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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON PRIMARY INDUSTRIES AND REGIONAL SERVICES

Reference: Primary producer access to gene technology

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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON PRIMARY INDUSTRIES AND REGIONAL SERVICES

Wednesday, 5 April 2000

Members: Fran Bailey (*Chair*), Mr Adams, Mr Andren, Mr Horne, Mr Katter, Mr Lawler, Mr Ian Macfarlane, Mr Leo McLeay, Mr Nairn, Mr Secker, Mr Sidebottom and Mr Cameron Thompson

Members in attendance: Mr Adams, Mr Andren, Fran Bailey, Mr Griffin, Mr Horne, Mr Lawler, Mr Ian Macfarlane, Mr Leo McLeay, Mr Nairn, Mr Secker, Mr Sidebottom and Mr Cameron Thompson

Terms of reference for the inquiry:

To inquire into and report on the following areas, with particular emphasis on the capacity of small and medium sized enterprises to access the benefits of gene technology:

- the future value and importance of genetically modified varieties;
- the ability for producers to compete using traditionally available varieties;
- the commercialisation and marketing of agricultural and livestock production varieties;
- the cost to producers of new varieties;
- other impediments to the utilisation of new varieties by small producers;
- assistance to small producers to develop new varieties and the protection of the rights of independent breeders, in relation to genetically modified organisms;
- the appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms; and
- opportunities to educate the community of the benefits of gene technology.

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Committee met at 5.05 p.m.

CAIN, Ms Elizabeth, Assistant Secretary, Interim Office of the Gene Technology Regulator, Therapeutic Goods Administration

MATTHEWS, Ms Andrea, Legal Consultant, Interim Office of the Gene Technology Regulator, Therapeutic Goods Administration

PITTARD, Professor Jim, Chairman, Scientific Subcommittee, Genetic Manipulation Advisory Committee, Interim Office of the Gene Technology Regulator, Therapeutic Goods Administration

SLATER, Mr Terry, National Manager, Therapeutic Goods Administration

CHAIR—I declare open this public hearing of the inquiry by the House of Representatives Standing Committee on Primary Industries and Regional Services into primary producer access to gene technology. Today's hearing is a continuation of the hearing held on 15 March, which unfortunately could not be completed on that day.

I advise the witnesses that the committee's public hearings are recognised as proceedings of the parliament and warrant the same respect that proceedings in the House of Representatives demand. Witnesses are protected by parliamentary privilege in respect of the evidence they give before the committee. Witnesses will not be asked to take an oath or to make an affirmation. However, they are reminded that false evidence given to a parliamentary committee may be regarded as a contempt of the parliament. The committee prefers that all evidence be given in public, but should at any stage any witnesses wish to give evidence in private, you may ask do so and the committee will give consideration to such a request. I now call the representatives of the Interim Office of the Gene Technology Regulator and the Genetic Manipulation Advisory Committee.

At our hearing on 15 March, Mr Slater began by making a brief statement to us. As the regulation of GM crops has been in the news recently, I thought I would give you the opportunity to add any comments that you might like to make to your previous opening statement.

Mr Slater—Thanks. I do not have any specific comments I wish to make in relation to the press comment. I want to reiterate that we have had out for public comment the draft bill, which we intend to bring to the parliament at the first available opportunity we have. That bill has been the subject of extensive public consultation. I think a lot of the press comment that has been around in the last week or so has given opportunities for some exploration of the proposed legislation and how it would deal with some of the issues.

CHAIR—Thank you. I think a good place for us to start this afternoon would be if you could take us through the main features of that legislation. I understand that you have some overheads that you are going to take us through. If I could I will just explain that this afternoon's hearing is high-tech in that not only are we being broadcast throughout the building but also we are live on the Internet. When you refer to any points on the graph, if you could explain for the *Hansard*

reporters exactly where you are referring to on your graph so that those watching this broadcast will be able to understand.

Overhead transparencies were then shown—

Ms Cain—Madam Chair, we thought it might be useful to take the committee through some key issues today. We would propose taking you through the responsibilities of the Interim Office of the Gene Technology Regulator, the development of the legislation to regulate genetically modified organisms working within the parameters of government decisions taken to date, and then take you through the regulatory system. I will be guided by members of the committee as to the areas that you would like us to focus on in that presentation.

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Briefly, the Interim Office of the Gene Technology Regulator has two major functions. The first is to oversee administrative arrangements, including providing secretariat support to the Genetic Manipulation Advisory Committee until the new regulatory system is established. Then, secondly and importantly, it is to work with Commonwealth agencies, with state and territory governments and with a wide range of non-government stakeholders to develop the new regulatory system for genetically modified organisms.

We are working within the parameters of some government decisions that were taken in the context of the May 1999 budget. The key elements of the government decisions were that an Office of the Gene Technology Regulator would be established, headed by a statutory office holder. The regulator would derive its powers from state, territory and Commonwealth legislation. This is not just a regulatory system relying on Commonwealth legislation being passed by parliament. An important element of the regulatory system is that we achieve minimum duplication and overlap with existing regulators and we would like to take you through that in a bit more detail shortly. The original decision was that the new Gene Technology Regulator would be fully operational by July 2001. Government has since revised that operational date back to 3 January 2001.

The policy objectives underpinning the new regulatory system, which will replace the administrative one, are that, first and foremost, the regulatory system has to protect the health and safety of the community and protect the Australian environment from any risks associated with genetically modified organisms. We have a requirement on us that the new regulatory system be based on a scientific risk assessment process but that it also factor in some broader considerations, including ethics considerations. As I mentioned, we are required to operate in conjunction with existing regulators and to avoid unnecessary duplication, which leads into the requirement for an effective, efficient regulatory system that is nationally consistent, bearing in mind the need for state, territory and Commonwealth legislation to be passed. We are required to develop a regulatory system that is transparent and accountable in the decisions made under the regulatory system, it should include extensive community and stakeholder input into the decisions made by the regulator, and, importantly, it should provide a streamlined and efficient path for industry. They are the key policy parameters that we are operating within in the development of this legislation.

A brief update on where we have got to thus far: since Dr Wooldridge as the Minister for Health and Aged Care was given the responsibility for developing this regulatory system with states and territories, states, territories and the Commonwealth have firstly produced and disseminated a discussion paper on the new regulatory system. We referenced it at our earlier appearance before the committee. It was circulated in October last year with an overview that complemented the discussion paper. That was circulated around, including to members and senators in October last year.

CHAIR—I think we made the point to you at our last meeting that we actually did not get that paper.

Ms Cain—That is right, you did. I am not sure what happened there, but thank you for the reminder. We will definitely follow that up.

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The discussion paper was a plain English guide to how a new regulatory system for genetically modified organisms might work. We really wanted to go forward with a plain English guide rather than having the first contact with the community being draft legislation that is difficult for people not familiar with legislative frameworks to follow. So we put out some proposals in the orange book and we went through a series of national consultations. In each state and territory we met with primary producers, researchers, industry, health professionals, community groups, environment groups—basically anyone we could find who was prepared to talk to us about what the regulatory system would look like. We also invited written submissions. The written submissions and the public consultations enabled us to proceed with the states and territories to develop an initial draft bill and an explanatory guide, another plain English guide. Those were circulated directly to around 2,500 people that we have on our mailing list, our database. We advertised it extensively in around 30 newspapers around the country, posted it on the web site and encouraged people generally to access those documents.

Mr SECKER—What was the regional centre?

Ms Cain—In relation to the draft bill there were three regional centres. We went to Rockhampton, Tamworth and Albury-Wodonga.

Mr SECKER—Is that likely to be expanded?

CHAIR—Patrick, if we could just get through the introduction and then we will open up for some questions.

Ms Cain—Once the draft bill was out there, we had a series of public meetings. We advertised in the newspaper for people to attend open public meetings to walk through the proposed regulatory system with us and to provide us with input. We got a pretty good roll-up to the public meetings. In large capital cities like Sydney and Melbourne we got 150-plus people. In the smaller centres, it was down to as few as 15 or so people. So the interest—

Mr HORNE—What was the background of the people who attended the meetings—industry based or what?

Ms Cain—It was very diverse. We got a number of people who were just interested members of the community who did not work with the technology. They were just aware of the legislation and interested to talk through the system. Industry, including Australian based industry. Others who attended were a lot of individual farmers and their representative groups across a fairly broad range of areas, a lot of researchers involved with institutional biosafety committees, and health professionals—there was a very wide range at the public forums. We could provide to the secretary a list of attendees at each of those forums, if the committee were interested.

In relation to primary producers—we were just touching on whom we were consulting with—the consultation has been at a number of different levels. We have talked to national organisations like the National Farmers Federation and to a number of state based organisations. Also, on a 'by sector' basis, we have talked to people from the Bee Keepers Association, the Northern Territory Cattle Farmers, the Grains Corporation, the Red Meat Association, pork producers and the poultry farmers. There was a fairly broad range. As I said, a number of individual farmers came along and also wrote in with their submissions. We will table for the committee a copy of the relevant submissions received to date where we can clearly identify that they are from a primary producer background.

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Of the issues that primary producers were signalling—this is obviously just an overview summary—as areas of interest or concern, one was the need for a one stop regulatory shop. We will cover in a moment the interface between this regulatory system and the existing regulators. There was concern about the multiplicity of regulators acting in the GM area and what we were going to do about that. The proposition of 100 per cent cost recovery for the agency was a concern for most stakeholders that we dealt with, including primary producers.

