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TRANSCRIPT OF PROCEEDINGS

PRODUCTIVITY COMMISSION

INQUIRY INTO COST RECOVERY BY COMMONWEALTH REGULATORY, ADMINISTRATIVE AND INFORMATION AGENCIES

MRS H.J. OWENS, Presiding Commissioner
PROF J. SLOAN, Commissioner
DR R. STEWARDSON, Associate Commissioner

TRANSCRIPT OF PROCEEDINGS

AT MELBOURNE ON MONDAY, 20 NOVEMBER 2000, AT 1.30 PM

MRS OWENS: Welcome to the first day of the public hearings for the Productivity Commission's inquiry into cost recovery by Commonwealth regulatory, administrative and information agencies. I'm Helen Owens, the presiding commissioner on this inquiry, and with me on my right is my fellow commissioner, Judith Sloan, and our associate commissioner, Robin Stewardson. Public hearings will be held. Apart from in Melbourne they will be held in Sydney and Canberra and by video in Adelaide and Perth.

The scope of the inquiry is specified in the terms of reference. Copies of this and other inquiry documents are available on the table near the entrance. The commission has three main tasks in this inquiry: to review existing cost recovery arrangements by regulatory, administrative and information agencies; to develop guidelines for the future application of cost recovery by the Commonwealth; to review cost recovery arrangements under the Trade Practices Act 1974 as part of the legislative review required by the competition principles agreement between the Commonwealth and the states and territories.

Public submissions are vital if the commission is to be successful in these tasks. The public hearings provide the opportunity for participants to make an oral presentation and discuss submissions with the commissioners. This is an important part of the public inquiry process as the commission is also able to seek clarification and pursue particular issues in greater depth. While we'll try to keep these hearings informal, we do take a transcript for the public record. Transcripts are normally available on the commission's Web site within a couple of days of the hearing and we will send each participant a transcript of their session's proceedings. At the end of the scheduled hearings for today I will invite any persons present who may wish to, to make oral presentations.

Now I turn to our first participants, which is the Plastics and Chemicals Industries Association. What I'd like you to at this stage is each to give your names for the transcript and your position with the association and then you can speak to your submission. Thank you.

MR SWANN: Ian Swann, general manager, Plastics and Chemicals Industries Association.

MR VAN KRIEKEN: Ashley Van Krieken, commercial affairs manager, Plastics and Chemicals Industries Association.

MRS OWENS: Good, thank you. Would you like to make a few opening comments at this stage?

MR SWANN: Thank you, Commissioner Owens and fellow commissioners. It's a great opportunity for the industry to provide some input to this review. We're certainly very pleased that the government has taken this opportunity to review the cost recovery initiatives for our industry, the National Registration Authority, the Therapeutic Goods Administration and the National Industrial Chemicals Notification

and Assessment Scheme, three which have most impact upon our members and upon the sectors that those members service for chemicals and plastics supply.

A lot of the comments in our submission were noted as largely directed towards NICNAS, that's not on the basis that NICNAS has a system which is any more difficult or rigorous or has more concerns from our members than the TGA and the NRA; it's that for our industry association NICNAS is the one that we have probably the most contact with and so the most knowledge of their systems.

As an industry association ourselves and our members have a sound recognition for the need for strong controls in health, safety and the environment. We'd like to ensure that those are outcomes which are achieved in a regulatory environment which is prioritised, efficient, accountable and transparent. So the thrust of our submission covers I think an improvement upon the systems that we have in place at the moment and working with the Productivity Commission to achieve those goals.

MRS OWENS: Thank you very much. Ashley, would you like to make any other comments?

MR VAN KRIEKEN: No, that's - - -

MRS OWENS: No. I'd like to thank you very much for the submission. I think we enjoyed this submission because it gave us some very, very good examples, and we like having good examples, as we said to you before we started today. I think that one of the things that we will be doing in our draft report and ultimately the final report is using examples such as this to just provide background. We're particularly interested in the impact the current arrangements are having on firms and we're interested, as our terms of reference indicate, particularly in the impact on small and medium sized firms.

So what we will be trying to examine is what the impact has been on those firms in terms of changing behaviour. In terms of the companies that are your members, what impact does that have in terms of them actually getting chemicals into the Australian market, importing chemicals, doing particular activities in Australia, what that means for the downstream industries which are associated with you. It's that sort of information which will provide the sort of colour that we need and the background. If there are to be any changes in the arrangements, we need to be able to put a very good case as to why that needs to happen, and part of that building the case is going to depend on that information.

So I was wondering whether it would be possible, for example, to get any examples of any chemicals that haven't been introduced into the Australian market that perhaps have been introduced into overseas markets, that sort of example. You mention I think on page 4 of your submission that some fees have actually had the impact of reducing innovation and the uptake of technology, so examples that we could use relating to those claims would also be useful.

MR SWANN: We can certainly seek to get some of those examples provided to the commission over the next few days. We've tried to get a lot of that information from members, and whilst we're still pursuing that and we do have some at the moment, there are some issues of confidentiality and we might need to talk to you a little bit about how to present those in a form that maintains that confidentiality. For a lot of companies, an opportunity which they may have missed in the past may well be one that they might be able to take up in the future, and so they're hesitant at times to provide us with missed opportunities, missed markets.

But a general example of how this has an impact is largely identified in the downstream industries. For example, a company may be tendering for the BMW contract for leather, and where there's been a circumstance where one of the additives for the treatment of that leather in the process has not been on the Australian inventory - and this is not an example which is the submission - the company, the motor vehicle company and the supplier of the leather were not able to take up that opportunity to tender for it. It's a German contract set in Germany with the processes basically laid down by that company on the basis of what's available in Germany. So there's an example where innovation or the sale of an Australian product was unable to be taken up.

This is, I suppose, one of the key issues for our industry: that the impact upon say the supplier of that particular additive for the industry may well have only been $10,000 or a very small annual income on that particular additive, because it may go in at .01 per cent of an actual finished product, so it can go in in a very, very small percentage, but the impact then on the company that was supplying the leather is multimillion dollars in terms of the contract that they were not able to pursue. That's a typical example and one which we see in a number of downstream industries, particularly automotive, where it's a very global market, textiles and fabric supply for these where dies and pigments may be used in very small quantities. So again for the chemical supplier it's a small market but for the user quite substantial.

MRS OWENS: There was no provision with the regulator to say fast-track an application for that additive?

MR SWANN: Unfortunately, the way the legislation is worded, NICNAS has taken a lot of time to try to identify some categories where that opportunity can be realised but the structure of the act, the way that the legislation is worded, if the particular additive did not fall into that category it was not possible for that company then to take that opportunity up. The legislation, the way it's set up, is basically that the first person to introduce the chemical into the country takes responsibility for considering all the health, safety and environmental impacts of that substance, allowing its use by any other user once it's available and noted on the inventory after an initial introduction period.

On that basis NICNAS has to be reasonably rigorous with its approach to it to ensure that it may not be impacting on that particular application or use as a concern, but if there's another future use which they haven't really considered, then that needs

to be taken into account. So they have some constraints, and the way that the legislation was worded was to address that particular situation. What we're finding now with the industry, though, is that it is very dynamic. It certainly is very global. In Australia a lot of our larger members are subsidiaries of multinationals, so where a decision once may have been taken in Australia for Australian supply of chemicals, a lot of those decisions are now being made on a global perspective and if Australia is not able to meet the global product design that has been set up it has a negative impact then on the supply of that into Australia.

PROF SLOAN: One of the things that your submission highlights is the potential for much greater mutual recognition across boundaries. Often when we talk to the agencies themselves they clearly hear that message, but they'll also point to the special and unique conditions in Australia which require separate registration of whatever. Let's take the plastics and chemicals industry. What are these special conditions? Is it the weather or underground water? Presumably - - -

MRS OWENS: Salinity? Anything really.

MR SWANN: I suppose we have unique conditions. There's no doubt about that. But in Europe as well, northern parts of Europe versus southern parts of Europe have extraordinarily different climatic conditions and unique situations as well. However, an assessment that's in use on the European market doesn't take those issues into account. What does happen, though, is you have a very stringent control regime which addresses the substance in use in terms of discharge rates, how a particular substance when it falls into a particular hazard category is used, is labelled, the information provision etcetera. So our perspective on that is that so long as we have a robust chemicals management infrastructure in Australia, which I think we do have, there should be some flexibility allowed in the use of substances which are in use in other countries.

The other issue is that in Australia we have what's called a priority existing chemicals program, which for the substances that we have on the Australian inventory, which at the moment is about 38,000, not all of those have gone through the rigorous assessment process that NICNAS has at the moment for those substances and their uses. We would consider that, so long as a substance was clearly highlighted under the existing chemicals program, it would be prioritised along with all of the other substances and assessed in use along those same lines.

So there is a mechanism, if there's a potential for inappropriate or inadequate controls in its use, for it to be assessed under that system which we fully support. It's a prioritisation issue in our view, but in having said it's a prioritisation issue, that's clearly premised on the understanding that so long as you have very good controls in healthy, safety and environment in its management and its use, you can manage these issues without limiting or reducing our health, safety and environmental standards. I hope that has answered your question.

PROF SLOAN: No, I think it has and I think that's useful, that section. There's a section at the end of page 5 which I'm not sure I quite understand. There's this issue of slight differences and the regulatory regimes between the countries and the fact that they grandfather certain active ingredients presumably onto these foreign lists. Is the upshot of that paragraph that you wouldn't bother to bring that into Australia?

MR SWANN: That's the paragraph just under the example box, is it?

PROF SLOAN: No, the last one on that page.

MR SWANN: No, sorry, the upshot of that is that yes, for the company involved, they would not introduce that onto the Australian market because if you had, as an Australian agent, to cover $250,000 in your initial year, you wouldn't do it, unless of course it was a very, very high volume and high impact substance, in which case it may be justified to do that. But usually where it's a high volume or high impact substance, it's likely to have had that assessment package developed anyway.

MRS OWENS: But the issue with grandfathering is not so much the fact that you've got a cost recovery regime in Australia, I see it more as an issue about our regulatory arrangements per se and the cost of complying with those.

MR SWANN: Yes. Where it comes into a cost recovery issue in our view is that the timing of the legislation when it came in really dictated what we grandfathered and how we set up our inventory. If we had have set up an inventory five years or six years after Europe or the US had got to a clear point with theirs, with some hindsight, we may well have just picked up or adopted that entire inventory firstly. So in terms of cost recovery, when every substance which is not on the Australian inventory but is on an international inventory has to go through a full assessment or process and the costs of doing that assessment are recovered through the government agency that does that, that again then goes towards prioritisation of efforts and recognition that industry is getting value for the service of assessment of those particular substances and the community getting value for assessments there.

PROF SLOAN: Because there's no exclusive benefit then to that company that's gone through that $250,000 process once it's on the inventory.

MR SWANN: They have a period where it's not actually listed on the inventory and available for other use for a period of five years. After that period then, it's on the inventory and anyone else may use it. If another company in that initial period wants to use that substance, then they need to apply to be listed on the assessment form or the notification form with that company, so there is, I suppose, some sort of benefit for the company in that period. But even under those circumstances, if it's not a very high volume market, that's not a very long and significant protection.

PROF SLOAN: But that, to a degree, minimises that free riding in that period?

MR SWANN: It does, yes.

MRS OWENS: So it's a bit like having a patent protection for five years.

MR SWANN: Yes, it is, it's very similar in that respect.

MRS OWENS: And your members are happy with that five years or would they be pushing for longer or how do they - - -

MR SWANN: I don't think that they would be pushing for longer; some may. I suppose it would depend upon the nature of the substance. If a substance is very commercially sensitive, they will undertake what is known as a confidentiality listing on the inventory which means that it gets added, but the name of it is withheld from going onto the inventory. They then have to justify on a five-year basis whether or not commercial confidentiality should be maintained on it and whether or not that's compromising public interest in doing so, so there's a new process which is being developed to cover that. Any other substance, five years would probably be considered adequate before it's added onto the inventory.

Just getting back to the original question, the grandfathering issue, it may not tie in directly and it is a result of the way the legislation has been set up, but it does have an impact when the whole scheme is reassessing, to a large degree, substances which we consider we should well have access to already.

PROF SLOAN: One of the big impressions I get from your submission is that your association doesn't oppose regulation and in fact probably sees benefit in government regulation designed to protect the public health and safety as well as, I suppose, enhance the reputation of your industry in a sense.

MR SWANN: Yes, that's correct.

PROF SLOAN: But what you're really saying is that it's really the full cost recovery regime and various features of that that you object to.

MR SWANN: Yes, that's correct. It's the way it's set up to deliver the most efficiency with the regulatory controls and mechanisms. As an industry, we recognise that government regulation is an important role of chemicals management. We recognise that in the sense of a co-regulatory framework, and also that the community must have a confidence that the government is monitoring and controlling to a large degree how substances come in and are maintained, so we fully support that.

PROF SLOAN: So the fact that it's a hundred per cent cost recovery - I mean, it's clear that you're suggesting only partial cost recovery and you might like to expand on that because I think that's an important point and what kind of proportion you plumb for, I think that's quite interesting, but you have also got some points about how the regulations are actually undertaken and the nature of the regulations, because you've got some ideas, haven't you, about - you know, instead of building a bureaucracy, a lot of these activities could be outsourced, contracted out and the like.

MR SWANN: Yes. Do you want me to cover some of those - - -

PROF SLOAN: Yes, I think the partial cost recovery one is an important one.

MR SWANN: Yes. The partial cost recovery goes to the issue of niche markets largely. Small companies may be servicing, as I say, for a chemical company a small volume, and clearly can identify a benefit to the Australian economy by the introduction of that and its impact on downstream markets. In those circumstances, firstly, we would see some value in bringing the margins back to where they may have been in the past, so we recognise that we would never have a hundred per cent government-funded schemes, but something which regenerated some of those lost markets which companies have noted in the last few years since the hundred per cent came in. That's the first point.

The second point is that cost recovery of elements which are specifically related to the service of the notification and assessments, people then gain a greater understanding and recognition of the value that's being provided by that need. Where it's funding an administration and support team etcetera that goes behind that, it becomes very difficult for companies that may not have dealings on a day-to-day basis with the administration to understand why. The third thing with that is - - -

PROF SLOAN: That's your transparency and accountability, is it?

MR SWANN: Yes, that's right.

PROF SLOAN: And in your opinion, NICNAS, but also NRA and TGA are failing that test for your members?

MR SWANN: I think they're all working harder to achieve that goal but I think that there is probably some further elements of it that could be improved upon. I know that NICNAS, through its industry-government consultative committee, has worked very hard to provide an open budget. There are elements of that budget though that concern the industry, I suppose, in terms of the administrative and support base arrangements that are noted in there which are probably not, even to a large degree, the NICNAS's issues, but more the administration that they sit underneath and some of the imposed costs upon them for being part of that administration.

Just going back to that point, the third thing I was going to mention was efficiency, where with the cost recovery - and going maybe to just sort of partial cost recovery - if efficiencies could be improved, that therefore reduces the overall costs of the scheme and also gives a lot better ability to target, where you may even be able to apply a partial cost recovery process to certain sectors. If it's a high hazard or potentially high impact material that would require a full assessment before it came into the country, then you may want to apply a full cost recovery approach to the significant amount of work that might be needed to do that. Where it may fall into a category of low concern or limited use or something along those lines or it can be

clearly justified that the costs of introduction outweigh the costs of what that particular one company may get back, then there may be some elements to provide assistance, because of the benefit that it's providing to society.

DR STEWARDSON: You suggested that one way of improving efficiency was to outsource the testing. Are there in fact sufficient private agencies in this country to make that possible and also to make it a competitive market, rather than just switching from a government monopoly assessor to a private one?

MR SWANN: There are three agencies that I am aware of that could provide those services professionally and independently. These are the companies that currently I think do a lot of the assessment work in a lead-up to a submission. Now, obviously their nature of business would need to change to accommodate that, but I believe that they have the skills and the ability to do that and there would be enough to make it a competitive marketplace for it.

DR STEWARDSON: I see. It's something that one could, say, have three firms economically doing?

MR SWANN: Yes.

DR STEWARDSON: You also suggested that it would be a good idea to perhaps allow limited usage of a new chemical while it's in the assessment process. How would you envisage that working without totally undermining the whole rationale of the testing, that you don't let the chemicals loose until they're tested?

MR SWANN: As I mentioned, we have a very good chemicals management infrastructure there, so there would be a lot of controls on its use already at that particular point in time. Secondly, at the time that it's introduced, it is in most circumstances introduced only by one company for a particular market, so under those circumstances, it would be under a controlled use approach. There would be an ability to track how it's used at that particular time by that company and it wouldn't be out in the broad market, so to speak.

In fact, I would find it very difficult to conceive of a situation where a chemical, in its introduction period, was to be undergoing use at that particular point in time for a problem with its use to be raised that hadn't already been considered in the preliminary package that would have been developed by the company in its presentation to NICNAS. Something which I don't have the figures on at the moment, but I'd be interested to follow up actually, now that I think of it, is to us a question about how many substances may well have been knocked back in its assessment or that required significant modifications to its use. I would be surprised if there were many out of the number of substances that have gone through already.

DR STEWARDSON: It would be an interesting thing for us to know, if you had the answer, although of course the mere existence of NICNAS might be partly determining the answer that you got.

MR SWANN: Yes. As I mentioned, commissioner, NICNAS is an important agency and we certainly see its fundamental role in that area. If there was no NICNAS, it would be very easy for companies to bring substances in, in potentially an uncontrolled manner, without having done enough assessment work in its lead-up. Simply having NICNAS there and the requirement to provide an agency with information since it's been in place I think has improved the quality of the notification assessment packages that companies provide at that time. So whilst NICNAS is there and the company provides the data package for assessment, to me, I think a lot of the issues would be covered off at that particular point and it would be able to be used in a controlled manner, simply because of the agency being there.

