity to implement further controls to protect human health and the environment. That concludes our statement. Generally, we are largely supportive of the proposed amendments to the act.

CHAIR—Thank you, Mr Penna. Dr Khoo, do you wish to make an opening statement as well?

Mr Khoo—Just very simply to say that I concur with what Mr David Penna has said. Our position is very much a similar position and I would like to support what he said about the inclusion of the word ‘experiments’ in section 50A. We do not think it is necessary to have the definition of ‘experiment’*s*. We think that the word ‘experiments’ should be replaced with something like ‘dealings’ or ‘contained dealings’. The important point is that dealings under this section should be contained and limited as opposed to commercial releases. As long as it is contained and small scale, the purpose for which those trials are conducted is not really relevant. The relevant point is the risk assessment carried out on it.

CHAIR—Thank you both for those statements.

Senator MOORE—I only have two questions. The first one is: Mr Penna, in your submission and your statement you were clear about the make-up of the new committee, whatever it is going to be called, having people who have not got predetermined ideas. I am worried how you are ever going to find a committee that would meet those requirements. The other statements and submissions that we had along a similar vein just said that they did not want people who were opposed. Is there any reason for that variation, or have all the groups agreed that it should not be either in favour or opposed?

Mr Khoo—Could I answer that?

Senator MOORE—I hope so, Dr Khoo.

Mr Khoo—The submission from Bayer CropScience said that we did not want people opposed to the technology or actively campaigning against the technology I think is the words that were used.

Senator MOORE—Yes.

Mr Khoo—We are prepared to accept the industry view that we should not have people polarised on either side of the fence included on committees.

Senator MOORE—Just on that basis I would like to hear from both of you, how would you select for that? I know it is not an industry decision it is a ministerial one. How would you actually ensure that people did not have predetermined ideas?

Mr Khoo—It is not so much that people do not have predetermined ideas. I think everyone is entitled to an opinion for or against. It is just those people actively carrying out a campaign, for example, raising funds for it, or carrying out demonstrations in a public manner, I think those people, because they appear to be ideologically opposed, maybe should not be included on those committees.

Senator MOORE—Would people have to make some public statement that was their position to be eligible under the proposal that you put forward?

Mr Khoo—We do not see that disqualifies them as long as they are not engaged in actively campaigning against the technology. That is an ideological point of view.

Senator MOORE—Do you have the same position, Mr Penna?

Mr Penna—Yes, if you look at the public record, media and other varieties of the public record, it is easy to see that organisations such as CropLife that I am representing today are out there campaigning actively for the technology, and it is also easy to ascertain which organisations and people are actively campaigning against the technology. In that way it should be relatively straightforward to identify those organisations.

Senator MOORE—I would like to get some more clarification—once again it seemed to be a similar submission around the issue of the definition of ‘small processes’ and how it could be seen. Could you restate for me exactly why you do not like to have the word ‘experiment’ or the background to experiment public if it is all open and transparent?

Mr Penna—Sure, there is a range of reasons why we do trials under limited and contained releases. One of those is really doing experiments to gather more data to support risk assessments, and indeed to identify whether there are risks or not to human health or the environment. There are other reasons why we do undertake such trials or such work in containment and one of those is, for example, increasing seed, which strictly is not an experiment, but you do increase seed for several reasons, one of which may be to increase seed to give you seed to do more experiments in the future.

Senator MOORE—Or dealings.

Mr Penna—Yes, indeed, to do more research at different locations, at a wide variety of locations, at a greater number of locations. Another reason is to prepare ultimately for the eventual commercialisation of the technologies. I can cite examples where, when we are ready for commercialising a product and have the necessary approvals in place, the demand for our technology far exceeds the capability to produce that technology. Even though we have already produced enough seed to meet a limited demand, the seed companies involved have had to resort to ballots to allocate the limited quantity of seed they have available. That seed was produced under contained licensed conditions and provided enough to meet a quarter of the demand. To eliminate the ability to do that under contained licensed conditions, you

would be lucky to meet, I would hazard a guess, one per cent of the demand in that first commercial application of the crop.

Senator MOORE—Is it a form of commercial-in-confidence? I still cannot get my head around it, for the sake of the legislation, because that is a very reasonable explanation you have given us in terms of, in a contained area, what you would be doing under licence with the licence you have.

Senator SIEWERT—They are producing a crop that is not yet ready for commercial release. They are building up seed in a seed bank for a crop where all that information that Greenpeace has just highlighted, which you want for assessment, is no longer going to be made available. They want to be able to produce that without those safeguards.

Senator MOORE—So you agree with the evidence given by Senator Siewert?

Mr Penna—No. We are saying that we still want to produce it with the safeguards and the containment measures.

Senator MOORE—Which would be known—

Senator SIEWERT—But the community does not know about it because section 49 is being repealed.

Senator MOORE—You have to apply for a licence, which you do. To get that licence you would have to be clear about what you were doing. You just do not want to have certain terminology used. You would still have exchange with the regulator about what you were doing.

Mr Penna—All we are advocating is basically the status quo in terms of doing work under licences until you have enough data to prove that it is safe to proceed to the next step. From what we understand, the proposal that is before the committee at the moment would exclude any dealings that are not of an experimental nature. I will give specific examples. We produced seed under the same containment conditions as we were doing research in. That then went into storage that met the regulator's guidelines for storage of dealings that had not had commercial release. There were quite stringent storage conditions there. But whenever it was—I think it was six months later—that the regulator made the determination that the product was safe, we were able to satisfy a grower demand for that product. We are not arguing for conducting that work without the conditions; we are arguing for exactly the same conditions—limited and controlled release. All we want is to have the ability to do whatever we are allowed to do within the confines of the four walls of that trial.

Senator MOORE—How does this proposal stop you doing that?

Mr Khoo—The word 'experiment' is used. We could not carry out work under that section of the act, even if it is small scale and contained dealings, if it did not fit the definition of 'experiments'. As we said, if we do seed increases, they do not fall into the category of experiments.

