

ROYAL COMMISSION OF INQUIRY
ON GENETIC MODIFICATION

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PRESENTATION BY ERMA (CONTINUED)

IR: Yes, good morning. Thank you for coming back. Do the cross-examiners have an agreement as to the order in which they will proceed? Who is first then please?

BODLE: I am, sir, for the Organics Industry.

25am]

BODLE: Most of my questions this morning, I guess, I'll address to you, Mr Walker, but there might be others on your panel who wish to answer. My name is Gareth Boodle, I'm with the Organics Industry's group.

To start with, I wish to ask questions from your main submission, starting with paragraph 27 on page 14 of the submission. I hope our page numbering is the same. It is under the heading "economic strategy", para 26 - I'm sorry, page 13.

WALKER: Okay, we have it.

BODLE: Okay. In the middle of paragraph 26 is the statement, "In its darkest form this is set out as a choice between a GM-free organic agriculture future as compared to futures which GMO have a positive role". My question, Mr Walker is, does not conventional agriculture have a role in its own right separate from agriculture involving GMOs?

WALKER: Oh, indeed, and I think the intent of this statement was to say that there are a whole range of choices that are available to society and to economy in this area.

BODLE: But in short it is not simply a question of either GE or organics?

WALKER: Absolutely not.

BODLE: Thank you. Turning the page to paragraph 27. I'm interested in the first two bullet points. There is an acceptance that genetic research might be pursued in the context of potential medical applications, and then the second bullet point. The questions I have is that I'd like to look at this in a slightly different way perhaps, and when people are calling for a GE-free New Zealand, or say a moratorium on GE in the generic sense, is it your view that what they really mean is no GE out in the environment in agriculture?

WALKER: Well, you're asking me to put myself in the minds of people who've expressed views on that subject, and I'm not sure I can do that. I think the reality is that there are a whole range of views out there in society which range all the way from an absolute "no" to anything that represents the use of genetic engineering, to possibly more pragmatic views, and I think frankly that's one of the issues that needs to be debated and crystallised a bit further through mechanisms like the Royal Commission.

BODLE: It seems to be your observation here that there seems to be a difference between supporting medical research, the pursuit of knowledge, even knowledge perhaps that has commercial advantage in a laboratory situation, and commercial release, the pre-release of GMOs in the environment. What I'm driving at is perhaps in the main this generic term of the GE-free does not intend to preclude the research side or description in that first bullet point. Would that be the case?

WALKER: I certainly wouldn't argue with your contention. I'd make the point that in part of the submission, and I think it's said there quite clearly, we were simply representing to the Commission the views that had been put to the Authority in the course of making submissions; so really we were just acting as a post box and passing on information.

BODLE: Thank you. If I can then go down to the bottom of the page to paragraph 32. This is the suggestion about policy statements from Government; you alluded to this again in your oral submissions yesterday. As an example, a moratorium on the use of GE in agriculture in the field, that would be one example of what a policy statement could be?

WALKER: Yes, it is.

BODLE: Now the Producer Boards, Federated Farmers and so forth, all agree it's not favourable to introduce genetic technology at present; so therefore we don't need a moratorium, however that position is not exactly the same as a policy direction from Government, is it?

WALKER: No, it's not.

BODLE: So, this pro-choice option relating to the market, relying on the market to give us indications, is not really a policy direction, is it?

WALKER: Well, you can say it's an implicit policy stance in the sense that the Government can choose either to interfere or not to interfere in the operation of markets. But certainly a policy

option is to stand back and say that, providing certain basic criteria can be met, that market should be left to operate on their own. Now, I'm not saying that that should happen, I'm saying that's the range of policy options available.

Since you've given me the lead can I go a bit further and say that, probably something there is a strong feeling on, certainly within my own organisation, is that there may be justification for setting policy boundaries which reflect, if you like, some of the key risks that might be associated with the technology, or some of the uncertainties that may relate to that. And, that's a different proposition than trying to dictate how the technology might be used.

BODLE: Thank you. With respect, we're all confined to time, so I would be grateful for brief answers as possible.

I'd like to continue in that vein and move on to paragraph 37. And, again there are two bullet points here where you differentiate between work carried out in a contained laboratory and work carried out under the less rigorous conditions of containment, for example, in a fenced field. There is a distinction between a contained laboratory and the second bullet point where GMOs are released in a situation where they're affected by the wider effects of the environment, isn't there?

WALKER: Is that a question?

BODLE: It was, yes. Was that a nod, was it?

WALKER: No, it wasn't either a yes or a no, it was an indication that I was going to explain a bit further.

I think in fact it's not that quite clear-cut, but the problem in writing legislation is that you tend to be forced to describe clear-cut boundaries where they don't exist. In fact, as I indicated yesterday, laboratories and field trials actually represent a continuum, and you may find instances where a field trial situation is actually more secure than a laboratory situation. So, it's not entirely clear-cut.

BODLE: Yes, you mentioned that yesterday particularly in relation to issues of security, didn't you?

WALKER: Uh-huh.

BODLE: My concern is - or the point I'm trying to make is that we can look at this under a number of different perspectives, and one would be to say that a field trial and commercial release would be similar because they're both in a situation where they're exposed to environmental influences. Is that correct?

WALKER: Well, that of course may be one of the reasons for carrying out a field trial, although in the Act there are other reasons for doing that.

BODLE: In other words, they are exposed to the environment?

WALKER: But again - no, it's not that simple - in fact, it's not possible to recreate something that looks like an environment in a laboratory in some cases. In other cases it's more appropriate to go to a field trial situation.

Now, the case that always springs to mind is the one where you're doing work on animals, large animals particularly, and indeed if you look at the kind of standard of containment that applies to animal trials, there's often much more rigorous controls than would apply to low risk work in say a PC 1 contained laboratory. I'm just trying to discourage you from creating simplified boundaries where in fact there aren't simplified boundaries.

BODLE: Clearly the boundaries depend on the perspective as you say security is one perspective but there is also the other perspective of whether or not you are doing the work in the open environment or a contained environment. Perhaps it might be better to look at some examples. For example, ERMA has two kinds of approvals, shall we say. There are those that you inherited from the Interim Assessment Group, and those that you've granted yourself. I'd like to take two of those, one from each, the first being the Kerikeri tamarillo trial.

In evidence we were shown a number of photographs; unfortunately despite the best efforts of staff yesterday we can't provide you with the pictures, but they showed big holes in the netting that was supposed to prevent birds coming in and out. In fact there were big holes there, birds were able to travel in and out. Now, we can ask whose fault it is, who's to blame and so forth, and who should police it, but my question is that, the real problem or the critical problem is that, because of those holes, the trial was able to interact with the wider uncontained environment. Is that the case?

WALKER: Uh-huh, that's true.

BODLE: While the elements of wind, rain, sun etc are very powerful elements of nature, the fundamental need for organisms to eat and reproduce are equally powerful forces of nature, aren't they?

WALKER: Nods.

BODLE: So, in the case of the tamarillo trial, and in fact it doesn't have to be tamarillos birds eat tamarillos, other fruit

insects and so forth, so basically this is just carrying out a very fundamental part of the process in nature, isn't it.

So, when we - there are also other issues; we see the food chain as one area where GMOs could move from one site to another. The other issue is cross-pollination, and another one is horizontal gene transfer. So, whilst we can see the birds, we're not necessarily able to see things that happen under the ground, are we?

WALKER: Yes, well, one can't argue with that proposition.

BODLE: So, in this respect field trials and commercial releases are the same because whilst, as you say, you can fence in large animals you cannot actually fence in soil organisms in a field trial, can you?

WALKER: That's quite true, and of course the key issue there is whether that represents a risk which needs to be considered in making a decision on a field trial, and what controls should be set. I think it's important to remember that all the time the key question that's being asked is, what kinds of risks are being created, can we control those risks adequately by setting controls. If we can't manage those risks adequately, should we say no. I mean, that's the train of thought that's involved here.

BODLE: There has been evidence of course submitted to the Commission that there is a big issue with soil organisms, and for example AgResearch under cross-examination, Dr Goldson, said that they really don't know enough about it yet to even comment. And, in the vein of AgResearch, perhaps I could turn to the trial that's approved by ERMA, GMF 98009 which is probably better known as a the transgenic cows trial at Ruakura.

WALKER: Are we in difficulty here?

IR: Mr BODLE, you heard the discussion yesterday, did you?

BODLE: I'm sorry sir, are we unable to explore this particular trial because of the High Court?

IR: Yes, that's the position.

BODLE: I'm sorry, sir.

Okay, in that case, can we just move on again to this matter of differentiating environments. When we call something a field trial, or whether we have commercial release, effectively we're releasing GMOs into the environment. And despite regulations, and I'm not taking issue with regulations, a field trial and commercial release still have to either guard against or be influenced by the elements

of the natural environment and the forces of nature, don't they?

WALKER: That's quite true, although remember that even a contained laboratory sits inside the natural environment.

BODLE: Well, that's quite true, as you say, but I think the issue that, in a contained environment you are able to regulate the decisions of the people who operate it, and I think we all accept that. That you cannot, with regulation, control what happens through the forces and causes of nature, can you?

WALKER: Well, that's not entirely true, it depends on the conditions imposed on the trial. But certainly, obviously, if you're talking about things that might be influenced by the weather for example, wind, rain and so on, then that is clearly a natural effect to which a field trial was exposed, and of course that becomes a factor in decision-making. That's why for example, in the case of the risk of cross-pollination, the view that's been taken latterly, particularly by the Authority, has been to avoid the possibility altogether by not allowing pollen to be created. And that's a good - I keep using that as an example because it's a good example of a logical response to a situation where there isn't an ability to control the natural environment.

BODLE: Yes, I understand that, and I think that the point is that I guess we're very much aware of the elements and, as I asked in an earlier question, there's also the issue of processes of nature themselves are very powerful, aren't they, and that's the important thing.

Now, so if we were to try and draw a line, which is my point, where these things stop and start, we have to draw the line at the laboratory door, don't we?

WALKER: No, I think the most important line to draw is between work in containment and uncontrolled release, and I think I made that point quite clearly yesterday. We may well choose to differ on that, but that's certainly my own opinion.

SUTHERLAND: I'd say it is the view of the Authority as well.

IR: Mr BODLE, the time which you agreed to take has expired.

BODLE: That is my final question, sir. Thank you, sir; thank you gentlemen.

50am]

FITZSIMONS: Good morning Your Honour and members of the panel and members of ERMA. I'd like to address a few questions to Dr Hannah please, of which are scientifically based, and it deals with the risk assessment issue.

In order to carry out a risk assessment, do you need first to define the nature of the various adverse effects which might result from an application?