MRS OWENS: I think you raised an interesting point, which I'd like to go back to, and this is the idea of bringing in competition in the assessment phase. We did an inquiry which I was involved in a few years ago on the medical and scientific equipment industries where that was one of our recommendations, that the conformance assessment should be done in a competitive way, where the TGA could do conformance assessment but compete with other bodies out in the marketplace, because we looked around the world and saw that in most other jurisdictions, that's exactly what happened and we couldn't see any need to have one provider of those services there, doing it in a fairly expensive way, so that was the proposal there. So I was quite intrigued that you raised it in this context as well.

MR SWANN: Yes.

MRS OWENS: I think good ideas bounce back in various ways.

MR SWANN: I think that's right. From what we have seen of those people that are able to conduct those sorts of assessments, it seems that the level of skills in the industry are as high as those which are within the NICNAS administration and I think that to us, it would be a sensible option to at least explore further in being able to use that.

MRS OWENS: Of course if you set up that sort of system, then you have to have some sort of accreditation arrangement for those other bodies. You just don't let it all go.

MR SWANN: That's right.

MRS OWENS: So you're replacing one form of regulation with another form of regulation. But if you end up with more efficiency in that part of the process, you could end up ahead, I would assume.

MR SWANN: Yes, that's right.

MRS OWENS: And if it doesn't work, those bodies will die a natural death and you'd go back to just having NICNAS doing it.

MR SWANN: That's correct, yes. Another benefit that would come out of that would be that one of the time-limiting factors in NICNAS is the availability of resources to get through the massive workload that's placed upon them. Given that the cost recovery for that element of it is on an hourly basis of use, you can actually spread the resource out and get access to maybe three or four times the number of people to do that work, so your costs stay the same but your time frames for getting something through the system reduce dramatically.

MRS OWENS: So you increase efficiency.

MR SWANN: Yes.

MRS OWENS: That's another argument that is often put for having cost recovery. The fact that you've got a cost recovery system promotes efficiency within the regulator, and I think there was something on your page 3 where you're basically I think inferring that - this is in the third paragraph, you say:

> Industry expects the greatest efficiency in the delivery of that service -

which is the - - -

MR SWANN: Yes.

MRS OWENS: Yes.

> Agencies should be provided with strong incentives to seek ways of increasing efficiency -

which is sort of inferring that that efficiency is not there now. Is that the correct inference?

MR SWANN: That is the correct inference. We have had a long experience of measures being developed by NICNAS to provide us with information about how efficiently it is operating. Over the last few years, there have been a number of circumstances where submissions have not been completed within the statutory time frame that we've set up for the notification and the assessment of that particular chemical. This has improved over the last 12 to 18 months but it's an inherent issue that there has been a backlog of substances there and the administration has not been able to cope with the demands on their time and meet the requirements. So if people are paying a lot of money for a substance to go through and you have a statutory time frame for it to be done as well, people expect to have it provided within that amount of time.

MRS OWENS: I think the theory is that if you're paying for it, you're going to demand to have a good system in place, but if they're a monopoly provider of the

system and you've got very few mechanisms by which you can actually go and say, "Well, this isn't good enough," you've got no fall-back, have you?

MR SWANN: No.

MRS OWENS: What do you do if you find that there's a backlog and they're not doing it quickly and efficiently? You haven't really got much fall-back at all, have you?

MR SWANN: No, you don't. You don't have a fall-back and you don't have many benchmarks that you can get a clear understanding. I'm hesitant to say that it's an inefficiency in the system of NICNAS without having some other measures to be able to judge that against.

MRS OWENS: There are international measures. I suppose the question is how quickly these entities are getting through the system in Europe or America or wherever. I mean, there's the potential to benchmark internationally.

MR SWANN: There is. You can do that on a standard assessment, but the US and the Europeans have a lot of exemptions within the system which doesn't require those substances to be introduced through that system anyway as well. I think also the difficulty we have is that in Australia, we are a small market. In Europe, they may have a market of 300 million people that they're servicing, so the administration can be substantially higher for possibly a similar-size introduction program, whereas in Australia, we have a vast range of markets that we're trying to service and provide substances to, and yet we don't have the volumes to allow it to be a very big administration as well.

DR STEWARDSON: Could I follow on from that. You have talked about the disincentive effect of the charge from NICNAS stopping various chemicals being introduced into Australia. Can you give us some sort of rough feel for the proportion, in terms of the total cost of developing and/or introducing into Australia the chemical? What's the proportion of the NICNAS charge in relation to the total cost of which obviously must be significant in other parts? I've no doubt that it varies a lot between chemicals, but can you tell us anything sensible in answer to that question?

MR SWANN: Sure. The proportion of costs of the NICNAS fee against the costs of doing the testing and assessment is actually not all that high. It's only probably 5 to 10 per cent of what the actual costs of doing the testing assessment is. But where it becomes significant is where the testing and assessment may have been done on a global basis already by a particular multinational company, so then the actual cost becomes the cost of introduction into the country because the company has already provided or can provide the data package and probably the support to prepare the submission in the first place. So that is where the 10 to 15 or 20 thousand dollars for the introduction has an impact on those markets who are recovering in a small volume application or maybe a short-term turnaround market where the dynamics of the market changes dramatically.

NICNAS has tried to address that currently through a low-volume permit scheme and also through the commercial evaluation category to open those up. To date, they have not delivered efficiency across all of the sectors because we're still having these concerns raised by companies about lost markets from the cost of the introduction impacting on the smaller niche market.

MRS OWENS: Is that just a problem with something new that they're trying to introduce that's just finding its feet or is it something more - - -

MR SWANN: Yes, I think the low-volume permits, the quantities in that are quite reasonable but they're still probably not as high to cover all of the circumstances and a commercial evaluation has always had a number of stipulations on it and they are looking at the moment as to how to broaden that to suit it. A commercial evaluation is really meant to be a prior-to-market evaluation. If that particular market or category was able to be used for a short-term market category, that may alleviate some of the concerns.

DR STEWARDSON: Can I be a little clearer about this: a low-volume permit, I take it, carries a lesser charge?

MR SWANN: It does.

DR STEWARDSON: Does it also imply that there is a lesser extent of testing?

MR SWANN: Yes, there's lesser testing and data provision requirements and less cost in terms of that market, but it is only provided where you have a small volume of the substance coming in per annum, so it's considered that because it's a very low volume, the exposure is very minimal out in the marketplace, so therefore there's no need to do the complete assessment. Once it goes over a certain volume, then you have to go through the entire testing program - assessment program.

MRS OWENS: Could you have something that's very low volume but very, very high risk?

MR SWANN: You can. In those circumstances, those substances may well be asked to go through some sort of an assessment program.

MRS OWENS: So they make that judgment?

MR SWANN: They could. The company would probably also make that judgment, but with the way that the low volume system is set up, if it's notified, then there would be probably some negotiations from NICNAS.

DR STEWARDSON: You're not happy with that system as yet. What is the problem? Is it that it stops at too low a volume for your purposes?

MR SWANN: Yes, the low volume stops at too low a volume. The commercial evaluation category doesn't cover market opportunities to a large degree. Some modifications in those areas would assist companies. I suppose it's really a case of looking at where is the cost benefit between the cost of the introduction fee against the volume that you need to bring it in to make it viable to market in this country. That's an area that we can probably get some further information for you. We'll see to get that.

DR STEWARDSON: That would be helpful.

MR SWANN: That's really I suppose where the decisions are made by companies about whether they will go down the notifications path.

DR STEWARDSON: That would be helpful.

MR SWANN: There have been some companies that have gone through commercial evaluation and use the substance for that particular market at that time, but have reached a point where then, to go through full notification, they have found the market volume was just not high enough to justify going to that next step. We will seek to get some of that information as well for you.

MRS OWENS: Ian, you mentioned before when we were talking about Europe and America that they have more exemptions.

MR SWANN: Yes.

MRS OWENS: Is that an indication that they have a different attitude to risk more generally? Are we more risk averse in Australia?

MR SWANN: It's a good question. I don't know the exact answer of it. I think that they have probably had more experience with the use of these materials over a longer period of time that have given them confidence in the exemptions that they have put in place and I think that is always going to be one of the difficulties in Australia, picking up an exemption or a different category that is in place in, say, Europe or the United States because our administration hasn't had that history and that experience with a particular substance such as, for example, polymers, and when they seek to find the logic behind why a decision was taken by the Europeans or the United States, they may not find that that decision can be justified in a robust manner, so therefore giving them that same sense of confidence.

So at times it needs to be a pragmatic decision that's taken. I think that some of the decisions that have been taken in the US and Europe have been pragmatic at the time without a full scientific justification for why they have introduced those exemptions, but also one that's based on a broader issue of prioritisation which is saying, "We have the full spectrum of potential hazard from substances. The ones which are down the bottom end, we're going to cut out," without actually looking at those from the perspective of, "What is the top cut-off of those substances?" because

they're all so far below what we consider are the priorities that we should be focusing on.

NICNAS has undertaken a review of the polymers of low concern category recently to help to achieve this. Industry would like to have seen it completely exempted, which would have impacted on costs, time, efficiency within the administration. When NICNAS did their assessment of the United States reasons for that category being in place, they found it difficult to find a lot of the justifications behind why they had made those decisions, which could be historical, could be because the people in the administration aren't there now that made those decisions at the time. Hence on that basis NICNAS didn't introduce the full exemptions that we would like to have seen. Maybe with some experience of the category over the next few years, we hope that that will be an outcome that we still see.

MRS OWENS: I can't second-guess that what NICNAS does or their thought processes, but I would have thought that, rather than looking at - maybe it's important to look at the underlying reasons - why that decision was made in the US relating to these polymers, it's more important to look at the actual outcomes, whether those polymers have been introduced in the market and actually caused any problems, the outcomes at the end. I suppose we're getting a bit of the track with cost recovery, but cost recovery is related to the underlying regulatory arrangement we've got in place, and we are concerned about the costs of cost recovery to industry. It just makes me wonder if there are exemptions in these other markets and there are no untoward results from that, negative impacts from those exemptions, you need to say: are we being too risk adverse?

MR SWANN: Cost recovery is a lot more palatable to industry when you can see a justification for why something has to undergo it. Where you have your cousins in Europe and the US not undergoing the same process and, to my mind, not suffering any health, safety and environmental consequences from not having that control there, it's very difficult to justify to our members that there is a need in those circumstances.

PROF SLOAN: One of the things that we're interested in is the differential impact of cost recovery, and I suppose you can't completely uncouple that from the actual nature of the regulations on large and small businesses. You seem to be an association which is covering a wide range of member companies.

MR SWANN: Absolutely.

PROF SLOAN: From the very large to - have you got sort of family companies?

MR SWANN: We do indeed, yes. We have many companies which are two or three-person operations.

PROF SLOAN: Would you like to comment on that? It's not just the NICNAS fees, but haven't they got some kind of ongoing registration arrangements so if you've got sort of a large number of products but with small volumes it looks as though the

nature of the cost recovery processes are quite harsh compared with say one company with one large selling chemical?

MR SWANN: That's right. The nature of the industry is very diverse, so it's very hard to actually answer that question without probably disadvantaging some sector of our membership. For example, you do have some large companies that have two or three key products, and for them the cost recovery as it currently stands is probably not as significant. But they also do invest a significant amount of money into the consultants and on-board staff who provide a lot of the technical information and backup to those areas.

You then have other companies, for example, CIBA Specialty Chemicals, which is a large company but has a product range in the order of several hundred to maybe even several thousand substances that they have on their books at the time. So a small fee over a number of particular substances actually mounts up to be quite substantial for those.

Then down, as you say, to the small companies, where all impacts are significant for the small companies who are starting out. With a lot of the small companies, if they're not linked to a multinational or a trading agency that has access to the technology, it becomes very difficult for them (1) to negotiate the system but (2) the costs of putting something through, and then, thirdly, they have to outsource their own consultancy costs, which has a lot in the preparation of submissions, the time for negotiation of it through and then the outcome at the end of the day. So it is complex for our industry and there isn't one rule that suits for all in terms of impacts against small versus big companies, unfortunately.

PROF SLOAN: Although that issue that you raised before that time is money and the way that it's set up at the moment doesn't seem to be particularly favouring speedy resolutions, presumably there would be support throughout the industry for an arrangement which got more rapid outcomes.

MR SWANN: Absolutely. Timing is the other issue. In fact, a lot of companies have said the costs in their circumstances sometimes doesn't make the decision; the time through the system does. So reductions in requirements, which I suppose again goes towards efficiency, is an issue in those circumstances.

PROF SLOAN: I suppose one of the concerns for us is that in fact you might have a regulatory and an attached cost recovery regime which ends up being a barrier to entry to these industries. Would you see it like that or is there rapid growth in this industry at the bottom end?

MR SWANN: I think that a lot of companies would consider that this is almost a barrier to growth and a barrier to entry for a lot of the substances. There is growth in some sectors of the industry. The areas where the growth still may occur is probably in those areas where if it's a niche or a small market it's a high value added product, in which case they can justify reasonable turnaround in return to justify the costs of

introduction. Where the volumes or the value are not high enough, for those companies they won't be able to access those technologies.

The other difficult driver in this is that the chemical industry is a service provider. We don't always make the decisions about what new technology comes on board. Quite often it's a case where a customer - say a person who's a fabric designer has just been to Italy and comes back with a couple of new-range products and goes to the supplier and says, "I need these colours and these conditioners for the fabric like tomorrow because I'm going onto the market to take on some of our global competitors. They will then drive the process and the supplier will then have to ask the question, "I have to be able to try and find that product for that company," and if the costs are too big for them because it's only very small volume, they won't be able to do that. The impact then is that that company which was the fabric designer won't be able to take access to that market and the imports will come in and take over, because as a finished product there aren't the same controls on the finished product in its final application.

That's always going to be one of the trickier aspects of this legislation and its application. You can bring a motor vehicle into the country with the latest paint on the surface but you might not be able to make that same paint in the country.

MRS OWENS: Or tinted windows, you've got.

MR SWANN: Or tinted windows.

MRS OWENS: Yes, I think the examples are very good.

DR STEWARDSON: Can we look at the process of industry having a proper say in which NICNAS for example does. You speak a little bit about that in your submission. As I understand it, NICNAS in fact does give to its advisory industry committee quite a significant amount of information, budgetary information, planning type information. What would be your suggestion for industry advisory boards having a proper say without them actually going to the extent of being the controlling authority, which would presumably be counterproductive to the whole exercise?

MR SWANN: NICNAS has been very forward-thinking and proactive in the provision of their information and industry certainly appreciates that. The industry-government consultative committee which was set up does provide different groups to have access to budget, to its allocations, and have probably gained a far better understanding of the administration and the costs and the pressures from other agencies that lie underneath that. Having a strong link between that budget process to the performance indicators I think is an important issue. Secondly, having some form of ability to influence the direction that that budget takes as it comes in, in the forward years, through a need for greater efficiency or maybe some cost-reduction activities would be beneficial.

It's all very well and good when you're not the one who has to prepare the budget to say such things. I can sympathise with the director of NICNAS in those areas, and I think that Dr Hartley is very cost-conscious and has looked to provide that. So I suppose the model is a good one. It's a good start. There would probably be some improvements which we would suggest in terms of the ability to influence and maybe the transparency of some of the costs from the administration side of the activities, but the real issue I suppose then goes down towards the efficiencies and the prioritisation and the on-costs: how do you restructure the budget, how do you get restructured into the budget a push for maybe reduction of all assessment by X per cent per year or something along those lines, that makes you start thinking laterally about then how do you improve the prioritisation.

DR STEWARDSON: I think the key issue is, to use one of your words, how does industry influence this, because you can have internal management being efficient and keen to reduce costs or not, as the case may be, but how does industry effectively influence them without actually having the control of them?

MR SWANN: I don't have an answer for you on that one. I agree with you, though, that the industry should not be in control of the budget. Having an ability to input to it and provide some advice on it is something which we've found beneficial, but I haven't got an answer as to how we might influence it without taking it over, as you rightly suggest.

MR VAN KRIEKEN: Perhaps the solution would be for industry to consult more with the internal management in terms of setting targets so in two years' time fees will be at such a level or something like that. Perhaps in that way then industry is still removed from it but it's making the internal management a bit more accountable for what they're doing with the moneys.

MRS OWENS: It's always a bit tricky, I think, with industries influencing management in this way when you're talking about a regulator, because then you quickly get to the point where people will say, "That regulator is subject to regulatory capture by the industry," and then the community loses faith in that regulatory process. So it's always a bit of a fine dividing line, and I suppose it's a matter of what the industry may want to influence. You talked about the budget, and I thought that your idea in your submission and that you've just raised then about somehow setting targets on fee levels in the future, what can be raised, is a good one to try and get the incentives back on the regulator to operate more efficiently. That could actually happen through the way you structure the fees as well, so that they're not actually necessarily recovering their full costs through the fees. So there are mechanisms to do that.

So you could think about that, but then the next stage is saying: should industry then have some say in the regulator's attitude to risk, for example, and what gets reviewed and where the exemptions should lie and so on. There's a whole lot of other questions which the regulator could consult on. Again, the dividing line between providing advice back to the regulator and influencing the regulator's decisions on

these things is a very fine one. But has the industry tried to push the envelope, tried to get involved in the, sort of, bigger issues?

MR SWANN: In terms of where - - -

MRS OWENS: Well, risk.

MR SWANN: Risk etcetera?

MRS OWENS: Yes.

MR SWANN: Yes, we do, and we constantly raise these issues. The Industry Government Consultative Committee has been a forum for provision of that, but even before that our industry association worked very closely with the administration and I think that we considered one of the key ones that were fundamental in some of the reforms that went through in 1998 - 97, 98. At that particular time that introduced some flexibility that addressed some of these issues, and we'd like to continue that approach going on. The final decision is always made by government of course. But where it breaks down is that NICNAS has responsibility for the delivery of that approach. If you get into issues on policy that becomes an issue for the Department of Workplace Relations and Small Business so you have a different group of people that you're in touch with and influencing at that particular time and that's where it becomes a political issue. Now we will use that option and work with people such as Mal Brough who's been given responsibility for management of that from a policy level, but we don't like to address those particular issues unless there wasn't any way to manage that through with the NICNAS administration in the first place.