Senator MOORE—That would be seen as scientific operation rather than an experiment. You are not experimenting.

Mr Khoo—It could be pre-commercial.

Senator SIEWERT—But you said yourself that you are preparing commercial quantities of seed.

Mr Penna—Absolutely.

Senator SIEWERT—So that is in fact not a trial. It is about commercialisation of a GMO that, while you are preparing it, may not be approved by the regulator.

Mr Penna—And if it is not approved then we have to dispose of it in a manner prescribed by the regulator.

Senator SIEWERT—In the meantime, you have been building up commercial tanks of seed.

Mr Penna—Absolutely. If we are building up seed—

Senator SIEWERT—That is what it is about.

Mr Penna—We and our seed company partners might build up a quantity of seed. If it gets to the point where the regulator decides it is not appropriate to release it commercially, we then have to go to great expense and dispose of that seed in a manner that is consistent with the regulator's requirements. At the moment, for example, in our contained cotton licences we have to bury it under one metre of soil, incinerate it or take whatever other options there are. If the regulator chooses not to allow a wider release of that technology then we have to comply with the conditions of the licence, and they are the conditions of the licence imposed when we were doing that original work.

Senator MOORE—Was this concern raised with the regulator when they were developing the changed guidelines?

Mr Penna—I guess we were not fully aware of the implications until we saw the final writing in the amendment bill.

Senator MOORE—In effect it changes something you were already doing and you were unaware of that during the consultations.

Mr Penna—That is correct.

Senator SIEWERT—I want to go back to the issue around who is represented on the committee. Who do you foresee would be on the committee? Who would be left?

Mr Khoo—There are lots of experts in universities and in CSIRO, for example.

Senator SIEWERT—What about the community? This is a community consultation committee. Who from the community, who is not engaged in GMO debate and who takes an interest, would you suggest becomes involved?

Mr Khoo—We are not excluding those people, as I said. Everyone will have opinions. We are not excluding them. It is just that there are people actively campaigning or who belong to an organisation that actively campaigns against the technology or for the technology. For example, we have an organisation like that called the Producers Forum, who want to see GM canola introduced, so they are actively campaigning for it.

Senator SIEWERT—Who do you suggest from the community would be involved? You know community organisations. I know you do because you engage with them. Who would

you suggest from the community, with enough information to make informed input into this debate, would be involved?

Mr Khoo—I cannot give you an answer because I do not have knowledge about who in the community has sufficient knowledge.

Mr Penna—I agree; I do not have that information. There is a whole range of farmers, academics, researchers and people in local government, for example, that could be representative of the community that may have that information, but I cannot specifically today point to who that might be.

Senator SIEWERT—Do you not acknowledge that people like Gene Ethics and Greenpeace have played an active role in the debate—in trying to ensure that there are some safeguards and that there has been community debate to date?

Mr Penna—Regardless of how the committee is formed, we would see that they would still have an active role. There are many avenues, through the media and through the consultation processes of the regulator, that would continue to involve those groups—and, indeed, groups such as our own, and the Producers Forum, as an example mentioned by my colleague. So there still remains ample opportunity for those groups to be involved in the debate, and indeed processes such as this are very important to that as well.

Senator MOORE—Has it been so dysfunctional? This group of submissions has particularly raised this issue. It is the only place it has been raised, so there must be a reason. Have you, as someone involved in the industry, felt that it has been dysfunctional in the way it has been operating?

Mr Khoo—We have had some experience over the past few years where that has happened. In New South Wales, for example, there is a ministerial advisory committee and there have been people on that committee who have not respected confidentiality and who have released confidential information.

Senator MOORE—The state ministerial element of the national group?

Mr Khoo—This is a committee set up by the New South Wales minister for agriculture to advise him on GM crops.

Senator SIEWERT—So you think the better way to handle community debate is to have them outside rather than in and being able to sit down and discuss things around a table? I am quite astounded at your proposal—I have to put it on the table—that an acceptable way to debate things in the 21st century is to have people who have declared an interest outside the room. You know very well that those who have knowledge of GMOs are more likely to be included around the table from the academic perspective than people with a community perspective. You will not be able to find people who are not engaged in the debate who will be knowledgeable enough to sit around the table with you.

Mr Khoo—We would not like to comment on our views of some of these organisations, except perhaps to say that we think their views are sometimes are very extreme and not helpful. That is all that we would say about them.

Mr Penna—It is admirable to get people in a room and around a table to debate these issues; there is no questioning that and that is the cornerstone of our community. The concern

is that, where you get a polarisation of views on either side of the debate in a committee to provide advice, for example, to the regulator, where you will never get both those sides of the debate to agree one way or the other, that could hamper and indeed may hamper in the future the advice that that committee gives, when the committee will or could never agree on particular issues.

Senator SIEWERT—You have obviously had a different experience from my experience of sitting around many tables. Moving on to the emergency provisions—obviously, you have heard the evidence that has been given this afternoon about the emergency dealings provisions. Have you looked into those or do you have any comment on those?

Mr Penna—I have not personally looked into them in a great deal of detail. Our position is that we are neither for nor against those particular provisions. Really, that is up to the community, the government and the regulator, as they see fit. One comment that I think may need to be made is that there has been a lot of talk this afternoon about enacting emergency provisions to, for example, overcome problems with the drought. Certainly, if you look at the time scales involved to get plant varieties into the ground that are robust, there is very little scope for that to be used. If you look at the breeding time frames and, as the representatives of the GRDC mentioned, backcrossing and bulking time frames, it is difficult to see how that could be used in a genetically modified crop situation. So our view is very much that we are neither for nor against them and we believe that is up to others to debate.

Mr Khoo—Speaking for Bayer CropScience, I would say that, yes, we welcome those provisions. There are safeguards, and we do not think there is any fear that they would be used to override the current processes for approvals.

Senator SIEWERT—What is the basis for your comment that you do not think they would be used to override those processes?