HANNAH: That's one way we could describe it. Our terminology is that we undertake a process of risk identification that may arise from the proposition before us. So, we try to identify as extensively and as laterally as we can the total risks that may possibly accrue. And, some of those can be even quite off the wall type of risks when we do that particular process.

FITZSIMONS: And, is that process then followed by an assessment of the probability that each adverse effect may occur, and the consequences if each one does occur?

HANNAH: They are two of the aspects of assessment that we then embark on, and the third part of that - it's at least a three legged stool, if not more - is to try and characterise the uncertainty which we have around each of those particular components, of more detailed analysis of what the risks are that we're looking at.

FITZSIMONS: So, that would be the uncertainty of the identification, the uncertainty of the probability assessment, and the uncertainty of the consequences assessment. Is that right?

HANNAH: Yes.

FITZSIMONS: Thank you. Do you agree that genetic modification involves the random insertion of a gene construct into a close genome?

HANNAH: A number of them do, that's quite complex in its technology; I don't know that I'd be quite bold to say that as an overarching generalisation for everything, but there are a number of them that do use that type of technology, yeah.

FITZSIMONS: So you'd agree that in those cases the genetic engineering has no control over the place within the genome that the gene construct will lodge?

HANNAH: Again, that's a very broad generalisation to try and characterise in a very wide range of levels of control that do or do not exist, and I wouldn't want us to be left with that as the only perception of the level of control. There are different techniques

which can be more targeted than other techniques which are less targeted. So, I don't know whether that helps, but I'm just not totally agreeing with the single assertion.

FITZSIMONS: So, you wouldn't agree with the witness to the Commission, Dr Antoniou who said "Once injected into the cells of the organism the introduced gene is randomly incorporated into the DNA of its new plant or animal host"?

HANNAH: Without knowing the context on which it was said, I would neither agree or disagree; I'm afraid I would need to have more information.

FITZSIMONS: Can you describe some of the cases that have come before ERMA where in fact the positioning of the construct in the genome was able to be accurately controlled?

HANNAH: Right off the top of my head I can't bring those out and put them right on the table, but I can look at that type of - the examples we've had which have been more controlled in a sense, that the researchers have targeted particular types of genes to be associated with particular types of functions within the genome, so that particular types of expression will be observed, and that is much more controlled than just random insertion.

We have seen examples of those, and I would have to look back through our precise details to get that. I'm willing to do that, and to provide the Commission with that information, rather than take up time speaking outside at the moment.

FITZSIMONS: I'd be grateful if you could provide some examples, because we and the expert witnesses that we have drawn on, are not aware of any ability to precisely locate the gene construct within the genome. So, that would be helpful, thank you.

Do you agree that the behaviour - but at any rate, you agree that in many cases it is not possible to target it?

HANNAH: Yes.

FITZSIMONS: Do you believe that the behaviour of the transgene may be affected by its placement within the genome?

HANNAH: Oh absolutely, yeah.

FITZSIMONS: And you'd agree that, as well as being theoretically possible, there are some unpredictable consequences of transgene insertion that have been empirically demonstrated?

HANNAH: Oh, yes, in fact that's a key part of the post modification

selection process, which is usually carried out in the laboratory to narrow down the range of insertions which actually have occurred to reject or to get rid of those which are undesirable and not wanted, and to focus, depending on the proposition the researcher is following, and to target in and focus in on those that they do want, and then to characterise those constructs in a way which the precise nature of that insertion then is much more clearly understood so that, while the process of modification has been random, the particular result that has been selected is much better and understood rather than just a whole random range of products that may have come out of this.

So, there are techniques to try and bring certainty to what has previously been quite an uncertain start to the process.

FITZSIMONS: And those post modification tests are carried out by the applicant before they apply to you for permission to do a field trial, for example?

HANNAH: Invariably, yes. I can't think of a situation where we haven't been dealing with a field trial for quite specifically gene constructs. Yeah, I think in every case that's been true.

FITZSIMONS: And would the applicant carry out research before applying to you, to test for effects that were not of commercial interest to the applicant?

HANNAH: At the development stage they would be looking for, I guess, a whole range of effects as to whether they were commercially - I don't know, I'm not really - can't always go inside their minds, but commercially desirable or not. By the time we've ever got to field trial stages, we have been dealing with quite precise constructs in each case.

FITZSIMONS: Can I just clarify what you mean by "construct"? I understood the construct to be the gene and its associated promoter marker gene, and probably some bits of non-coding DNA that goes in as a package that is defined before they put it into the cells, is it not?

HANNAH: I'm also meaning how they've actually got it inserted inside the overall genome of the animal that they - or the plant or the target organism that they are looking at.

FITZSIMONS: We'll come back to that, I think, in a little while. Do you agree that the insertion and the manipulation of gene fragments can lead to unpredictable consequences?

HANNAH: Yes, in general terms, yeah.

FITZSIMONS: And would the work published by the Department of Virology in the University of Tromso where, in the early 90s, supposedly harmless naked genomic virus DNA fragments were injected intravenously into rabbits and mice and, instead of being broken down by nucleases, it resulted in viral genetic expression and full productive viral infection. Is that an example of an unexpected - and unpredictable consequence of the insertion of gene fragments?

HANNAH: Well, I'm not specifically familiar with the particular study you're describing, so I don't know whether they predicted - you know, that was predicted, one predicted response; but from what you say it seems to be a response that did occur, but I can't tell you about the predictability of it. I am not familiar enough with it, I would be prepared to have it looked at if you so wished.

FITZSIMONS: We have some abstracts to table, perhaps at the end of my cross-examination.

Do you agree that the random insertion of the gene construct, complete with a promoter, a marker and unavoidable pieces of non-coding DNA, is theoretically capable of disrupting the host genome in unpredictable ways? This is not the behaviour of the transgene, this is theoretical, potential disruption of other genes in the genome by the insertion of that construct.

HANNAH: It's possible for those things to happen. They are seen to happen at different times, yes.

FITZSIMONS: Do you agree with the following statement by the Canadian Royal Society in their report of just last month entitled "Elements of Precaution, Recommendations for the Regulation of Food Biotechnology in Canada". And I quote, "The conclusions relevant to this discussion are that unanticipated changes can be induced by expression of a novel gene".

HANNAH: That's certainly true to the extent at which I would agree with it. I would want to look at its context in a slightly broader fashion, but it's certainly true, as we've already discussed, that unintended consequences of inserting foreign DNA into host genomes can produce unpredicted behaviours, and the key thing for us is to understand the extent at which those behaviours have been tested for, have been analysed for, so that we can try and appreciate the extent at which there is uncertainty in risks that remain or not. And. I would be very pleased to, again, look at that particular context of that and to see whether I fully agreed with it as a generalisation or not.

FITZSIMONS: Your Honour, does the Commission have that very recent Canadian report? We'd be happy to table it if not, it's 245 pages, we've brought the 20 page abstract with us to table.

CURRIE: We believe Greenpeace has tabled that report, sir.
FITZSIMONS: Right, thank you.

Turning to those unpredictable outcomes. Could one of these unpredictable outcomes be the unintended turning on of a gene which until then has been silent in the genome, by the insertion of a powerful promoter?

HANNAH: Could it? Yeah, there's a possibility that it could, yeah. I can't deny that.

FITZSIMONS: Does ERMA assume, in its risk analysis, that horizontal gene transfer from plants to bacteria is likely to occur?

SUTHERLAND: Maybe I could answer that because we've looked extensively at horizontal gene transfer in probably all of the field trial applications. And, in a straight answer to your question, no, we don't agree that that is likely to occur. From all the evidence that's been given to us, there's uncertainty about it; there is certainly horizontal gene transfer between bacterial organisms, but from transgenic plants into soil microorganisms, which I think is what you're asking, we've not been convinced that that is likely to occur.

FITZSIMONS: Are you aware of recent peer reviewed publications by - and I'm referring to three here, by Smailler, by Pertollen, by Neilson. You've read those?

SUTHERLAND: Yes, we have.

FITZSIMONS: Do they highlight that horizontal gene transfer from plants to bacteria, and do they show that there's now experimental proof that DNA from transgenic plants can be captured by bacteria?

SUTHERLAND: Yes, we've read those papers. The question is, for us at least, is what's likely to occur in the field trial situation, and those particular papers haven't convinced us that that's likely to occur in a field trial situation.

FITZSIMONS: What is different about the interaction between plants and say soil bacteria in a field trial, compared with plants growing anywhere else?

SUTHERLAND: Well, from my memory those are laboratory studies, and they entail particular plants and particular bacteria, and I can only say that, having looked at those, they have not convinced us that that is likely to entail or incur a risk of horizontal gene transfer in the trials that we've looked at.

FITZSIMONS: And, is that because those associations of plants and bacteria don't occur outside the laboratory, or is it because the environmental conditions don't occur?

SUTHERLAND: Yeah, it's all those things.

FITZSIMONS: So, you believe that horizontal gene transfer from plants to bacteria only occurs in laboratory conditions?

SUTHERLAND: No, I didn't say that.

FITZSIMONS: But can't occur in field trial conditions?

SUTHERLAND: I didn't say that either. I said that we have not been convinced that that is a risk of occurring in the field trials that we have considered.

FITZSIMONS: Can you tell me why?

SUTHERLAND: Well, because of the particular species of plants and the particular environmental situations that are embraced by those trials.

FITZSIMONS: Can you give us an example of how you went through that analysis with a field trial and came to the conclusion that it couldn't happen?

SUTHERLAND: Well, I haven't said it couldn't happen, I've said that there is - the risk of it happening is not one to convince us that we should decline the application.

That literature on horizontal gene transfer has been developing, I guess, a lot in recent years, and the papers that you mentioned, for instance, weren't available to us and some have been published since; for instance we made the first approval of a field trial of a transgenic plant, the sugarbeet one, in 1998 or whenever it was.

So, we're trying to match, I guess, our assessment of the risk of that happening with the progress in the scientific research surrounding that area. And so, the way in which we would have analysed it with respect to sugarbeet would be different to the way in which we would have analysed it in respect of pinus radiata.

FITZSIMONS: So, did you specifically include the conclusions of those three papers when you looked at the pinus radiata trial?

SUTHERLAND: Yes, I'm sure we did. I'm sure we did.

IR: Can I just come in there? I'm interested to hear the way you

put that, Dr Sutherland, that you weren't convinced that there was a risk. So, the onus lies on the opponent of an application to establish that there is a risk?

SUTHERLAND: No, no, that's not so.

IR: But it sounded like that.