Across the board people emphasised the need for an independent regulator and they were interested to know what powers were being written into the legislation to ensure the independence of the regulator. There was some interest in proposed amendments to the Environment Protection and Biodiversity Conservation Act, but they came through mainly in submissions rather than during the public forums. They were concerned about transparency and accountability leading to public confidence. There was a concern generally about the lack of public confidence in the use of GMOs and the benefits of having a transparent, accountable regulatory system.

They were also very clear about their right to choose. It was about the availability of the technology but not the enforcement of adoption of the technology. Segregation as being a market issue rather than a regulatory issue or an issue to be dealt with in the regulatory system was one of the overriding messages. And statutory time frames for decision making was also particularly important.

Mr ADAMS—Can you just go back over segregation being a market issue?

Ms Cain—One of the big issues that we talked to people about was the issue of contamination, gene transfer from a transgenic crop to an organic crop or a traditionally farmed crop. People felt that the regulator should be able to impose conditions to manage contamination but that the systems management within farms to meet a GM marketing potential was something that should be dealt with as a sector issue and industry issue.

CHAIR—Ms Cain, perhaps I could just interrupt you for a minute. When I asked you to go through the outline of the steps that were taken to reach the draft legislation, I was envisaging that you would give us some headlines and then we would come into those in greater detail. I think probably what we really need is an overview of the steps that you have taken and then we will come in and ask specifically about the main concerns that you have started to cover.

Ms Cain—Okay. The regulatory system as it is currently drafted has an object of protecting the health and safety of the people and protecting 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. The governance structure, very briefly, within the draft bill sees a Gene Technology Regulator who is responsible for administering the legislation, providing advice to the public, providing risk advice to other regulatory agencies, developing guidelines and standards, undertaking research on risk management and GMOs, and maintaining links with international organisations. Those are some of the key functions that are set out in the bill.

The legislation will regulate all dealings with genetically modified organisms and all dealings with GM products where they are not regulated by existing regulators. So the regulatory system deals with regulating live, viable, able to propagate genetically modified organisms. That is one of its areas of coverage. The other area is to pick up any GM products, such as cotton trash or stockfeed, that are not currently covered by an existing regulatory body such ANZFA or the National Registration Authority.

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The regulatory system as drafted is based on a system of prohibitions and approvals. Basically, all dealings with GMOs are prohibited by the legislation, unless they fall within one of the exemptions under the legislation or the regulator approves them. There are various approval paths for the regulator. They range from notifiable low risk dealing approvals where you can get a class licence in respect of dealings with the GMO that is assessed by the regulator as being particularly low risk—that would be for a lot of the contained laboratory work undertaken with GMOs—through to licensed dealings with GMOs, for example, with a very thorough risk assessment process. So if you were proposing to release a genetically modified organism into the environment that had the potential of presenting significant risk to the environment, it will go through a much more comprehensive risk assessment process.

In summary, the most detailed of the risk assessment processes undertaken by the regulator is in relation to, as I said, the GMOs to be released into the environment where there is a significant risk posed to the environment by the GMO. The risk assessment process in that instance is that the data package is provided by the applicant in accordance with the requirements under the gene tech bill, and the Gene Technology Regulator then makes that application available to anyone with an interest. So the full application under the regulatory system, excluding commercial-in-confidence information, is made available to anyone who is

interested. It would be provided as a matter of course to state and territory governments and local governments affected by a general release. There would be notification of its availability to anyone on the GMAC database. It would be advertised in newspapers and in the *Commonwealth Gazette*. The GTR would then provide a period of time for consideration of the application and submissions to be made.

The new Gene Technology Technical Advisory Committee, which will replace the Genetic Manipulation Advisory Committee, will be responsible for providing scientific risk assessment advice but, for example, the Victorian EPA might also want to provide environmental risk assessment advice to be taken into account in the risk assessment equation. That is the mechanism for ensuring that broad input can be provided into decisions made. The GTR would then prepare a risk assessment and risk management plan. For these high risk GMOs to be placed into the environment, the GTR would then go through a second round of public consultation on the draft determination, including with states, territories, local governments and so forth. It is the same sort of draft determination process that other regulatory systems use when they are dealing with particularly serious matter. If the GTR is satisfied as to the health and safety considerations as well as the environment considerations, the decision could be made by the GTR to licence the GMO. We can give you more information on any particular aspect—

CHAIR—I think you have probably given us a heap to start with. If I could pick up on one issue: could you explain how the environmental assessments would work?

Prof. Pittard—In terms of some of the proposals that we have looked at, such as BT cotton for which there is now a commercial release, one was very much concerned in establishing whether or not the BT gene in the cotton plant could move from that cotton plant to other plants nearby and whether hybrids could be formed from that. We were satisfied that that could not happen.

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CHAIR—There is obviously a fair amount of community concern about this issue. If we look at genetically modified products in the health arena, such as insulin for diabetics, there is not the same level of concern. It has been put to this committee in a number of different ways and on a number of different occasions that there is a very stringent, rigorous, regulatory system there that is very transparent. There are a whole lot of steps that a company would have to go through to show that it has no detrimental effects before that product can be released on the market. There is not the same degree of public confidence in regard to crops. How are the environmental assessments going to work to achieve the same level of security that the community demands?

Prof. Pittard—If I could respond by saying one thing that is different is that the media do not attack new insulins and new drugs with the same ferocity with which they attack GM foods and GM crops. There has been an incredible amount of misinformation—

CHAIR—Granted all that but I would still like to know what the steps are.

Prof. Pittard—Let me come to the next point. As far as I am aware, the introduction of the GM crops involves more detailed and careful testing, examination and scrutiny before they get to the point of being released than has ever occurred with any new crop in the past.

CHAIR—Is that going to be spelt out in the legislation?

Ms Cain—Yes. The new regulatory system proposed in the bill ensures a prohibition on dealings with GMOs unless the risk of the dealing has been assessed and approved by the regulator. This regulatory system actually applies to the research and development of the genetically modified organism. It is hands-on regulation right from the word go, from the first development work of a GMO, which is even more comprehensive than the other regulatory systems where research and development are not explicitly prohibited unless a risk assessment of the dealing has been undertaken.

I understand the observation about the lack of confidence. One of the differences between therapeutics and crops is that we have not had a regulatory system with penalties applied to it. We have not had—on the face of it—the clear piece of legislation saying what the prohibitions are and how they will be dealt with if they are breached. So the introduction of the legislation itself balances what has been there for quite some time, as you observed, for therapeutic goods. The detail of the risk assessment process is something that will be spelt out in the regulations to be developed under the bill. The bill provides the framework and the requirement for risk assessment and spells out the key steps that have to be undertaken, and then the regulations will provide that detail. We have set aside the period of time April to August this year to consult nationally on the development of the regulations.

CHAIR—How was the legislation going to harmonise all of the different safety regulations at the different local and state levels of government?

Ms Cain—You will see in the draft legislation that there is a legislative requirement on the regulator to harmonise risk assessment processes used by the Gene Technology Regulator and by the existing regulatory agencies. So we have set up in the bill the requirement that that happen. The detail of the processes and the time frames for that harmonisation is the next stage in what we are doing.

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Ms Matthews—The GTR will be working on the harmonisation of the risk assessment on genetic safety. There would be a centralised regulator assessing those genetic safety risks but there may be downstream regulators who are assessing other aspects of the product. For example, with a genetically modified fish, there would be a central regulator who would look at the effects of that genetic modification. But approval still might be needed under WA fisheries legislation to enable that fish, regardless of whether it is genetically modified or not, to swim in the Swan River.

Mr ADAMS—Some of the concerns that have been put to the committee are the environmental questions that you touched on. Is the legislation going to deal with the possibility of some of the genetically modified crops getting away from the farm they are on and therefore

contaminating someone else's crops and the legalities that that will bring into law? Have you dealt with that? Does the legislation deal with that in any way?

Ms Cain—Yes, it does. The issue of contamination and the GMOs getting away from where they are supposed to be was one of the things that was of considerable concern everywhere we went in the consultations. We have included a very broad definition of the 'environment' in the legislation that includes 'ecosystems and their constituent parts, and natural and physical resources, and the qualities and characteristics of locations, places and areas'. That definition is broad enough to ensure that the issue of contamination is one that the GTR must deal with, which means that the GTR can set conditions to limit contamination. Breaches of those conditions would then be breaches of the act with penalties attached to them.

Mr ADAMS—But then does it come to common law for the neighbour to prove that the pollen of somebody's genetically modified crop has blown into their crop and changed it?

Ms Matthews—Yes. Basically, the legislation establishes avenues for liability on a number of levels. Firstly, as Liz mentioned, there are criminal penalties for breach of the legislation. Secondly, there is the power for the Gene Technology Regulator to issue a direction directing someone to clean up or to rectify a problem where there has been a breach of a condition of licence. So if someone has breached their buffer zone and there has been contamination of neighbouring crops, the GTR could direct them at their expense to clean up the areas around it. What the legislation does not do is affect existing common law rights. If a third party wanted to bring an action in relation to contamination, their recourse would be through common law trespass, negligence, and nuisance—actions of that nature. The legislation does not establish a compensation fund per se; it focuses on criminal liability for breach of legislation and capacity for the Gene Technology Regulator to rectify, at the licence holders' expense, any breach of those conditions.