Mr Khoo—Because the minister has to get advice from certain chief scientific officers. I think in an emergency you would really want some powers to be able to deal with any adverse outcomes.

Senator SIEWERT—We have been struggling to think of an emergency. Bearing in mind what Mr Penna has just said, other than the example of bird flu, we have been struggling to think of another emergency type scenario where you would need emergency regulations like this.

Mr Khoo—No, I cannot think of any practical situation today, but that is just my lack of knowledge.

Senator SIEWERT—The point is that people can think of reasons not to have these provisions, but not many people can think of reasons to have them.

CHAIR—Just coming back to the question of consultation mechanisms, you might say that there are two possible models of community consultation about new proposals in, say, gene technology. One is the model of a sort of community jury where you get people without any predetermined position and perhaps without even any predetermined knowledge of an area and you give them all the available information—hopefully, as impartially as possible—and they give you a view that would appear to reflect what the ‘average citizen’ might think

about a particular proposal. The other model is where you bring the relevant stakeholders around a table and you attempt to at least include them in a discussion about issues that affect areas that they are knowledgeable about and have a capacity to project some community voice about in that context.

The latter model is by far the more usual model for attempting consultation with the community. I assume that you feel that the former model is actually the better one where you do not have people with any particular motivation to be involved in these areas because they do not have any active role in those areas except perhaps as a scientist or something of that sort—but, with respect to the community consultation side of it, presumably they have no active involvement in areas of gene technology. Why do you feel that model would be somehow superior to the more usual one where you have the stakeholders around the table?

Mr Khoo—No, I do not think that is our point of view. We think that the act has provisions to consult with expert bodies and also provides the general community some input into the consultation process. We do value both kinds of consultation. It is not true to say that we prefer the kind where you consult people who have no prior knowledge.

CHAIR—Are you saying the body set up under section 108 ought not to consist of stakeholders—that is, people with a demonstrated interest in the area—because they will tend to be active either for or against particular gene technology proposals?

Mr Khoo—No, I guess the distinction is a subtle one. Say, for example, that you are consulting about a GM crop. You would, of course, consult agronomists or people involved in the supply chain.

CHAIR—You do that under section 108 of the bill. That is the section that you have recommended ought to be amended to exclude those who have campaigned for or against gene technology.

Mr Khoo—Yes.

CHAIR—That is obviously a key process. You effectively say that process should not include stakeholders.

Mr Khoo—No. It should not include people who actively campaign for or against the technology. We are not talking about people in related fields, for example.

CHAIR—So you can include people who work in related fields?

Mr Khoo—Yes, of course. You can include people who work in related fields and you can include people with stated opinions as long as they do not belong to some organisation which raises money and actively campaigns against the technology in an ideological way.

Mr Penna—Or for the technology.

CHAIR—That distinction is fairly hard to maintain. Organisations like, say, Greenpeace—and I do not want to put words into their mouth—could have a member who is well versed in this area resign from the organisation in order to qualify to be appointed. Let us face it, that would be easily sidestepped.

Mr Khoo—I accept that the distinction can be difficult.

CHAIR—I want to come back to your second point about experiments. I take your point that, with the controlled release of a GMO, the reason for the release is not as important as the circumstances of the release. Would it not also be true to say that a release is necessarily a risky exercise because it involves putting out into the community something that is not yet fully assessed and understood? That carries a risk. Should not the risk only be entertained where it is being done for the purpose of advancing scientific knowledge about the use or effect of that organism in the community? Does that not carry the notion of experimental research with it? Perhaps ‘experimental research’ is not the right expression, but would it not be only in those circumstances that you could justify taking the risk of releasing a GMO?

Mr Khoo—No. Currently, under the act, as long as you have the contained conditions, the purpose of the trials is not taken into consideration. That is my understanding. Under this new provision, I think the intention is to include those sorts of work that can be restricted and controlled with conditions. The crucial point is that they are well contained; the purpose is not really relevant. As David explained before, there are legitimate reasons why you would want to carry out some small-scale plantings which do not legitimately fall under the definition of ‘experiment’—for example, seed increases for a variety of reasons, including pre-commercial reasons.

Mr Penna—I want to go back to the point on risk. These dealings are perceived to have risk associated with them and that is the very reason why the regulator requires that certain controls and limits be placed on them. Indeed, I can point to situations where we have taken dealings purely for experimental purposes and limited the area and the number of locations. As more knowledge has been gained, we have made a second application to the regulator still to do work under contained and limited and controlled requirements but in a slightly larger area and in a slightly larger number of locations—but still not in an unrestricted commercial sense. So, as you gain knowledge, you can gain confidence, but that does not mean that you would want to release it on a commercial scale before you have the full set of questions answered by the regulator. If the committee wishes to refer to a specific instance of this I can refer to licence DIR035, which was initially issued, and licence DIR055, which was issued subsequently. Both were issued prior to the commercial licence, which was DIR059.

CHAIR—So you understand that the arrangements in the bill for controlled release are more restrictive than the present arrangements for controlled release?

Mr Penna—Only insofar as it restricts the specific purpose of these particular dealings.

CHAIR—So some of the releases that would now be possible under the legislation will not be possible because they cannot be constituted as experiments?

Mr Penna—That is correct.

Senator ADAMS—This is getting down to the practicalities of all of this. We heard that some of these experimental crops have been exported. I am a farmer. Can you step me through what happens when there is contamination when it goes to the bin? How are we going to deal with this if the neighbours are growing GM and we are not, or the other way round, and the trucks are carting it backwards and forwards? What is going to happen there with contamination?

Mr Penna—The very controls that the regulator puts in place on the dealings are designed to prevent that. I have the greatest knowledge of controls put in place for cotton trials that require, for example, a 20-metre pollen trap or pollen buffer to prevent pollen from transferring to neighbouring crops whilst the trial crop is being grown. When the trial is harvested, there is a requirement that it be harvested completely separately from any cotton that is used commercially. When the trial crop is ginned, it must be dealt with completely separately from any commercial crops. It is really the controls that the regulator puts in place to separate it from commerce that are critical to preventing that. That has worked successfully. There have been 24 licences for cotton field trials of that nature, and in a number of other crops, without any discernible impacts.