SUTHERLAND: No, it's more us being convinced by the information gathering, principally of our own staff, but also the information that comes from applicants and the information that comes from submitters. I mean, in many cases submitters have drawn our attention to information that might or might not have been gathered by our staff; but it's our assessment of those different streams of information.

IR: Yes. I was interested in the question of the onus of proof. You made it sound as if it was on the opponent to establish a risk. There is a point of view that it should be on the proponent of the application to convince you that there is no risk, or no sufficient risk.

SUTHERLAND: Well, that's true, but we also form our own judgment on that.

IR: Well, which is ERMA's approach? Could you tell us?

SUTHERLAND: The approach is to look at the application and to be convinced by that that there is no risk. That's true. And the applicant is --

IR: I have to say, that's not the way you put it. I'm glad you to hear you redefine that. Thank you.

FITZSIMONS: Thank you, sir, and just to follow-up on that then, you believe that it is your job to determine that there is no risk rather than, that there is only a small risk, or that the occurrence is unlikely, or that - or any of those qualifications?

SUTHERLAND: No, not --

IR: He didn't say that either.

SUTHERLAND: Not no risk. I didn't say that. No, not no risk. We've already said - I can't remember if I said, but there's no absolute certainty of no risk. The question that we have to weigh up is, whether the risk is substantial or how substantial the risk is, and whether it's manageable.

FITZSIMONS: How do you apply the Precautionary Principle in a

situation of uncertainty like this? And how do you quantify what is small in terms of risk?

WALKER: Can I just jump in there and just give a part of an answer and pass it back to Dr Sutherland and Dr Hannah. I think, in looking at risks, there are actually three steps that are gone through. The first step is to look at the proposition that there might be a risk. And, I think the test that has to apply here is the test of reasonableness. In the light of all of the information available, is it reasonable to suppose that there might be a risk which we ought to consider. And, if the answer to that is that, well yes, it is reasonable to suppose that there might be a risk, then you look at the information available, you try and assess the consequences and the probabilities associated with that risk, and the uncertainty that surrounds all of that information, and that then becomes a part of the decision-making process.

In the particular case of field trials, of course, and this is one of the huge distinctions between the field trial and release, you are talking about a piece of work which is occurring in a particular location, probably a fraction of a fraction of the total land area of the country over a period of time, and the circumstances where, at the end of the trial, all of that's going to disappear and where you have the ability to set controls and set conditions. And, that does influence the way in which you look at the risks.

But I just wanted to re-emphasise that, as best we can do it, it is a balanced process, and we try and look in a balanced way at the risks and the benefits associated with an application.

FITZSIMONS: Ahh, so you balance the uncertainty of adverse effects against the benefits to be achieved by the experiment?

WALKER: No, it's a more complicated process than that. I think it's fair to say that the Authority is more risk averse in looking at risks than it is in looking at benefits. In other words, the standard of proof is consistently higher.

FITZSIMONS: Thank you for that --

WALKER: And that is a reflection of the requirement of the Authority to take account of the need for caution.

FITZSIMONS: Uh-huh. Is it possible, I guess returning to either Dr Sutherland or Dr Hannah as the scientists, is it possible that the disruption of the normal functioning of the transgene or other genes might not be apparent under all environmental conditions?

HANNAH: It's possible, it would be a very bold scientist to say that it wasn't, I would dare to say. The big question that we are

often faced with is, how much of that possibility are we likely never to know, and that constitutes part of the uncertainty that we try to frame up when we are doing those assessments.

FITZSIMONS: In your view is it possible, as was suggested in a paper last year by Smaller, which we'll table Your Honour Your Honour, that horizontal gene transfer of antibiotic resistant genes may happen at different rates depending on different environmental conditions?

HANNAH: I think that's entirely possible from my understanding of the work and the literature that's been described, and in fact I would even go so far as to say, it is most likely that there will be different rates of any transfer that does occur, depending upon the environmental conditions. In fact, I would be most surprised if there wasn't a range of rates at which that occurred.

FITZSIMONS: If then, unforeseen and unpredictable effects are inherent in the nature of current technologies for genetic modification, how do you determine which risks to assess? Going back to your terminology in the first question, how do you identify the risks if there is a possibility that quite unanticipated changes to genetic expression may occur?

And, how do you assign probabilities and how do you assign possible consequences, scale of possible consequences, when you do your risk analysis?

HANNAH: That's a very big question, and --

WALKER: I'll have a go at that if you want me to.

FITZSIMONS: I was really getting at the question of how do you relate this highly technical science, much of which is very new and still evolving; every new paper seems to show greater uncertainty than we thought. How do you relate that to the process of risk analysis?

WALKER: Okay; well, the question is really, how do you deal with the unknown unknowns, which is a problem you always have in this kind of decision-making. And, I don't know that I would agree with the statement you've just made incidentally. I think that what's happening is that, as more research is being done, our total knowledge of this whole technology is improving. And, I take a pretty open view of that.

FITZSIMONS: Can I just then ask. Do you mean your knowledge of the technology, or do you mean your knowledge of the possible perturbations of the genome as a result of the technology?

WALKER: I think, both. I think total knowledge about the technology and its applications, and its effects, is increasing all the time. But, getting back to your question, you're asking about really the unknown unknowns, and of course dealing with that kind of dilemma is at the essence of science, because that's what science is about, it's about pushing the boundaries of knowledge.

Now, I think at the end of the day what you do is you do the best you can to think about and identify the possible risks that might occur, and that's not - I mean, it's difficult, but it's not an intractable problem, because you have a whole body of previous knowledge to draw on in doing that. And then at the end of the day you really have to rely on the judgment of informed, sensible, wise people to make a call on whether or not something should be done or shouldn't be done. And, of course, that's why we have an Authority, this is not done by a single individual. That Authority is sectorized to represent a range of experiences and expertises so that they can be entrusted with making that kind of judgment. But the others may wish to add to that, I don't know.

HANNAH: I wonder if I can just narrow it down, having thought about it for a couple of minutes on this. When we are trying to work out the probabilities and the consequences of things that could occur, even if we don't know exactly what the nature of them might be, we then need to go and look at what is the whole context of the situation that this proposition's being set in, how well we can manage or control the situation if we were to apply controls to those particular unknown risks, if we can call them that. And then, for example in terms of the probability of something happening, we might say that there's a very distinct size limitation and a location limitation on where this proposition would occur; that means that the probability of other places being exposed to that risk is managed may be reduced to a minimum or negligible level. So, the exposure component of a risk, which is tied in with probability, is able to be managed to a low level. It's those types of processes we work through. And that's what makes the field trial situation quite different to the general release, because if we have a general release and we have got these unknown risk type of situations, we have no ability to come to a sensible analysis of what the probability of exposure to other things would be. And, we have not yet been confronted with that situation.

FITZSIMONS: Could we perhaps conclude that one by asking, in your Annex 1 in paragraph 3 you state that ERMA uses the information in the application to decide whether the risks fall into one of three categories; that they're negligible, that they're potentially tolerable, or that they're unable to be categorised because of lack of information. Given the unpredictable nature of the risks that we've discussed this morning, shouldn't all applications to use GMOs

outside a secure laboratory be in that third category? In other words, unable to be categorised because of lack of information?

WALKER: I think the straight answer to that question is, no. I think in fact there is a large body of information already available, which you can use to make judgments about how to categorise risks. I have to re-emphasise the point that to date all the decision-making has been in the context of field trials. And, therefore, there has been the ability to deal with uncertainties by setting very strict controls. That is a very important distinction between a release and a field trial.

I feel bound to say that when the Authority is confronted with its first release application, it may well do exactly as you suggested, decide that it really does need to be very careful, and if there is significant uncertainty, it's going to go in the direction of taking a careful view of that uncertainty in making a decision.

FITZSIMONS: Thank you, looking at field trials then. Are you aware of any research that suggests that genes can be transferred horizontally from DNA persisting in the environment, even though the organism from which that DNA came is no longer living? I guess that's one for Dr Hannah or Dr Sutherland?

SUTHERLAND: I think the answer is yes, I think that's well-known.

FITZSIMONS: For how long to your knowledge can DNA persist as a potential donor of genes after the organism it came from has died?

SUTHERLAND: That's exceedingly variable, the answer to that, from fractions of moments through to much more quantifiable periods of time. I have seen in the literature claims of it being into the thousands of years. I have yet to be convinced that the viability is still there at that time, but have I seen those claims of thousands of years, and I believe that's a point of contention amongst scientists at the moment, as to whether that's a valid claim or not; but it certainly is very variable.

FITZSIMONS: Could you put a figure on a minimum time that wouldn't be contentious?

HANNAH: Not off the top of my head, no.

FITZSIMONS: Do you accept it's possible for DNA persisting in the soil after removing from a trial crop field trial to be transferred to natural soil bacteria which could then migrate off-site?

HANNAH: Well, that's a proposition which we would want to test by doing exactly the same type of assessment of; you know, it's a component of anything else, we would want to look at the

characteristics of the organisms, the rate at which they might - soil organisms actually move through the soil. I mean, that's an interesting study in its own right. And, the general view of soil microorganisms is that they remain within the soil ecosystem to which they've adapted to. And, without - unless that's - soil microorganisms tend to be quite specific in those ecosystems, that's the general view of it. So, they don't tend to go on holiday.

FITZSIMONS: Does the ecosystem end at the fence around the field trial?

HANNAH: No, not at all; I'm not trying to say that, but they are relatively immobile within that ecosystem. They don't tend to have wings and legs and things and move around the way the higher organisms do.

FITZSIMONS: But dust from soil and dust storms could presumably spread them?

HANNAH: Yes, but dust is also a very interesting ecosystem; it's a highly perturbed ecosystem or compartment of the ecosystem compared to the natural ecosystem, and most soil organisms and dusts tend to desiccate very quickly. And so, only those that are adapted to survive in those very highly desiccated situations tend to survive, and again it's a risk that needs to be looked at from its probability and its consequence perspective.

FITZSIMONS: What controls has ERMA put on the field trials it has approved to prevent horizontal gene transfer from material remaining in the soil after the crop has been removed?

[Presenters pause to confer]

SUTHERLAND: We're sort of trying to remember the controls on 13 field trials over a period of years. But I think the answer is probably none, but that we've required researchers or applicants in a number of cases to dispose of organic material in various ways depending on the particular field trial.

FITZSIMONS: Have any - can you actually imagine any conditions that you could impose on a field trial to prevent this kind of horizontal gene transfer from DNA remaining in the soil after the crop's been removed?

SUTHERLAND: Well, I can. I mean, you could entirely fumigate the soil with something like chloropicrin, and kill off every soil microorganism within it, and you'd need to weigh up actually the environmental risks and benefits of actually doing that. That would be one way of doing it.