MRS OWENS: I get an impression that there is a reasonable relationship between the industry and the management of NICNAS which may differ from when we talked to some other industry groups and their relationships with their primary regulator, if you'd like to call it that. So you're reasonably happy with the way the consultation arrangements are going and generally the way NICNAS operates as a regulator? Given the legislative constraints under which they're working, are you reasonably happy or have I misinterpreted?

MR SWANN: Yes. No, you haven't missed that. Given the constraints that the NICNAS has to operate under, we have a very good working relationship with the director and the teams within NICNAS. I think the last few years have probably seen an improvement in that relationship. There is always going to be areas where we all differ but at least we have the opportunity to raise those with the administration and take it forward from there and have a clear answer as to whether or not it's something that they can influence or whether it's something that we need to be putting pressure on the department. So it is an open relationship; we're very comfortable to continue fostering that relationship. I suppose the areas where that could be improved, as you'll probably find from all industry people, is that they don't pick up all the recommendations that we'd like to make to them.

MRS OWENS: And we probably won't either.

MR SWANN: Absolutely.

MRS OWENS: Or we might. That was very helpful. Thank you very much for attending.

MR SWANN: Thank you.

MRS OWENS: And thank you for the submission once again, and I think the discussion was excellent and you've clarified a lot of things for us, so thank you.

MR SWANN: Thank you very much.

MRS OWENS: We'll just break for a couple of minutes.

MRS OWENS: We'll now resume. The next participant this afternoon is the APMA, the Australian Pharmaceutical Manufacturers Association Inc. Could you please give your names and your position with the APMA for the transcript?

MR EVANS: Alan Evans, chief executive officer of the Australian Pharmaceutical Manufacturers Association.

MS MONK: Deborah Monk. I'm the manager of scientific and technical affairs at the APMA.

MRS OWENS: Good. Thank you for coming this afternoon to another state and everything, and we have received the submission and I'd like to thank you for preparing that submission. We found that I think very useful and I found all the attachments you gave us also of great use. Would you like to make a few opening comments and then we might ask you some questions?

MR EVANS: Thank you very much for that. The inquiry you are conducting and the issues which it raises are I think significant issues of public policy which have to be dealt with. If you look at the particular area we focused on, which was the Therapeutic Goods Administration, where the government now seeks 100 per cent cost recovery for the activities of the TGA, it significantly impacts on our industry. About 62 per cent of the budget of that authority are raised directly from our members, the prescription pharmaceutical industry. So we do have a very significant interest in what TGA does and how it does it. I mean, that's by far - and when you look at the others, the self-medications through the medical devices, they also pay. But we account for 62 per cent of their revenue; their outlays in a sense. So the fact that we're into 100 per cent cost recovery does focus our industry's mind quite sharply. I guess what it does is bring to the surface these vexed issues. How do you be certain that you're getting value for money in the fees that you're paying to a body which also has the monopoly over the regulation? Those are issues which are not easy to come to conclusions on, but there are a number of options which could be pursued.

The issue that is constantly referred back to us as being the reason why we can't have a greater say in terms of the costs of the activities, the budget of the organisation, is that it is the regulatory authority, it is the one that set the standards, it is the one that assesses risks and of course protects human health and in terms of whether a product is able to be registered in Australia and then be eligible to be marketed. We don't have any quarrel with the fact that it has to be separate from industry in carrying out those functions in terms of what I'd call a pure public policy role. But in terms of then the activities of evaluation and the costs of those evaluations, there needs to be mechanisms in place which ensures that the industry is getting value for money.

If you look at the cost of getting a prescription product, a new chemical energy, into the market in Australia, it can be in the order of around about - I think the top fee would be about $208,000 - to a market at the maximum of 20 million people. In the

US, if you had the same product going through the Federal Drug Authority, you would be looking at a price of around $US250,000 for that product because you're going into a market in excess of 200 million people. So the relative cost of entering the market in the two countries is quite disproportional, and that's a factor which I think in many instances influences the decisions of pharmaceutical companies as to whether or not they'll seek to register a product in Australia if it's a very, very small market. Because in Australia, unlike in the US, once you've got the registration, then you're given its market which is a much more open market, essentially your costs are met, whereas in Australia you've then got another stage of the process and again an additional substantial cost to meet to get your product through into the market, given that the pharmaceutical benefit scheme so dominates the pharmaceutical market in Australia, as you'd be aware at the commission.

So these are issues which need to be teased out. I think the industry needs to have the confidence that it has got an organisation which is performing to standards which are both acceptable in terms of the cost effectiveness and efficiency but not exorbitant, that efficiency or productivity is a key driver in the organisation's performance and that we can see measures of that and see reports on that. The second point is that there is clearly activities of the TGA which are of public benefit which are public good activities, you might say, which the industry is bearing the cost of, and one could argue that that's something that should be met out of the public purse because it is not of benefit to industry; it is a public benefit, albeit the industry might receive a small part of that benefit.

So we believe that that issue needs to be teased out and determined whether or not there should be some proportion of the costs of the organisation met from the public purse. There are also arguments I think you can take up about separating activities into different bodies so you get (a) the accountability to government and to the public, but (b) ensure that industry gets value for money in the charges it meets in getting its products registered. I'll leave it at that at that stage unless you've got - - -

MS MONK: No, thank you.

MRS OWENS: Good. Thank you very much for that. I think that you've raised just now some interesting issues and I think there are some issues that we'd like to tease out from the submission as well. I suppose the first one is the philosophical question of who should pay for what, and when you got started - not you personally, Alan - but when the TGA got started, initially there was a 50 per cent cost recovery arrangement which you mention in your submission and you give this background as to how it gradually crept up to 100 per cent. I suppose the question is what's happened in the meantime? Did anything very significant change in terms of what the TGA was doing or meant to be doing that might justify going to 100 per cent? That's the first question. Or was it just the change of government attitude?

MS MONK: Indeed, when the changes were made we challenged the government to explain to us how the situation had changed whereby they didn't continue to feel obliged to pay for those public health risk related responsibilities but no explanation

was ever given to us. So both in the move to 75 per cent cost recovery and also to finally 100 per cent cost recovery, there was no explanation of why there was a change of feeling as to that industry should now pay for those activities rather than government.

MRS OWENS: It does raise a really interesting dilemma as to how you decide who should pay for what. There's two approaches. One is that the beneficiaries should pay and that could be divided up between the industry. It might see itself as a beneficiary to the extent it has a community out there that trusts what it's supplying in that market or it could be some elements of the industry could benefit to the extent that they register the drugs, list the drugs here and they can then get those drugs into other markets, say South-East Asia or wherever, and they've got consumer's benefit by being reassured that they're getting a product which is not going to kill them or whatever and the community more broadly may be seen to be benefiting. There's a public benefit, as you said before.

So you can either look at it that way or you can look at it another way and say the reason you've got a TGA in the first place is because the industry is there, the industry is there supplying products. You need to regulate those products because potentially those products could have an adverse impact on human beings, or in other words, some sort of externality which the industry should be paying for, and the industry can cover that externality through the very fact that it is regulated and has to take certain steps to ensure that its product is of a standard - or there's information available or whatever to make it marketable, or it can pay through paying fees and charges. So the complexity of this whole thought process they are going through is, you know, which way do you go, or is it a bit of both?

So you see, if I was in the health department I might say, well, really the industry - we have a regulatory process because there is an industry there. If I was you I'd say, "Well, you have consumers out there that want these products that the industry is supplying and the consumers, you know, may get benefit from having those products and access to those products. Do you see the dilemma that - - -

MR EVANS: Absolutely. It's something that has exercised my mind since I've arrived into the organisation. But in fact you have to, I think, take some steps back. For example, the FDA is seen as a premier regulator in the US. In the US the FDA is seen as a premier regulator. You have the European regulators and then you have an Australian regulator, a New Zealand regulator, and one has to ask in a market which is essentially a global market - I mean, it is not the case that a product will be registered in Australia and Australia only. Well, it would be very unlikely.

MS MONK: In most cases, no.

MR EVANS: Yes. Is there any?

MS MONK: You could argue perhaps for an indigenous population you might need something special.

MR EVANS: Yes. So, you know, this is a process an industry has to go through in each of these nations. Now, we recognise that countries feel a higher level of comfort if they've got their own regulator looking after the interests of their own population. I mean, I think there are some political elements in that and we're not advocating that there should be just an automatic recognition in Australia of products which have either FDA or any of the European regulatory authorities' approval. But one can argue that there's clearly the action of having your own regulatory authorities because government decides there is a public benefit from doing that and that the industry - yes, it receives a benefit because once a product is registered it is then eligible to be marketed as it goes through the next stage of the process.

I think the industry's attitude is, "Look, we're prepared to pay in order to access the market. We recognise there's a benefit from that. However, what we do have a concern about is we meeting the total cost when they're clearly actions that are driven by public policy interests rather than private interests." Because if there were not, then the simple action would be to say if a product has FDA approval it could be marketed in Australia. I mean, there's not - - -

MRS OWENS: I think that's a good point. You're really inferring that just about all products could be regulated in these other markets in the US or in Europe and that we should take those results as given and accept those. There would be no circumstances as far as you can see where you might have to do something here as well?

MR EVANS: No, I wouldn't want to suggest that that's what I'm saying but it could be an argument that could be put forward. We're not. I mean, we accept our role and our responsibility in the Australian society and there is good reason I think to go through the process we do, because there is a public benefit. You're actually maintaining a skill base. You're ensuring that people with the requisite skills and the qualifications, the expertise, are available in Australia for more than just the purpose of evaluating a prescription product which can come onto the market. There is spillover benefits from that sort of activity, that you've got people trained in evaluating clinical trials, in evaluating products etcetera, which may not be of direct benefit to the pharmaceutical industry but are of general benefit to society.

On that basis we're not arguing for the abolition of TGA, because there is a next stage I think which comes, which is that if you have a regulatory authority of world standing then given the peculiarities of markets and given the peculiarities of nation states who sometimes want to have their own regulatory authorities, that in the region we live in the ability to have a sort of regulatory authority of the standard required is pretty difficult to achieve and probably Australia is in the best position to have a regulatory authority which could have global standing and then being perceived in the region as a regulatory authority whose standards are high enough that if a product gets through that it can work in the region.

In the Asian countries for example they're pretty keen to see clinical trials conducted on their indigenous population. Now, the ability to conduct those trials is

not present in most of those nations, nor the ability to evaluate the outcome of those trials. So we can see a benefit down the track from the TGA being seen as that premier regulatory authority, which will have a flow-back both into the industry, because it will open up potentially export markets, but also back into the Australian community in terms of economic benefit etcetera, job skills, training, through into the education system. It is arguable you can say, "Look, if we're looking at these terms in terms of absolute efficiency we just adopt the FDA approval," or European.

DR STEWARDSON: Can I ask you to clarify something. You said that when the cost recovery was officially 50 per cent there was an agreement with government that government would fund those functions that are related to "public interest activities" and industry would have the other costs recovered and that the split between those two things was fifty-fifty, that that was what was justified, the fifty-fifty arrangement. Two questions: (1) what were regarded as public interest, as distinct from industry at that time? You've talked about, I think, the assessment. I think you've implied the assessment is perhaps something that industry might pay for.

What other things are left, other than answering ministerial questions and so on, as public interest, and do you still see the split between what you would regard as public interest and something that industry might legitimately pay for as being fifty-fifty, notwithstanding that you're paying for 100 per cent? The fifty-fifty, what I'm really asking you, just the 50 per cent public interest activities seemed quite a surprisingly high figure and I wanted to know what you're putting in that category.

MS MONK: There were some quite detailed analyses done at that time and that's included in one of the attachments to our submission. I think it's attachment 3, which itself has some attachments to it, and in there it lists some of the activities that at that time were decided to be attributable to public health or public interest, and they were things such as the conduct of the Australian Drug Evaluation Committee, which was regarded as being an independent committee and should remain so, and therefore it was felt that the government should pay for its costs. Similarly there's the Therapeutic Goods Committee which is also intended to be an independent committee, activities such as post-marketing surveillance, so monitoring any adverse outcomes to medicines that might occur post-marketing and the reporting of those, both from industry, from doctors, from pharmacists and from consumers.

There are some activities of education that might be undertaken by the TGA. There's lots of surveillance activities in the marketplace to make sure that there's no counterfeit medicines in the market, those activities. So many of those are listed here in the outline of what was then attributed to be what should be public health related and which should be industry service related. I don't believe that we could make an estimate at this time of what we thought that split should be. What I would suggest is that we would need to do is sit down with the TGA and have a discussion about all of their different activities and try to make a determination which we agreed were public health related and which were industry service related.

DR STEWARDSON: Thank you.

PROF SLOAN: Could I just sum up their view - and you might correct me. It seems to me that APMA are in favour of partial cost recovery, you know, but I mean, done with some degree of sophistication about the nature of activities. But added into that presumably is this issue of accountability and transparency because if you're cost recovering you want to know what the costs are, don't you?

MS MONK: Exactly.

PROF SLOAN: So that's particularly in relation to the nature of the costs being recovered, which then in turn relates to the nature of the activities. I don't know whether you were here in the earlier session. We talked about, you know, are all these activities necessarily held in-house? Are there different models? Are there different models that might generate some efficiency gains? And let me just finish my point, that you seem to have a third string to your bow which is with appropriate mutual recognition for - but would you like to comment on that second aspect, you know, defining the costs in terms of the costs being appropriately recovered partially and the nature of the activities which are generating the costs, particularly in relation to the TGA which, you know, does generate quite a lot of criticisms.

MR EVANS: Look, I have to say that we think the TGA's performance has certainly improved over time and it is, in terms of a regulatory authority, quite proficient and efficient. But I mean, it highlights the issue about, you know, the person being the regulator setting the standards, doing the evaluation, and no testing it, you know, no market testing in a sense.

PROF SLOAN: Yes.

MR EVANS: And there could be an argument to say it will set the policy, it will set the standards and it can out source the evaluation, and it measures, checks and assesses the quality of the evaluation or the evaluators. There's a bit of a parallel in this field. For example, once a product goes through the TGA then to get into the Pharmaceutical Benefits Scheme, which accounts for some 90 per cent of prescription pharmaceuticals or the prescribing of pharmaceuticals in Australia, it goes through another evaluation process, cost effectiveness process, and that's in a sense out sourced from the Health Department. So there is some allied examples in the portfolio where they can out source some activities.

I think what you then have to do is to say is there capability within Australia to out source, to have some competing out sources or competing evaluators, or do we diminish their capabilities, or is there a benefit which will arise from having this concentration of expertise in the single authority which performs all this multitude of functions? That has not been done either.

PROF SLOAN: Is that a fair test though? I'm a bit worried people might say, "The market is thin" - in other words, there aren't many providers - but it seems to me, yes, of course the market is thin, because there's no demand. Presumably you would

create a market if you decided to outsource a lot of activities, presumably including from perhaps some of the current incumbents.

MR EVANS: I think that's what I'm suggesting: there's been no testing. I mean, it's just assumed that you can't go out and do it, when there's not been a testing of that or an evaluation as to whether that can occur.

DR STEWARDSON: Isn't that the sort of thing that has to be done on a big scale to be economic? I mean, could one envisage having three or four such testing facilities in Australia that were economic and could provide competition with one another?

MR EVANS: I think one could.

MS MONK: The vast majority of the evaluation of new medicines for supply in Australia is a paper based system. It's not a physical testing of the product, of its chemical or microbiological qualities; it's very much a paper based system. So you need people who have the scientific ability to do that paper based assessment. I guess perhaps one example is the pharmacological and toxicological evaluations. There are very few people in Australia with the appropriate qualifications to be a toxicologist, and I think TGA finds it very difficult to maintain their staffing levels of evaluators in that particular field. So if that were outsourced, I think it would be very difficult to find those capabilities within Australia. Perhaps you could look beyond our borders to international sources, but it's very difficult I think to find the capabilities out there.

MRS OWENS: You don't necessarily have to outsource into Australia to do it.

MS MONK: No.

MRS OWENS: But maybe if you were setting up a more competitive system those skills would come; there would be positions, maybe better paid positions than the TGA can supply; I don't know. The TGA has its laboratory in Canberra, which we have driven past. I haven't actually been into it, but it looks like a very grand structure.

MS MONK: That building at Symonston now holds all of the TGA, not just the laboratories part. So all of the different branches of the TGA are housed within that facility.

MRS OWENS: Which your industry is helping to support, I presume.

MS MONK: Yes. I was going to actually raise the laboratories.

MR EVANS: It's not one of the prettiest buildings in Canberra, I have to say.

MRS OWENS: It's not?

PROF SLOAN: It's one of the bigger ones.

MRS OWENS: Like the Taj Mahal?

MS MONK: The laboratories in the past have accounted for about a quarter of the TGA's overall budget and the APMA in the past has been quite critical of the large amount of money that was spent in that laboratories function. Most recently, over the last couple of years, there has been a restructuring of the laboratories, which we thoroughly support. So now the laboratories, instead of driving their own agenda for the sort of work that they will do, have entered into service level agreements with the different regulators within the TGA, say, for example, the prescription medicines regulator, non-prescription medicines and devices regulators. So instead of driving their own workload and saying what they're going to do, now that's driven by the regulator outside. I think that's a very good model for the TGA to have adopted internally for trying to improve their efficiencies and cost-effectiveness of their activities, and we support that.

PROF SLOAN: You seemed to have some reservation about the TICC though, didn't you?

MR EVANS: Yes, it - - -

PROF SLOAN: Because in a sense that on paper looks like a mechanism whereby accountability can be improved and potentially also transparency, but I think your submission was little less than fulsomely enthusiastic about the TICC.