Senator ADAMS—We have heard stories from Canada about neighbours and cross-pollination and someone ending up with GM when they have not been growing it and all that sort of thing. How are we going to deal with that, because these are the issues that are going to come from community consultation?

Mr Penna—I guess it is important to distinguish between the dealings and the sorts of dealings that this legislation covers. I cannot state with any certainty about what is happening in Canada, but I think they would relate to dealings once the regulator has approved them commercially. I do not believe they relate to limited and controlled dealings. When the crop becomes commercial then our position is in many ways outside the scope of this particular review because this act pertains largely to human health and the environment and to the protection of the safety of human health and the environment. I am not here to comment on those issues, because how they can be managed is currently being considered by a range of jurisdictions around the country and by the industries involved. That is very much my position.

Mr Khoo—Senator Adams, if you would like information about what is happening in Canada, we can undertake to provide you with more information.

Senator ADAMS—That would be good, thank you.

Senator SIEWERT—We heard earlier from Mr Phelps about GM turning up around Mount Gambier—and I think you were here.

Mr Penna—That was about crops that had been designated as safe by the regulator and allowed commercial release. The contamination, for want of a better word, did not relate to dealings under the act but rather to matters under state jurisdiction.

Mr Khoo—On the contamination in Mount Gambier: there has been no contamination in Mount Gambier. We do trials in Mount Gambier, and they are all done under state legislation that has very strict containment conditions in it. There has been no instance of contamination in Mount Gambier. The so-called contamination refers to the finding of some GM canola in non-GM canola of the variety called Grace, and that happened a couple of years ago.

Senator SIEWERT—So why is that not contamination?

Mr Khoo—It was not in the Mount Gambier region.

Senator SIEWERT—I beg your pardon—it was in another region.

Mr Khoo—Yes, it was a different thing.

CHAIR—Thank you very much, Mr Penna and Mr Khoo, for your evidence this afternoon. Thank you for wearing so many hats at the one time in front of the committee.

[4.09 pm]

ADDISON, Ms Linda, First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing

MURNANE, Ms Mary, Deputy Secretary, Department of Health and Ageing

MEEK, Dr Sue, Gene Technology Regulator, Office of the Gene Technology Regulator

CHAIR—Welcome. As departmental officers or agency heads, you would understand that you are not being asked to give opinions on matters of policy. That does not preclude questions being asked for explanations of policy or factual questions about when and how policies were adopted. I think you are all familiar with the rules of parliamentary privilege and protection of witnesses.

We have received short submissions from both the OGTR and the department. I want to thank you for coming a little bit earlier than was originally scheduled to be here today; that helps us to keep things moving along. We are grateful for that. Before we ask you questions about the various issues which have been raised in the hearings this afternoon, I would invite you to make, if you wish, an opening statement about the issues that the committee is examining at the moment.

Ms Murnane—Thank you. I do not think I will make an opening statement. I will just say the department is here with the Gene Technology Regulator, and that represents the distinction between the department's role and the role of the Gene Technology Regulator and the Office of the Gene Technology Regulator. We are there to provide advice on policy, including the policy around regulation and the policy around legislative changes, and the Office of the Gene Technology Regulator has the onerous job of executing the legislative requirements. That is why you have both the department and the agency here.

CHAIR—Is there anything you wish to say at the opening, Dr Meek?

Dr Meek—I did not want to add anything to my submission, thank you.

CHAIR—We might deal with a number of issues thematically, so we might all of us come in as we see fit. Perhaps we might turn first of all to the question that has been raised by Greenpeace and Gene Ethics about emergency dealing determinations. There have been, as you would be aware, a number of criticisms of the wide ambit of the emergency dealing determinations provisions in part 5A of the bill. The question that has been raised is whether these powers are excessive, given their capacity to be misused—for example, to release untested or inadequately tested GMOs into the community in order to confront a so-called emergency. Could I ask you to outline to the committee, to the extent that it is possible, what kind of emergency we might be talking about that is envisaged by this legislation.

Ms Murnane—I will give you a precise one: we might have either a livestock disease in Australia or a human disease in Australia where the defence against that was a vaccine that included a genetically modified organism. To allow the rapid importation of that vaccine into Australia, there would need to be a pathway that was much faster than the pathway as laid down in the act for all normal circumstances. This would be regarded as a power that would only be exercised, as a clause that would only be exercised, where there was serious and

imminent risk to Australia in the form of some sort of economic threat, say, to animals, or some form of human threat, say, in the nature of an epidemic—and we are not saying that this is going to happen imminently, but we need to be prepared should there be an influenza pandemic or another disease where we needed a rapid decision made to import a pharmaceutical, probably a vaccine, that contained a genetically modified organism.

CHAIR—Have there been any emergencies of that kind in Australia? Obviously, we might not necessarily have had a response that included some kind of GMO, but have there been any emergencies in the last decade or so where such a power might have been exercised had it been available?

Ms Murnane—To my knowledge, no, but I will ask Dr Meek to comment on that.

Dr Meek—I am certainly not aware of any either, but I am aware that the emergency provisions that have been suggested by the review panel and agreed by governments is not dissimilar to the ones that exist in other comparable agencies.

Ms Murnane—The Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Regulatory Authority.

CHAIR—So, as far as you are concerned, these powers reflect the structure and the intent of those sorts of emergency powers?

Ms Murnane—They are last-resort powers. They would be used sparingly and they might never be used at all, but, if they were needed, they would be there to be invoked. I would also say that there are, even with the use of these powers, very stringent safeguards around their use. For example, the Gene Technology Regulator cannot consider an emergency licence at all unless there is a recommendation from the Chief Veterinary Officer and the Chief Medical Officer.