IR: Ms Fitzsimons, you've got a bit under five minutes left.

FITZSIMONS: Thank you. Have any of the field trials that ERMA has approved been designed to assess risks to the environment or to human health?

SUTHERLAND: I'd like to answer that. In a general sense the answer is, no. And I think, speaking on behalf of the Authority, we've often encouraged, though we can't require it for a field trial, encourage researchers to do some longer term environmental impacts, I guess, and in particular that was true of the Forest Research pinus radiata and spruce applications, because that did - they were field trials that were going to run for up to 20 years, and it struck us, and we said I think in our decision that it provided a perfect opportunity to do some of that sort of research you're talking about, and indeed we were encouraged by the applicant to believe that they were consulting with another Crown Research Institute to do that sort of research, probably funded by the foundation.

FITZSIMONS: Are there costs in doing this kind of scientific experiment?

SUTHERLAND: Oh, I imagine there are.

FITZSIMONS: What are the chances of a commercial enterprise undertaking non-commercial scientific investigations in order to assess risk to health and the environment, if the regulatory Authority doesn't require them to?

WALKER: Could I answer that? I think the answer to that is that, if they know that they need to do that in order to get an approval, then they're very likely to carry out that research, and certainly there is an increasing tendency on the part of the Authority to give those kinds of signals to applicants.

FITZSIMONS: Can a single field trial, which is what you approve, evaluate the behaviour of the GMO and its desired trait in a range of different environmental conditions, such as temperature, moisture, soil type, and nutrient regimes?

SUTHERLAND: Well, I would say, no, given the small scale of those and the very localised nature of them.

FITZSIMONS: Can those different environmental scenarios be tested and modelled in the laboratory?

SUTHERLAND: I don't know.

HANNAH: The answer is, yes, you can try and model them and you can

try and test for them. There's a whole aspect of development of mesocosms as what people use to try and do that, but once again we're dealing with environments which are artificially designed and they are removed from the real thing. So, it is a limitation and we would like to see if there are ways in which the uncertainties which result from those limitations can be overcome, because we are left with that residual uncertainty.

FITZSIMONS: To your knowledge is that kind of laboratory work usually done on the organism before application is made to ERMA to field test it outside a laboratory? Have they usually used mesocosms and models to test for different environmental conditions?

HANNAH: Some have and some haven't, and there's a variance.

FITZSIMONS: Isn't field testing for its commercial applications and behaviour rather premature when there's so much more that could be learned about a new organism in the laboratory before it were to move outside?

WALKER: Can I respond to that? I think you've raised quite an interesting series of important questions there, and certainly I don't think anyone on the Authority would disagree with the proposition that it's sensible to do as much work in the laboratory as you can, both because the environments are more controlled and because, generally speaking, it's cheaper; field trials aren't cheap. And, I think one of the conundrums for us is to always think about just how interventionist we should be in dealing with applicants. In the strict terms of the Act we only have the right to say "yes" or "no", and these are the controls. We're not actually, sort of, an intricate part of the whole research and development process.

FITZSIMONS: But you could say "no" if they hadn't done the prior work that you felt they should have done, couldn't you?

WALKER: Only if we thought that this could create risks that could not be adequately controlled. It may sound like a fine point, but it's not a fine point. If we started telling applicants how to do their business, we'd probably end up in court fairly quickly.

FITZSIMONS: Isn't it your job to tell applicants --

IR: Ms Fitzsimons, time has expired; thank you very much.

IR: Mr Clark, you're on behalf of?

CLARK: GE-Free New Zealand.

IR: And also on behalf of ECO, am I correct, or am I wrong about that?

.30am]

CLARK: Yes, sir.

First of all, I think Dr Sutherland, if I could refer the first question to you in response to an answer you gave to Ms Fitzsimons, and when she asked about the possibility of decontaminating a field trial site, if I recall, you made the comment that chloropicrin could be used; is that right?

SUTHERLAND: Well, I was probably going outside of my area of knowledge.

CLARK: Did you make the comment?

SUTHERLAND: I can say that would be one way of overcoming the risk of transfer of soil bacteria, which was to kill off the soil bacteria, and I think chloropicrin can do that.

CLARK: Do you know that when chloropicrin is used in a fumigated situation, it is used with methyl bromide as well?

SUTHERLAND: No, and as I said, I might be going outside my realm of scientific knowledge.

CLARK: Would you accept the hypothetical proposition that it would?

SUTHERLAND: I may change my comment and simply say that there are ways that I believe that soil bacteria can be killed, and that that would be one way of reducing any risk of transfer of DNA to them.

CLARK: But you're not aware of any others at the moment?

SUTHERLAND: Any other?

CLARK: Any other ways?

SUTHERLAND: There's probably a lot of ways, but it's not in my area of science expertise.

CLARK: To assist the point raised yesterday in the Commission, would you agree that mycorrhizal fungi are involved in nutrient cycling, including the element of the nitrogen?

SUTHERLAND: Yes.

CLARK: You would confirm that for the Commission, thank you.

But agree that myccorhizal fungi infect soil?

SUTHERLAND: I'm not sure whether "infect" is the right word. And again, I'm getting out of my area of science expertise. Myccorhizal fungi are associated with plants in the soil.

HANNAH: In the rhizosphere in the soil, so they are usually intimately attached to the organism's roots and related structures in --

CLARK: If I refer you, Dr Sutherland, to your decision of the 19th or 20th December last on the genetically engineered pines for the Forest Research Institute at Rotorua, you made much reference to the activity of myccorhizal fungi. Is that correct?

SUTHERLAND: Yes, we did.

CLARK: And also, you do not know whether they infect the soil?

SUTHERLAND: Oh, I was only hesitating only whether the word "infect" was the right word, but Dr Hannah has clarified it. I'm perfectly aware that myccorhizal fungi are in the soil environment.

CLARK: And infect?

SUTHERLAND: Associated with plants. Well, I just don't know whether they infect soil.

CLARK: Would you say that any graduate level soil microbiology textbook infers that they infect the soil? Would you disagree with me, or would the panel disagree with me?

SUTHERLAND: If you can show that they infect the soil, I would agree with you.

CLARK: On that hypothesis, would you agree that infections spread?

SUTHERLAND: Well, infections spread, yes.

CLARK: I refer you to the HSNO Act and the requirements for maintenance of the life supporting of the soil in the ecosystem; are you aware of that?

SUTHERLAND: Yes, I am.

CLARK: You would agree with me, doctor, that the soil is the basis of our food supply?

SUTHERLAND: Yes, it is.

CLARK: So, it's rather important?

SUTHERLAND: Yes.

CLARK: I cannot find any clear reference to soil in the risk analysis section of your submission.

IR: Your question is?

CLARK: Can you help me find reference to "soil" in the risk analysis section of your submission?

SUTHERLAND: Well, short of reading right through it right now -

CLARK: You're not aware?

SUTHERLAND: It may be there, I'm not sure. Donald? Well, I could ask those who know more about that aspect of it than I do.

HANNAH: I wonder if you could refer us to the sections you're talking about; I'm a little lost.

CLARK: I could ask that, you're not aware of it at the moment?

HANNAH: No.

CLARK: Carrying on to Dr Sutherland or Dr Walker, that in terms of field trials the Authority is having - a yes or no answer please - is having some difficulty complying with the current law on the definition of field trials?

WALKER: Well, I'll deal with that. The straight answer to that is, no, I don't think we are having difficulty, but you'll have to go a bit further if you want a more explanatory answer.

CLARK: Thank you, doctor. But would you agree that it was ERMA's position, if I quote from the field trial for the FRI pine, given current - I'll recommence, "If the mere possibility, however remote, of an organism not being retrieved at the end of the trial disqualified a proposal from being a field test, the field test category would be redundant". Can you accept that was your comment?

WALKER: Are you now quoting from the decision?

CLARK: Yes.

WALKER: Can you give us a reference?

CLARK: Yes, the reference is page 6, decision 9901, page 6.

IR: And the question is?

CLARK: Would they accept that that is their position?

WALKER: Yes, I think that that was a - it's an interesting comment, the --

CLARK: You accept that that's your position? Yes or no?

WALKER: I think the - I must admit, that comment was made by the Authority in the context of a particular line of discussion. I'd have to ask Dr Sutherland if he recalled the discussion that led to that particular comment?

SUTHERLAND: No, I don't.

CLARK: The heading was, I have the document here; the heading was related to the words "jurisdiction" in relation to the definition of "field trial". Perhaps, if I could ask the next question because we are short of time, doctor.

May I refer you to your protocol interpretations and explanations, this is the ERMA protocol, number 3, series 2, I believe it was 1998, number 4, and in there I quote, "for field testing of genetically modified organisms the Authority will need to be assured that the genetically modified material will, "will", be contained".

Would you accept that stance? Yes or no?

WALKER: Yes.

CLARK: Thank you. Also in that protocol in the same page, doctor, the comment is, "if this containment is not possible, the application should be for release". Would you agree with that stance?

WALKER: I think so, but in both cases I think we - I mean, in practical terms you have to qualify that with the acceptance that we're talking about very low probabilities of things occurring or not occurring. And again, to be blunt, it's one of the difficulties with the legislation, the legislation --

CLARK: You accept the stance?

WALKER: No, let me finish. Legislation does impose black and white boundaries that, in practice, in the real World don't exist, and that applies as much to laboratory work as it does to field trial work. Now, the comment you referred to before --

CLARK: Doctor, we're short of time, and I did ask for a yes or no answer. Could I ask you, yes or no, do you believe that those different stances indicate that ERMA has changed its view, and now considers containment of field trials impossible in terms of the original interpretation of the HSNO Act? Yes or no?

WALKER: No, I'm quite sure that's not the case.

CLARK: That doesn't change your interpretation of the Act?

WALKER: No.

CLARK: I'll refer you to the comment again, doctor, that if the mere possibility, and I go on, it would render the field test category - it would be redundant. So, what you're saying is that you cannot use the field test category under their definition. I put that to you; yes or no?

WALKER: Frankly, I wasn't aware that that particular phrase existed in the decision, and I would need to know - I have it in front of me, I know it's there, and I would really have to know why the decision-making committee made that particular comment before I could really respond properly to the question.

CLARK: If I could carry on. In terms of liability, doctor, ERMA's submission in relation to inter-liability in your submissions made no mention of liability to ERMA itself. Is that correct?

WALKER: That's true.

CLARK: Has ERMA considered its ability for approvals?

WALKER: Again, I'd have to - why don't I get a proper legal answer to that.

CLARK: Is that a yes or no?