MR EVANS: It's better than nothing, but the problem is - and I in part can understand it - that the TGA is part of a department of state, so it's very reluctant to let anyone in to make determinations about its budget and its budget allocations. So whilst there's information provided to us, it is in a sense post the event, post the decisions made about budget allocations or post the performance.

So whilst it's nice to get the information, the inability to influence decisions as to allocation of funds or whether that's the most efficient way of funding - I mean, Deborah has talked about the restructuring of the labs where they've now got service level agreements. It would be useful for us as an industry, given we meet the bulk of the costs, to be part of setting some of those service level agreements: are there real performance measures in those service level agreements, will that part of the TGA buying the service be itself getting value for money which it then passes on to us in terms of improved charges, or lower charges?

MS MONK: But, for example, the recent service level agreements that have been set up between the laboratories and the other regulators, we're told that they're in place but we haven't been provided information about the detail that sits behind them or had any opportunity for input into their establishment. So we'll be told after the event, as Alan says, but we don't have any influence about how they might be structured. Similarly, if you look to the current terms of reference of TICC, we are

able to examine and comment on various activities but we have no ability to decide or influence in any particular direction.

DR STEWARDSON: I think we then come back to the question that I think you may have been here for, that I asked the last people: if you had your way and were making a recommendation uninhibited, what sort of arrangements for the TICC would you make? Apart from getting more information and getting it before the decisions are made rather than after, which you've just said, how would you organise the TICC to have an effective influence of the TGA without actually itself running the TGA? I mean, what's to stop them just saying, "Yes, well, that's all very nice, thanks. Have a cup of tea and now we'll go and do what we want to do ourselves"?

MR EVANS: I've thought about that. In part you've got to split the functions. If you retain the TGA as a single entity, then in terms of the policy and the standing, clearly it has got to be accounting to parliament, to the ministers, and we wouldn't want to interfere with that. But then in terms of how those standards are met, in terms of the performance of the organisation, you can have a dual responsibility, one to the industry itself in terms of how those tasks are performed, their efficiency and effectiveness, and are they cost effective, and then back to government saying, "Here's how we've met your standards, by carriage of these activities, which the industry is satisfied have been carried out effectively and efficiently and from your point of view the policies and the standards have been met. So it's a bit of a split of functions. It would be a tricky exercise to do, but it would be an improvement on the situation at the moment.

DR STEWARDSON: Can you just elaborate a bit on that? The TGA would talk in terms of policy matters to government but in terms of actually having determined the standards you're suggesting that it would report both to industry and to government on whether in a technical sense it was implementing those and testing for those standards effectively, and if industry thought it wasn't doing so - - -

MR EVANS: And at a cost-effective price as well.

DR STEWARDSON: The TGA would be obliged to take notice in some way, would it?

MR EVANS: I think it would be obliged to - I don't like using the word, but defend the prices it charges for industry, and industry can look internally to itself. As Deborah said, it is a desk-top exercise, much of the evaluation. We have a sense of how much it would cost to prepare the material and how much it would cost to evaluate it internally. There are external providers to many of the firms who prepare applications on behalf of companies, so you get a sense of costs involved in that sort of activity. You could look at a number of measures to see whether there is value for money in the prices being charged.

MS MONK: But we could also have some extensions of some informal agreements that we have currently about their performance. We could say, "This is the

performance level we want you to attain in relation to speed of evaluations, numbers of evaluations, and in return we will pay X amount of money. If you do better than that and give us better performance, we'll give you higher fees to help you achieve that, or if you don't achieve the performance we expect from you, we will not pay any more higher fees and indeed we might try and negotiate the fees to come down." So there could be a negotiation there between performance and the amount of money that the industry was willing to pay.

MRS OWENS: So really the industry is going to contract with the TGA to regulate it. Is that what you're saying?

MS MONK: In a way, yes, but the standards externally that the medicines would have to achieve would be internationally accepted. We wouldn't have any say over those; it was how quickly those functions are performed, the service provided.

MR EVANS: That's where I say that the TGA would then report back to government that it's met the standards by the work it's carried out. If, for example, it said it took X amount of time to evaluate these aspects of a submission and negotiated with us that this would be the basis on which the fee was set: if it did an X minus, the fee would rise; if it did X plus, the fee may come down.

MRS OWENS: So it's an output based funding arrangement, yes.

MR EVANS: Yes.

PROF SLOAN: I suppose the trouble is that it might be criticised as being seen where the regulated are kind of undermining the independence of the regulator.

MR EVANS: We're very conscious - - -

PROF SLOAN: Yes, you've got to be careful about it, don't you? Ideally it would be best really if an organisation itself sort of floated a series of benchmarks which were then put out for consultation effectively.

MS MONK: To some degree the TGA endeavours to do that because it internationally compares its performance with other major regulators, such as the FDA and the EMEA in Europe. We politely try and encourage them to achieve the same performance standards. So we have some very positive discussions along those lines.

MRS OWENS: And do they?

MR EVANS: They're getting towards it.

MS MONK: Yes, I think they've moving very close, but the TGA, probably quite rightly, comes back and says to us, "The FDA has several-fold more staff to achieve those performance targets than they do in Australia but they're basically doing a

similar evaluation with much less people." So there is that side of the argument as well.

MRS OWENS: We go back on the circle again and say, given the FDA has got all these staff doing these things and they're doing similar things, why are we doing some of the same things? But maybe if you had your sort of performance agreements and things weren't going well and they weren't reaching these standards, then it would force the TGA to look internally and say, "Can we do this better?" - or "Can some of this be contracted out?" - or should we be looking more closely at the FDA approvals and accepting more of those? I mean, it would be a trigger for them to actually start to think about these things or take these things more seriously. They would probably say they take those seriously now.

MS MONK: Many of those issues came up in the TGA review that was done by KPMG two of three years ago, yes.

MR EVANS: It has focused the industry's mind as the charges have risen and you've gone into cost recovery, which in turn has then caused us to be much more focused on the TGA's performance and certainly much keener to comment on that performance.

PROF SLOAN: That's been a positive outcome then.

MR EVANS: Yes, it has been, but we're still in a sense dancing in the dark because if they want to they can say very politely, "Well, thank you," and keep doing it. So we really don't have the ability to influence performance other than the basis of goodwill. I must say the relationship is very good and I wouldn't want to be seen to be critical of that, and their performance has improved, but in this very dynamic world one of the issues that affects investment in a global sense is the performance of regulatory authorities, their efficiency and effectiveness, and we're conscious we need to make sure the TGA is amongst those in terms of both its standards and its efficiency.

PROF SLOAN: Presumably your association represents both small and large players, including of course essentially branches of big multinational companies. Do you see there being kind of a differential impact of these cost recovery arrangements on, say, your smaller members compared with your larger ones?

MS MONK: I think there would have to be, just as the amount of money each company has available to it to spend on an evaluation, but also I might mention that we've noticed in recent times as the fee for drug evaluation has increased companies are making decisions now as to whether they will event attempt to get their product on the market in Australia. They're making a decision much earlier on, and that's combined with the difficulties in getting their product listed for reimbursement on the pharmaceutical benefits scheme. So the rising fee of drug evaluation through TGA plus the increasing difficulty of getting a listing on the PBS are making companies make decisions to not even bring products to the market in Australia.

PROF SLOAN: So they would try and bring a product to market overseas before they brought it to Australia?

MS MONK: Some products would be available overseas that are not available in Australia because the company has made that decision.

MRS OWENS: Any examples, any good examples?

MS MONK: It's difficult to find examples. If the commission wished we could try and find you some examples.

PROF SLOAN: That would be helpful.

MRS OWENS: Before you arrived we were saying to the last participants that any examples like this, just give us some substance on which we can base comments, because it's easy to claim, "These products aren't coming in because of the regulatory system," and I guess we've got to distinguish between the regulatory system and then the costs associated with the regulatory system, and our primary concern is the costs that come from the fees and charges, although it's very hard to then distinguish those from the other compliance costs.

MR EVANS: It's more a consequence of what happens further down the chain, but the fact that the regulatory cost is so high then has an influence because of your ability to recover those costs if you've got a product which is going to have a small market or, more importantly, is unlikely to get listed on the pharmaceutical benefits scheme because it's got a much sharper focus these days as well, whereas before people would get a range of products on within a particular therapeutic class. The PBAC itself now is being (a) much more conscious about having a limited number, but (b) much more conscious about price.

MS MONK: There was a downturn in the number of new products being brought to the market noticed by ourselves as well as the TGA over the last year or so. The TGA invited us to see if we could explain why that might be occurring and we did a survey of our members to ask them exactly that and I could provide some comments that the members gave us, not specifically identifying products, but some of those comments as to why they were making the decisions they were. But also we'll try and provide you with some examples of products that have not been brought to Australia for those sorts of reasons.

MRS OWENS: Yes, that would be really useful because there's a whole range of things that your members could be worried about and one is the price they get if it goes onto the PBS because of potentially reference pricing. So whether it's the costs further down the line when they're just getting into Australia through the TGA or whether it's something further along the process, it's hard for me to gauge that.

MR EVANS: We've been doing some of this work and in the main it's the consequences of what happens further down the line, coupled with the cost. I mean, if the cost was lower I know on a number of occasions they would actually proceed with the registration because they would recover those costs, or (b) they were prepared to take the risk that the market could develop. It's also true with what I call some of the very specific products for illnesses which are not widespread. You know, there's a small incidence of that disease in the country. In fact we know that on a number of occasions they've used other mechanisms to get the product in to treat the disease. They're not trying to be hard-hearted but they're paying 200,000-odd to get a product in when there might only be five or six people who are going to use the drug.

MRS OWENS: Is that 200,000 - you mentioned that up-front and I meant to ask you earlier: is that the costs, the fees, or is this the whole cost of complying with the - - -

MS MONK: That's just the evaluation fee. That would be for a major new application at the highest page count for the three different types of data provided and that's just the evaluation fee. Then there's an annual fee for maintaining the product on the Register of Therapeutic Goods and that's per product of $950.

MRS OWENS: Then there could be a huge amount of other costs associated with additional tests that they might have to undergo or further information they've got to actually collect in the first place.

MS MONK: There are enormous activities in the company.

DR STEWARDSON: I presume that most of the products that we're talking about are researched and developed overseas and that you're talking about bringing them into Australia, rather than having had them researched initially in Australia. Is that correct?

MS MONK: We have a very good clinical research infrastructure in Australia and research based companies endeavour to do part of that research in Australia, so they'll be conducting clinical trials for example in Australia of those new medicines. So we participate in that activity as well as just bringing the product to the market. Those research based companies do.

PROF SLOAN: We do have a small pharmaceutical industry.

MS MONK: Yes, it probably is small but - - -

MRS OWENS: Some of it's in Adelaide.

MS MONK: And some of it's in Adelaide.

MR EVANS: Certainly, yes.

MS MONK: Some of the most important parts are in Adelaide actually.

MR EVANS: Absolutely.

DR STEWARDSON: So in terms of the domestic development then, roughly what proportion of the total development cost is represented by the fee? I mean, are we talking about a very tiny percentage?

MS MONK: You would be. There's some research out of the Tufts University in Boston, in the US, that says that the cost of discovering and developing a new chemical entity and bringing it to the market - I think it's $US500 million. I could provide that research if you're interested and it's about to be updated with a new study that's going to be released in December this year. But that's a very large investment so the evaluation fee obviously is a very small part of that and the time period, those studies from the Tufts University say that it takes between 12 and 15 years to bring a product to market.

PROF SLOAN: But that is an issue even at this sort of part of the chain, where time is an issue, isn't it? You know, if they've got to the stage where they're seeking registration or whatever we call it, for there to be delay at that stage is a critical factor, isn't it?

MS MONK: Yes.

MR EVANS: Yes, because if you've got a product which is either a breakthrough or is, you know, a major advance in the market then you can - the sooner you get it to market then you're going to get the return on that investment. We notice that with the further development of the biotechnology industry there's some changes occurring there. I mean, they have an expectation of a much higher return over a much shorter space of time.

PROF SLOAN: Well, they're listed companies now, there are so many.

MR EVANS: yes.

PROF SLOAN: And that has changed the dynamics.

MR EVANS: Absolutely, so there's not that patient capital that there was in the pharmaceutical industry and I think - - -

PROF SLOAN: Impatient capital.

MR EVANS: Very impatient. I think that's altering the dynamics quite markedly and the regulators right through the chain are having difficulties adjusting to that. The expectation of the investors to get the return over a shorter period of time is much higher and they're much more inclined to sort of say, "Well, sorry, if you're not prepared to pay the price then we're not prepared to put it in the market."

PROF SLOAN: And one of the criticisms we've heard in our travels of the TGA is that basically, you know, the top level are all as 100 per cent cost recovery but because they can't actually forecast the number of units of demand they'll get it wrong both ways. So some period of time they'll under-recover so they up the price and then in another period of time they might over-recover. I mean, is this a sensible way to be pricing their service?

MR EVANS: We try and assist them in their projections by - Deborah, you know, regularly surveys industry in terms of what are the products they expect to have evaluated and seek registration, so we can give the TGA an ability to predict a bit better what their market is going to be like. But that's not easy.

PROF SLOAN: But is that not undermining of the issue of accountability, because I mean, should you not be able to identify the costs associated with, say, an evaluation and they should be charged that irrespective of how many other participants are putting in applications that year?

MR EVANS: In theory, yes.

MS MONK: And that's the point we tried to make in our submission, that the actual fee charged for an activity is only notionally related to how much that activity costs, because built into that fee are a myriad of other activities that there isn't a fee attributed to, that have to be taken account for. So historically we have always calculated the fees based on historical trends. But when it comes down to it, it's the bottom line of how much revenue the TGA needs from each sector. Then we go back through and try and calculate the fees related to that. So there's only a notional relationship between the fee and how much it actually costs to do that activity.

MRS OWENS: So there's no predictability from year to year. If you're a company and you're going to put one new drug in this year and you put in a similar drug next year, they could be totally different prices?

MS MONK: There shouldn't be an enormous amount of difference between year to year. We have in the past had annual negotiations of the fees and charges and they have very rarely gone down. Indeed they've mostly gone up. But it's not a very large increase on a year-to-year basis. I would have to go back through the records and say how much the difference was on a year-to-year basis. I guess the biggest increase would probably be around 15 per cent on a particular fee item, something of that order, and the company would know how many applications of their own they would be expecting over the next period of time. So then they could work out their own internal budgeting.

DR STEWARDSON: Are you saying merely that because there's 100 per cent cost recovery and you think it should be a lesser percentage that each charge is higher than you think it should be, or are you saying that the actual distribution of that

100 per cent of the TGA's costs, the distribution between different things that are charged for, is wrong and unbalanced in some way?

MR EVANS: I will answer the question this way. Some other parts or some other sectors who deal with the TGA certainly have a feeling that they'd like the charge to be less. But we in fact, because we meet such a large bulk of the TGA's costs, we probably pick up - and I think we do - some of the charges or costs that might rightly be attributed to others, be it the medical appliances or the self-medication or the complementaries. There might be occasions where we're probably carrying a greater share of the burden than one might think we should, given the circumstances.

MRS OWENS: Can you identify that? Is it identifiable from the information you received through TICC?

MS MONK: Not very easily. The TGA itself did an activity-based costing study with Ernst and Young - I think it was - Consultants and in that way they tried to attribute all of the different activities to different sectors like prescription medicines, devices, non-prescription medicines etcetera. In going through that process they did find that there was some cross-subsidisation between the different sectors and they tried to sort that out and make sure that it was balanced out so that there wasn't that continuing to occur. But coming back to your question I think what we're really saying is that we feel that there are activities that the TGA is performing that are not industry service related, but are public health service related, and we feel that we shouldn't have to pay for those, that the government should have to pay for those, and that we should have a discussion with the TGA as to what those activities are, work them out and then we pay for all of what we see as industry service related but not else.

PROF SLOAN: In fact the use of consultants was brought up as an issue in our industry and you've mentioned - a presumably quite expensive use of expensive consultants, which is fine, you know. But basically the costs of all those consultants is then slated back to the consumers, and so that's kind of another thing that - and one of the things that was mentioned through the TICC. You might mention something and they say, "Yes, that's right, so they're going to employ a consultant," but then the industry is paying for the consultant, you know.

MR EVANS: Yes, and so you get fairly cautious when they've suggested consultancy. I mean, there are some odd things - not that we're complaining. The government decided that the consumers should be represented on the TICC and should get some funding to enable them to carry out their tasks of being part of that, and that's a cost we now bear. So, you know, a government decision - we're quite happy that consumers are involved in the process. We spend a lot of time talking to consumers. But we did think it rather ironic that the government made a decision to include them and then charged us, so - - -

MRS OWENS: You've got deep pockets.

MR EVANS: Absolutely. Well, I think it's the general view. I politely protested but got short shrift.

PROF SLOAN: TICC is the Therapeutic Goods Industry Consultative - - -

MS MONK: TGA Industry Consultative Committee.

PROF SLOAN: TGA Industry Consultative Committee, you're right, and in fact back on transcript we probably need that in brackets, the TICC.

MR EVANS: Yes, sorry, my apologies.

PROF SLOAN: But dare I say it, although I think it's quite important we can't really take interjections from the audience because of the transcript arrangements. But this is a general area which is absolutely replete with acronyms.

MRS OWENS: Which we found in the first week we were doing the inquiry. It was one of the first things I asked that the staff prepare was a list of all the acronyms because every government department, every agency, has one and each of these agencies has consultative committees that all have one and so it goes on and on. We've got about 10 pages of them and I'm sorry, I'm falling into the trap that I've asked others not to fall into, which is to use them myself.

MR EVANS: Could probably be our best seller.

MRS OWENS: Yes. Look we won't hold you up much longer. I was just going to ask you one last question and my colleagues may have one last question as well. I was going to ask you, once TGA went to 100 per cent cost recovery whether there was a noticeable difference in the performance of the TGA in terms of increasing speed of reviewing applications and so on, whether it actually meant that they were able to perform their duties more efficiently and effectively.