Mr ADAMS—I think some state governments have asked that no more trials take place until after the legislation is in place. The Commonwealth legislation will need to be passed. Then there will need to be corresponding legislation in each state and territory. Is that correct?

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Ms Cain—That is correct. The way the legislation has been drafted is that, from the date the Commonwealth legislation takes effect, a broad use of the constitutional powers available to the Commonwealth will be used to give maximum coverage in all jurisdictions. But, as each state and territory parliament passes their complementary component of the legislation, the Commonwealth legislation will wind back in that jurisdiction to give joint coverage between states and Commonwealth.

Mr ADAMS—How many hits did you have on the web site?

Ms Cain—I do not know.

Mr ADAMS—Will you take that on notice?

Ms Cain—Yes.

Mr IAN MACFARLANE—I wanted to clarify a couple of things. First, in terms of the new time frame to have this completed, 3 January 2001, are you confident that you can meet that time frame?

Ms Cain—We have a draft Commonwealth bill that has been signed off by officials from states, territories and the Commonwealth. It is ready to be introduced. Then there is the parliamentary process to go through.

Mr IAN MACFARLANE—I probably did not ask that question properly. In terms of changes in recent weeks, let alone days, in the attitudes of some states—I can nearly include in that some farm organisations but I will stick with the states—towards the way we are developing GMOs, will the consultative process that you have had and the draft legislation that you have developed out of that still hold up in terms of being introduced into the parliament? Or are there states saying, 'Hang on, we want to go back and have another look at that?'

Ms Cain—States have not come forward at an official level, that I am aware of, to say that they want to go back and revisit that issue.

Mr IAN MACFARLANE—My second question is in terms of protection for growers of GMOs. In the situation not dissimilar to the way they grow some hybrid seeds, where a producer deliberately moves out of a normal production area into a production area to allow his producing the crop without pollination coming from other areas, does he have any protection in maintaining the purity of his genetically modified organisms if another producer of conventionally produced crops decides to move within his proximity?

Ms Matthews—Again, notwithstanding any regulation that there may be in relation to those conventional crops—and you have issues of spray drift and that kind of thing that are regulated under the National Registration Authority—assuming the absence of state, territory or Commonwealth legislation regulating the use of that traditionally grown crop, again the only recourse open to the person who had been growing the GMO crop who impacted the traditional crop would be common law recourse.

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Ms Cain—The focus of this piece of legislation is on identifying and managing any risks associated with the GMO rather than the broader issue that you have raised.

Mr IAN MACFARLANE—I was taking it to the other side of the mirror, which was: what protection is there for the producer of the GMO in this legislation? You are saying it is only common law.

Ms Matthews—Yes, that is right in a sense. I cannot comment on the impact of existing state, territory and Commonwealth legislation in relation to traditional farming. But, in relation to GMOs, the legislation does not provide an absolute right to do something and an absolute right to be protected in doing it. It simply says that you are prohibited from doing this unless you have an approval. It does not give an absolute right to freedom from interference from others or anything like that.

Mr Slater—Or negligence.

Ms Matthews—Or negligence, that is right.

Mr ANDREN—This question is to Ms Matthews again: are you monitoring the Canadian farmers' challenge to apparently a claim by a seed company for inadvertent use of a copyrighted seed? And also is the group action still under way in the USA—was it against Monsanto? If you are monitoring them, do you see any ramifications for this particular legislation?

Ms Matthews—I certainly would not profess to be an expert on what is happening in relation to actions overseas. But, in the first action you were talking about, there were claims and counterclaims made by both sides arguing, on the one hand, that there had been interference in relation to a genetically modified crop but, on the other hand, that genetically modified seeds were used illegally and not within contracts of Monsanto's. I guess the ramifications for Australia is recognising that, yes, litigation is increasingly occurring in relation to this area. One of our concerns is to make a regulatory system that is so strenuous, clear cut, transparent and understandable that you can withstand a lot of that pressure. But, by the same token, the legislation itself is not going to be able to prevent actions between, for example, multinationals and their clients in relation to arguments over proprietary rights in relation to seeds. But we are keeping a fairly close eye on developments overseas—not only litigation but also legislative developments which are changing very rapidly.

Mr ANDREN—Are we looking at template legislation for all the states—providing they come on board—that would be similar throughout with the overarching federal legislation to tie it all together? Is that what we are seeking?

Ms Matthews—Yes. The state legislation at this stage would do one of two things. Some states may introduce a very short piece of legislation that simply applies the Commonwealth legislation in that jurisdiction, and New South Wales at this early stage has indicated a preference to do that. Other states will enact model state legislation, which is currently being developed by Victoria in consultation with others. That will effectively mirror the Commonwealth legislation but will be substantial legislation and will look like the Commonwealth legislation. That would then be enacted by all jurisdictions that did not wish to just directly apply the Commonwealth legislation. One of the big things underpinning the legislation is an intergovernmental agreement to ensure national consistency over time in relation to legislative amendments of the various pieces of legislation.

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Mr NAIRN—That, in fact, was my question. I was concerned that you could have the Commonwealth legislation and then there could be so-called agreement—it has happened before—between all the states to enact similar legislation. But when it finally ends up through each of the state parliaments, you have differences. Particularly in the circumstance of the borders between New South Wales and Victoria and New South Wales and Queensland with crops being grown on both sides—crops do not understand borders—even though they may try to be the same, there could end up being some slight differences in the legislation. Will the Commonwealth legislation be able to override, because that would not normally be the case?

Ms Cain—As I mentioned earlier, the way we have structured the legislation, with the agreement of state and territory officials, is that the Commonwealth has the maximum coverage from day one, and the coverage of the Commonwealth legislation would wind back at the point that states introduced consistent legislation. So, to the extent that it was inconsistent and was not maintaining the national system as set out through the intergovernmental agreement, it may well be that the Commonwealth legislation might be maintained for an additional period of time until those things were sorted out.

Mr HORNE—You have already mentioned buffer zones. I would assume that, in the event of someone growing a genetically modified crop, a buffer zone would be determined. Who will determine the buffer zone and who will monitor the effect of the crop on the buffer zone?

Ms Cain—Under the bill it will be the Gene Technology Regulator, the independent statutory office holder, that will issue the licence that establishes the conditions, including buffer zones. The GTR will act on the advice of the Gene Technology Technical Advisory Committee, which will replace the Genetic Manipulation Advisory Committee. But it will also actively seek input from state and territory governments and their agencies that might have something to contribute, from other Commonwealth agencies and from anyone in the community for a general release. The intention is that the maximum expertise is available to the GTR, but the GTR is the decision maker and establishes those buffer zone conditions or any others. The GTR is responsible for monitoring compliance with the conditions. The way the GTR monitors compliance will certainly involve some obligations being put on the licence holder. But the draft legislation proposes very strong monitoring enforcement and inspectorial powers for the Gene Technology Regulator, who is also able to commission independent research in his or her own right. So if there were some question about needing additional information to establish a buffer zone, for example, the GTR could commission that independent research.

Mr HORNE—In the event of a violation, would a bond be required from the grower so that the regulatory body could step in and clean it up, or would you simply say to the grower, 'We want you to clean it up'?

Ms Cain—Under the current draft the GTR has the power to take whatever action the GTR believes necessary and to require action to be taken to clean up a breach. The requirement is there for the holder of the licence to foot the bill for the remediation action. But the GTR is not limited in his or her capacity to take action before money is in the GTR's hands because you want the ability to move very quickly in some circumstances but to always have the ability to recover costs for remediation. So that is built in. The other thing that is built in is the capacity for the GTR to require as a condition of licence a bond in relation to a certain dealing, if the GTR thought that that was warranted.

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Mr HORNE—The reason I asked that question is that, in my own electorate, there are many oyster growers who have exited the business and have left their oyster leases there, which are now a major problem to other oyster farmers. The state of New South Wales is trying to establish a fund simply to clean up those non-operational leases. It is a major problem. So I see a parallel here.

Ms Matthews—That is right. Because this legislation is going to cut across many different subject matters—ranging from animals, to plants, to vaccines and to viruses, the whole lot—we have tried to work into the legislation enough flexibility for the GTR to respond to particular circumstances. So perhaps at the lowest level, if there is a concern with conditions of licence, the GTR has the power to vary licence conditions, add licence conditions and remove licence conditions. Then at the next level there is the power to issue directions requiring something to be done. For example, you could require the oyster farmer before exiting to remove the oyster lease. The GTR has the power to say that they must do that themselves and report back to the GTR about how it has been done. Or, if the GTR is not satisfied that they are capable of doing it or there is an imminent risk to public health and safety or the environment, the GTR can organise for those steps to be taken.

Mr LAWLER—You have partly answered my question following on from Mr Horne when you have talked about the ability to impose fines and make orders to clean up. One of the concerns that has been brought to us is: what if a catastrophe happens, not just cleaning up a paddock next door or something? What are the maximum fines or maximum penalties that you can impose? This may not be your brief, but what is the likelihood of something like that happening?

Ms Cain—The maximum penalty imposed under the legislation is equivalent to a \$1.2 million fine for every breach of the legislation. So if you were breaching licence conditions, there may be multiple breaches each attracting a particular penalty. The second part of your question probably is not really within—

Mr LAWLER—It is a bit outside your brief.