SHARPE: In general terms, yes, because liability comes in terms of negligence, and ERMA New Zealand performing its functions adequately and correctly, so in that context, yes.

CLARK: So, you agree that ERMA owes a duty of care under common law, in its interpretations of the Act?

IR: Well, that's a question of law, Mr Clark, it's not for ERMA to express a view about that.

CLARK: Thank you, sir, I have no further questions.

IR: Yes, thank you Mr Clark.

.43am]

IR: You're cross-examining on behalf of the Pacific Institute of Resource Management?

WEIR: Yes. My name is Kay Weir, and I'm cross-examining on behalf of the Pacific Institute of Resource Management.

WEIR: It would seem that the research done to date on GM crops in New Zealand has been very partial in that - and that very little is known about the effects on our flora and fauna, yet there is existence of a wide range of studies worldwide presented to this Commission, and more probably, showing unintended impacts of GM on soil, butterflies, bees etc. This body of work would provide a fruitful starting point to do some serious studies on the impacts of GMOs on our flora and fauna, wouldn't you say?

WALKER: Well, let me answer that, because in essence I agree with you, yes. I think that we would like to see a great deal more research done on impacts specific to New Zealand's environment.

WEIR: Do you see any contradiction in ERMA's named mandate as the Authority assessing risks of GMOs and the lack of studies conducted on the ecological impacts of GMOs in field trials which ERMA has allowed to be conducted in New Zealand over some years?

WALKER: Well, you have nicely expounded the essential paradox here, which is, if we don't do the work, we'll never know what the effects are. And, I think it's - if we are serious, if we wish to have the opportunity of using the technology, and I don't say that we should or shouldn't, then we have to be prepared to do the research and investigation which will tell us something useful about effects.

Now, that's the conundrum of course, and I guess that's why scientific knowledge has been such an important driver in looking at the benefits of many of the proposals that have come to the Authority to date. Because, that knowledge is going to be essential if we ever are in a position of having to consider a release application.

WEIR: Could it be construed by the public as a huge waste of taxpayer's money and the opportunity, which ERMA has facilitated, agreeing to such field trials of GM crops etc, when no such ecological assessments have been made in the trials in progress over some years in New Zealand?

WALKER: That got a bit garbled. Just say that again slowly.

WEIR: Could it be construed by the public as a huge waste of taxpayer's money and the opportunity which ERMA has facilitated agreeing to such field trials of GM crops etc happening in New Zealand, when no such ecological assessments have been made?

WALKER: I rather think that informed members of the public might take exactly the opposite view, that they might see that it is sensible to carry out carefully designed and properly controlled research so that we do understand the effects that might be created.

WEIR: But there have been no real ecological assessments made, that's what I've been saying, during the construction of these trials, which have really been designed around commercial viability, haven't they?

WALKER: I think in most cases, no, not in all cases. I think that in some cases the - a lot of the GMO development work is genuinely curiosity driven, if you like; in other words, as it's being done by scientists who are genuinely interested in finding out more about the technology and its effects, without necessarily having a commercial motivation.

WEIR: But they're not really designed around ecological impacts, are they?

WALKER: As you say, it's pretty hard - with some exceptions it's hard to do ecological work in a laboratory, you really have to start to go out into the environment.

WEIR: Well, no, it could actually happen, you could construct them in laboratories and test them on bees and butterflies and birds potentially.

In your estimation, would you say that these field trials of GMOs in New Zealand, with their lack of studies on impacts on our flora and fauna, do they provide any basis for the assurance of the safety of the growing and commercial releases of GM crops in New Zealand?

WALKER: Well, I suppose that's a rather hypothetical question which we haven't had to consider. I think I would say, and Dr Sutherland might like to comment as well, that we have been concerned from time to time that some of the proposals put in front of us have not taken a broad enough view of the kind of information that would have to be generated in order to properly consider a release application. And that comment, I think, is being increasingly made back to applicants.

WEIR: Is ERMA capable of detecting ecological impacts of GMOs at an early stage?

WALKER: Is it possible?

WEIR: Capable of detecting impacts, ecological impacts, of GMOs at an early stage?

SUTHERLAND: Well, I think the answer is that - I mean, we don't attempt to detect ecological impacts of field trials.

WEIR: So, since there seems to be a vast lack of knowledge, is absence of knowledge the same as knowledge of absence? In other words, because ERMA doesn't know of environmental impacts of GM crops and animals in New Zealand, does this mean that nothing has been happening in the environment during these field trials of GE crops and animals? Quite a lot could have happened, could it not, since little economic impact studies have been done?

HANNAH: Could I make a comment on this, possibly, in response? I'm aware that there are a number of groups who have done some work, and would dearly like to do more if they were able to get the appropriate funding for it, to pursue the line which you are advocating, but there has been some work; as we have said, we have tried to encourage the organisations that are undertaking this work to build them into our programmes. We have tried to encourage the Foundation for Research Science and Technology to fund this type of work as well, but we ourselves are not funded and that is a plank of our submission to this Commission, that there is more work put into doing that.

WEIR: So, there is no basis for commercial releases at the moment. CRIs are business companies these days, aren't they, they can apply - yet they can apply to the Public Good Science Fund for money to do research into GM; but so far no CRI has applied to ERMA to do research in containment into the flora and fauna of Aotearoa.

If not, why do you suppose this is, that they haven't applied? It would seem that the Public Good Science Fund would be better served by contained research into the effects of GMOs on our flora and fauna much more than whether GM crops are commercially viable. The Public Good Science Fund would be served better by that sort of research, wouldn't it?

SUTHERLAND: We've often argued for applicants to approach the foundation to fund that sort of work, and I think the good news is at least, that last year the Foundation allocated a tender of \$200,000 or so for that sort of work to be done, and probably it's not enough, but I was quite encouraged that that work was going to be funded by the Foundation, and also, we were encouraged that it

could have been linked with the Forest Research pinus radiata and spruce field trials which seemed, to us, to provide an excellent opportunity to do that work, and I still hope that that will happen.

WEIR: Just one final question. An analogy has been sometimes used in the Commission hearings that genetic engineering is similar to the technological advances made from horse and cart to the car or railway. In ERMA's summation is the comparison of the construction of a mechanical device, such as a car or train, a true or grossly inaccurate comparison to the construction of genetically modified organisms in animals, given that while animals may - humans may wholly construct a mechanical device, such as a car or train, humans have never constructed genes or natural systems in which organisms interact, and genetic engineering is a technology to transgress natural organisms' species barriers, which is quite different from starting from scratch and constructing a mechanical non-living device, such as a car.

So, in ERMA's estimation, is the analogy of the construction of a mechanical non-living device, such as a car, a true or grossly inaccurate comparison to genetically modified organisms and their potential impacts?

WALKER: No.

WEIR: It's not grossly inaccurate? You mean, despite the fact that we know less than 5% of soil organisms --

WALKER: Hang on a minute, let me give you a better answer. I think that was a statement rather than a question, was it not?

WEIR: Wouldn't you say it's a grossly inaccurate comparison to say that the construction of a car is the same thing as the construction of a genetically modified organism? That's the question.

WALKER: Well, the truth is, it's not possible to give a yes or no answer to that kind of question.

WEIR: Well, I think it is.

WALKER: Well, I understand that that's your view --

WEIR: A car is not a living organism, is it?

IR: Let Dr Walker finish his answer, please

WEIR: Sorry.

WALKER: I'm sure that the people who make those kinds of statements are trying to say that this is a very significant

technological change, and it could have a big influence on us in our environment, and I think in that sense that's a correct statement. But, you know, it's difficult to make, other than that kind of very simple comparison, it's very difficult to draw analogies between different technological advances, which really are of a quite different character.

WEIR: Right. So, it is.

WALKER: So that's why I find it difficult to answer the question. However, I feel bound to say that, you know, in various ways human beings have been, if you like, interfering in the behaviour and the performance and the characteristics of natural organisms ever since we came out of the caves and started tilling the ground and growing crops. What you have here is a technology which does that in a much more dramatic and directed way than has ever been possible before, and of course that has implications which have to be very carefully considered in deciding where to develop and where to take the technology.

IR: Yes, your time as expired, Ms Weir, we'll take the morning adjournment now for 15 minutes.

Adjournment taken from 10.53pm to 11.00am

IR: Mr Currie for Greenpeace.

CURRIE: The theory was 30 minutes, but --

IR: 20. 20 minutes.

CURRIE: 30, I thought, somebody worked out. Well, I'm at your disposal, sir. I think I'm the last before the Commission.

IR: You are the last, and you have 20 minutes. Everyone else had 20 minutes, but they gave some of their minutes away to other people.

CURRIE: Dr Sutherland, firstly just to follow-up some questions from my friend Mr Clark; have you had an opportunity to look at that wording any more in 99001 on the jurisdiction?

SUTHERLAND: Which wording were you referring to?

CURRIE: He was drawing your attention to the paragraph beginning, "if the mere possibility, however remote, of an organism". You should have a binder of decisions. We've prepared a binder, just

for convenience, of some of the decisions, but I do know you have it in front of you.

SUTHERLAND: I have it in front of me. I have had a look at it.

CURRIE: The definition of field tests appears in italics further up that paragraph, doesn't it?

SUTHERLAND: Yes, that's right.

CURRIE: And that definition finishes, "but from which the organism, or inheritable material, arising from it could be retrieved or destroyed at the end of the trials".

SUTHERLAND: That's right.

CURRIE: The emphasis being on "or inheritable material".

SUTHERLAND: That's right.

CURRIE: And at the bottom of that paragraph the decision states that, "Provided there is a sound, reliable method of retrieving or destroying heritable material remaining at the site at the end of the trial, the committee does not think the application is brought outside the definition of a field test".

HOP RANDERSON: Mr Currie, before you go on, we've just got it.

CURRIE: If you see the blue stickers on the back of yours, or a different colour? The pineapple case is towards the back with a blue sticker, and it says GM - it should say GM 001.

HOP RANDERSON: I've got page 13 of 26. Is that 12 of 26?

CURRIE: That's right, sir, it's actually 99005 but the same wording appears in this decision. And we're on page 5 of 26, sir, definition of field test, page 5626.

HOP RANDERSON: The definition?

CURRIE: Definition of field test, that's right. Dr Sutherland, to continue my question, in response to your - to questions from, I believe it was Ms Fitzsimons, you gave an answer that the committee has not placed any controls on soil, as far as I understand. Is that correct? Controls on what is done with the soil at the end of the field trial?

SUTHERLAND: On what is done with the soil, yes, I think that's correct.

CURRIE: And in the pine tree, the stumps were - many remaining on the ground, is that right? The trees are cut off and the stumps remain on the ground; that's correct, isn't it?