CHAIR—A recommendation in favour of that licence?

Ms Murnane—Yes—or, I should say, because you would not expect to be importing both vaccines simultaneously, although you might.

Dr Meek—May I add that there is a second component to that. Not only must there be a recommendation from people who are well versed in determining whether or not there is an emergency situation, which is not for me to determine, but also I would have to consider whether or not I believed that the risks to people and the environment could be managed. As Ms Murnane has mentioned, it is a fairly stringent test that needs to be gone through.

CHAIR—You would accept that there is a high level of risk associated with releasing into the environment a GMO which has not yet passed all of the appropriate tests that your office would undertake, Dr Meek, wouldn't you?

Dr Meek—I accept that there is potentially a hazard there which would have to be evaluated to determine whether there actually was risk. This is getting into the kind of detail of the process that we go through, but a hazard is something that has the potential to cause harm, while a risk is only when there is a determination that harm may eventuate. So, certainly, such a thing may be hazardous, but there needs to be consideration of whether it actually does pose a risk. Of course, the requirements of the act are that, if I make a determination that something may pose a risk to people or the environment, I then have to

make a determination as to whether or not I believe those risks can be managed. So there are several stages to actually coming to a decision on whether or not to proceed.

CHAIR—Any questions about this particular power? Senator Moore?

Senator MOORE—Ms Murnane, the explanatory memorandum to this bill does point out the fact that it is similar to the other two pieces of legislation providing emergency powers. Are they so similar that they are almost the same? I did not go and check. Particularly under your area, having the TGA and gene technology together, would they be shadowing each other?

Ms Murnane—It is modelled on the Therapeutic Goods Act, yes.

Senator MOORE—They are both under your department, so they would be—

Ms Murnane—The Therapeutic Goods Act is, yes. The veterinary medicines legislation is not.

Senator MOORE—I did not check.

Ms Murnane—That is under DAFF, the Department of Agriculture, Forestry and Fisheries.

Senator MOORE—The discussion we had earlier—I am sure your officers told you about it—was with people who felt that the degree of urgency around these emergency powers was not fully discussed in the consultations leading up to this particular process and that, whilst the explanatory memorandum talks about the degree of consultation on the changes in this bill, there was a view that the import and the impact of the emergency legislation was not fully understood or discussed when people agreed to it. I asked specifically if there had been extensive debate in the various elements of the consultation, and the witnesses said no. They then went on to say they did not think the lack of debate was because people understood the legislation. In your understanding, both yours as the regulator, Dr Meek, and yours as the department, Ms Murnane and Ms Addison, do you believe that the people who were involved were aware of the import of part 5?

Ms Murnane—There was extensive discussion on the emergency powers at a ministerial meeting of the advisory committee on gene technology in Adelaide in October last year. Some misgivings were raised by a small number of jurisdictions, but went down to one. But, as a result of that meeting, we talked about how these powers would be administered. We agreed on the safeguards of the Chief Medical Officer and the Chief Veterinary Officer and agreed that there would be consultation to the degree that was possible, given the emergency, with all ministers.

Following that, in early December or late November last year, there was a meeting of the Gene Technology Ministerial Council. Issues on the emergency powers were also raised by one jurisdiction. The parliamentary secretary, Mr Pyne, who had responsibility at that stage, answered that and, when the meeting ended, there was agreement on all the clauses of the act. Following that, we continued to refine the detail around the administration, particularly of emergency powers. There were a number of other parts of the act that we were still talking about, and that was then agreed. We had a final teleconference with the jurisdictions about two months ago, and Dr Meek will talk about another meeting since. So there really has been

a lot of discussion around this, and that is reasonable because it is an emergency power that gives a faster pathway without some of the same station stops as there are in the act generally. But we are dealing with an extraordinary situation here.

Dr Meek—As Ms Murnane has discussed, there have been a number of ongoing discussions. The states wanted to explore this very thoroughly and indeed have done so. One other thing that I think has given some greater structure to the discussion has been a decision to also develop a guideline. It is very difficult to plan for something when you do not know what it is. We have obviously been racking our brains as to what the emergency things might be and have been trying to work around that as an issue. That was why the idea of putting these guidelines together came up.

Ms Addison—To add to the conclusion, as Ms Murnane and Dr Meek have said, there have been a number of discussions at the ministerial council level, at the standing committee level and at a working group level. As part of those discussions, which commenced in Adelaide last year around these issues—or probably a bit before that—we have worked up some guidelines in consultation with the states and territories that go to ‘operationalising’, if you like, how things will be managed in the case of an emergency. Those guidelines were signed off at the last steering committee and will be considered by ministers on 4 May. I cannot release them for you today because they still need ministerial consultation, but after 4 May, if the ministers agree with them, we would be happy to share them. I should add that there has been extensive consultation with the states and territories, and I think it is fair to say that there has been no rollover in terms of the discussion. It has been very vigorous and very carefully worked through to come to a position where the states were comfortable. I should add that getting comfort on this issue was one of the things that were critical to the states and territories and to their ministers signing off on the legislation.

Senator MOORE—That is really comforting because, in terms of the evidence we had, there did not seem to be certainty that that had happened. When I checked the website, the final sentence of the joint communique of 27 October 2006, which I think would be the key meeting, was:

New arrangements for dealing with emergencies will also form part of the changes.

Obviously it has moved on since then, but in terms of the public stuff on the website that is the last bit. That is very positive.

Ms Murnane—That is a good suggestion and we would look at putting in more detail about the administrative procedures that will be underlaid by guidelines.

Senator MOORE—That would be useful.

Senator SIEWERT—The Gene Ethics submission expressed concern—you probably heard the evidence—that there was not enough definition around what constitutes a threat. How can the community be confident that the two examples you have just used, which were good examples, are the types of things that would be the subject of these emergency provisions?