Prof. Pittard—I would comment and say that, in terms of the proposals we have looked at to date and the ones that are envisaged, the likelihood of a catastrophe of the type you mentioned is remote. This is an area where there has been ultra caution instead of going the other way. Many of these things start off in contained work and go through quite a lot of contained work before they even go to limited field trials. Limited field trials are carried out under conditions in which the thing is almost semicontained before it goes to bigger trials. So there is a process before you get to this stage.

Ms Matthews—It was impressed on us very strongly during the consultations that it was important that this regulator be able to manage the full life cycle of the genetically modified organism. There we are talking about right from the very early stages of the original genetic modification, through any GMOs that are produced from that offspring of GMOs, if there are offspring, through other organisms that carry the traits of the parent organism and right through to the GM products or trash that might result from the GMO. Then working in feedback loops at each of those levels to ensure that each stage occurs in a staged way with each of the risks being considered going through the life of the GMO.

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Ms Cain—The other thing that was impressed on us, as Professor Pittard mentioned, is that we have to have a regulatory system that is able to accommodate a vast range of dealings with different GMOs. A large amount of the work that is dealt with at the moment—probably over 85

per cent but we could get you the exact figures if the committee were interested—is dealings with contained work in GMOs. It is laboratory type work. We have had only one general release application in 1999 and none at all in 2000. It has to be able to respond to a very wide range of different levels of risk.

CHAIR—Are you confident that we have that level of expertise?

Ms Cain—In the current system and in the future regulatory system? Yes, for example, the single general release application has been dealt with in very much the same way that we are proposing for the most comprehensive risk assessment under the new regulatory system. The full application for the general release proposal, which was in respect of Roundup Ready cotton, has been released to anybody who wants to see it, and we have invited submissions on that proposal for a period of over two months. The Genetic Manipulation Advisory Committee has looked at not only all of the preceding field trial and research work undertaken with the cotton but also all of the submissions that are coming through from state and territory governments, from Commonwealth agencies and from the general community. A draft determination will be issued once draft conditions have been prepared. That will be the subject of scrutiny by the community and by people who have concerns about possible risks. All of that will happen before a decision is finally taken.

Mr SECKER—Has local government been through the consultation process and at what level?

Ms Cain—It has varied from state to state. We had the local government representative organisation—

Ms Matthews—ALGA.

Ms Cain—In Western Australia, for example, a representative of the local government overarching body came along to our consultations on the discussion paper. It has differed from state to state. I could take that on notice and provide the committee with some particular details on that. Andrea has just reminded me that I should mention that they are on the database. In respect of all proposals that come through at the moment, they get information and we have also mailed out information directly to them making the information available. I am just not sure of the level of attendance at public meetings that there has been.

Mr SECKER—At the moment in the Mount Gambier area, for example, there has been a publicity problem with GMOs and possible breaches, which you are probably aware of. The local government councils down there—this is in my electorate so I know it pretty well—say that they have not been given much information. I have had complaints from three of them saying that basically they get a letter that says there may be some GMO crops in their council area. They are saying that they are not really getting the information. Perhaps you could explain whether they will get more information and whether there are problems with getting specific information about what area it is on?

Ms Cain—I was aware of the reports coming out of the meeting in Mount Gambier on Monday night. We were very concerned at the reports in the press that only one notification in relation to a field trial had been received in respect of trials conducted in that area. We did an immediate search of the documentation and were able to confirm as of yesterday afternoon—we had gone back to the beginning of 1998—that all of the notifications had been provided, which was reassuring. But in terms of the level of information, we are trying to develop a very open system. So it is modelled pretty much on the same process that I described for the general release, except where a particular piece of information in relation to a GMO application can be proved to be commercial in confidence—and we have a fairly stringent test for that. The proposition in the bill is 'open release of information'. So that is the basis that we are working from, except where a reasonable commercial-in-confidence test is met.

Mr SECKER—ANZFA has made what could be termed a fairly political decision in saying 'all foods containing GMOs'—and I assume that this is part of the GTR?

Ms Cain—No. The Australia New Zealand Food Authority is an independent statutory organisation.

Mr SECKER—Yes, I know that. But will you be enforcing the regulations that come as a result of ANZFA?

Ms Cain—No.

Mr SECKER—What if they say 'food labelling'?

Ms Cain—No.

Mr SECKER—You will not have anything to do with that at all?

Ms Cain—No.

Mr SECKER—That is fine. So I do not need to go on with that question. Just as an example, say that a GMO product—and it was a GMO canola—had gone through all the approval processes and was then used in a traditional breeding program. What safeguards are there to say that the new resulting canola plant from traditional means is classified as a GMO; or is it not because it has been gone along with traditional breeding methods?

Ms Matthews—With the definitions in the legislation, any dealing with the GMO canola needs to be regulated; you need to apply for a licence to undertake certain dealings with a GMO. Using that GMO canola to traditionally breed with another strain of canola would be a dealing that is required to be licensed by the GTR. The definitions in the legislation then specifically provide that the GTR may continue to regulate—if necessary, on the basis of risk—the offspring or progeny of a GMO, where that offspring continued to have the traits of the parent GMO.

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For example, if you have GM canola that has been genetically modified for herbicide tolerance, you breed it with a traditionally bred canola. Then with the canola that results from that breeding continuing to have that genetically modified trait—that is, it is herbicide tolerant—it could continue to be regulated by the Gene Technology Regulator, because obviously, even through traditional breeding, you could increase the risks rather than decrease them. So that is something we have tried to build into the system to enable regulation, if it is necessary, on the basis of risk.

Ms Cain—Equally, because we have been conscious of the requirement that the level of regulation has to be commensurate with the risk, we have tried to build that into the legislation. There might be something like the current genetically modified carnations. They have been genetically modified to be violet or have a long vase life. They have been around for a while, their risks have been assessed and they are well known. It is definitely a live, viable, able to propagate GMO. It falls within the regulatory system. The regulator should know what is happening with that GMO. They might not necessarily want to subject it to conditions on an ongoing basis or to the requirements of holding a licence. So we have built a thing called a GMO register where, once a GMO has been licensed for a period of time, it can be reassessed according to its risk and moved to the register. So you continue to know what is out there and what is happening with it, but you do not necessarily subject it to—

Ms Matthews—The effect of being on the register would be that anyone can do any dealings with it at any time, because you have already assessed its safety and it does not require direct oversight through licensing.

Mr SECKER—From that earlier answer, I am not quite clear whether it is certain that those GM crops in Mount Gambier were properly disposed of. The company says that they were; one of the councils thinks that they were not. What is the answer?

Ms Cain—The Interim Office of the Gene Technology Regulator has been investigating the proposal that there was a breach of GMAC conditions. Obviously it is important to establish the veracity of the claims, and we have been pursuing a range of different paths to that end. We are in the middle of that consideration.

Mr SECKER—So you do not have an answer yet. When would you be likely to have an answer; and can this committee be informed of it?

Ms Cain—If I may, I will advise the committee when we are in a position to be able to—

CHAIR—I think we would be very interested in knowing where the system failed and whether that has been picked up with what will be put into the legislation.

Mr GRIFFIN—I will just follow up on that. So you are really saying that you cannot say much more about Mount Gambier at this stage. I know that we have had some discussions about that privately in the context of where it is up to. I am just looking at some of the key questions that I think have come out of some of the media reports so far on that. There have been claims from the company that, in fact, it has been properly disposed of. There have been issues about the question of whether, in fact, there were tarpaulins, et cetera, involved that would contain

significant amounts of GM pollen. There is the issue around the question of notification. On the subject of notification, in answer to Mr Secker's question earlier I think you said that your records show that councils were notified of each release. How many notifications had occurred over that period?

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Ms Cain—I will have to take that on notice. This is the information that I obtained yesterday, which I have confirmed: that the notifications—both upon receipt of the application in respect of a field trial proposal, and the subsequent one advising of GMAC's decision in relation to the field trials in the Mount Gambier area back to the beginning of 1998—had been provided.

Mr GRIFFIN—To the councils in that area?

Ms Cain—Yes, and I can provide details to the committee.

Mr GRIFFIN—We would be interested in having a look at copies of that. I know that one of the concerns also raised was the issue of what sort of notification occurs in an area such as the one in question. I think Aventis was quoted as saying that they do not actually use the term 'genetically engineered' or 'genetically modified'; they use the term 'hybrid transgenic'. Also, there is the question of common usage of terms and, therefore, whether a notification is, in effect, a notification if it uses terminology which no-one understands—or misunderstands.

Ms Cain—Sure.

CHAIR—Is that a point that is covered in the legislation also, that the terminology is very clearly defined?

Ms Cain—Yes. We have been seeking, through the public consultations that we have been doing, advice as to whether the sort of notification that we did, for example, with Roundup Ready cotton was clear enough and widely enough disseminated. We took special pains to make sure what was notified was a decently headed, decently sized advertisement. People would have been left in no doubt that what we were talking about was Roundup Ready cotton, 'a genetically modified cotton for the purposes of'. This is a point that we are very conscious of: providing information through a range of mediums and pitched at a range of different levels. Obviously we have an obligation to provide the very detailed rigorous scientific analysis, but we also have the obligation to provide that information in simple terms so that it is very straightforward.

CHAIR—You spoke initially about it being in plain English. You cannot get much plainer English than 'genetically modified'.

Ms Cain—That is right.

CHAIR—So, instead of using any other term, that is the term that will be used.

Ms Matthews—Yes. The term in the legislation all the way through is 'a genetically modified organism'.

Mr GRIFFIN—Is that the term that has been used throughout? That is my question on from that.