SUTHERLAND: Yes, that's correct, can.

CURRIE: And also in the course of answers from Ms Fitzsimons you agreed, did you not, that there is the possibility of horizontal gene transfer from organisms to the soil, through bacteria and so on?

SUTHERLAND: Yes, I wanted to actually refer to that, because in looking - I didn't give a very adequate answer, I think, to Ms Fitzsimons, and in looking at the question of the possibility of horizontal gene transfer, what we did was to analyse how - or what would need to happen for horizontal gene transfer to lead to the transfer of a gene capable of producing an active gene product. And, we looked at a whole sequence of events that would have to happen for that ultimately to - that leakage, if you like, of the gene to occur. And, having gone through all the sequence of events that would have to happen in that, we simply reached the conclusion that the probability of that was very low indeed. That's on page 14 of the decision.

CURRIE: That's right, and you came to that decision against a background of scientific papers that you read, some of which are provided by objectors, some provided by applicants, some of it provided by yourself; correct?

SUTHERLAND: That's correct.

CURRIE: And those papers are coming up all the time, aren't they? In fact, in 99/2000 there was virtually an explosion of papers about horizontal gene transfer?

SUTHERLAND: Yes, that's right, and our staff right up to the last minute were getting them off the internet or whatever.

CURRIE: That's right, and the science does change all the time, doesn't it?

SUTHERLAND: That's right; I actually said that.

CURRIE: And so, it's certainly conceivable, isn't it, that your analysis of those series of events will be quite different in a year or two from now?

SUTHERLAND: I don't know that.

CURRIE: No, you don't. And, in answering the question from

Sir Thomas, you answered that you look at the application to determine there is low risk, I believe you say, but I forget the words you say, "low" or "no risks", but that was your answer; that you look at the application to determine there is no risk?

SUTHERLAND: Well, what we do is to look at all of the features of the application and what possible risk there might be to the environment, and we assess them and then we consider whether or not we feel that those risks are serious enough to decline, or not serious enough given the benefits to approve.

CURRIE: And you're doing that against a background of, number one, changing information and, number two, a certain inadequacy of information and scientific uncertainty, aren't you?

SUTHERLAND: Yes, that's true.

CURRIE: And, in doing so, you are mandated, are you not, to use the precautionary approach, or the Precautionary Principle, in assessing the scientific uncertainty, aren't you?

SUTHERLAND: Yes, we are, indeed we weigh that up with each decision.

CURRIE: When you do so, do you have regard to the Precautionary Principle as effectively Principle 15 of the Rio Declaration?

SUTHERLAND: No, we follow the wording of, I think, it's clause 7.

CURRIE: Section 7 of the HSNO Act?

SUTHERLAND: Section 7 of the HSNO Act.

CURRIE: And so, you do follow Section 7, and until the Act is amended, you will not then follow Principle 15 of the Rio Declaration, which is recited in the Biosafety Protocol? Is that a correct statement of your position?

SUTHERLAND: I don't know what might be in any future amendment of the Act.

WALKER: Can I respond to that? I think in principle the Authority's been more interested in the spirit of that part of the Act rather than the strict letter of the law, and I think it does take a cautious approach, which I don't think is inconsistent with that in the Rio Declaration.

CURRIE: Dr Walker, do you understand the difference between a cautious approach and the precautionary approach?

WALKER: I think I do.

CURRIE: If I may read to you Principle 15 of the Rio Declaration, "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

WALKER: Yes.

CURRIE: You would apply that, would you?

WALKER: I don't think that anything the Authority has done is inconsistent with the spirit expressed in the Declaration. Again, I'd need to remind you that we have been dealing exclusively to date with laboratory work and field trials.

CURRIE: And, do you accept that evidence given before this Commission over the last number of months has pointed to a number of threats of serious or irreversible damage which may arise as a result of field trials?

WALKER: I think a number of those kinds of threats have been postulated. I don't - I'd have to refer to my more knowledgeable colleagues, but I don't recall that anything has been raised that we weren't previously aware of, at least in a general sense.

CURRIE: You were aware of these threats, or what you call, these postulated threats?

WALKER: I believe that's correct, but again I'd have to refer to my colleagues to confirm that.

CURRIE: Are you aware there is lack of full scientific certainty, for example, with regards horizontal gene transfer?

WALKER: I think there is a great deal of debate about horizontal gene transfer, and in all of its decisions the Authority has had to take, I think, a reasonable view, and that takes account of the uncertainty involved about whether or not that might create a significant risk in the case of the particular applications being considered. And again, I have to stress --

CURRIE: Can I be very clear; do you accept or don't accept there is lack of full scientific certainty with respect to horizontal gene transfer?

WALKER: There is a lack?

CURRIE: Yes.

WALKER: No, I don't think.

CURRIE: You think there is full scientific certainty? It is a double negative, I know. Is there a lack of full scientific certainty? I'm using the words of the Declaration?

WALKER: I think the answer I give is that there is a lack of full scientific certainty about virtually everything.

CURRIE: And there is also a threat of serious or irreversible damage, is there not?

WALKER: I think that's probably something over which there is still debate.

CURRIE: And you attempt to deal with these threats by way of containment measures, do you not?

WALKER: Partially; I think there are two steps involved. One step is to consider the risk itself, and the second step is to consider whether that threat is significant enough to warrant the application of controls or containment measures.

CURRIE: When you consider the risk, do you use the definition of risk contained in your annotated methodology, which is set out in the Methodology Order of 1998?

WALKER: I'm sure we do, without actually checking it.

CURRIE: If I may read the definition of risk there, it means, "the combination of the magnitude of adverse effects and the probability of its occurrence". Does that sound right?

WALKER: That sounds pretty good to me.

CURRIE: And we've spoken about the two, the magnitude of the effect and the probability of its occurrence, and we have heard, for example, discussions - Professor Traavik for one example gave the example of BSE and the infinitesimal probability of something happening which had a very very serious consequence?

WALKER: Yes, indeed, and I'd comment back that that is something that the Authority's always conscious of, that there may be effects that are so significant in terms of their consequences, that even a low probability is one that may not be satisfactory.

CURRIE: I'd put it to you, in the absence of time, that ERMA here is really being asked to do an impossible job. We've heard a lot yesterday about ethics, and to paraphrase Dr Roberts, that ERMA

comes very close to be professionally and culturally unsafe, which is not intended in this context as a criticism, it is a reflection of the reality. I put it to you, in the context of risk, that ERMA is trying to do a job which is very close to impossible in assessing some of these risks against the background of scientific uncertainty?

WALKER: My response that to that is, no, because the Authority always has the option of saying "no".

CURRIE: And you haven't used that option yet, have you?

WALKER: No, we haven't, and that's been for good reason, because to date the Authority has been satisfied, in the case of applications it's looked at, that the risks were able to be contained or controlled down to a sufficiently low level to justify approving the application.

CURRIE: I'd like to look at the petunia trial, for example; you recall that application?

WALKER: I recall it in general terms.

CURRIE: All right. Well, I've put it in front of you, and I think it's the first tab. And the first tab I have noted is on page 2, additional information, on GM petunia. And there's a question, "What insects are likely to carry pollen between and away from the plants?" The answer is, "We do not have any specific knowledge of potential pollinators for petunia at the proposed trial site", and so on. And then further on, "What is the range of these insects?" Answer, "We do not have specific knowledge about the foraging behaviour of potential pollinators".

I would like now to move to your decision, and I have then highlighted page 3 of the decision, and that - sorry, page 2, under "Self-Sustaining Populations", "The Authority was satisfied that, provided the field test was operated in accordance with the management plan and controls imposed by the Authority, that the likelihood of escape of pollen and seed is very low".

SUTHERLAND: If the question relates to the possible escape of pollen, then we imposed a control that said that all flower buds should be removed prior to the buds opening, and we accepted that the researcher was competent to do that.

CURRIE: And, if the researcher fails to do so, and we have number of instances, don't we, of where failures in containment have happened, then you really don't know the results, do you? You don't know the percent of their range, you don't know what will happen?

WALKER: Well, I'll let my colleagues deal with the question, what might happen. But, you raise a good point in the sense that - and I think we've made this point before, that sound decisions are not useful in the absence of good implementation, and that's why so much emphasis is placed by ERMA New Zealand in ensuring that conditions are complied with.

CURRIE: I'd like you to --

WALKER: And I think in that sense we - I mean, we have a very rigorous enforcement regime, and I think the science institutions that are involved, and by and large these have been science institutions, are aware of the fact that they need to have very high standards of practice and reliability to ensure that controls can be met.

But, I'd have to refer to my colleagues to talk about the risks themselves.

CURRIE: Are you involved in a trial involved with peas?

WALKER: That's an IAG trial.

CURRIE: And, are you aware that the evidence, about the net around this trial, was not large enough to control the bumblebees; the bird net? Were you aware of the trial?

WALKER: I wasn't here to hear that. We've made the point several times, and I'll make it again, that the regime under which those approvals were given was the one that preceded HSNO. It was very preliminary, it was developed without a statutory backing, there were no provisions for legal enforcement. I just don't think it's terribly helpful to look at what happened during that pre HSNO regime.

CURRIE: Let's look at the salmon trial. You imposed controls, did you not, which presumed, in the case of a flood, the applicant will be able to remove each and every salmon before flooding releases of those salmon into the wild, didn't you?

WALKER: We did require there to be a contingency plan which covered the possibility of flooding, yes.

CURRIE: Are you aware of the possibility of flash foods?

WALKER: Colleagues?

HANNAH: We were.

CURRIE: Are you able to give a categorical assurance that in the

event of a flash flood the controls will prevent salmon being released into the environment?

WALKER: As we've said repeatedly, it's impossible to give a categorical assurance to anything. What you can do is look at the probabilities involved and try and ensure that measures are put in place which reduce the risk to as low a level as possible.

CURRIE: And you, for example, rely on metrological information as to the frequency and magnitude of floods in this case, for example?

WALKER: I recall that that was looked at, yes.

CURRIE: Are you aware, with climate change, the magnitude and frequency of storms are likely to increase in the next 100 years?

WALKER: I think this was a limited duration field - it wasn't - it was a limited duration piece of development work, and in fact the development work has now ceased.

CURRIE: And we have had extreme weather events in the last two years, haven't we?

WALKER: But there certainly haven't been any flash floods in that particular part of Marlborough.

CURRIE: We were lucky, weren't we?

WALKER: Not particularly, but I understand the point you're making.

