ANNEX 2

PANEL ON AUSTRALIA - MEASURES AFFECTING IMPORTATION OF SALMON PANEL ESTABLISHED AT THE REQUEST OF CANADA

Transcript of the Joint Meeting with Experts, Held on 4 February 1998

Chairman

1. Let me first of all begin by welcoming the scientific experts and the parties to this meeting, let me start by informing you that this meeting is being recorded. Therefore, when you take the floor, please be sure to turn on your microphone by pressing the green button. A red light is visible on the microphone when it is on. Equally important, please turn off your microphone when you have finished speaking; this system only permits one microphone to be on at a time. I think there is one other thing in that context, if you could also speak reasonably slowly and clearly because there will have to be a transcript prepared afterwards and it will help to facilitate that process.

2. Now the purpose of this meeting is to permit the experts to expand on their written responses to the Panel's questions, highlighting the main points, and to permit a full exchange of views between the experts, the parties and the Panel.

3. Now I would like to take the opportunity to thank the experts for having agreed to serve as advisers to the Panel, and for having responded within such a short period of time to the Panel's questions. As you know, we do have to operate under time constraints and we must produce reports within certain periods. This puts considerable pressure, not only on use but on you as well and I am grateful to you for responding as you have.

4. For your information, that is to say for the information of the experts, following today's meeting and a second meeting tomorrow with the parties to the dispute, the Panel must then proceed to prepare its report. The first part of this report summarizes the facts of the case and the arguments of the parties and will be provided in draft form to the parties for their comments. An element of this first factual part of the report will be a compilation of your written responses to the Panel's questions, and this will be circulated to you and you will be given the opportunity to make any necessary corrections to this summary of your responses. Subsequently, the Panel must provide first a complete, interim report to the parties and then its Final Report, and we intend to include a transcript of today's meeting as an annex to the report, it will probably appear at the interim or even the final stage because I doubt that the transcript will be ready in time to go out with the factual part, in any case it will appear and will be a verbatim record of what has taken place today. So I thought you might like to be aware of that before we actually launch into the proceedings.

5. Now I must stress that the process of this Panel, the proceedings in the Panel meeting are confidential and everything which is said in this room is subject to the WTO rules of dispute settlement and the Panel's working procedures. When the Panel has concluded its work and a Final Report is circulated to all WTO Members, that report is normally considered to be a public document, including the summary of your responses to the Panel's questions and the transcript of this meeting, so we expect that the Final Report will be circulated in that form in, probably late May.

6. In terms of this meeting, the Panel intends to proceed as follows: I will first give the experts the floor, one-by-one, to make any general introductory remarks which they believe to be appropriate. There is no need to repeat at length what is already in your written responses, but I would invite you to highlight your main points in the areas where you see the most important issues and points of contention. Should you wish to comment on any points made by another expert, please feel free to do so. I would also draw your attention to a number of additional questions that were sent out by the Panel, they were additional to the first round of questions. Perhaps if you could take the opportunity of your opening statements to

address the ones that concern you - they are not all of them for all experts -but please address those which concern you. It would be helpful if you could do that in your initial statements.

7. When this is concluded we will then open the floor open to the parties and begin with Canada. Canada will be given the opportunity to put questions and comments on the experts' views and the experts will then be invited to respond. We would like to take the questions one-by-one in order to ensure an orderly process, but should Australia have any follow-up question directly linked to one that has just been raised by Canada, it would then have the opportunity to raise that question at the same time so that we do not subsequently crisscross backwards and forwards between the subjects - if we get into a subject let us deal with it and dispose of it. Similarly, after the responses from the experts to Canada, Australia will be given the opportunity to raise their questions and comments on experts views. If Canada has any directly related follow up questions, they would be permitted to insert those as well. Again, the experts will have the opportunity to respond to each question as they are raised. Now I would emphasize that it is really up to the experts how they respond to these questions, this is not an interrogation or court of law, they should feel relaxed about it and obviously offer their expertise as they see fit. I have to say that my experience with these sort of sessions in the past, has been that they have been conducted very satisfactorily from the point of view of the expert advice, there is no real, no element of interrogation in any way.