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Prof. Pittard—I can respond to that. To my knowledge, the information that goes out from GMAC to shire councils uses the term 'genetic modification' in referring to the purpose of the trial and how it will be conducted. Those are the terms that are used, as far as I am concerned.

Mr GRIFFIN—And the notifications that we are talking about here are the ones coming from GMAC. Looking at an article in today's *Age*, it was mentioned that there are at least 26 genetically engineered canola crops growing across 90 hectares in the Mount Gambier region. Just looking at the system now versus the system proposed, are you looking at a situation therefore where there would be 26 notifications; or would there be one notification saying that there are 26 sites? How would that be handled currently and in the proposed legislation?

Ms Cain—Under the current arrangements, the notification will be in respect of 'the trial', and the notification would be required to be provided to each local government potentially affected by the trial. I think that would be the case under the new regulatory system as well. Bearing in mind that, under the new regulatory system, the proposal is to make information such as the complete application, excluding commercial-in-confidence material, available to anybody who wants to have a look at it if, for example, you are talking about a general release proposal.

Ms Matthews—I think what will also assist in relation to the legislation is that we have tried very hard to make it as transparent as possible. So the primary legislation sets out requirements and then, for example, the regulations will set out precisely the information that is required from applicants in relation to an application. So anyone can request a copy of that application, and they have the legislation on the face of it to check that the information that has been provided is appropriate. All the way through, they will have a comprehensive set of legislation, with regulations and guidelines issued under it. That will present the complete picture to enable them to—

Mr GRIFFIN—I understand. But I think the issue here is partially a question of making sure that the information is not only capable of being understood by the average punter and accessible but also very clearly user-friendly. I will take on that question again though. For example, with the situation of the 26 GE canola crops growing across 90 hectares in Mount Gambier, there would have been one trial. Is that right?

Ms Cain—Perhaps we could deal with the example as though it were one trial, because I do not know whether the one we are talking about was one trial or a number of trials.

Mr GRIFFIN—So you do not know that yet?

Ms Cain—The information is available. I cannot confirm that for you here; I do not have that information to mind at the moment.

Prof. Pittard—When we receive an application for a trial, the trial will include a number of locations. So it is quite possible that you could have one trial with a number of different locations. It seems to me that a point of issue is the exact location of some of these places where the trials are taking place. As I understand it, at the moment it is argued that the exact location is commercial in confidence, and the local councils are told, 'There will be a trial of genetically modified crop for the following purpose, and it will occur in your shire.' I do not think they get the exact locations of that. Of course, there are two reasons for that: firstly, the argument that it is commercial in confidence; secondly, the extreme action of the activists who want to go and pull up all the plants.

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Mr GRIFFIN—Yes. I do not defend that sort of behaviour; it is stupid.

CHAIR—On this whole question of notification, I understand that the site is not declared; but, when the local council is notified, are they given an outline of the steps of approval that took place before that notification was issued? If we are on about transparency and accountability, I would have thought that that would have been a good idea.

Mr SECKER—Like an education program almost.

CHAIR—Is that part of the process?

Ms Cain—I will just clarify: for example, with a field trial, the history of the development and the approvals?

CHAIR—Exactly.

Ms Cain—No, I do not believe that that information is part of the notification given in respect of the field trial. But the information would be available. For example, a fact sheet—

CHAIR—But, if the information is available, would it not be simpler to provide it with the notification?

Ms Cain—Yes.

Mr GRIFFIN—To follow that through a little further: I understand that you cannot tell me the detail on the issue of Mount Gambier at this stage and that you do not have the information around the question of whether it was one or a number of trials—although, as far as we know from the public record, there were 26 sites. A notification goes to a council. A notification I think, as the Professor said, says that 'there is going to be a trial in your area'. It mentions what the trial is for. It makes it clear that it is, in fact, genetically modified—and that I think is important to establish because that is at odds with what has been on the public record to a degree so far. Does it say, for example, 'Okay, there are X number of sites in this trial'? I understand that it does not tell you exactly where, but does it tell you how big and how many sites?

Ms Cain—If I may, I would like to provide the committee with information about what was provided in that there were a number of notifications in the Mount Gambier area. The committee might find it useful if I were to make those documents available. With the number of documents that were there, I would not like to recall back and inadvertently mislead the committee. So, if I may, I will make them available.

Mr GRIFFIN—Okay, yes.

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Ms Matthews—I was hoping to clarify what would happen under the new system. The legislation requires that there be notification in the *Government Gazette*, in newspapers, on the GTR's web site and in direct mail to anyone who has lodged any interest. In terms of what would actually be provided to those people, it would literally be the full application, excluding any confidential commercial information.

CHAIR—That is what I was getting at, yes.

Ms Matthews—The definition of 'confidential commercial information' is quite tight in the legislation. In many other pieces of legislation that regulate products and other things, the assumption is that if the proponent tells you that it is commercial in confidence, then it must be kept as commercial in confidence. By contrast, the assumption in this legislation is that information is released, unless they can establish that the information is a trade secret and it would diminish the commercial value of the information or it would be likely to cause them harm—financial detriment or other detriment.

Mr GRIFFIN—How are you defining that? You will have some idea in your own minds what that means in terms of what sort of information. So, exact location?

Ms Matthews—The assumption would be that the exact location would be released, unless the proponent can establish to the satisfaction of the GTR that, against the criteria detailed in the legislation, it should be treated as confidential commercial information.

Ms Cain—That decision would need to be taken on a case-by-case basis. But what we can use as an example, I think, is the Roundup Ready cotton application that we have dealt with recently. There, the only information that was withheld was the actual gene construct itself and the names and addresses of people who participated in a workshop. It was the conduct of the workshop rather than the individuals who participated that was important.

Ms Matthews—Yes, information protection under the Privacy Act.

Ms Cain—Yes, and an attachment that was provided to us but was not relevant to our regulatory system. It was in relation to another regulator, so we could not release that. But, apart from that, everything else was put out.

Mr GRIFFIN—That was a general release application. Is that correct?

Ms Cain—Yes.

Mr GRIFFIN—The issue with a general release application will then be the question of what notification occurs when a grower decides to grow. The question there will be the notifications to council as to what they constitute, and the issue will be what the notifications are to surrounding property owners.

Ms Cain—Yes.

Mr GRIFFIN—Trials are a little bit different. With trials, we will be talking about the fact that there are specific locations and they are limited in number by definition of the fact that it is a trial.

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Ms Cain—Yes.

Mr GRIFFIN—That is my point in terms of that. Let us take that notification question on from that. I am particularly concerned about the question of the notification system now, as in operation today, versus the question of what the notification will be under the legislation in terms of councils in respect to making sure that they have clear information. This is another issue: if what you have said is correct and what councils have said is correct, then there is a problem around the question of what actually happened with the notifications. Is there any requirement for a council to actually respond to your notification, to acknowledge that they have received and considered it?

Ms Cain—No, there is not.

Mr GRIFFIN—So there is a question of occasionally mail going west and so on and so forth. But that might be an issue, the question of actually ensuring that notifications are received and are responded to. Again, we are talking about a fairly new system here. The concern I have—I say this as a former councillor—is that you get a lot of correspondence through your organisation. Quite often with rural councils there are smaller staffs and lots more issues coming through that they have to consider. There is an issue there of the question of it just becoming part of the paperwork flow and going through without any proper consideration occurring. That concerns me. On from that is the question of notifications with respect to individual property owners around trials and around general releases. Could you just outline that very briefly?

Ms Cain—In relation to the current arrangements?

Mr GRIFFIN—Current, yes.

Ms Cain—Under the current arrangements, there is information provided of a proposed field trial, in advance of it happening, through direct mail to people on our mailing list, through the notification to local government about which we have been talking, through *Government Gazette* notices and via our web site. Also provided is information about the local government area in which the field trial will occur. There is not direct notification of individual farmers, unless the individual farmers are on the mailing list—that is, the GMAC database. That is under the current system.

Ms Matthews—Under the new system, similarly there will be the broadly based consultation and notifications, but we have worked in mechanisms. One you could have as an application requirement—and this will be detailed in the regulations—that an application must contain details from the applicant about how they have notified or consulted with surrounding farmers and other people who are affected by the application. Similarly, you could have a condition imposed on the decision requiring notification or education or training, or whatever is required in order to manage the risks and ensure that everyone is properly notified. But, again, that would vary on a case-by-case basis.

Mr GRIFFIN—Correct me if I am wrong, but what you are saying is that there is no requirement to notify under the legislation surrounding land-holders. It will be a question of case by case as to what requirement is made of the licence holder. Is that correct?

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Ms Matthews—The draft regulations are currently being developed, setting out information requirements for the submitting of an application. That will be subject to public consultation and it may well include that. It would be something that I would expect to come up in public consultation.

Mr GRIFFIN—But the draft currently does not include it?

Ms Matthews—Currently there is no draft; we are still developing that.

Ms Cain—The bill provides for those regulations to be made covering that issue. What we now need to do, through that period April to August, is consult on the detail in those regulations covering the issues that Andrea has mentioned.

Mr GRIFFIN—But currently, if someone is a property owner, unless they have actually registered an interest in GMOs and therefore have either some concern or some interest in the area at the moment, they would not be receiving notification of a trial occurring next door?

Ms Cain—They would not be receiving notification. They would need to seek the information from the office.