MS MONK: I think the TGA's performance has definitely improved over the period of time where from when 50 per cent cost recovery was instituted and now we are at 100 per cent cost recovery, but I don't think that there's a causal link between that and their performance. I think the ground-breaking change was the Bone Review of Drug Evaluation which happened at about the time of cost recovery being instituted, and it was because of those recommendations that large change was made within the TGA. I also think with succeeding national managers of the TGA there's been definite improvements in their performance. So I wouldn't attribute their improved performance to the cost recovery issue.

MR EVANS: I mean, I think it has an indirect effect inasmuch as they're much more conscious of their performance now that we're paying 100 per cent.

MS MONK: And we're watching them much more closely.

MR EVANS: Absolutely. You know, it's easier to justify a fall-off in performance if you're only asking for half the cost to be met by industry. It's a bit harder when you're sitting down across the table and having to justify a fall-off in performance but you still pay 100 per cent for our fall-off. So it does have an effect.

MS MONK: But there wasn't a dramatic change, as you might be aware of perhaps in the US., where they introduced user fees and there was a dramatic change.

MRS OWNS: Yes. I was thinking of the US. experience with that, yes.

DR STEWARDSON: Not so much a question but just a comment, that listening to what you've been saying it does seem to me that one of the things you offered to do for us after this is to my mind very important, that is, evidence of drugs that haven't been brought on to the Australian market because of this charge, because we seem to have a situation where overseas the research, if it's been done there, has cost hundreds of millions. The fee appears to be a fairly small amount in relation to that. So it really is interesting. I don't have much of a feel for how the costs of the fee in relation to the size of the Australian market and to the other things, the listings and so on that you've talked about. I think that if you can give us anything that helps to isolate that as to whether it really is an effective thing in terms of deterring people, that would be helpful.

MS MONK: I think it might be difficult to attribute it just to the cost recovery part of the TGA because it's part of the whole sequence of events, as Alan explained, that you can't isolate just because - I don't think we'll be able to, but we'll certainly look into it for you.

PROF SLOAN: But also the possibility that in that issue they opt to get recognition and registration overseas prior to Australia; that would be very interesting.

MRS OWNS: I think the survey that you referred to earlier might be very useful for us to look at. I don't know whether it will be commercial-in-confidence or not.

MR EVANS: Yes, it will be, and that's been one of the issues we've had. I mean, as you can understand, companies - there is commercially sensitive information they provide us so we might have to - - -

PROF SLOAN: If you could just make it generic that would be fine.

MR EVANS: Yes.

MRS OWNS: Yes, we would appreciate that. I think we might break now, unless you've got any further comments you'd like to make.

MR EVANS: No, thank you.

MRS OWNS: Thank you very much for coming, and we'll break until 20 to 4.

MRS OWNS: We will now resume. The next participant this afternoon is the Australian Food and Grocery Council. Would you please give your name and your position with the council for the transcript.

MR ANNISON: Yes, certainly. My name is Geoffrey Annison and I'm scientific and technical director of the Australian Food and Grocery Council.

MRS OWNS: Thank you, Geoffrey, and thank you for coming in today. We've read your submission with interest and we appreciate the submission and the visit that we had earlier, to visit you and to see you, and if you would like to make some opening comments we will listen and then we will open it up for some discussion.

MR ANNISON: Thank you. Yes, I will just make one or two opening comments, if I may, which are really to just paint a picture of the food industry or the food and manufacturing industry that we have in Australia and then to just touch very quickly on some broad policy principles which are reflected in the submission, and then continue on to answer the questions. But I'd just like to point out that the Australian Food and Grocery Council represents in Australia the Australian food manufacturers of food and beverages, and we also represent some other companies making non-food grocery items. But our primary representation is of the food industry, the processed food sector, and it is indeed a very large sector.

It is Australia's largest manufacturing sector. It has a turnover of approximately $46 billion per annum in food products, $54 billion per annum if you take the non-food grocery items. We're responsible for employing approximately 160 to 170 thousand Australians. In the last 10 to 15 years it's an industry that has had a great deal of success. In that time we've gone from a net importer of process foods to a net exporter of process foods. We've had growth in export markets over the last 10 years in the region of 10 per cent per annum and we're looking forward to exporting about $7 billion of highly processed food this year and perhaps another five to six billion dollars of semi-processed food. So it is a substantial industry and it's very outward focused in terms of its focus on export markets.

The submission that we presented to you is really in response to a request from a visit by the commission to put down some of our policy principles. We have done that within the submission and we've also focused specifically on the role of the Australia-New Zealand Food Authority and the cost recovery debate which we had with that authority between 1996 and 1999. We've also touched on the operation of the Office of the Gene Technology Regulator which is currently being established by the Commonwealth government and that will be finalised once the Gene Technology Bill 2000 has passed through the parliamentary processes. As you know, cost recovery is a key issue in the setting up of that agency and we've addressed those in the submission.

I would just like to say as one further point that we see this as a first submission that we will be making to the commission. We have put out some broad policy principles which are within the submission. We look forward to reading the draft

report and we will make a further submission on the draft report. But our submission may also expand some of the points that we've made in this submission. So we would like to think that this is the very first part of our input to the commission and we've got it as a high priority in the activities of the Australian Food And Grocery Council.

MRS OWNS: Thank you very much and we look forward to further interaction with you. I found the submission a very, very useful one. It provided us with lots of, I think, very useful information about the agencies which you're dealing with and I suppose I have a particular interest in ANZFA because you've probably focused on that more. But it's in this interesting position of just introducing charges for specific purposes and I would be interested in teasing out some of the issues relating to that with you a bit further.

PROF SLOAN: We should probably say what ANZFA is.

MRS OWNS: Yes, the Australia-New Zealand Food Authority is ANZFA, isn't it?

MR ANNISON: It is.

MRS OWNS: And the Office of Gene Technology Regulator, we can use the whole term for that I think, if we get onto discussing that. I think that there are some broad issues of principle that we will need to discuss with you. I'll ease into that gently. But perhaps just for my curiosity I'd like to understand just a little bit better what it is that ANZFA is protecting the Australian community from. What is the actual issue that it is addressing? What problems can we expect if we didn't have an ANZFA?

MR ANNISON: That's a very good question. I think that if you go to the ANZFA Act there is some guidance within the ANZFA Act and its function, or its objectives, it has three primary objectives. The first is to protect public health and safety. The second is to prevent fraud and deception and the third is to ensure that there is adequate information for consumers to exercise informed choice. I think if you look historically at the derivations of food standards they arose out of two fundamental issues, one of which it was recognised that the food industry not only could but did adulterate food in a manner that caused fraud and deception. So it was easy to add low-value materials to high-value food products and sell them for the same amount of money and therefore create fraud and deceive the consumer.

Now, when I say this, historically we're going back 100 years now. This isn't recent practice. So it was recognised that there was a need to produce standards which specified what foods were. So we had standards for milk, for example, and one of the classic adulterations of milk was simply watering it down. For flour, a classic adulteration of flour was to add chalk. So in order to protect the public from fraud and deception a lot of food standards were built up actually describing what foods were, what commodity food items were. On the other side of the equation it was also recognised that even though an understanding of food and microbiology was not advanced, it was recognised that food that was prepared in unhygienic circumstances

was often associated with the carriage of disease, and this was at about the time when microbiology was beginning to take off as a science.

The basic sanitation with the bringing in of antiseptics and the basic treatment of food was recognised as being important to ensure that the food was safe. Of course hand in hand with that, it was recognised that these treatments not only rendered the food safe but also was able to preserve it through time and therefore enable it to be transported and all that type of thing. So those two things grew up side by side. There was the quality linked to safety and as the sciences became more advanced, the needs for those food standards became more and more demonstrable in more than just empirical terms. The science behind it was understood and things like pasteurisation is a classic example of where it was recognised that milk was a major vector of a disease and it was appropriate to step in with a food standard that says that all milk should be pasteurised.

Now, that took a long time to take off around the world and indeed there are still many countries that don't have it. But in Australia, across almost all jurisdictions, milk has to be pasteurised as a fundamental protection for public health and safety. Accompanying that of course also was the development of, if you like, philosophies about labelling and what should appear on food labels or should accompany food when it is provided for sale, and that's related both to public health and safety and the prevention of fraud and deception. So foods have to be identified accurately in order for consumers to make purchasing choices, both for their safety but also just so that the product is described correctly.

In the last 100 years a number of things have changed. Food adulteration isn't the problem it used to be, because the food products themselves have become so cheap and in many cases the adulterants are potentially more expensive than the food products. I mean, we enjoy a food supply which is much cheaper than it has ever been and a greater range of food. So there's really no commercial imperative - even that's the wrong word. There would be no advantage to adulterating food. The other thing is that food companies themselves are much more aware of the important nature of their business which is to provide safe food, apart from the basic regulatory requirement to provide safe food.

Food companies rely on repeat business. Food businesses are built on branding of food products and if particular brands become associated with food poisoning outbreaks then the commercial damage is extreme. So the food companies recognise themselves that there's a need to make the foods as safe as possible. Now, that brings us up to the present day and what is the role of food regulation. It is true I think that food regulation should still be primarily to protect public health and safety and whereas I don't think it's such an issue as it was before, in the sense that it seemed to be a common goal now between the food industry and the regulator, and in fact that is being represented now in changes in our regulatory arrangements, whereas before the food standards were saying, "You must do these processes to ensure that food is safe."

So we had very prescriptive standards on the amount of time that foods could be held at certain temperatures in order to kill off bugs and this type of thing. So they're of a prescriptive nature for pasteurisation processes, for canning processes, how hot foods could be held before sale, in restaurants and that type of thing. They're moving in another direction and they're saying, "Well, we don't want the responsibility of telling you how to run your business and provide for safe food." What the food standards in terms of the food safety standards will say is that, "You have to demonstrate that you have in place food safety plans which can then be inspected by any third party including the regulators, which demonstrates that not only do you know how to produce safe food and have a plan to produce safe food, but we want to also see a record that demonstrates that you have produced safe food."

So we're moving from less prescription into more responsibility provided for in the standards, this is in food safety standards, for the production of safe food. Now, having said that, because the regulations are changing from less prescriptive regulations, we're also moving to general permissions for some of the additives and ingredients and processing aids that can be used in foods. So we're moving from vertical standards where we used to have a product by product permission to use additives into general standards that allow a general use of additives and processing aids. But we're also seeing ushered in another dimension of food standards which is case-by-case approval of foods, of processes and also of claims that can be made about food.

Now, you could argue that some of that is very necessary and there are some examples where it is very necessary. For example, to give you an example of a novel food you would be aware of the debate about elestra which is basically a fat replacement which passes straight through you and has no calories associated with its use in food, and it's completely novel. It has never been exposed to humans before, or animals for that matter. It's a synthetic compound and it's appropriate that there's a full regulatory examination of that before it is approved. There's also provision for new technologies, and gene technology is one and we can talk about that. But another one which is perhaps of interest is the use of irradiation in this country.

Irradiation has been used for sanitising food for well over 40 years. It has been the subject of a huge amount of investigation from a scientific point of view and it has been demonstrated that essentially it's a very useful and a very safe technology for sanitising food. But the regulatory arrangement in Australia is that they have just approved irradiation as a technology but we're moving to a case-by-case approval. So it's not a blanket approval across all foods, subject to technological requirements, but rather food companies who wish to use it have to make a case-by-case application. Now, you could argue, given the scientific background, that it has been demonstrated to be perfectly safe. It's used safely across a whole range of food products in other countries.

You could argue what is the purpose of having a regulation that requires a case-by-case approval? Now, the industry hasn't argued against that overtly in the submissions it has been making to ANZFA and it has basically supported the

case-by-case process. But from a technical point of view and against the objectives of the food standards, which is to protect public health and safety, you could say, "Well, what is the additional protection which is being provided by this approach?" and the answer would probably be, "Very little." However, you could also say that food irradiation still has - well, it's somewhat topical when discussed from a consumer perspective.

PROF SLOAN: It's a squeaky wheel, isn't it?

MR ANNISON: It's a squeaky wheel and given that, the regulators recognise that the community requires confidence in the technology and perhaps it is appropriate from that point of view to have a case-by-case assessment. But as far as I can recall, there's nothing in the ANZFA Act that says that the purpose of food regulation is to give confidence to consumers about the safety of food.

MRS OWENS: Yes, thank you. That answers it very well. I think it's safe to say I can understand about regulation relating to pharmaceuticals and drugs and so on. But I think in terms of food I was wondering how far you needed to go with regulation, how costly it needed to be? What's the size really of the negative impact on the community of having food that we can't trust? The reason I'm going down this path is trying to understand why we need to think about a user pays system vis-a-vis some other approach, where the beneficiary pays vis-a-vis thinking about the industry paying whenever there's a sort of a negative impact on the community.

I think most of the foods that are regulated, if I'm correct, still there's no cost recovery because there's a presumption that the community benefits from the limited amount of regulation that's left, and if the industry wants something additional done - and I gather some of that case-by-case work would be at the request of industry - then the industry will pay. This is where we have this requirement now for exclusive capturable commercial benefit.

MR ANNISON: Yes. I think if you compare food standards which are the food safety standards which are being brought in with the other standards which are permissions for either processes, products or claims, you can certainly see that there is a very clear divide, not only in public good but an imperative to actually have regulation. One of the biggest threats coming from foods is naturally occurring hazards which are in foods and these are hazards which are there either because of natural toxins which might be present or because of pathogenic organisms that can be vectors in food.

Now, of course we have a general requirement that all the food is safe and you could argue that that should be sufficient, that just the food that is presented for sale should be safe. For the reasons that I went into, in the past one of the ways they ensured that was being prescriptive of the sorts of treatments that foods had to go through before they were allowed for sale. That's becoming less prescriptive and we're having the onus, responsibility, thrown onto food companies. Although their figures are in debate there is still certainly a large number of people each year who

become sick through food poisoning and there's almost certainly some of those people die through food poisoning although the figures are very difficult to decide on exactly what they are.

So there is a clear public health and safety imperative of clear public good coming out and a clear obligation on the government to have a food standard which addresses that in some way and says that foods have to be safe, and there are a number of ways you can do it, as I've described. Now, there's another side of the coin which is bringing foods to market, or food additives to market, or food components to market, and ensuring that those individually are safe, or indeed that if you make a claim about a food that the claim is not only accurate but also will cause no harm and that's a different approach and a different imperative upon the government.

But there are probably less public health and safety imperatives these days associated with those additives and those novel foods and those claims, because the industry itself is very responsible in the way it uses new technologies, in the way it brings new products to market and in the claims that it would make, because we have other rules like fair trading rules and so on. But also a lot of these products - and it reflects to some extent what the previous presenters were discussing. Many of these additives and products have approvals overseas anyway, so they've gone through a regulatory approval process and a regulatory screening, and that's the case of a lot of the novel foods and many of the claims that are made about them.

So on one side there is a clear role of food standards where the public health and safety requirement is unequivocal and still a great imperative, and on the other side there is an area where it's more to do with bringing new products to the market and the way that would be regulated, and in some cases there is an exclusive commercial capturable benefit associated with that and it's under those situations which the AFGC in going through this debate with the ANZFA proposed and it was subsequent agreed that that would form the basis of charging for imposed charges, not necessarily for voluntary charges.

PROF SLOAN: I mean, a cynic might say you've got a pretty good deal actually, the food industry, compared with the pharmaceutical industry, because after all these are products we ingest and they're all potentially dangerous. Maybe the kind of claimed benefits are very different. I mean, I'm interested in this concept of exclusive capturable and commercial benefits. That sounds like a pretty strict test. Presumably only a very small fraction of food products are going to meet that test.

MR ANNISON: Certainly a small fraction of the products which are on the market now would meet that test and that reflects the different nature between foods and drugs. Foods are not drugs.

PROF SLOAN: No.

MR ANNISON: And they are used in different ways from drugs. For example, in order to bring - it really comes down to the fact that drugs, at least in the first part of

their lives whilst they're still under patent, the only companies that can benefit commercially from them are the companies that develop them and subsequently market them. So they have an exclusive capturable commercial benefit to that company. Now, a lot of foods are not like that. For example, if it is demonstrated through nutritional research that a particular dietary fibre has a particular health benefit and it might be - and there are examples - it might be the dietary fibre from oats. A company might put in a request to the Australia-New Zealand Food Authority to be able to make a claim about the beneficial effects of that oat fibre and the food authority might agree and might approve such a claim.

However, any company that made an oat product which contains a sufficient amount of that fibre could then use the claim so there's no exclusivity to the commercial advantage of using it. So there was a charge associated with gaining that approval the companies who were not paying would get a free rider effect and it wouldn't be equitable, and that was the basic argument. But we do foresee as nutritional science progresses that there may be occasions where a company indeed can capture exclusively the commercial advantage of that product, at least for a period of time, that would make it attractive for it to pursue it as a product and it might be able to ensure the exclusivity of that, either through former ways, through patenting the material that might be found in the food, and patenting its use as a food product, promoting health.

Alternatively it might just hold a particular process of how it had, if you like, rejigged the food to enhance its - either levels of a particular bi-active material. It might hold the details of that process secret and so it would have exclusivity to the commercial benefit associated with it until the next company came along and could demonstrate that it had a similar process that produced a similar bi-active compound or formulation. So just from the policy position of wanting to have an equitable arrangement for when the Australia-New Zealand Food Authority imposed charges for applications to change the food standards code to either allow a claim or to allow the use of a novel process, or to allow the sale of a novel product, we thought that was very important.

We didn't, however - I'm sure you read in the submission - rule out that on some occasions a company might not have exclusivity tied up, either through patent arrangements or either through secrecy. But because of its advantage in getting speed to market it might still consider it - or just because they thought they had a strong position in the market they might decide to voluntarily pay ANZFA to speed up an application through the process and get some commercial advantage, but not necessarily an exclusive one.