Ms Murnane—I understand the Gene Ethics concern—and they used an example—was that these powers could be used to override the state moratoria. But that is not their purpose. This has to be an imminent and serious risk, so it cannot be something to leverage a preferred

policy position on the part of anybody. That is simply not possible. We have to be facing something that is imminent and very serious and, what is more, there has to be a well-established view, supported by the Chief Veterinary Officer and/or the Chief Medical Officer, that what we are talking about importing is very likely to be a defence against this threat or that it is the best defence we are going to have and that if we do not use it there is going to be risk to either the population or to the economy. So it could only be used where there is a severe and imminent threat.

In terms of whether there could be such a threat that would be alleviated by allowing the importation of a food, I will ask Dr Meek to comment on that. But I would consider that it is so unlikely as to be virtually off the scale that the importation of a genetically modified organism to grow a food would be able to alleviate an immediate threat. For one thing, there is a passage of time there.

Dr Meek—I find it very hard to imagine how a plant of any variety could be classified in an emergency sense. And, as I said, there is the second element of the assessment: once there has been the assessment by the people who are experienced in determining whether there is a threat—which is not proposed to be the regulator; it is proposed to be people who do that as a matter of course in their current duties—the regulator then has to make a determination about whether or not there are risks posed to people or the environment. In all conscience, the regulator has to make a recommendation to the minister to say, ‘That is what we believe is the situation.’ In the context of things like plants, quite apart from the fact that I find it hard to imagine how there could be an emergency around a plant, there would need to be a situation where we had the data about what this would mean in the context of growing it in the Australian environment, and there is unlikely to be that data to be able to form an opinion.

Ms Murnane—The normal procedures under the act are cautious and thorough and they are also quite long. Ms Addison has just reminded me that there are 170 days for the regulator to consider an application in the normal course of events. Clearly, that is far, far away from an imminent and serious threat, which is what we are talking about now. Remember, this is in legislation. Although I know they have used a number of examples this is not something that is uncovered by law, and if anybody were to attempt to use or to invoke these powers for something that was later found by a court not to be a serious and imminent risk then there would be severe consequences. I do not think policy makers and decision makers would be taking this decision lightly at all. It certainly could not be used to get some sort of leverage over a policy position that was simply thought to be a desirable one. That does not come within the meaning of ‘imminent and serious’.

CHAIR—There being no other questions on this issue, can we move on to the question of controlled release of GMOs. A number of points were made about that. I want to turn first of all to what Greenpeace said about that. On page 2 of their submission they have said that, under the provisions of proposed section 50 and 50A, if the regulator is satisfied that the controls and limits of controlled release—field trials—are appropriate, the regulator need not seek advice from the states, the Gene Technology Technical Advisory Committee, Commonwealth authorities, environment ministers or local councils. Is that in fact the case?

Dr Meek—No.

CHAIR—It is not the case? In what circumstances is consultation with those bodies required before controlled release is approved?

Dr Meek—Perhaps I can quickly compare the two proposals, and I hope it will be a little clearer then. Obviously one can always wish to be clearer. At the present time, all applications for a release into the environment require two rounds of consultation. One is on the application, and the question that is asked is: are there issues that the people who are consulted, who are the Gene Technology Technical Advisory Committee, the environment minister, various other Australian government agencies and relevant local councils—have I missed anybody out?

Ms Murnane—No.

Dr Meek—Good. That grouping is consulted at that point in relation to the application, and then when a risk assessment and risk management plan is prepared by my office that same group of people is consulted, as is the public. There is an extra rider in there that the public would be consulted if there were a significant risk determination. I think there will be separate questions about that so we can leave that aside for the moment. The proposal in the context of the controlled release is that, rather than having two rounds of consultation—one on the application and one on the risk assessment and risk management plan—there will be one round of consultation when the risk assessment and risk management plan has been prepared.

The rationale for that is that looking at the application on its own, without an understanding of what assessment has been reached, is somewhat limiting. It is more helpful to actually go through the whole process of looking at what we believe the risks may be, determining whether or not there are any there, whether they need to be managed and what measures might be imposed through the licence conditions, then laying that out as part of the consultation process for this mixture of experts, agencies and authorities that we consult with as a matter of course, as well as for the public.

That is the differentiation. So it is not a matter of removing them from the consultation. They would still be consulted; it would be one round of consultation in a situation where there are significant measures that have been proposed by the applicant to limit the spread and persistence both of the GMO itself and of any introduced genes.

CHAIR—Thank you for clearing that up. It has also been argued by Monsanto and a number of other companies with a commercial interest that section 50(1), including the words that the controlled release can occur to conduct experiments, effectively winds back the present provisions of the legislation which allow controlled release in other circumstances, such as to test the compatibility of GMOs with certain soil types or whatever, and that this winding back means it will be harder to prepare for the release of GMOs in a commercially effective way, among other things. Do you accept that the provisions are indeed a winding back of the present arrangements?

Dr Meek—No, I do not, Senator. If we think about it as a situation where we have a process now which is not proposed to change—we have the two rounds of consultation. The other type of application that is being proposed is the controlled variety which must be for experimental purposes, which, if you like, is a reduced version of the consultative process that happens now because it has that one round of consultation removed. I do not understand this

perception that suddenly some forms of experimental work are not going to be covered. I do not quite follow the logic of that understanding. At the moment, all intentional releases must go through this comprehensive process which essentially is proposed for things that are for commercial purposes, ultimately to commercial release; and for situations where it is mainly experimental and it is under limited and controlled conditions, there would be a one-round consultation process. If anything, there is an opportunity for enhanced research and development as a result of this process, provided that the applicant can indicate that there are measures proposed which will limit the spread and persistence of the GMO and its introduced material into the environment.

CHAIR—But even in the context of where you would have the shortened consultation process under 51A, is it appropriate to limit that only to circumstances where the applicant is to conduct experiments with the controlled release or should there be wider use in those circumstances such as to prepare for a commercial release down the line?