Prof. Pittard—Perhaps I could return to the answer that I gave you earlier just in case I got it wrong. I know that GMAC makes publicly available a statement about the organism's genetic modification. That is made available on the web site, in the *Government Gazette* and so on. But in the initial step, they send the notice of proposal, and I cannot be sure whether that is not the proposal that comes in from the—

Mr GRIFFIN—We would be pleased if you could get some information on that back to us.

Prof. Pittard—Sure.

Mr ANDREN—Professor Pittard, you may respond to this and then perhaps Ms Cain could too. There is a feeling out there among farmers and consumers and, no doubt, increasingly councils that scientists are telling us that GMOs are good—and indeed good for the world—and

that they are the future of agriculture. That is very hard to challenge because it is coming from scientists. As a lay backbencher, I find even our first term of reference quite complex—the future value and importance of genetically modified varieties. I do not know where I will arrive at after this wealth of information. But are you working in the legislation from just a pro-GMO standpoint. Is the continuing validity of organic agriculture respected in this legislation?

Prof. Pittard—Let me respond in a number of ways. First of all, it is quite important that GMAC not be seen as a group that is actually there propagandising for GMOs. Our role over the years has been to ensure that the work and development of GMOs has been done under conditions that are safe for the public and for the environment. However, obviously you cannot do that without also being aware of what is happening around the place. Certainly what I have read recently tells me that, in fact, the GMO crops that have been released in other countries have yielded immediate benefits in terms of reduction in the use of pesticides and herbicides and increased yields and so on. I have no reason to believe that they will not be extremely important in terms of agriculture.

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As far as the question of organic farmers and farms is concerned, I think that the interesting dilemma that must be resolved really is how two different things can live side by side. I must say that I think at the moment the organic farmers, in maintaining a zero contamination figure, are setting up a situation that is very difficult to resolve. I think there has to be some negotiation so that people who wish to grow GMO crops can do so and people who want to be organic farmers can do so. They have to work out what is a suitable distance of separation or what the controls are that are required to do that.

At the moment, from what I read, it seems to me that the organic farmers are saying: a bee can take a pollen grain five miles, and we want absolutely zero per cent contamination. It seems to me that that will be a difficult position from which to talk about things. The only other comment I will make is about something that I read this morning. It was said, I think, that it takes something like four acres of ordinary fertilised crop to produce enough manure to have one hectare of organic farm; and that the suggestion that organic farming is going to solve the world's problems is not supported by these sorts of analyses. That does not say that organic farming is not something that is worth doing.

Mr ANDREN—We could have this argument all night, I suppose. But in terms of the legislation and the fact that I guess there is potential for enormous returns to non-GMO agriculture, and given the standpoint of some markets at the moment around the world, is the legislation aimed at protecting that sector at the moment with perhaps the view of revising it down the track, depending on which way this technology goes?

Ms Cain—Your initial question raised a couple of very important issues that I would like to address briefly. During our public consultations with a very wide range of stakeholders across the country, there was a lot of considered debate about whether this legislation should be about assessing the risks associated with gene technology, or whether it should be about assessing the risks and weighing those up against the benefits. You will see in the draft gene technology bill that it is not about a cost benefit analysis. It is about identifying the risks, if there are any, and managing them. That is the first part, and I think that is an important point. It is not about pro-

technology or anti-technology. It is just about: if there is a risk associated with the technology, how do you identify it and manage it carefully?

Given people's concerns about the possibilities of benefits outweighing risks or economic return outweighing environmental impact and things like that, what people stressed was the need for an accountable, independent regulator. So we have included in the legislation things addressing things like conflict of interest, accountability provisions and so on, so that people can be certain that there is not a 'captive of industry' capacity in respect of the regulator.

In relation to the organic farming issue we were talking of a little earlier, what the regulator can do is take into effect gene flow from a GM crop to an organic crop and set conditions to limit contamination. That is a part of the regulatory system that is being proposed. Professor Pittard's point about the need for the regulator to consider establishing some sort of contamination threshold is an important issue that the regulator will have to come to terms with. I would imagine that will be the subject of considerable debate and input from the wide range of stakeholders over a period of time.

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Nevertheless, in the Victorian public meeting forum that we had on the draft bill, it was proposed by one of the organic organisations there that there was a need for a threshold to be established similar to the threshold for contamination established for pure seed. You can have some level of contamination for pure seed and it is still pure seed.

Mr ANDREN—But the regulator will determine whether the bee can carry it five kilometres or whether, in fact, you have a 200-metre buffer.

Prof. Pittard—Whether one bee carrying it five kilometres is enough, or whether you need a few more.

Mr GRIFFIN—I do not think we should be embarrassed about it. The nature of GMAC and the IOGTR will be pro the technology because you design to actually regulate the technology—and there is nothing wrong with recognising that. Let us say we were regulating motor racing. You would not intend to have non-petrol heads organising motor racing. Your job is there to regulate a technology in order to allow it to be introduced with proper guidelines. But the nature of that will be a situation where you will have a lot of people involved as part of that organisation who are pro the technology. The question is: how do you regulate it?

Ms Matthews—In fact, the reverse argument has also been put during consultations: that the GTR will turn into a jackboot regulator who will not let anything past him and who decides it is his responsibility in life to enforce to the letter of the law and identify every possible risk, harm and so on and seriously go for it in a regulatory sense. So I guess that will be an important balancing role for the Gene Technology Regulator.

CHAIR—But, as well as the regulatory process, in your submission you actually say that the GTR will 'provide advice to the minister on not just the release of GMOs, taking into account scientific, economic, trade and ethical issues'. Is that being reflected in the legislation? Who makes these conclusions? How does this advice come to the minister? That is a wide range.

Ms Cain—Yes, and I think the point that you are picking up in the submission shows that we have moved a long way in our thinking as a result of the further work we have done with—

CHAIR—It sounds like the ultimate Big Brother.

Ms Cain—At the moment, the regulatory system proposes that the regulator will be required to look at risks to the environment and risks to human health. As part of that consideration, there would be a requirement to make sure that ethics issues had been dealt with properly. Those are the parameters of the regulatory system as set down.

CHAIR—Who bears the cost for that?

Mr Slater—Madam Chair, I think Ms Cain is saying that, at the date of 23 September, when the submission was drawn up, the object or view of what would be the regulator's role was different from what is now in the objects of the bill. I think it is important for the committee to note—and this is in response to Mr Griffin's point—that the role of the regulator here is to protect the health and safety and the environment; that is the regulator's role. It is not to approve or promote a particular technology. It is to protect health and safety and the environment.

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CHAIR—And part of that is providing advice to the minister?

Mr Slater—Indeed.

CHAIR—Does that still include on grounds of trade and ethics?

Ms Matthews—We should just distinguish between the current system, which involves advice to the minister, and the proposed new system, where the focus of the attention is on the Gene Technology Regulator. Under the new system, there would be a Gene Technology Ethics Committee established to examine ethical issues, and it will have determined guidelines that must be complied with in relation to research. It will be working very much in the way that the current Australian Health Ethics Committee works on animal welfare.

CHAIR—And that reports to the ministerial council?

Ms Matthews—It would report to the ministerial council. The ministerial council would or would not endorse those guidelines. Once the guidelines were endorsed, they would come in through the bottom of the system. So any researchers undertaking work would have to observe those ethical guidelines. An application would come to the GTR. Then the GTR would ask whether that application was in accordance with the ethical guidelines issued by the ministerial council, and the answer yes or no would be given. That would work in exactly the same way as approvals come up in relation to research involving animals—that is, where there are issues of animal welfare, there needs to be satisfaction by the regulator that guidelines in relation to ethics in animal welfare have been properly considered by the applicant.

Ms Cain—Also, as has been mentioned, we have drawn heavily on the model established under the National Health and Medical Research Council legislation in relation to human health ethics considerations under the Australian Health Ethics Committee for the model.

CHAIR—And the applicant bears the cost for this?

Ms Cain—As I have mentioned, the policy at the moment is that the regulator will be 100 per cent cost recovered.

Mr ADAMS—I just want to go back to the ethics. To what extent did ethics come up during your consultations?

Ms Cain—It came up quite a bit. When we began the consultations on the discussion paper, we had a policy principle that was agreed by states, territories and the Commonwealth that ethics would be part of the regulatory system. But there was also a requirement on us that the regulator not be required to balance ethics against scientific assessment; they had to be separated out. So we proposed the establishment of a community consultative group and that we would have the community consultative group deal with the ethics issues, together with policy advice and things like that. We put that into the discussion paper and went on our first round of national consultations, and it was brought home to us that that really was not the way that people felt ethics should be dealt with.

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We were referred back, for example, to the report from the First Australian Consensus Conference on Gene Technology in the Food Chain, in which the layperson panel had said that they did not feel able to deal with the ethics issues themselves. So people said that, if the lay panel were not able to, why would the community consultative group be able to? We were pointed to the Australian Health Ethics Committee and the way that animal welfare things are dealt with as a proper model for us to go and investigate. We have done that and, as a result, we are proposing the establishment of a purpose specific ethics committee to deal with these issues. But, as was mentioned, very much in the way AHEC does, in the development of the guidelines they are fed into the research base so that, from your first dealings with the GMO, you are having regard to the guidelines.

Mr ADAMS—Could you let us have a copy of those?

Ms Cain—What I could provide to you at this point is the model that we have used, the Australian health ethics—

Mr ADAMS—That is what I mean, yes.

Ms Cain—Yes, sure.

Mr ADAMS—You are still working on the model, I take it?