MRS OWENS: With the exclusivity you should be able to predict ex ante that there's going to be these exclusive, capturable, commercial benefits. The company is going to be able to know when it comes to answer that it's got a patent on that material or that it's in a position to keep that process secret for some time. I presume the company would make a judgment about that before they came but then would have to - - -

MR ANNISON: That's exactly right and indeed, that's not a completely unresolved issue in the sense that ANZFA has a commitment and certainly is supported by the food industry to open consultative and transparent processes for amendments to the food standards code. But by the same token if you - not so much if you have a patented claim - but if you have a claim or a process or a food which is protected through secrecy there is some difficulty in having an open consultative process which divulges information which might be commercially sensitive. Now, ANZFA would argue that they have the ability to hold certain parts of the information confidential to the inquiry process that they go through and we would expect that and that would be of a similar situation in the TGA.

One of the disadvantages is that the ANZFA processes are long, they're often 12 to 18 months in timing; they should finish in 12 months but they have the ability to stop the clock and they often go a bit longer. So unless the secrecy - although probably that's the wrong word - but unless ANZFA is very careful about how it holds that information commercially and in confidence, then some information could come out to the disadvantage of the company making the application. In the food industry in particular lead times in the development of products is very, very short in terms of - and certainly in terms of month before copy cat or, as they're known, "me too" products follow a successful product onto the market. So that is going to be an issue for the food companies but I suspect that it will be resolved by the food companies just making the judgment about whether it's worthwhile to pursue it in the manner that it might be pursued.

MRS OWENS: Yes, there is a tension between this requirement that the regulator be transparent and so on and the needs of the companies that are going down this other track to maintain secrecy and confidentiality.

MR ANNISON: Yes. It's a tricky issue, there's no doubt about that.

PROF SLOAN: I suppose I'd like to see some examples of goods, processors or whatever that do meet the exclusive capturable commercial benefits test because that's - I mean, we have heard it said that it's not a particularly workable concept, but if we - - -

MR ANNISON: As far as the food industry is concerned or in other industries?

PROF SLOAN: Well, as far as the agency was concerned there's problems.

MR ANNISON: They haven't reflected that to us.

PROF SLOAN: Let me put it this way: there is a view that there's clearly a limit to cost recovery activities.

MR ANNISON: And it was intended to limit cost recovery activities against the basis of what you would - well, of what we consider the equitable way that cost recovery should be provided.

PROF SLOAN: I just think some examples would be quite interesting to see how something would fit into that category as opposed to the general category.

MRS OWENS: Have there been any cases yet that have come up? Because it's only been introduced this year, hasn't it?

MR ANNISON: Yes, and to date there have been none, to my knowledge. I think they're still finding their way.

MRS OWENS: Because there's a bit of attention for the companies, if they go that route they've got to then pay fees. If they don't go that route they don't, but then they've got the potential that the information that they're holding will go into the public domain. Would that be right?

MR ANNISON: Certainly that is an issue. One of the problems at the moment is that the regulatory system isn't quite complete in the sense that the - if it's a proprietary production, for example, it might be a new sweetener. In fact there is a new sweetener which is coming out. I can't quite remember whether they've put their application in, but it will be a proprietary product, it will be patented and it will be protected and I think ANZFA will be able to argue that there is an exclusive, capturable commercial benefit associated with that and they will charge and I think the company will pay. For things like claims the sorts of claims that companies are foreshadowing associated with products are health claims in particular. So claims about the way foods can contribute to promoting and protecting health, and some of those claims will be based on proprietary products that only one company can make.

But at the moment we have a situation in Australia where there is a prohibition on health claims, a blanket prohibition and there's no regulatory framework at the moment to change that but it is under review. So until we have a general health claim system brought in, and assuming a general health claim system is brought in, which is something that the companies and the food industry has been advocating and ANZFA has slowly been moving towards, but until we have that there is a regulator disincentive to companies exploring food products and bringing food products to market which are able to make these claims and so we don't have a lot coming along the line where there will be - - -

PROF SLOAN: There are claims made, there is that new margarine that claims to lower cholesterol and there are - - -

MR ANNISON: That's not strictly speaking a health claim, it's a function claim and - - -

MRS OWENS: So it's not going to say that it's going to prevent heart disease? What's that all to claim then?

MR ANNISON: Let me give you an example - - -

PROF SLOAN: That's saying it's lowering cholesterol, it's not saying anything further.

MR ANNISON: No. An example might be calcium is important for healthy teeth or bones, this is - this is a nutrition message, let me say. First of all, let's have a nutrition message, "Calcium is important for healthy teeth and bones, this food is a good source of calcium." That's an allowable nutrition claim under the current regulation. A health claim would be, "An adequate intake of calcium may protect against osteoporosis. This food is a good source of calcium." So that's a health claim. If a particular disease is mentioned it's a health claim. The definitions are currently under review and some people in ANZFA would say that the former is also a health claim and the industry would say, "Well, we don't think it is. It's a generally accepted fact of life and you can find reference to it in any nutrition tex book."

PROF SLOAN: But nutrition is part of health, isn't it?

MR ANNISON: That's a good question. We would argue that there's no point in giving nutrition information unless it's to influence health and the food industry has been fully supportive of that concept. The regulators have attempted or have suggested that there is in fact a difference between providing nutritional information and providing information that helps consumers select healthy diets and they have attempted to regulate one - they have regulated one and given advice about the other. We are finding, and I think it gets back to your original question about examples, that as nutritional science is advancing, certainly we can make more and more - or certainly attribute biological activities in much greater detail to particular components of food and how they might be brought together in particular foods and in particular diets, such that we can begin to give really very specific advice about nutrition and nutrients that people should be eating to provide protection against particular diseases and in particular population subgroups.

Now, as we go down that route it becomes more and more of a challenge to the regulator - at least they would say that. The industry would say, "Well, it's really quite simple, as long as the claims are substantiated and you can demonstrate that it's truthful then it shouldn't be that difficult." The regulators think it's a little bit more difficult than that but it's a debate that's probably a little bit outside the scope of your inquiry.

MRS OWENS: Yes, I think it probably is. The difficulty we have in this inquiry is that we're looking at cost recovery and that's embedded in the regulatory arrangements. So we have to, to some extent, understand the regulatory arrangements and to the extent that they may complicate the cost recovery arrangements or vice versa we need to sort of think about these issues. How far we

take this in our report is another matter. The other rationale for introducing cost recovery was to fast track applications, if I understand it correctly, so that it can speed up getting a product to market. Is that right?

MR ANNISON: Well, certainly, as we've documented in our submission, one of the problems that ANZFA was facing is that it was reliant upon the budgetary application to resources activities, but it also had a legislative requirement to complete applications within 12 months. Indeed, it also had an ability to charge but it had no market power to enforce charging because it had this regulatory requirement to finish applications within 12 months. So they are in the unenviable position of having a regulatory requirement to do as much work as was put onto their plate, but they had a very limited budget to do it with. So they had a resource management issue and they considered that one of the ways around that would be to seek cost recovery for people putting in applications or parties putting in applications to change the food standards code as a way of resourcing the progression of those applications.

We've been through the concept of exclusive, capturable, commercial benefit. That was to determine what would be equitable in terms of fees being imposed, but it didn't negate the idea that companies, if they wished to, rather than having their application being right at the end of a queue which might be quite long and run to two to three years, could fast track their applications and therefore make a voluntary contribution to the costs, even to the extent of full costs recovery on that application, to speed it up. Now, we recognise that that in itself, although that might be useful for the companies, it had certain implications and one of which we didn't like the idea of other applications necessarily being bumped down the queue and we didn't like the idea of ANZFA's own work being diverted from its core business of developing food standards to protect public health and safety due to the fact that a food company decided to pay for the application.

So another of the key things that we advised, and it was agreed upon, was that the resources that are devoted to applications for which fees are paid, be it imposed fees by ANZFA in the case of exclusive, capturable, commercial benefit or if they're paid voluntarily, those funds would commission additional resources within ANZFA. In that way it protected the core activities of ANZFA and it also protected other applicants who may be within the queue. That was basically the idea behind that.

MRS OWENS: How do you guarantee that will actually happen and the other activities aren't jeopardised?

MR ANNISON: It's within the - I think I'm right in saying as well - one of the things that we, I think it's in the ANZFA Act. It's either in the ANZFA Act or it's in the pursuant regulations, so it's actually a requirement upon ANZFA to commission additional resources rather than using internal resources or diverting resources I think was the terms we used.

MRS OWENS: They'd have to actually presumably report on that and they'd presumably have to say something about the existing resources required to undertake

their core activities and the additional resources they have employed to do this other work, wouldn't they? There would have to be some reporting mechanism.

MR ANNISON: There is indeed a - well, it's actually a management or program mechanism. That was the other thing that we thought was very important and we're very well aware of the public good function of ANZFA and the public good role of Food Standards and we thought it was critically important for the confidence of the community in the function of ANZFA that their core activities were protected. Also within the legislative requirements are that ANZFA now develops a three-year work program saying what they are going to work on and prioritising their activities on the basis of public health and safety imperatives. That work program has to be reviewed and it's a rolling three-year work program.

So I think in the submission we describe it as, if you like, a framework of safeguards, I think, is the term we used in the submission, whereby we thought it - basically we protected the public good of ANZFA or the role of ANZFA by insisting that exclusive, capturable, commercial benefit was the condition for imposed charges by ANZFA; that they were required to develop a work program addressing their core activities each year; that any funding from cost recovery either for imposed charges or voluntarily to move applications up the list was to provide additional resources rather than divert resources and another thing that was discussed and I think resolved was the fact that the revenues generated returned to ANZFA rather than going into general revenues and we thought that would provide a useful incentive for them to work efficiently.

PROF SLOAN: That last one is probably the most contentious actually. I don't think, you know, private benefits, it being efficient and effective, additional resources, I think are hard to argue, but economists would call that hypothecation. In fact, it's a very unusual arrangement as a matter of fact. By and large all these agencies that cost recover are essentially warehouses that - and the money is sent back into consolidated revenue. It seems to me one of the arguments against it is that where the agency retains the money directly as opposed to indirectly, you know, they kind of may dream up additional cost recovery activities and it may be an incentive to build activities that are kind of eventually quite a long way removed from their initial objectives.

MR ANNISON: I think that's a possibility but I think we imagined that it gives a higher degree of accountability to the basis of charging and the expenditure of resources within that charging framework. If you look at organisations like the CSIRO for example which I recognise is not a regulatory agency but when they seek to recover costs for research from industry those costs are returned directly to the research group that's doing the work rather than going into general revenue for CSIRO to then be distributed again. We, I think, would argue that we certainly don't want ANZFA to be, if you like, out there touting for work or for offering services to business, and we think that the safeguards against that are provided for by the objectives of the act, and the functions that they're allowed to follow in the regulations

pursuant to the act. So I take your point but I guess we would hope that those other safeguards are in place to prevent that.

PROF SLOAN: Presumably it's not a complete die-in-the-ditch issue, this one.

MR ANNISON: No, but it perhaps has some merit.

MRS OWENS: Your recommendation on page 15 includes that but your recommendation has been drafted as sort of a general recommendation applying to cost recovery more generally I think.

MR ANNISON: Yes.

MRS OWENS: Does the hypothecation or the last point there apply now for ANZFA or is something you would like to see?

MR ANNISON: We would like to see it. I think it applies to ANZFA now but it occurred to us when we were developing the submission that we had been up hill and down dale with all of these arguments about when it is appropriate for a regulatory agency like ANZFA to impose charges. We had discussed internally what the nature of the public good is that ANZFA provides and how you needed to protect some of those core activities from commercial arrangements, but nevertheless we also wanted a system that was accountable and also was encouraging of the regulatory agency to be efficient in their uses of funding. We thought that that final provision was addressing that to some extent.

The first three is what we were discussing primarily with ANZFA and the government when it was setting up the amendments to the act to address cost recovery but it also occurred to us that this would be - well, certainly in the terms of our preliminary submission an interesting recommendation to make to the commission because it seemed to provide a framework against which many of the tests for cost recovery could be - what's the word I'm looking for - but anyway, it's a way of testing whether cost recovery is appropriate and does it meet these criteria. There may be some agencies that it isn't appropriate for and there may be some others which it is.

MRS OWENS: Yes. I think that's one of the things we have to work through in developing the guidelines but one of the other things you have done for us I think which I found very useful was setting out the policy principles on page 7 and 8 which we won't go through now but I thank you for doing that and we will go through those carefully. Are there any other issues you want to raise at the moment?

PROF SLOAN: I don't think so. It's just that I find your section on the Office of Gene Technology Regulation particularly useful because there seems to me some inconsistencies in the way that has been proposed to be set up, particularly compared with ANZFA, but I think it's very well argued so we might leave it at that, Helen, because we have got some other participants who need to be given a fair go.

MRS OWENS: Yes, I think so. Are there any other comments you would like to make, Geoff?

MR ANNISON: I guess just two things in relation to the Office of the Gene Technology Regulator. We have attempted to graft the ANZFA model onto the Office of the Gene Technology Regulator and we have had difficulty in doing so for the reasons that are put in the submission so I think it's very important to realise that the two offices are quite different. The other thing is that perhaps doesn't come out as strongly as we would like in the submission having now reread it on the way down on the plane this morning. That is that one of the key issues for cost recovery with the Office of the Gene Technology Regulator is the extent to which cost recovery can act as a disincentive to research and development.

MRS OWENS: Yes.

MR ANNISON: We just think it's almost an anathema in a period of public debate that we're going into on both sides of politics acknowledging the importance of innovation to then actually impose what is effectively a tax on innovation to the detriment of the appropriate exploitation and exploration of the use of the technology.

MRS OWENS: No, you have raised a really important issue there because I think the clients if you like of the Office of the Gene Technology Regulator are largely universities and agencies that don't have a lot of money to be spending on the regulatory activity and there are not that many of them so it is a bit different from other areas.

PROF SLOAN: And we don't know what the results of the research are going to be actually as to whether they will be - - -

MR ANNISON: No, you don't.

PROF SLOAN: And whether they're going to ever end up going to market.

MRS OWENS: No.

PROF SLOAN: So I think it's a very interesting case and we will have a look at that. We're going to set up a number of case studies. One of the case studies is going to look at the whole area of health and safety. Your area is going to come into it. The Office of Gene Technology Regulator will come into it, the TGA and the pharmaceuticals, and I think we're going to bring in CASA and a whole lot of other safety areas as well and bring them altogether and compare the different approaches because I think the challenge for us in developing guidelines is to see whether we can do it. Is there a one size fits all or do we have to think about guidelines that differentiate between different areas. So that's our challenge.

MR ANNISON: Yes, indeed.

PROF SLOAN: So we look forward to the ongoing discussions with you, Geoffrey, and thank you for coming.

MR ANNISON: Thank you very much for the opportunity to do so.

PROF SLOAN: I understand there are two people here in the audience that would like to come and talk to us. We have got Mr Neville Ford. Would you like to come up please.

MRS OWENS: First of all, can I just apologise to Neville and Ross about some confusion about the starting time and the fact that perhaps the ground rules weren't entirely clear to either of you so I'm sorry for that. We tried to extend the time a little bit so we hope that 20 minutes - - -

MR FORD: Yes, I will be brief.

MRS OWENS: Also I wouldn't want you to feel disenfranchised by the process so if you want your involvement participation to go further we're quite happy to accommodate that as well.

MR FORD: Thank you.

PROF SLOAN: Would you please, Mr Ford, give your name and your affiliation for the transcript.

MR FORD: Yes. My name is Neville Ford. I live in Notting Hill. I am here in the capacity of chairman of Whistleblowers Melbourne. I'm sorry my voice is awful. I have got out of my death bed to come.

PROF SLOAN: I hope you - - -

MRS OWENS: It's quite attractive.

PROF SLOAN: Could you please give us some background as to what Whistleblowers is.

MR FORD: Yes. Whistleblowers is a self-help people who have done whistle blowing and generally copped it in the neck for doing so. In general our members tend to have either come from regulating bodies or have been internal regulated in companies, that is, associated with safety or ethics or the like. I'm here because as chairman I'm supposed to know everything that's going on and I didn't know until this morning that the Productivity Commission was having an inquiry into cost recovery. I have got a list here of the submissions that have been made to your committee and it's rather - I have been informed that despite something like 2000 associations of various forms contacted, despite you being on the Internet, and despite visits to industry and government agencies having knowledge of your work, you have only got 31 submissions. That represents in my view a total failure of the Productivity Commission because I think this is an important inquiry by the Productivity Commission. It affects all and every Australian.

Australians either pay too high a user charge for various services. That's because Canberra basically lacks knowledge of how to restrain itself on spending, or

(b) pay too high a tax bill because others are not paying high enough user charges through the regulating bodies. I particularly refer to mates' rates which is the sort of rate you charge favoured groups in society as distinct from those not so favoured. I believe the costing of some of these regulating activities is important. My reason for saying that is primarily because the hip pocket nerve is a great demand management device. We have many things where efficiency can be improved but every improvement efficiency is overcome by additional demand that comes from that. So I believe the cost recovery is important and we support that as part of the regulation, deregulation scene. It does get back to who polices the policemen.

PROF SLOAN: Right.

MR FORD: In a sense you're setting yourself up as a policer of policemen and that involves some moral questions. I thought the most fundamental moral question is that you do a full and proper consultation. As I said, I would have been the first to make a submission and I feel left out of the process. Now, I didn't see the ad in the paper. I don't know where it was, and as I said, it was only this morning that I was informed by a member that was in.

PROF SLOAN: Do you want us to respond to that? First of all, I'm not sure we can drag the horses to drink. The processes associated with this inquiry have been the same as with all our inquiries which is to place advertisements in all the major newspapers. There is a lot of information on our Web site which I think you have been able to access.

MR FORD: No, I'm one of those technological illiterates not connected to it.

PROF SLOAN: Well, Neville - - -

MR FORD: But other members are. I mean, look, I don't want to get into a debate but to give you an example, there was a public consultation by the parliament, by I think it was the parliamentary committee, on the MAI. It got 900 to 1000 things because it was a sexy subject and it was well publicised, and in a matter of two weeks something like 1000 people made considered responses. In comparison to that your 31 responses just don't rate.