Dr Meek—If it were easy to make this division, probably there might have been a differentiation in the first round of the development of this legislation. To a degree, there is a matter of judgement involved here. Again, certainly it is our intention, if the amendments are approved, that some form of guidance would be issued to assist with this, but it will have to be pretty much in a case-by-case situation of making a judgement as to what is reasonable in this context. Obviously I have read the submissions that have come in. For example, the suggestion that the commercial seed increase for sending out seed to somewhere else in Australia where it is approved for commercial release is clearly a commercial dealing. It then becomes a matter of judgement in the context of what the act is intended to do. It is intended to oversight the use and development of genetically modified organisms, and there is a continuum on this basis.

There is an anticipation that it starts off usually in contained facilities, then glasshouse, then limited control trials of increasing scale towards commercialisation. There are multiple points along the way where data is being gathered for a range of purposes, one of which is to satisfy the regulator that conditions that have been imposed are suitable for containing that release to the size and duration that it was intended to be released for, but it is also anticipated that experimental data could be gathered to get information on the agronomic performance of a plant in the environment in order to enable the company to determine whether or not the GMOs it is trialling are actually going to become something that is going to perform as a commercial product.

There is a third type of data collection for which, if it becomes a commercial product, there may be other regulators that the applicant has to satisfy. For example, if it is in the realms of something that is herbicide tolerant, there will be information that the Australian Pesticides and Veterinary Medicines Authority require. All of those are experimental. Maybe there is a perception that experimental means only the information that the regulator needs for the performance of the GMO in the environment in relation to regulation, but I think it is accepted that there are a range of different types of research that could be conducted under these limited control conditions for which there would be no impediment in relation to the amendment bill.

CHAIR—Are there any questions about the controlled release issue?

Senator SIEWERT—I have a couple of things. One is the removal of section 49. If I understood correctly what you just said, you have taken away one of the rounds of consultation over dealings under that section of the act, but the things that are required to be done under section 49 are still required but under the one round of consultation rather than the two. Is that correct?

Dr Meek—It is a little more than that. There is not a removal of section 49.

Ms Addison—I could probably add to part of Dr Meek's answer there. Senator, you will find that section 49 has been moved. If you go to page 24 of the bill, you will find that section 49 is now paragraph 52(2)(b) and paragraph 52(2)(d) of the new bill. So it has not been removed. It is still there; it has just been moved. I will hand back to Dr Meek now.

Dr Meek—Thank you. That was the point I was about to make. The consultation has not changed in the sense of the range of experts, agencies, authorities and the public. But, if I can revisit it again, in the current bill a decision under section 49 has to be made on essentially a preliminary determination of the application by the regulator. It is a very short period of time and it does not give my office the opportunity to have the sort of in-depth look that we would prefer to. It means that we may be raising a view that there may be a significant risk which, on further investigation, may not be the case. It also may be the obverse: that we become more convinced of it. But the idea of moving the requirement for section 49 up until the point when the risk assessment, risk management plan is being released is along the lines of what I said earlier. If people have the opportunity to see the development of the assessment, to have a view as to—in this case, if we are talking about something where a significant risk is determined—what the risk is and what measures might be proposed to manage it, that means that it is much clearer than having a situation in which people can only look at the application, which is a very technical document which is quite convoluted in its structure.

There is a very good argument, I think, that being able to see the risk assessment, risk management plan as well as the application, if people wanted to see it, at that point gives a much more informed situation. On top of that, if the regulator has determined that there is a significant risk then there is also to be an extension required in the legislation of the minimum time period that I must allow for consultation. So it is trying to open up the situation rather than to remove it.

Senator SIEWERT—So people can still get the original application, get your assessment and, as you have just said, there will be an extension if it is required.

Dr Meek—Yes.

CHAIR—Turning to the question of the composition of the committee that is proposed under proposed section 108 of the bill, we understand that there are two committees which are being merged for that purpose—to make it a single consultative committee. It has been put to us that those two existing committees have different contexts or different terms of reference. One deals with ethics and the other has a different focus. Surely we would get better consultation with two filters or two processes than simply one. Why merge those two into one?

Ms Addison—I think that is something that directly came out of the review and the consultations undertaken as part of the review. I think there was a sense that the consultation

committee and the ethics committee had a degree of overlap in terms of consideration of the issues. The review saw benefit in bringing the two committees together so that the consultation still occurred and, clearly, that the ethical considerations still occurred, but within a streamlined consultation process which would enhance the operation of the act and assist the regulator.

Dr Meek—As a matter of assurance, there has been no loss of function. The two functions of the committees have been brought together, so there is no reduction in the oversight in that sense.

Ms Murnane—And there are no changes to the eligibility for membership of the new committee.

Ms Addison—There are not proposed to be. I think some of the submissions might have suggested that, but it is not proposed as part of the regulatory changes.

CHAIR—How many members were on the two committees compared with how many will be on the single committee—that is, how many fewer people will be involved in the process of consultation?

Ms Addison—It was 12 on each. I think there are intended to be 12 on the new committee. So it is half.

CHAIR—So halving the number of people involved in the process is not a loss of feedback to the process, to the exercise?

Dr Meek—It comes down to the point that Ms Addison raised, which is that the committees were having difficulty in distinguishing their roles. It is a situation where trying to get the views in the same room at the same time might actually enhance the quality of the advice rather than trying to in some ways artificially separate these two things. It is very hard to draw the line between the concerns of the community and, if you like, the more formal ethical consideration. The review panel formed this view based on advice. At least the ethics committee put in a strong submission that they felt that their deliberations would be enhanced significantly if they could cover these two areas.

Senator SIEWERT—There are different types of expertise for community consultation and, to a certain extent, ethics. Concern has been expressed that you may lose some of that level of input by having one committee. Was thought given to expanding—I hate to say it—the size of the committee? I know it can start getting difficult.