Ms Cain—Yes.

Mr ADAMS—Who is paying the bills; and how does that work out from the point of view of the state governments? We might get a situation where state governments want to push an area of research or an area that they are not happy with—I can see the local politics working—and they might want some research or further work done in a certain area. Will we get into a situation of who is paying? What arrangements have been made in relation to this?

Ms Cain—Bearing in mind the 100 per cent cost recovery policy, we have proposed that the Gene Technology Regulator have responsibility for the funds of the Gene Technology Regulatory Office. So there would be a reserve fund established in very much the same way as I think the Therapeutic Goods Administration arrangements work. Under the draft legislation, the Gene Technology Regulator is then responsible for determining priorities of work, including your example of research priorities, and meeting the costs of those things. So states and territories, for example, through the ministerial council, might be able to highlight a particular area of research they were or were not interested in, and that might be advised to the Gene Technology Regulator. But then the regulator is the independent person who is responsible under the bill for meeting the responsibilities of the legislation.

Mr ADAMS—Who will make up the IOGTR—well, after the legislation has been proclaimed, I suppose it will come down to the OGTR. Who will actually sit on that, or who will make the decisions? Is there a chief scientist who will make all these decisions and write the papers?

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Mr Slater—The legislation envisages that a statutory office holder be appointed. That statutory office holder will be required to be approved by the ministers of the states and territories and the Commonwealth. I guess that they will be the determinants or determinators of the sorts of requirements and qualifications of that individual.

Mr ADAMS—What is written into the bill to say that he or she has to take consideration of information received from certain people?

Mr Slater—He or she will be required to take into account certain policies, practices and standards.

CHAIR—And that criteria will actually be set out?

Mr Slater—Indeed. But the legislation does make it very clear and has a specific provision that, 'subject to this act and to other laws of the Commonwealth, the regulator has discretion in the exercise of his or her functions or powers'. In particular, it states that, 'the regulator is not subject to direction from anyone in relation to whether or not a particular application for a GMO licence is issued or refused or the conditions to which a particular GMO licence is subject'. In other words, ministers will not be able to make decisions about applications.

Mr ADAMS—How long are they appointed for?

Ms Matthews—The GTR will be appointed for three to five years.

Prof. Pittard—Perhaps I could go back to ethics just for a moment. I just want to make the point that all experiments involving people, such as in human gene therapy, are outside of this because a separate committee deals them with. Any experiments that involve animals have to be approved by an animal ethics committee as part of an ongoing thing. The main thrust, if you like, of the current GMAC is to ensure the safety of the community and the environment. I think that is probably a highly ethical thing to want to do.

I find it interesting that, although there seems to be a general agreement there must be an ethics group commenting on the ethics problems in genetic manipulation, it is very difficult to find out what those problems are. Once you take the people out of it, the animals out of it and so on, what you are left with is a bag of concern. So there are some people who say that to work with a multinational company is unethical. There are other people who say that to take a gene from a fish and put it in a cabbage is unethical. I am interested really in trying to work out what this ethics component will eventuate into.

Mr ADAMS—I think we are going into an area that is pretty new and it will change a lot of the way we think and the way we have done things in the past.

CHAIR—And it is a very difficult area to regulate.

Mr ADAMS—It is very hard to regulate but also very hard for people to come to grips with very easily. I think people are asking for those ethical questions to be brought to the fore. I think they want to look at them. Scientists give us the view, 'It is just a piece of DNA and we are just operating on that basis; it is just an enzyme,' or whatever. People think differently from that, and I think it is the ethics that they want to know about.

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CHAIR—Do you see the GMAC or the GTR as having a role for community education?

Mr Slater—Yes.

Ms Matthews—Yes, and that is explicit in the legislation as a function of the GTR. Again during consultations, it was very, very clear that one of the key roles of the GTR is that he or she has to be able to disseminate and make available information about risk assessment of GMOs—not information that promotes the industry, not information that has an end point in terms of the marketability of a GMO; just information that is purely factual, based on the GTR's assessment of the risks.

CHAIR—And in plain language.

Ms Matthews—Yes, exactly.

Prof. Pittard—The government did have a gene technology information unit for two years. It produced some really first-class fact sheets and nice pictures, descriptions and questions about things. That was between 1995 and 1997, I think.

Mr HORNE—Professor Pittard, firstly, you have said that you could not imagine a catastrophe of the magnitude that someone envisaged occurring.

Prof. Pittard—Yes.

Mr HORNE—Does not that depend on time frame? For example, think of rye grass. People are still planting that in various parts of Australia, but in other places it would be regarded as a catastrophe, particularly if you suffer from hay fever. Do not be in the Hunter Valley in the spring if you suffer from hay fever. So I would say that there is a potential for catastrophe—

Prof. Pittard—I am sorry, but what is the catastrophe that you are alluding to?

Mr HORNE—Earlier on, in answer to someone's question, you mentioned that you could not envisage a catastrophe through genetic modification. I am just asking: doesn't that depend on time frame? With any genetic change, isn't it possible that only time—and long periods of time—will tell whether an organism that has been created, a modified organism, is potentially harmful to the environment?

Prof. Pittard—Yes, I guess that is true. But you could say that about almost any aspect of life, couldn't you?

Mr HORNE—Of course.

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Prof. Pittard—I understood with the question that we were talking about trials and releases. I thought the question was more or less asking: if you are in the process of doing this and suddenly there is a catastrophe, how do you respond? My answer was that the way in which the trials have been examined and the information that is to hand by the point in time when that is there is to make the probability of that sort of catastrophe remote.

Mr HORNE—Of course. But we have introduced many species to this country that at that time we thought advantageous and now we consider major pests.

Prof. Pittard—We have indeed. I think the introduction of rabbits, foxes, blackberries and cane toads had nothing like the careful scrutiny that these things are having.

Mr HORNE—There is a note in the papers that we were given about a South Australian farmer on whose land GM canola had been grown. That farmer claimed that his cattle were grazing on volunteer GM plants and, therefore, he would not be able to market his beef as GM free. To my way of thinking, it does not matter what the cattle ingest, it will not change their genetic structure; they depend on their parents for that. If they have ingested genetically modified material, what would be the withholding period to make sure that it had gone through their system?

Prof. Pittard—It would be broken down very rapidly in one or two days. I cannot see the point.

Mr HORNE—The point I am making is that this misinformation is out there. In reading that, it is implied that the genetic structure of the cattle would be changed by the fact that they have eaten GM product.

Prof. Pittard—I understand that. It is a big problem.

Mr GRIFFIN—Just considering the common law issue, I would maintain that the experience overseas is that the incidence of actual litigation has almost always been common law. I guess I am a little concerned here that, when we are talking about the question of a regulatory system, there is maintenance of common law rights. One issue in that context is whether the regulatory system will not evade common law rights but ensure that there are fewer things likely to be taken up under common law—otherwise we will face a situation similar to that which is starting to kick off in the US, and that has serious implications for having a system that works. Can you comment briefly on that point?

Ms Matthews—Certainly it is the intention that the regulation reduce a number of things taken up in common law. If it is assessed by the regulator as not being safe, then it never enters the marketplace, and there is never capacity for litigation to evolve regarding the safety or otherwise of that product. But, as I mentioned earlier, that is not to say that the legislation will be able to impact something like contract or related disputes between users of the technology and the companies that promote the technology. That is what is subject to a lot of the litigation overseas at the moment.

Mr GRIFFIN—There is that and also contamination issues in that context.

Ms Matthews—Yes, and control of biological resources.

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Mr GRIFFIN—To take up a point that relates to a comment that Professor Pittard made about what GMAC's role is now, GMAC has that responsibility for assessing health and environmental risks. But it is my understanding—and we have had this in written responses from questions in the Senate—that it does not have a responsibility on the issue of contamination on non-health related and environmental related risks. So we are speaking of commercial contamination, in effect. That again, in terms of the experience overseas, is one of the major issues that is coming up. Could you give me a comment on that?

Prof. Pittard—I could comment and say that, in approving trials, we certainly are insisting on buffer zones between GM crops and other crops and that there are other sorts of zones required in terms of seed purity. So the whole purpose of the separation is to prevent contamination. The only area, as I understand it, where there is currently some conflict is with regard to the organic farmers group where they are maintaining a zero contamination and a notion of five to 10 kilometres of pollen transfer.

Mr GRIFFIN—On that point though—correct me if I am wrong—on the issue of contamination, other than strict environmental contamination, we have had written responses that say GMAC does not have a role. Is or isn't that the case?

Ms Cain—Yes, I am aware of the written responses that you have received to your questions on notice, and they are correct. What we are proposing is a change in the way that some of those issues are dealt with under the new regulatory system. That is what we have been trying to test with people through the consultations.

Just to go back a little, being aware of the concerns there were about things like marketability impact through contamination of organic crops, we did originally propose the inclusion of what was being called 'a national interest provision' in the legislation where things like that would be taken into account. The strong feedback that we got from industry, environmental groups and everybody who looked at the national interest provision was that it was too broad, too subjective, that it was open to interpretation, that it would change in application over a period of time and that it was not an appropriate provision to have in legislation in a regulatory system.

So, as a result of taking that out, we have done things such as broaden the definition of the environment, reconsider things such as the amount of information that could be retained under commercial-in-confidence provisions. We have gone through the bill to try to rework the system so that it does have the broader applications.