MRS OWENS: Could I just say something else. I think at this stage in the process in any of our inquiries sometimes we get very few submissions and we get a lot later because we called for further submissions after our draft report. Often what you find is that people hold off early in the inquiry and then subsequently once they see what others are saying and what's coming out and what we put into our report, then they choose to put in a submission later. Sometimes you end up with a lot of submissions. I think Judith has been in this position with one of her other inquiries where you get the rote letters where a letter is copied, people sign the letter, and you could get quite a few hundred submissions that way but they don't actually add very much.

MR FORD: You can get thousands if you - - -

MRS OWENS: So just adding up the numbers of submissions is not necessarily very useful. I think what we really want are submissions which are useful to us, that are thoughtful, well argued submissions, and I have to say that the submissions that I have read so far have been extremely useful.

PROF SLOAN: They have been very high quality.

MR FORD: Right.

MRS OWENS: Having said that when we are actually trying to get to people - I mean, we are limited. We put our advertisements in the newspaper. We put a lot of information on the Web site as Judith has said but, but some areas don't attraction because people don't really see it as, as you said, sexy. They don't see what cost recovery really is. That's I think the challenge for us. We'll take on board what you've said, but it is very difficult getting to the actual users of the services. We find that it is a challenge in all our inquiries to get to those people. I've done it in another inquiry. I did an inquiry with my colleague Gary Banks three years ago into private health insurance, and we wanted to get to the people that actually used the health system, those people that took out private insurance and those people that didn't take out private insurance. That was a difficult challenge and in the end I went on the 7.30 report to do that.

MR FORD: Exactly, and I believe that if you really want a decent response here you'll have to stage a fight or something on television.

MRS OWENS: You've got to get on television first.

MR FORD: I'm sure your colleague knows how to deal with the television.

MRS OWENS: I won't comment on that but, yes, would you like to continue with your comments?

MR FORD: Yes. I would have expected or we would have expected to get responses from, say, the rail, road and aircraft users. Aircraft in particular have a problem with counterfeit parts and user charges of the various bodies like CASA that constitute the aircraft industry. I would have expected things like general manufacturers to respond on the basis of things not done because of the costs. Mining, for instance: I would have expected in particular - Whistleblowers Australia, which we're a trainee member of, has a member who was very involved in site remediation of coal mining, so I would have expected that. Agriculture, we've got cane toad problems. I would have expected someone to make a submission on how the cane toad could have been suppressed if the right action had been done early in the process. It wasn't, and now the cane toad is in Kakadu, which gives you an idea of the cost of not regulating.

MRS OWENS: Can I interrupt again. We're not doing an inquiry into regulation.

MR FORD: I appreciate that, but the point is that cost recovery is an integral part of regulation. So, whether you like it or not, you have to understand a bit about regulation in order - whether the cost recovery seems sensible or not. You haven't got users of pharmaceuticals, for instance, responding. It so happens my daughter has a rare genetic disease, so I know something about that. It's really the responses that you have not received that I am very upset about and in fact quite angry about, and I would really recommend or even demand that you do something to get a better set of responses.

I'd like to make a comment, if I may, and that is that this question of regulation and payment for it is very tossed up in the idea that if there's no payment - it's the no payment that's often the issue rather than no market. Basically we live in an economic society where if there's no money in it the action doesn't get done, and you will somehow have to try and come to terms with where regulation is not done despite the need for regulation and it's not done because there's no money coming forward.

I think that's all I really want to say. Thank you for listening to me. We will certainly be making a submission after we see what everyone else has said, now that we're in that category. However, I would like to make a point. It's clear that the government agencies have failed completely to make some submissions and I think they should receive some demerit points on that score. It really isn't acceptable to wait until you've seen what everyone else says and then have your saw.

PROF SLOAN: We're aware of human nature, and that is that sequencing issue. I think the agencies are likely to respond to the draft report, but they are involved in the process of important data gathering. They're filling out a quite extensive questionnaire, so it's not as if - - -

MR FORD: So they are working on it?

PROF SLOAN: They are, yes.

MR FORD: Thank you very much.

PROF SLOAN: Okay, thank you very much. If you'd like to use your networks to drum up some of those groups to debate some issues we'd be very grateful.

MR FORD: I have some ideas in mind.

MRS OWENS: Thank you.

MRS OWENS: Our next participant this afternoon is from Aircar Industry. Could you please give your name and affiliation for the transcript.

MR NOLAN: My name is Ross Nolan and I guess I'm affiliated with Aircar Industry, which is a research and development organisation.

PROF SLOAN: Again can I extend our apologies to you, Ross, too, because I know you came early and it was unfortunate.

MR NOLAN: Thanks for your concern. The sort of common thread through all this is that the government feels there's a responsibility to look after the interests of its citizens against various kinds of threats. The ones we've been looking at, at the moment, have been things you ingest, as in drugs and food and so forth. The other sort of area of threat which is reasonably definable is the threat of moving around, as in transport. It's the other major area the government gets itself involved in. My main area of activity has been in aviation or to some degree in the automotive industry. I have a very short amount of time, so I'll focus on one or two very, very specific pieces of legislation which I think you'll find utterly indefensible in terms of cost-benefit ratio or public interest or any other such thing.

PROF SLOAN: You have got about 20 minutes at least.

MRS OWENS: Don't rush.

MR NOLAN: Okay. My work is primarily involved in capturing a public benefit. That public benefit is the quantum improvement of urban personal transportation by means of an improved vehicle. The vehicle that I'm talking about is a flying automobile. Before you start falling over laughing, you may be interested to know that it is the major area of activity outside the international space station that NASA is now involved in. Here is an article here which is entitled, "NASA figures to revitalise general aviation by making flying basically as cheap and accessible as driving cards." If you want to go the NASA Web site, the NASA Web site is NASA.dot.lirc, which is Langley Research Centre, dot.gov, I think it is, or dot.aug. Anyway, type in AGATE. AGATE is Advanced General Aviation Technology Experiment

NASA have been looking at this thing for a number of years. I've been researching it for 25 years or more. The public benefit will be that you'll be able to completely obsolete - like CityLink. You could for instance fly yourself home to Adelaide from here in probably an hour and a half door to door. The historical thing is, aviation is an entirely invented activity. It hasn't grown out of agriculture. It grew out of nature pretty much and so forth, and aviation grew out of intellect and very little else, so it's only limited by the same things. We have come to the point in time where the technology is now able to be applied to the particular field, and the main area there is through the space program giving us GPS navigation, and electronics and so forth now make it cheap, so that you can basically fold your arms and be flown like you are on a major aircraft; you're merely a passenger. This is one of the things underpinning this whole thing.

At the moment I consider my technology to be at least equal with anything else in the world, if not better. I have given lectures overseas from 1991 onwards at various NASA presentations and so forth and I monitor the area, but I'm absolutely unable to capitalise on my work or to bring it to the use of the Australian government or people, for a very simple piece of legislation. I've been fighting it for 25 years now. I have letters going back to 1976-77. I had a letter from the Department of Productivity there telling me not to worry, go to (indistinct) in America because it's very easy to approve in America.

Present legislation here - this is a copy dated 1 October 1988(?), and I bring that date to your attention because it is after the issue of the new airworthiness regulations by Governor-General Deane. This legislation has fallen under the radar screen, I suppose, again. It was supposed to have been eliminated in 1987. I have a here a copy of the report.

PROF SLOAN: So what is the name of the legislation?

MR NOLAN: It's Civil Aviation Orders part 101.28. Once again by analogy, somewhere somebody in a laboratory is cooking up some new drug or pill or something or other based on some degree of foreknowledge and whatever else, but they intend to generate new information to come up with something that hasn't been done before that's going to have some positive effect. The equivalent in aviation is taking some piece of research which has been done which hasn't been yet applied and at some stage you have to build an experimental flying machine. In Australia that is effectively outlawed. We don't have an industry left in Australia now. Boeing has taken over the remains of what used to be the Australian aircraft industry, government aircraft factory and CAC, which is a monumental shame.

This piece of legislation says that it applies to aircraft that are built for educational or recreational purposes. Educational purposes are also the acquisition of new knowledge, which means it applies to experimental aircraft. Any time you want to make a better aeroplane of some kind or other, this is the legislation you come up against. It has various subsections. The one that offends comes in a copy called Design Standards. There's one called 3.3 and it says:

> An aeroplane of Australian design must comply with the design standards specified in paragraph 3.5 and subsequent of this subsection and with the design standards specified in Federal Aviation Regulation part 23 of the United States of America or British Civil Airworthiness Requirements, section K.

The next paragraph says:

> Subject to paragraphs 3.3 and 3.4, an aeroplane of overseas design must comply with the design standards specified in paragraph 3.5.

There's a notable omission there. There's no requirement for an aircraft of "overseas design" to comply with the American civil certification standards. The strange thing is also in Australia at the moment there are about 160-odd aircraft designs that are approved for construction here. They come under the educational and recreational part of this thing, but any new aircraft, it doesn't matter what it is, provided it's going to generate new knowledge, gets thrown into the same category. So it's a horrible misfit but that's the way it is, and I can confirm that from 25 years of experience.

25 years ago I came back to Australia from working in America in aircraft design and started to try to commence to build what was to be the first aircraft in the world made out of what's called monolithic composite construction. That's a picture of the aircraft there, called the Opal. After 25 years the aircraft was eventually destroyed by the department. These are various articles out of the paper and so forth I can leave you with to read about it and whatever else, but the fact of the matter is this legislation puts in front of any Australian designer a barrier of a minimum of $US50 million. It's double that now in Australian dollars. That's based on the certification of an aircraft called the Lanceair, which was built about 15 years later than the Opal, once again a similar method of construction in fibreglass.

But they were able to start because in America you can basically build anything you like and sell it and people can fly it and there are no standards whatsoever. As far as I know, I'm still the only Australian ever to have worked in the US as an experimental aircraft designer, a company in Ohio which subsequently built about 380-something-odd of the glider, which just coincidentally has more aircraft than had been built in Australia since the war.

PROF SLOAN: But is it an issue of inappropriate regulation killing off innovation?

MR NOLAN: No, it's cost recovery. There's an imposed requirement. The government imposes it unilaterally and mandatory. The words "must" appear in this legislation. I once had took a department through a court case. They can do an accident investigation as a result of a fatal accident. It can be a 747 plunging into, you know, Darling Harbour for instance. They can find that the control stick came out in the pilot's hand and therefore it crashed. They're not obliged to tell anybody that information. The investigation can go for 20 or 30 or 40 or however many years you like, all during which time it's covered by the Secrecy Provisions and so forth, and the word "may" eventually appears in the legislation. They can find the reason for the accident and they may "for the safety of future navigation" decide to release the information. It's absolutely abominable that that can be. I've got a videotape of myself on Channel 7 actually some years ago.

PROF SLOAN: So if you apply to have one of these experimental aircraft constructed you're saying you'd be led on a merry dance. You have to pay for that process?

MR NOLAN: That's correct.

PROF SLOAN: And in the end their kind of reasons for their decision would not be transparent necessarily?

MR NOLAN: There are no reasons. The department was unanswerable to anybody for 50-odd years. The Department of Aviation is a strange entity. It wrote its own legislation. Dick Smith, as you probably know - I mean, Dick Smith is in the food game now but he also was of course in the aviation game.

PROF SLOAN: We know that, yes.

MR NOLAN: He has made it a point of trying to bring some sort of commonsense into any sort of dealings between government and individuals, not always successfully. He made the point that these regulations don't ever seem to have been before parliament and they indeed were not. The Aviation Department - it goes back to 1920 when the Aviation Department was set up, one year after the great war finished, pretty much. I mean, it was like the space race now, you know. Would you take some country politician, which is what normally happens, put him in charge of NASA for instance, and let him make real decisions about anything? So the Aviation Department basically just kept a pet, you know, figurehead for their minister and kept him fed and watered and basically he didn't do much of anything too much a all, and they ran their own show.

Now, this has totally suppressed any innovation in Australia for the best part of nearly 50 years now. It came in, in 1956. Only one Australian aircraft ever got approval. That was an aircraft called the Corby Starlet, 16-foot span, wooden, single seater, open cockpit, fixed undercarriage, Volkswagen engine, the most basic possible thing. That even came under a grandfather clause which started in 1954. So nobody has ever complied with this regulation and nobody could, and the point is, as I've said to them many, many times - I've been through I don't know how many ministers for aviation it is now and all the other inquiries. What I started to quote before, the House of Representatives Standing Committee on Transport Safety, I'm the only person named in this report, on page 42.

I grounded an aircraft the department had given a certificate of airworthiness to, at which time the department hadn't even seen the aircraft incidentally. It's like getting a roadworthy through the mail. A bloke was killed in it. Six other people died in the aircraft because my first coming to the attention of the committee and this report. They then decided to call me back, even though I was odd man out, and this report tells you the results of it. I'll leave it to you to copy, if you like. At the same time I said, "Well, it's a Draconian piece of legislation." This legislation mainly covers people who build what's called home-built aircraft. You buy something from overseas, normally in a kit or a set of plans or whatever. You put it together and the Australian government won't stand in your way.

You can build anything you like from overseas and there are no requirements whatsoever in terms of airworthiness. It could be built out of bubble gum really. I

mean, there is no requirement that it has to be built in any fashion at all. However, you have some very competent people, usually professional engineers, who are building absolute leading-edge aircraft and there's a couple of examples there of aircraft you can build in your home garage, plenty of them built in Australia. I think I built the very first one in 1974 and there has been quite a few built and flown, flown across the Pacific, back to America, flown around the world in them. I haven't, but other people in the same aircraft. They were based on glider technology. I was the first foreigner to work in a glider factory in Germany in 1973 because Australia wasn't teaching design because it was basically outlawed and the industry here taught people to do maintenance, either for the airlines or the air force.

So we're talking about innovation now being the great hope for our future. Okay, we've got to make things. Well, there's no reason at all why we couldn't make the sort of vehicle I'm talking about here. That's an example of a flying car, which I don't know if you've ever seen a picture of that but it's 1948. I went and saw the fellow who actually designed that back in 1990. He has died in the meantime. But that splits apart and goes on the road like a trailer and a little motor car and it got approved by the government in the United States. The point was, you can do all these things in the US because you can have your experimental laboratory and the entire air space of the US is available to make flying machines in.

This piece of legislation, if I had to sort of point out one particular thing, I've had at least half a dozen committees, senate inquiries. One of them Norm Sanders was in charge of. He was an air traffic controller during the Korean War, flew himself. Senator MacGibbon, I saw him a few weeks ago at the Defence Consultation Committee and so forth. They all agree. They said it's just unbelievable this is kept on the books. Every inquiry, this one included, the House of Representatives Standing Committee on Transport Safety, have said that it's iniquitous and repugnant, and yet it is still there and it's still being enforced and it has killed off Australian industry. I know people have gone overseas. That's my only option, is to get out of the country and go and, you know, just walk away from the whole damn thing.

In terms of its reason for existence, the only reason for existence you can possibly come up with is to protect the people in the Department of Aviation who are fundamentally incompetent. No, I'm not joking about that. I'm not joking about it. I went to RMIT with people now that are in charge of airworthiness, okay? They were useless then and they're useless now. They have never had any exposure to the industry that makes flying machines, okay? There is a certain degree of up-close familiarity which is required to carry out the paperwork exercises and certification and they've never had it, they realise that. Australia is a buyer of aircraft, not a developer of aircraft, and it's a manufacturer of very little else nowadays.

So the only people who can possibly benefit in this - it puts an absolute barrier in front of anything that might carry a real responsibility. So what we've got is people that have sat at RMIT for three or four years and been lectured by people themselves who have no experience in the aircraft industry, and they get given a mountain of paperwork to approve a 747 literally. They say that they have now taken the idea that

there was no 747s anywhere else in the universe, okay, and someone has given them a pile of paperwork and said, "Is this thing airworthy or not?" Well, they wouldn't know if the toilet door was airworthy, in real terms, and yet this is the bizarre stupidity of our regulation here. Who pays for it? Qantas pays for it.

Would you believe this? Now, in Dick Smith's book you can get a copy of Two Years in the Aviation Hall of Doom. I'm sure if you ask Dick Smith he will supply one. I've got a couple of copies at home. It has also got a non-copyright in it. You're encouraged to supply it and put it around. Qantas were dead scared of ever getting on the wrong side of the department by talking to him, which they got information out of anyway. They send somebody to Seattle, actually to Everett Field, to inspect the airport where the only production plant in the world is that Boeing 747s fly out of, and the reason they go over there at Qantas' expense is to determine whether they will allow a 747, it has got Qantas registration, to fly at that particular airfield.

Well, it couldn't go anywhere else. I mean, it couldn't take off around the world. They banned 747s from Qantas, but nobody else, from flying into Wellington in New Zealand. Now, this is going to ridiculous extents in trying to protect people from some perceived threat. You know, we could ban flying because you might get hit by a meteor or something, you know. That aircraft, that TWA 800 aircraft that fell out of the sky, was possibly hit by a meteor, though they're trying to work out how. It's a long shot but it might have happened. That's the bizarre extent that they go to. You impose something like this, a $50 million standard on a prototype aircraft, which means you know you can never ever, ever satisfy the requirement.

Also in the industry we've got stuff which is called gold plating. You know, there's no end to which you can increase safety of something or perceived safety. But the cost benefit ratio just goes off the scale and no-one can afford anything made in Australia. The Nomad aircraft was sold for less than 60 per cent of the cost of production. I know they used to do baroscope inspections of the actual rivet holes in the wings bars. No-one else in their right minds would go to that ridiculous extent. This is not increasing safety really because those things, you know, are just - they're a waste of time.