CURRIE: And to turn, in the time I have, back to horizontal gene transfer, I'd like you to look again at the same page we were looking at, which was page 2 of the decision on petunia trials. And there you talked about the horizontal gene transfer in the bottom of that page. And you said that "The committee conclude", and over to the next page, "That for this application no new scientific information was submitted that would change its position on these issues. Nor did the facts surrounding the application present new risks on these issues". That's what you said, in fact, in 1999, didn't you, 18th of February 1999?

WALKER: Yes, that's right.

CURRIE: And, to turn to the pine trial, which I've included. Again we have 12 pages out of 26. You talked about horizontal gene transfer, and that's when you gave some more specific information, didn't you, and you said that horizontal gene transfer is known to occur naturally between some soil microorganisms but has not yet been extensively studied, and you cited a paper by Droge 1999. That

paper wasn't available to you when you made the decision, was it?

SUTHERLAND: No, it wasn't available to us when we made the petunia decision. That was the point I probably tried to make before, that if I looked back over the past three years since the first sugarbeet application, there have been a whole series of publications on this topic, each of which has given us better information on what does and doesn't occur, and what might or might not be relevant to the field trial applications.

CURRIE: That's right, and two years from now you may suddenly realise, whoops, we didn't put any controls on that, we should have, shouldn't we, at which time it's too late, we have an irreversible situation, don't we?

SUTHERLAND: I don't know what research discoveries are going to be made in the next two years.

CURRIE: No. With your sheep or cattle applications, did you have any controls on urine or faeces going into the ground?

CURRIE: No, we didn't, and I think in those cases we believed that the likelihood of viable genetic material, transgenic material, passing into the soil, and then further into the ecological environment, was minimal.

IR: Yes, your time's expired, Mr Currie, thank you very much.

.30am]

IR: Dr Walker, or Dr Sutherland, the current statutory membership of ERMA is eight, is it not, or a maximum of eight?

WALKER: Yes, it is.

IR: Is that a satisfactory number?

SUTHERLAND: Well, initially it was mooted to be six, and I didn't - that was put to me when I was approached by the Minister at the time, and I didn't myself feel that was enough, and perhaps others didn't as well. In any case, it became eight. I think the issue wouldn't be so much whether you needed more people, it's the knowledge of all the matters that we have to sort of cover. It's the depth of knowledge amongst those eight people.

If we want more people, as we have done often, we took on somebody, an expert in BSE, when we were worried about prions, then we can form a special committee and have a ninth person or even ten people

if we want to. So, I think the flexibility is there in the legislation, it's more the depth of expertise, and we've addressed that ourselves.

IR: Those additional members, where you have them, do they take part in the decision-making process?

SUTHERLAND: Yes. They're on the - we form the special committee, if we believe we need one, when we first have a look at the application, and if we think that we don't have the expertise, or if Nga Kaihautu thinks that we don't, then we just simply co-opt until we do, and those people are official members. We can also have experts who assist us who might not be on the actual committee.

IR: Now, turning to Nga Kaihautu. Is that - that doesn't have any basis in the statute itself, does it?

SUTHERLAND: No, it doesn't --

WALKER: I was going to say, it doesn't have any basis in the statute but it is specifically referenced in the Methodology Order in Council, which is a regulation. And, I feel bound to say that that was done at the instigation of the Authority itself. In other words, we wanted to give Nga Kaihautu some recognition.

SUTHERLAND: But Advisory Committees are mentioned in the First Schedule, and that's the basis on which Nga Kaihautu's been established.

IR: Do you see any difficulty about giving Nga Kaihautu, or a similar structure, statutory authority?

WALKER: Statutory authority to do what, if I may ask?

IR: Recognition in the statute?

WALKER: Again, I think we haven't discussed that specifically, so we all have personal views. I don't myself see any difficulty in that, just as we had no difficulty in referencing Nga Kaihautu in the methodology.

ALLAN: Can you answer, in the same way, how you find this new committee of kaumatua that you've called on board, how they fit into the structure?

WALKER: That's a different kettle of fish, so to speak. That group has been formed because, as has been said on several occasions, we think that some of the Maori issues that we have to consider would benefit from a general investigation. Because, the same issues come up in different contexts all the time.

SUTHERLAND: I think that Nga Kaihautu themselves, who strongly supported that, would say that that grouping of people provide even greater depth on tikanga matauranga than might be present in Nga Kaihautu's own membership, but I see them as having a very different role, and are much more guiding in the bigger issues, whereas Nga Kaihautu sits alongside us helping us with the specifics as well as some wider issues.

IR: You mentioned that the Chair of Nga Kaihautu sat as a ninth member on what you described as "governance matters", and I take it that that does not include applications, the decision on applications themselves?

SUTHERLAND: No, it doesn't, that's when we're sitting on the board of ERMA New Zealand. But I should say that, as it has happened, the Chair of Nga Kaihautu has twice been nominated to fill a special committee role with us, in a decision-making committee.

IR: Thank you. Reference was made to the enforcement powers, section 99, section 109 offences, and then part 9, the emergency powers. Overall, are those enforcement powers regarded as adequate?

WALKER: I think we have a particular concern over the ability to prosecute for offences and my colleague, Ms Sharpe, can perhaps speak to this, but the problem is that there is a requirement for things to be done knowingly, and that is terribly difficult to prove in this context. Do you want to add to that, Ms Sharpe?

IR: Just briefly, thanks.

SHARPE: That's a good summary, that most of the offences have quite a high knowledge component, whether it's pure knowledge, recklessness or negligence, and in a lot of the matters that we're dealing with, it's a very technical question whether or not something's a new organism, in particular if it's genetically modified or not, and to be able to prove that somebody knew that they were importing, say, a new organism or dealing with a new organism, is very difficult under those conditions.

IR: The emergency powers are very powerful, are they not? Some might say Draconian. There doesn't seem to be anything in between the prosecution powers and the emergency powers. Is that a gap?

WALKER: Well, there is the provision to use compliance orders.

IR: Is there?

WALKER: Yes, there is, and we regard those as probably the most usable and powerful part of the Act in a day-to-day enforcement

sense.

IR: That's a kind of injunction?

WALKER: Yeah.

IR: Our counsel was looking for that and couldn't find it, I think.

WALKER: Could I make the point, Mr Chairman, that that was one of our concerns about MAF not being an enforcement officer, an enforcement agency under the HSNO Act. It means that they cannot implement the compliance order provisions without us agreeing in particular cases to appoint enforcement officers or give them the power to appoint enforcement officers. We'd be much more comfortable if they could make their own decisions about when compliance orders should be imposed without having to reference back to us.

ALLAN: We also heard evidence about panic, the Rapid Response Group that Hawaii has put together. Have we got a similar Rapid Response Group?

WALKER: Well, that's a question you should probably put to MAF rather than to me. Certainly in the case of organisms more generally, yes, there is a good capacity inside agencies like MAF to respond to emergencies, and that's been demonstrated in the recent past on a number of occasions.

IR: Dr Walker, in your paper you referred to the proposition that Government should have - let me put that differently. That there are certain policy issues that you felt should more appropriately be dealt with at a Governmental level rather than as part of the decision-making process. You first referred to that at page 2 paragraph 11 of your paper, and you come back to it later on.

There is provision, isn't there, for Government to give policy directions in, section 17, is it?

WALKER: Yes, there is, but that --

IR: That's not what you were referring to?

WALKER: No, it's not. That specifically excludes anything that might impact on Part V decision-making. The independence of the Authority is very robustly protected in that part of the Act.

IR: Yes. You say in - with reference to that proposal, that in paragraph 8 of your submission - I'm sorry, of your witness brief, that what you suggest could be achieved by a very simple amendment, and could you just tease out for us a bit more what you have in

mind?

WALKER: Well, I think, so far as the Act itself is concerned, the provision is, I think, is relatively mechanical. It is a case of simply giving the Government of the day the power to make policy directions. My own view is that that should be hedged about with the requirements for consultation and publication that often apply in such cases so that the power can't be used lightly.

And, I think it needs to be constrained in the other direction by drawing a line between setting general policy directions and actually interfering in particularly Part V applications.

Now, in fact, the Government already has the ability to do that by exercising what are called the call-in provisions of the HSNO Act. So, it already has that power, but it's very clumsy to imagine that that power, which relates to individual applications, might be used to deal with more general policy issues.

IR: Can you give us an example, perhaps; I'm just having difficulty in seeing how this would work in practise?

WALKER: Well, I think a couple of examples have been raised in the course of these hearings, and I hasten to add, they're not examples that I would necessarily promote. But, it could well be that the Government was persuaded that certain types of applications, at least applications of genetic technology, at least for the time being, should be placed out of bounds as it were, and it would be possible to put a policy in place which made that clear.

IR: Yes, I think we can readily understand that. Can you give us an example relating to something that was in-bounds, in other words, where Government would make some declaration that something was to be regarded as acceptable?

WALKER: As acceptable?

IR: Yes, which I think is what you were saying?

WALKER: Well, again, I think an issue that's caused considerable difficulty has been that of dealing with spiritual concerns, Maori spiritual concerns, and others, and it seems to me again that there would be - it would be good to have the opportunity for a position to be taken on how those kinds of issues should be treated as a backdrop to Part V decision-making.

IR: How they should be handled, or how they should be treated?

WALKER: I guess it could be either, or both.

Perhaps I could add to that, that I guess the reality is that this kind of provision would probably be used most often in a negative sense, in saying that certain things are out of bounds, because that's the nature of the dilemmas that exist, I think. It's less easier to think about cases where Government might be inclined to say well, that's okay, you should not even bother to give much consideration to applications of that type. I mean, the politics of that, I would have thought, would be quite difficult quite apart from anything else.

IR: Dr Sutherland, could I ask you to look at paragraph 9 of your witness brief please.

WALKER: These are the presentation notes, Mr Chairman?

IR: Yes.

SUTHERLAND: I wasn't sure. Paragraph 9?

IR: Paragraph 9, Low Risk Development Versus Field Trials. You raise the question of delegation to IBSCs, and referred to a particular case where it seemed inappropriate for the critical step in that application to be dealt with hidden from public view, as you put it, and you point out that ERMA could have withdrawn the delegation. Are there instances where ERMA has withdrawn the delegation?

SUTHERLAND: Yes, there's one at the moment that an IBSC was called upon to look at low risk work on paua and lobster, crayfish, and that --

IR: Just, not to take up time; it has been exercised?

SUTHERLAND: That's the case, and we've done that with that.

IR: In the particular case that you mentioned at paragraph 9, any perception that the process was hidden could have been dispelled by reliance on the calling up of the withdrawal provision, couldn't it? What I'm really --

SUTHERLAND: I think, in the cases that I referred to, actually are not the ones I just mentioned.