Ms Matthews—To enable consideration of contamination. But, speaking about contamination, two distinct points came up during the consultations. One was that the regulator should take into account contamination and be able to apply conditions to minimise contamination—that is, minimise the impact on others around it. But by the same token, people stressed very strongly that the Gene Technology Regulator should not impose conditions that require segregation, accreditation, and certification of crops for export. People very much saw this as a market issue: the segregation of crops and marketability overseas and accreditation of processes for auditing—

Mr GRIFFIN—That was across all sectors?

Ms Cain—No, sorry, I was about to clarify that point. There was quite a difference of view on that point between primary producers generally and organic producers. I was going to highlight the fact that we have generalised across the board the concerns of primary producers in terms of all those groups that I mentioned previously. Whilst doing so, we have maintained a high degree of consciousness over the fact that, for the organic sector, the high priorities in their submissions and consultations have been things like a moratorium on the use of the technology, and contamination funds. There is quite a different view.

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Ms Matthews—Their concerns are quite distinct from the general.

Mr GRIFFIN—I understand. Just quickly, opting out was mentioned earlier. There has been an issue about states potentially opting out. There has certainly been an issue about local government areas calling on opting out—there have been a number in Western Australia and in some other states—and that have said they want that option. What is the position on that?

Ms Cain—At the moment the way the legislation is drafted is to achieve the objective that we were talking about earlier, and that is a high degree of national uniformity. There is not an

explicit opt out in the Commonwealth legislation. The Commonwealth's policy is that there are a number of impediments to including an explicit opt out, including constitutional problems and international obligations. We have talked those through with officials at state and territory level and provided them with the legal advice, which helped us to reach that point, and they are aware of what the issues are. What is not precluded under this legislation is the use by individual jurisdictions of residual powers to achieve jurisdictional specific outcomes.

Mr GRIFFIN—So what you are saying is that, under the land management powers currently in place in the states and territories, there will be the possibility to designate GM-free zones.

Ms Cain—For example, in New South Wales we understand—and I am not an expert in New South Wales law—that that will be an outcome that would be possible by using existing local government laws.

Mr GRIFFIN—And that will be allowed under legislation.

Ms Matthews—In the same way that you can have zones in New South Wales that preclude the growing of rice, you could have zones that preclude the growing of certain GM crops.

Mr GRIFFIN—My understanding is that Tasmania—at least publicly; I am not sure officially—have made comments saying they have real concerns about the technology and there has been some talk about the potential of Tasmania saying that they want to opt out as a whole. Is that the case or are you not aware of that?

Ms Cain—If I have understood the question correctly, I am aware of statements made in the media to that effect.

Mr GRIFFIN—But they have not been communicated to you in any official capacity?

Ms Cain—There has been communication between ministers, and I think that was referenced in some of the media statements coming out of Tasmania.

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Mr GRIFFIN—Hypothetically, let us say a state—whatever state—said, 'We want to be out of this system.' You are saying they cannot opt out so the system would be imposed over their heads or what?

Ms Matthews—No. I guess what we are saying is that, given the constitutional impediments and impediments in terms of our international obligations, the Commonwealth cannot provide a capacity to opt out under the Commonwealth legislation. However, that does not preclude states exploring other opportunities that may be consistent with the Constitution or international obligations, and that would be for them to pursue to examine that further.

CHAIR—But you are saying to us that you have not had any indication of that?

Ms Cain—No, sorry. The issue has been discussed through our Commonwealth-state consultative groups, and we have reached this point with the Commonwealth legislation where

an explicit opt out from the application of the GTR's decision about environmental risks and human health risks has not been included in the Commonwealth gene technology bill.

Mr ADAMS—What are the international obligations that we are under with this legislation?

Ms Matthews—The relevant agreements are the GATT, SPS and TBT agreements. Essentially, the agreements provide that individual countries cannot introduce legislation or take actions that preclude the involvement of other countries in the import or export of products on technical or non-technical barriers to trade. Australia can put in place a regulatory system to regulate public health and safety and environmental risks, and that will not be in breach of the international obligations. But if Australia puts in a system that says, 'On the basis of protecting our apple trade in Victoria, we will make legislation precluding genetically modified apples being grown here or being imported into Australia,' then potentially it could be argued that was a barrier to trade in terms of trade of like products. But, obviously, that is something that would always be subject to arbitration in an international forum, and what the decision would be is unknown at this stage.

Mr ADAMS—Do I understand you correctly that we could not stop genetically modified product coming into Australia?

Ms Matthews—We certainly could on grounds of public health and safety and environmental considerations. This legislation will regulate imported products in exactly the same way that it regulates genetically grown products and the risk assessment would be undertaken. If the GTR identifies that the risk cannot be managed, then the import would be refused.

Mr ANDREN—But if a state were able to declare a GM-free zone, then conceivably it could declare the state a GM-free zone?

Ms Cain—Yes.

Mr ADAMS—So where do you we go then with our international obligations? It is a big question.

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Ms Cain—It is a big question.

Ms Matthews—It is something that we are exploring.

Ms Cain—The WTO experts over in Foreign Affairs and Trade might be the best ones to help us out on that one. What we can tell you at this point in time is that we have worked with officials at the state and territory level to explore options for the good regulation of genetically modified organisms. We have a draft bill that we think reflects a good regulatory system. It has not been considered by parliament. It does not currently include an explicit opt out because we understand that there are various problems, including constitutional and international agreement problems. But it is a draft bill at this point, subject to consideration by the parliament.

CHAIR—You have taken a lot of advice and you have had wide consultation that you have told us about. Have you looked at the regulatory processes that are in place overseas? Are there some good features that we are doing? Is our draft tougher? Can you give us a quick analysis and comparison?

Ms Cain—Yes. We have done an analysis of the regulatory systems that are operating in the US, the UK, Canada, Japan, New Zealand and a number of other countries. We have been able to pick up some really good ideas from other countries. New Zealand has a very open system and we were able to pick up some pointers about community consultation and things, but so, too, are a number of Australia's regulatory systems open in terms of checking what was a good way to consult with the community. What we are really conscious of is that each of the countries has developed their regulatory systems in exactly the same way as Australia has in that they are being slotted into existing regulatory arrangements for agricultural products, therapeutics and all the rest. They are also being driven by different policy imperatives and community concerns. In terms of the accountability arrangements, the emphasis on community participation and open exchange of information, those things are coming out of the European council and various European regulatory systems at the moment. I think we are going to be at least as good in those terms as those systems, if not better.

Ms Matthews—Certainly our coverage is very comparable in terms of the activities—the GMOs and the dealings that are being covered. There are two distinct overseas models: one that is similar to this one that prohibits things from occurring unless they are licensed; and the other that allows it to happen except by exception, and that is certainly the US model. Then, of course, there are the systems that are based around non-regulatory controls. Even the UK is based around committee controls and a ministerial involvement. I guess it is a blend of the different systems.

Ms Cain—But there will be an analysis. One of the things we are preparing at the moment is a report on the submissions received, the public consultations, the issues that were raised and how they have been addressed, and part of that analysis is the analysis of the international regulatory arrangements. We can make that available to the committee in due course.

CHAIR—We have enough questions for at least another six hours. We would like to put a number of questions to you on notice and seek a response. You can ask one very quick one.

Mr GRIFFIN—Time lines for the Mount Gambier inquiry, when would you hope to be able to report back to us about what has happened?

Ms Cain—I am afraid that I will have to keep the committee informed of how we are going with the investigations. I can tell you that we moved very quickly to put a number of processes in train. When you put your processes in train, you often of necessity sometimes then have to follow up your processes. We are moving it along expeditiously but it would be—

Mr GRIFFIN—A week, a month, a year?

Ms Cain—Not a year and not a week, but somewhere—

Mr GRIFFIN—All I would say is that there are certain things that have to be gone through; and I understand that, in a situation where this is the biggest public example of concern being raised about the current regulator system, you need to be in a situation as a regulator to be able to say how long it will take. That is a real basic issue of public confidence.

Ms Cain—Sure. I can undertake that certainly within the next month, and hopefully sooner than that, we would have these matters resolved. If we do not have them resolved, there will be an explanation of why they are not, what processes are ongoing and why they are taking time. I would expect them to be resolved reasonably quickly and well within that month. But we can keep you informed as to—

CHAIR—Especially in regard to the draft legislation, you would want it resolved quickly so we could learn from that. Ms Cain, you have some documentation that you wanted to table for us.

Ms Cain—Yes. We wanted to provide you with a list of the submissions by primary producer and related organisations on the draft gene technology bill and the list of primary producer and related organisations that participated into the public forums on the draft gene technology bill. Some of the information contained in these documents was provided previously, but these lists have now been updated.

CHAIR—We will also provide both GMAC and the IOGTR with questions on notice. We would really appreciate it if you could get the responses back to us as quickly as possible because we are coming towards the end of this inquiry. I thank you all very much for your time today. We have gone well over time.

Ms Cain—May I just say: if I could offer the committee if not a final outcome on the complaints that are under consideration at the moment then at least a progress report within the next fortnight. So if it is not resolved, we will provide you with a progress report as to what is happening with the complaints.

Resolved (on motion by **Mr Adams**):

That the documents from the Interim Office of the Gene Technology Regulator be accepted as Exhibit No. 5.

Resolved (on motion by **Mr Andren**):

That, pursuant to the power conferred by section (a) of standing order 346, this committee authorises publication of the evidence given before it at public hearing this day.

Committee adjourned at 7.02 p.m.