Dr Meek—Just to make life even more difficult, all of the original expertise was wanted by the two committees, but there was also the addition of things to do with risk communication. I have a mental blank on one on the other hand them, but there were two additional things. It was a recognition that an additional level of expertise might be required in communication with people with solid expertise in that area. This may well provide an opportunity for a different mix in the membership.

We go through a very broad consultation process in trying to identify nominees for these committees. People do not come with just one skill. This is also true in the technical advisory committee. People may have a predominant area of expertise but they often know a lot about other areas too. So, to some extent, it depends on identifying really good candidates and

getting a good mix. That obviously comes down to the appointment process, which the states and territories are consulted on at length, and we have a cooperative process for those appointments.

Ms Murnane—Senator, in answer to your question, if you look at the membership clauses in the bill, you will see that it states:

(4) The Minister must ensure that the Ethics and Community Committee includes the following members:

- (a) a person who is a member of the Gene Technology Technical Advisory Committee;
- (b) a person who is a member of the Australian Health Ethics Committee.

So that is getting expertise. The other criteria that the minister must have regard to are broad, but it means that you can have people who have an interest in this, who are experts in community consultation and who have an interest in issues relevant to local government and issues of concern to consumers, religious practices and human health represented in the committee along with some experts on the technical areas and on the ethics area. There is a new category added—that is, that the minister is able to appoint a person who is expert in risk communication.

So you have one committee where there is overlapping concerns. In principal committees that have a number of sub or advisory committees, it is common to see a lot of synergies between the committees and the need for those committees to communicate. In this instance an amalgamation was suggested. That was taken up by the review in its recommendations and they have been accepted by the government. I think there is streamlining rather than loss.

Senator MOORE—Where does the term ‘risk communication’ come from? Is that a new group? Is that something that we have experts in? I heard that earlier. I am wondering whether risk communication is now an industry that we recruit from.

Dr Meek—I suppose it is part of the jargon, in the sense that it is international best practice in looking at risk analysis as a field. There are three components: risk assessment, risk management and risk communication. They are the three pillars or, if you like, concentric circles or whatever the diagram that you want to see. So we clearly have considerable expertise in both risk analysis and risk management in the context of the Gene Technology Technical Advisory Committee. So we saw the role of this third committee as one of providing advice in this other context.

Senator MOORE—So the skills that you have already identified in the technical committee can now be translated into the other new committee.

Dr Meek—It is more that there are these three elements; you need those three components to have a comprehensive risk analysis. As I said, it is the sort of internationally accepted terminology in this context.

Senator MOORE—I am sure it is, but I just have not seen it in all the other committees that we deal with.

Dr Meek—The risk analysis framework that we have actually lays that out, if you are interested at all.

Senator MOORE—Yes, I read that.

Dr Meek—There is a diagram in there that talks about—

Senator MOORE—Yes, the little circle in the middle there.

Dr Meek—Yes, there are lots of circles, unfortunately, in these diagram situations, but that is there too.

Senator MOORE—We had evidence—and I know you have seen it—from people about the importance of having on these committees people who are not public advocates of one side or another. Have you seen dysfunction operating that would lead to people having those serious concerns about the make-up of whatever the new committee is going to be? There is no objection to a new committee, and a smaller one—it always fascinates me when people support a smaller committee, probably in the hope that they will be selected and others will not. Has there been that degree of conflict in this area, where people who have very strong views one way or another—which seems to be the issue in many areas but no more so in yours than in others, I would imagine—a number of people experienced in the field, put forward in submissions that they think there should be a removal of advocacy from the committee?

Ms Murnane—This is something you strike with all committees where people are members because of their individual expertise or because they are representing a particular segment or group. Some people are more inclined than others to see things through the prisms of their own beliefs. But in something like this, where there is a high level of community interest and community concern, for those polarised ends to be subject to some debate and challenge within the committee and for people who are experts in one or another of the disciplines underlying it to be able to put on the table knowledge—and we talked about risk communication; there is risk in everything—that might result in some sort of opposites coming together is, I think, a good thing. If you exclude people who had a belief one way or the other, it becomes very difficult. On the other hand, I think that it would be difficult with somebody who was an extreme advocate of either side and had shown no signs of being interested in debate. but there is a process here and it is not the Commonwealth minister alone who appoints people to this committee, and I think it most unlikely that ministers would agree to appoint somebody who was taking up a very zealous advocacy position.

Senator MOORE—Either way.

Ms Murnane—Yes. But if you said, ‘Look, anyone who has ever spoken on it cannot be a member of the committee,’ then the situation would be bogged down. The right of somebody to be on the committee that was agreed by all ministers could be challenged by saying ‘this person said something at some time’.

Senator MOORE—Is there a process for revoking membership?

Ms Addison—No, I do not think so.

Senator MOORE—I do not need to see it; I have not got that far on the web. But there is a process whereby you yourself could leave or you could be kicked off it if you did not perform or if there was concern about your performance?

Ms Murnane—I think we had better get a specific answer to that. It is framed around diligence and commitment. For example, somebody who did not attend meetings—

Senator MOORE—I wish more things were framed around diligence and commitment. And that is determined by the group?

Ms Murnane—Yes. The chair would say to the minister, ‘Look, there is no point in having person X on this committee; he or she never appears.’

CHAIR—Are there any other issues arising from the evidence that members wish to raise with the officers? No. Thank you very much for your appearance today. It has been very useful and it has helped us to form a view about the legislation. We are grateful for the submissions and for the live evidence today.

That concludes our hearing into the Gene Technology Amendment Bill. We are due to report on both the food bill and the gene bill by Tuesday of next week. I hope to have a draft of the two separate reports to members of the committee by the end of this week. If we need to, we could have a meeting on Tuesday of next week when we are again due to be in Canberra for a further hearing to consider that draft—if we cannot settle it over email. I thank the officers who have been involved today from the department. I thank the other witnesses who have taken part in today’s proceedings. I thank Hansard for their assistance and the committee secretariat for their continuing fine support to the committee. That concludes our proceedings.

Committee adjourned at 4.56 pm