IR: No, I realise that.

SUTHERLAND: And I don't think we realised, when we got the application, when the particular developmental work had been approved by the IBSC.

IR: I'm not asking you to justify what happened. What I really

want to ask you is, is there a deficiency in the legislation here, or is the fact that a power exists to deal with this problem which perhaps has not been freely exercised?

SUTHERLAND: Yeah, I don't know that it would be something for the legislation. I mean, I think we need to be better appraised of when these things are appearing before IBSCs.

WALKER: Could I comment further, Sir Thomas? I think this may be an issue for the legislation in the sense that the HSNO Act is framed in the context of biophysical risk, and one can see that that's what the legislation had in mind when they wrote the Act. And, therefore, it is perfectly logical that they should say that developments are not a concern, because these are small quantity experiments in a contained laboratory. Whereas, once you start to produce larger quantities of the organism, and it's in a field trial situation, you need to be more careful and, therefore, the public need to be involved and so on and so forth.

That is, to me, a perfectly logical sequence. But of course, as soon as you admit spiritual concerns, or those kinds of issues into the process, then the distinction between what's happening in a laboratory and what's happening in field trial disappears, and that's the dilemma. What should the legislation aim to do? And, I guess that comes back to the point I made before, that it seems to me that it's very difficult to deal with that inside the legislation. It would be better to deal with that outside the legislation, as a policy issue.

IR: Thank you. I just want to get through a couple more questions, unfortunately our counsel was unable to be here today, and I'm asking questions that normally he would have put to you.

Can I turn to paragraph 12, Dr Sutherland, of your presentation notes on the next page. You speak there of the level at which GMOs could be detected. We have heard other evidence that perhaps theoretically, I don't know, they could be detected at a much lower level than that. Are the figures that you're quoting, the percentages, are you under the impression that those are the best results that are available, or are those the results that are a function of the particular test that was used?

HANNAH: May I answer that?

IR: Of course.

HANNAH: It varies from different crop type and those sorts of things, because it depends on the density of the DNA in the material. And for the corn, that is about as reliable as one can get testing at which would be substantiated for a regulatory action

and that type of thing. Other types of plants and circumstances can go - be more sensitive, but the corn situation is one of the more problematic ones.

IR: Thank you. So, that's the cutting-edge of the current technology?

HANNAH: In that area, yeah, certainly not by the order of magnitude.

SUTHERLAND: You could get more assurance of safety, you could get 99.9 assurance of safety if you sampled and extracted more seeds; up to the point of getting 100%, if you sampled every seed. So, the figure of 99% is a figure that the Government agencies have decided on is acceptable. But if you've decided that 99% is acceptable to do that, you - there's a certain number of seeds.

IR: Take a larger sample; yes, thank you. My final question relates to consultation with Maori, and we had some discussion yesterday about pan iwi issues or national issues. How are they handled at the moment?

SUTHERLAND: Our focus at the moment, and in fact being guided by Nga Kaihautu on that, has been to get the views of, and every angle of the local hapu, the local iwi, because for field trials it's the people with mana whenua status over the land who are the ones who should have the say, I guess, as to how the Maori view - what the Maori view is on that.

But, I think we've always seen that there are bigger issues, the use of human genes goes far beyond Ruakura, and that was really the reason for the establishment of the panel of kaumatua to look at some of these much bigger issues that affect Maori wherever they are, not necessarily just the local hapu.

IR: On that topic, section 6 of the Act, subsection (d), sub-paragraph (d), as of course you're perfectly familiar with, requires the Authority to take into account, among other things, the relationship with Maori and their culture and traditions with their ancestral lands and so on. How comfortable are you with the expression "take into account"?

SUTHERLAND: I think, within the context of all of Clause 6, I think I'm comfortable with that.

IR: You appreciate that many Maori are not?

SUTHERLAND: Yes, I know, and would want it to be more sort of directive, yes, I know. I probably can't go further than that.

IR: No; thank you. Sorry, I've used up a lot of time.

.52am]

ALLAN: That was exactly the issue, because Te Runanga o Ngai Tahu said that that was a low level of priority taken into account compared with section 4 of the Conservation Act, which required the Government to consult with Maori, and to give weight - I've forgotten the exact words; Sir Thomas, can you remember? Section 4 of the Conservation Act, which was a far stronger injunction to the Department of Conservation than the injunction to ERMA.

IR: Give effect to the principles of the Treaty.

SUTHERLAND: Yes, but we've always looked carefully at, whatever we've thought of 6(d) we've always coupled it with 8, and our protocol of taking account of Maori perspectives, which we want to table today, does address how we might embody the principles of the Treaty in reaching our decisions. So, I suppose we always think of the two together, I don't know whether it would need to be written into Clause 6 - 16.

ALLAN: I apologise for not being a lawyer and being able to look up the provisions and finding my way through the statute, but we also heard evidence that the 32 applications, more than half of them had been approved through a wash-up clause rather than through the bits laid out in ERMA.

WALKER: These are the transferred approvals, you're talking about?

ALLAN: Yes.

WALKER: Yes, well, that was simply a part of the tidying up process for commencing the Act. It was necessary to do something with trials that had been approved under the previous regime, but which were still in place, or which still had to be monitored or controlled. And so, it was just a tidy up mechanism to get those into the HSNO system.

ALLAN: Okay, I understand. I have one other question. Do you have a virologist on the Authority, or in your staff?

SUTHERLAND: No, we don't.

ALLAN: Well, given that at least a quarter of my job is, really, to deal with the very frequent and natural recombination that happens in viruses, do you not see that as a lack?

SUTHERLAND: What we've done on two occasions at least has been to gain special assistance from experts in that field; we've twice done that with an expert from Australia, Tony Robinson at CSIRO, and that's perhaps one of the concerns, if I can come back to the point Sir Thomas made before, that with the recent changes in our membership, we don't have a molecular biologist amongst our group either.

Now, it's arguable whether we should or shouldn't. The Government decided that we wouldn't. So, we're going to do more often what you've suggested, or what I said in response to your question, which is to call in those experts from outside when we don't have them and bring them on to a special committee.

ALLAN: It just seems to me that the distinction between, basically, human health and the rest of science, is becoming increasingly blurred; and ERMA, which comes from the rest of science really, rather than from the human health part of the system, is lacking in particular this area.

SUTHERLAND: Yes, I guess we do have Professor Mantell on the Authority as a medical specialist.

ALLAN: So, if you need to deliver babies?

SUTHERLAND: No, but we don't expect him to be an expert on virology, and I guess that's the difficulty. One could have a panel of 12 people and include all of the science disciplines, but in the end I think it can be achieved in the way I suggested previously.

FLEMING: Yes, I have two quick points of clarification. I took it from the discussion yesterday, and again this morning, that by the time applications actually arrive in your hands, in ERMA's hands, by then the researchers know quite thoroughly where those gene constructs are targeted within the genome?

HANNAH: It varies on the type of application. For development applications, in fact, that's often the purpose of the application, to try and elucidate that much more clearly.

FLEMING: Thank you.

HANNAH: For field trial applications, some of them are much better than others are, there's sort of a continuum that we're working through there.

FLEMING: And the second, but quick, I hope. When you were referring in the discussion with Ms Fitzsimons to the more accurate targeting of gene constructs these days, were you referring to tissue specific expression? For example mammary gland expression?

HANNAH: I was really referring there to the actual genomic definition. The ability for the expression to be targeted is more in the nature of the actual construct than it is of where it actually sits within the genome.

FLEMING: Okay, so that leads on to my final question, which is, are you seeing more applications that use, if you like, the cutting-edge of technology? For example, chloroplast expression or a means of controlling temporally in development, or in time, the expression of a gene such as the cre-lox system?

HANNAH: No, we haven't had any applications that have that type of stuff before us. I'm struggling to think - I'm aware the IBSCs have dealt with, but there are certainly --

FLEMING: That's all right, Dr Hannah, I'm just trying to get a feel for how fast the technology is moving basically. Okay, thank you very much.

HOP RANDERSON: Yes, just two comparatively brief points, but first a comment on the Maori - consultation on Maori discussion. That while Clause 8 talks about taking into account the principles of the Treaty, Clause 5 seems much stronger when it talks about recognising and providing for the following principles, which include the enhancement of people, communities, social, cultural well-being. Would I be right in thinking that you are guided by both those clauses, and that that actually strengthens the consultation in providing for Maori aspirations?

SUTHERLAND: Yes, it does, and Clause 5 has often been referred to by people who've argued their case with us.

HOP RANDERSON: The other question was really, page 30 of the main submission, and paragraph 6. At that point it's dealing with international obligations and decision-making. That, the operating treaties, you know, such as from WTO and GATT, are that they lean fairly heavily on sort of economic, Free Trade issues, and in section 6 where you mentioned - where there's to be an objection on importing, for example, that it must be based on scientific grounds, and that those grounds are generally - well, the only acceptable procedures that are automatically acceptable are those developed by international bodies that are referred to there.

You mentioned that HSNO actually provides for much wider concerns such as we've been noting, and it's that question of, you know, how would we get on in the international marketplace, you know, if we want to wring in some of our local provisions under HSNO for cultural and well-being of indigenous peoples or other concerns that we might have. Are the mechanisms - are our mechanisms able to foot

it in the international marketplace against those major trade agreements that seem to be pretty powerful in the impact that they have?

WALKER: Well, I'll give you an answer to that, Helen Sharpe might like to comment as well. I think we're satisfied that the HSNO Act, as it exists at the moment, is pretty defensible against the requirements of the international agreements and treaties that you're referring to.

We do get some worrying around the edges from departments like MFAT about that kind of issue, "you're not going to do anything that can cause trouble from a WTO point of view, won't you", and our view has always been that we don't think that will be an issue under the HSNO framework because it is a good, sound, robust framework.

But certainly, if you extend the Act itself to take account of a wider range of things, particularly things which weren't capable of being dealt with from an "evidential" point of view - perhaps I can use that word rather than use "scientific", then some of these questions might start to raise their heads, and I guess that strengthens my view even further, that if we're going to get into that kind of stuff, let's do it at Governmental level, not try and build it into the legislation. But, Helen, you may have a view.

CLARK: From a technical legal point of view, I think there are some tensions and some difficulties around the edges with the operation of some of the international agreements which we're a party to, and the HSNO Act, but in the real world I don't see it as being a practical problem in most cases.

IR: Well, we've run out of time. Thank you very much for coming along and submitting yourselves to a rigorous cross-examination, it's certainly been a helpful session as far as the Commission is concerned. We will adjourn our hearing for today.

Hearing adjourned at 12.05pm