But this particular thing here means that we can't have an industry which NASA - Boeing have actually done a design called a converty car which is a device that converts from a helicopter to an automobile. This report here is 152 pages in December 1994. It's called A Personal Aircraft, it's issued by NASA. In the preamble to this, they go to the development of the motor vehicle industry, or first they go from the time when railways were invented basically, or the canal system even first to that. Canals opened the door to railways. We could suddenly move materials around much more cheaply. Then you could drain mines because of the invention of the steam engine. You've got a steam engine on trails and it became a train. You could move things around for a twentieth or a thirtieth of the price you could put it on the back of a wagon.

Then of course that led on to the automobile. The engines out of automobiles made the flying machine possible. The flying machine led on to things like jet travel and so forth, and these things have a cycle to them, about a 54-year cycle called a candrati of cycle. The expectation is that the next big thing in transport - and bear in mind that everything is transported pretty much, so it underpins the whole economic system. They expect it to be the next stage which is taking air travel into the personal, short-range and urban market. It's totally hands-down, lay-down misere that we want to fly internationally, intercontinentally, interstate, intercity, and one market you don't fly around now is over cities. The other one - and that's also banned in Australia under a law that goes back to 1926.

In America when Dick Smith was flying around the world in his helicopter - I went to a lecture one time he gave at the Dallas Brooks Hall and I know him personally. It just happened to be this time. He said he was flying over Alaska and he saw these bears, you know, doing the usual thing, you know, eating salmon and stuff. He radioed up Fairbanks (indistinct) and asked permission to go down and do some low-level photography and there was dead silence on the radio. He waited for a while and he said, "Look, I'm requesting permission to do some low-level flying." They said, "Sir, look, if you want to, you do it. We're not going to stop you, you know. This is a free country."

Because in Australia if you fly below 500 feet in a powered aeroplane other than crop dusting, that's about it, in the middle of the Simpson Desert at 12 o'clock midnight, right, you're committing an offence. You can be jailed for it. I've actually been charged with low flying. I had to go through a court case in 1978. I put in a document to show their maps were in error, which they then admitted later on - went for about five years.

MRS OWENS: We've spoken to the mapping agency too.

MR NOLAN: Okay. Now, another thing about cost recovery. I'm talking about the engineering side of aviation, right, making the machines. No-one flies on their own. You've got to have something around you, otherwise you flap your wings or the handle doesn't really work.

MRS OWENS: We haven't got those yet. We haven't genetically advanced sufficiently.

MR NOLAN: Sure. There have been lots of cases of cost recovery gone mad in the operational side of the department. Dick Smith figures out the Australian Aviation Department was overstaffed by a factor of nine times, a minimum of nine times compared to the USFAA. If you worked it out per aircraft per movement per hour, whatever, that was the minimum. Some of the things, it was 20 or 30 times higher and in Australia of course we've had this - it's almost a civil war. The civil aviation war has been going on for many, many years. A friend of mine, a fellow called Captain Jack Ellis - he was called Captain Jack because he flew during the war in

Wellington bombers or Wellington aircraft on coastal patrol and so forth, and I think he sank a submarine at one stage, and he also flew during the Berlin air lift.

Now, I got involved with Jack one time when I found out he had this terrible problem going on. He was being charged $160,000 by what's now the Civil Aviation Safety Authority for airways charges. He owned four or five Cesna 150s that are a little two-seat aircraft that's used for training, that's about it, and he flew them out of Moorooduc. He owned a field at Moorooduc. He also owned a field at Lovely Banks just outside of Geelong. He made no use of any departmental facilities in terms of radar or airways of hangarage or any of these things at all, and yet arbitrarily they decided they were able to charge him sort of the maximum rate for these aircraft. He wrote back and said, "No, I'm not liable for any of your charges, don't use these things." They kept on charging him in the meantime anyway and they jackpotted this whole thing. They also fined him because he hadn't paid these things and they kept on jackpotting the fine.

It's unbelievable. This $160,000 was run up in about three or four years. I actually went with him to the AAT and we beat the case. It was the first thing under what's called general aviation infrastructure tariffs. These huge charges are imposed. They have nothing to do with costs. They are just called cost recovery and but for that, every aircraft in Australia would have been grounded with a lien on it from the department. Sometimes the actual cost would have been two or three times the value of the aircraft that's supposed to run them up and sometimes the aircraft were given these charges when they're sitting in the back of a hangar. All they were was a number on a registration form somewhere.

PROF SLOAN: I must go, Ross, because I haven't got one of your things and I actually have to catch a plane to go back to Adelaide. But it seems to me that you're bringing some examples of things that we're very interested in, which is about cost recovery affecting innovation, about this issue of gold plating of the regulatory agency, about the issue of inconsistency in the regulation that is between countries and I mean, I don't know if you have the time but it would be useful if you could put some of these thoughts down onto paper. I mean, we've got what you've said on transcript but if you do have the time - because I think you're right in saying we've got a lot on, you know, chemicals, food and the like but not so much on this area. So it would be very useful.

MR NOLAN: I'm certainly prepared to do that. I've got heaps and heaps of stuff here that has been written over 25 years or more. I can send you - the upshot of all these things is always they come around to agreeing and saying, "Yes, you're right," and nothing happens about it unless it's a retaliation measure. So I'd like to think that out of one of these inquiries - and I think it's best that it's an inquiry like yours which is divorced from direct involvement with the Civil Aviation Authority as such.

MRS OWENS: Absolutely.

MR NOLAN: It's just treating it as another government department whose sole business is regulation.

MRS OWENS: But we will be looking at CASA as part of our review of all the health and safety regulations. So we will be giving it our attention.

MR NOLAN: Can I make a suggestion to you? Could you possibly - because I mean, this cost recovery business has been the main thing which has been the bugbear in aviation. Could you possibly afford to put an ad in the Australian - - -

MRS OWENS: We will have to note that in the transcript. I'll have to close now because I don't have a quorum any more.

MR NOLAN: Sure, either something like the aviation section which is Friday in the Australian newspaper, just a little tiny thing. You'll get a monumental response. As an example, Dick Smith called for a Royal Commission into the Department of Aviation, mainly because of these sort of absurd and totally over the top sort of behaviours involving destruction of companies because of imposed costs and so forth that had no rhyme or reason to them. There were 6000 responses to Dick Smith's inquiry. Elaine Darling actually ran the thing. They got so overwhelmed they just focused on two or three simple issues and that 6000 responses, some of them were 100 pages or more.

Now, either in the aviation section of the Australian or for instance, say, in AEPA Magazine or one of those sort of things - because aviation has been probably the most regulated single industry on terms of a person to person basis and whereas you might certify a particular chemical or something or other once, and that's the end of the story, almost everything gets done in aviation. You know, even if it's done a thousand times over each time it still gets recorded. It still becomes an object for certification and this cost recovery thing, I notice in your report here Nullenby in the Northern Territory made a response and they said that their airport used to be owned by the government. Then at some stage they come under the local aerodrome ownership plan, at which point the department turn up and suddenly said everything had to be upgraded and they got it into their head, they said, "Oh, well, it might not be that they've got the grass this week," or something, right?

So they fly in there and charge - first they look and see whether they're right or they're wrong. Doesn't matter if they're right or they're wrong, they still charge them for the exercise and then they'd charge them for this whole sort of - you know, this farce. I mean, this is the way it works in aviation also. They can ground people on suspicion. People lose their licences - talk about cost recovery and whatever - and they've got to go to court to defend themselves. I don't know if it comes under your purview either, but something that really gets up my nose is this business about costs in courts, like $150 an hour for some junior, you know, governmental solicitor to prosecute some case or other and I mean, that's not cost recovery. It's not really the cost that they're actually absorbing, it's called that.

MRS OWENS: No, we're actually excluded from looking at the courts.

MR NOLAN: I expected you might have been.

MRS OWENS: We're looking at administrative regulatory and information agencies.

MR NOLAN: What you find in aviation is they deliberately - they go out of their way to force people either to capitulate or to have to take them through the courts. There have been numerous writs issued by various companies that have been put out of the air and their only course is to go back to the AAT initially or to go to the courts, whatever else, and these are costs imposed. They are indivisible from the act of trying to run a business in this particular industry and nobody - - -

MRS OWENS: So really you're worried about the costs that are imposed, which can be inhibiting innovation but you're also worrying about the costs of actually just doing business and the costs of gold plating on safety. There's a whole range of issues there you've actually raised with us today. So as Judith said, it would be lovely if you could put some of it down. But you did say that you'd give us some copies which we can give to our staff member here.

MR NOLAN: Yes. Are you able to copy them at the moment or some time shortly - probably easier for me to copy them and send them back in, I think.

MRS OWENS: Well, if you could just write us a short submission you could just attach them, which would be nice.

MR NOLAN: Sure. I'll make myself available for a follow-up.

MRS OWENS: Is that all for today? Are there any other comments you'd like to make before we close?

MR NOLAN: No, just the weighty thing is there ought to be some sort of democracy in terms of a mutually agreed set of requirements. Like I said, my problem is I'm an Australian citizen, therefore I come under this clause that says "an Australian design". I actually wrote to Bob Hawke, or he wrote to me first, one of these chain letters about what a great thing it was to be an Australian citizen. He was my local member in 1981. I wrote back and said, "I'm sorry, I can't agree with you. Because I am an Australian I am denied my living in my own country." The only country I've ever been paid to be an aircraft designer in was the United States of America. I wrote back to him and said, "I'm prepared to suspend my citizenship. I want to become a stateless person so that I don't get caught by this particular requirement."

I can't see how it's in the public interest to differentiate the engineering standards of a piece of equipment of any kind on the basis of the nationality, the passport in the back pocket, of the person that has designing it. I don't see that it is in Australia's interests or I don't think it's even constitutional or anything else - I couldn't

see it at the time - that we should actually allow foreign competitors open access to the Australian market, pay people in the Department of Aviation to give them approvals, sometimes even sight unseen, it doesn't matter how unworthy their aircraft were, or whether they were even illegal.

Now, I was wrong about that. In fact, there is no requirement whatsoever that the sovereign powers of a country be used in its own favour. I was staggered by that. When you think about it, there is nothing whatever that says you are entitled as a sovereign nation to treat your own citizens differently than those of any other nation. You can eject people out of the country when they're not your citizens; you can't eject your own citizens. But there is nothing whatever in fact - this is the staggering thing - which says you can't do it in reverse. It's one of the things you have as a sovereign nation: you can do what you damn well like differentially between your citizens and somebody else's. There is nothing to say you have got to do it to the favour of your country. This one is absolutely in favour of foreign countries to the detriment of Australia.

I even went to the Human Rights and Equal Opportunity Commission. I said at one point I was even thinking about registering a company called Overseas Aircraft, so I could have an overseas aircraft design. I thought something as ridiculous as that - the piece of legislation is so bloody ridiculous, like I said, the effect is totally destructive. There is no way you can get around it. $50 million as a starting point, and you say, how do you recover that? How do you, as a manufacturer in the same market - what you're doing in that thing there if this one is going to be made as a kit of parts as an aircraft, you would sell it to somebody who would put it together in their backyard. They have got a choice. They can buy one from America - and you can't possibly recover your $50 million by putting the price on the cost of the parts - and when they finish building it they get noble privileges.

In America if you build the aircraft to meet their legislation, then you can go and use it commercially, whereas a recreational aircraft by definition can't be used commercially, neither can a prototype. I'm happy with that. You develop a new technology to go and try and find investors and show something works better. It is your experimental prototype. But in Australia it has got to be fully meeting a commercial aircraft standard so your grandmother can go and fly it to church.

The equivalent would be in terms of what we were talking about before, about food and so forth. I had a friend actually who was a bacteriologist. He cultured things for Heinz and people like that. If you imposed that standard of requirement on people cooking their dinner every night at home they would starve to death, because you would never afford the equipment to do it. There is no doubt that it is safer for everybody every time they cook a meal to put it through a bacterial culture and to do all these other things, but it is just totally impractical. Here is the point about who decides what level of safety the public actually needs.

I decided, the other side here, that the Department of Aviation was approving what they called ultralight aircraft sight unseen. The aircraft were totally illegal. They

managed to kill seven people in the one kind of aircraft. I did an analysis of it and decided it should never get one inch off the ground. Their report confirmed that. They backed me up. I lost my business because of that. I was thrown out into the bloody street when this business came through. I had to fish my copy of this out of a mailbox that had been torn off the side of my building and thrown in the gutter. So that's the sort of retaliation the department is into, and you've got to read Dick Smith's book to understand it. He said he didn't understand how bad things were in Australia as he'd been told until (1) he went round the world in his own aircraft and found out how much different things were overseas, that it opened his eyes and then he decided to investigate a few things.

His book is a number of investigations: the most unbelievable things he found. One little example, a Bulco helicopter. A fellow wanted to bring Bulco helicopter in here. The Department of Aviation insisted on sending a technical team to Germany to go through the engineering of this aircraft. Once again, they have got no experts. There's never been a helicopter designed in Australia, not even one. They went over there, costing I think it was $850,000 from memory out of the book. The entire changes that they insisted on, on coming back here was a little sign saying the word "Exit" out of the only door in and out of the aircraft, and the usual one the department goes on for is the flight manual pocket on the side of the aircraft. Their story of that one is there was a Fokker Friendship, I think it was Ansett, flying over New South Wales, encountered some turbulence. The flight manual came out from between the seats and lodged in the controls and they had jammed controls for about 30 seconds. The thing did half a barrel roll.

Since that day on, every aircraft in Australia had to be modified, whether it's a 747, with a little pocket for their flight manual, and for this they will charge hundreds and hundreds of thousands of dollars and justify trips round the world. This is the point where you have to have some other oversighting body to decide just how much safety do we need, how much protection from ourselves do we need? On one side of the thing, they went from the sublime to the ridiculous. They gave people permits to fly aircraft. They required the pilot to have no training at all. The aircraft had no design standard, the aircraft had no manufacturing standard, there was no inspection of the aircraft - this is the ultralight thing when they first came along, who were killing themselves en masse.

I was on 60 Minutes at one stage and on Day by Day and on Willessee and a few of those shows and so forth, and you sort of think, "Really, what are they trying to achieve?" They don't seem to be interested. People have always said they don't care whether every aircraft in Australia falls out of the sky, as long as the paperwork is in order and they can't be shown to be liable. Unfortunately, my conclusion is that that is the thing, and if just the recommendations of all the prior reports on these things - for instance, the Air Safety Regulation Review Task Force. Their reports came from Adelaide.

I spent five days at Canberra at one time, in 1987, when Ros Kelly was acting minister for aviation (indistinct) whole bunch of information there. I needed a little

wheel-around, almost a wheelbarrow type thing. I spent a couple of hours with her people and they said, "This is unbelievable stuff, you know. We believe it but what the hell do we do about it?" She sent it all on to this aviation safety regulation task force. They came back and agreed with every single point that I've made. Now they have got this huge progress going through - it is still going through the department - of total reform of the regulations.

But this particular one, the one that I started the whole thing, has gone through. William Deane signed it and it puts in place - I call it aviation apartheid, literally. Apartheid has so far been acknowledged to be practised by Rhodesia, South Africa, Fiji, because the guts of apartheid is - it is an Afrikaner word, but most of our words come from Latin or French or Greek or somewhere else, so you don't have to - it's where the government writes a law which says, "We will deal differently with some of our citizens as against other of our citizens on the basis of something to do with their inherent qualities, the fact that they are black or they are white or they are - well, Fijians and Indians are fairly much the same colour, so it is just the fact that they come from a different country. That is exactly what this legislation does.

That is why it has been found to be repugnant. It has been found to be repugnant but it has been repeated and reprinted and enforced for all that time, and it will stop us having what NASA in its report - and I'll actually copy the pages - expects to be "the largest new industry of the 21st century." The automobile industry at the moment is the biggest manufacturing industry. They consider that if you can have an automobile that can fly you somewhere, like if you want to go to Mount Buller, 20 minutes away from here; if you want to go to Tasmania, an hour away, door to door, not going out there and waiting for your aircraft to line up and sitting there with your bags and everything else and all the hassles that go with flying now by airborne cattle truck. This is actually flying yourself Jetsons style, if you like.

So I'd like to think that somehow or other this regulatory impediment could be removed. If it could be, then you could go through the normal process of developing a prototype, of interesting investors and interesting big companies and so forth, you could demonstrate the thing and show that it worked. What we're doing at the moment effectively, they say one drug in about 10,000 candidates eventually makes it through to the supermarket shelves. Can you imagine the price if you enforced the same quarter million dollar - or maybe 500 million dollar, what the figures were before - procedure on every one of those possible 10,000 candidates. No new drugs of any kind would ever appear. The industry would shut down because it's clearly so ridiculous you couldn't possibly make it economic.

That is what we are facing now, so all I'm asking for here is that the costs that are imposed have to be justified in some fashion. The costs have to be imposed equitably. Like I said, I thought in the first instance - I was right about this - that Australia was going to be on my side because I'm an Australian, and I was totally wrong about that. We could, for instance, write a law, absolutely lawfully - there is nothing stopping any sovereign nation from saying that it will jail citizens of its own nationality and let other citizens walk the streets with no impediments. I think there is

something that says you can't actually export your citizens just outside the country or to any other country because it sort of enforces on them, but it doesn't require you to do it in your own favour. That's where I've got no legal comeback on this thing.

As somebody says, this is in fact an example of an imposition without a justification. It imposes a cost which is against everything to do with public interest and mutual public benefit and there's no cost recovery possible, so it is probably even unconstitutional. That will probably do the timing of it.

MRS OWENS: Thank you, Mr Nolan. I think you've stated your case very eloquently. I apologise that my colleague had to leave but, as she said, I think we have a great interest in looking at the incentives that are the result of these arrangements. Our real interest is in cost recovery, but it's hard to divorce cost recovery arrangements from the regulatory arrangements, and we'll take some interest in that piece of legislation that you have brought to our attention. So thank you for coming. I will now close today's proceedings and we resume in Sydney tomorrow afternoon at 2.30 pm. So thank you.

MR NOLAN: Thank you.

AT 5.30 PM THE INQUIRY WAS ADJOURNED UNTIL
TUESDAY, 21 NOVEMBER 2000

INDEX