8. That said, the primary focus today, is the discussion with the experts and I would ask the parties to refrain from the sort of statements and re-battle arguments which they will have the opportunity to deliver tomorrow. Tomorrow, however, will be the final opportunity for submissions from the parties but today the priority is to give time to the experts and the scientific factual issues under discussion with them.

9. Subsequent to the interventions of the parties, the Panel may wish to raise some further questions or seek some further additional clarification, and finally, I will give the experts an opportunity to take the floor again individually for any final statements which you may wish to make, so that you may stress what views and conclusions you consider most important. I would ask all of you, both experts and parties to try and be as succinct and to the point as possible and to avoid, for example any lengthy repetition of what has already been submitted in writing. So, with these remarks, I would now turn to the experts themselves, they are identified by name-plates and I will name them as I give the floor to them. I would ask, when we get to the parties, if whoever is going to speak from the parties would identify themselves, would introduce themselves as they take the floor, not just only for the benefit of the experts and ourselves but also so that we can identify them for the purpose of the transcript.

10. That said, unless there are any questions on procedure, I would propose now to invite the experts to take the floor. I will offer it to them in alphabetical order for want of any other basis, so perhaps I could begin by welcoming Dr. Burmaster to this meeting and to invite him to take the floor.

11. If you which to make a presentation or make use of the slide machine there is a portable microphone, but if you do not then please you will find it is better there.

Dr. Burmaster

12. Good morning and thank you it is a great pleasure to be here this morning and I must say that this is my first such experience so please bear with me as I work along to assist the Panel as best I can. I guess I have one or two comments only that I would like to make now, to supplement my written statement from last November.

13. The first is that I said in November, and I continue to say now, that a risk assessment for this type of issue, I believe should be done in quantitative fashion; that it should involve a numerical calculations as best as is known and with stated uncertainties. At its heart, I believe a risk assessment should be conducted with numerical arguments and to persist on that, I would think that it would use probability distributions and those probability distributions could take a number of different forms - there is no unique correct way to do this style of analysis - but I do believe that however one put together the information that it would include probabilistic descriptions of the variability of what we do know about events and the nature of fish diseases and transmission of fish diseases and so on. It should also somehow state

numerically as best as possible the degree of certainty or the degree of uncertainty in human knowledge associated with those calculations. I have been asked from time to time what would be the minimal, the minimum requirements of such a risk assessment and coming as I do from the United States, I would say that we, in the United States, have adopted a sort of generally, a four step process for risk analysis. The first step would be hazard identification, the second would be dose response assessment, the third would be the exposure assessment and the forth and final step of the risk assessment would be risk characterization. Typically, in the States, the hazard identification step is done qualitatively; one identifies the nature of the problem and in this instance what diseases might occur and what species of fish may be susceptible to those diseases. That would be a discussion qualitative in nature. But then, and the remaining steps, dose response assessment, exposure assessment and risk characterization, those steps would all be quantitative steps done with numerical calculations to display the probabilities of occurrence, the probabilities of dose response, the probabilities of exposure and the probabilities of risk characterization. That would conclude the risk assessment steps and then to go on, there would be additional steps: risk communication and risk management steps such as you and other risk managers might undertake.

14. On the second question that came up, here we have, in this situation, multiple fish diseases, potentially multiple fish diseases and potentially multiple target species of fish. The question has arisen if there are ten diseases of fish - ten different diseases - and five different fish species, to make up a hypothetical argument, do we have to multiply those and do fifty, ten times five, different risk assessments? I think, as a practical matter one need not have to do fifty different risk assessments. I think that there are ways to sort through that, it may be that you would have to do one or two or smaller number of risk assessments not a full number of fifty. Let me stop there and thank you.

Chairman

15. Thank you very much Dr. Burmaster, let me now welcome Dr. Rodgers and invite him to give his opening comments and you have the floor Sir.

Dr. Rodgers

16. Thank you Mr. Chairman, I will be a little more expansive than Dr. Burmaster, because I think my particular background expertise involves fish diseases, fish disease transmission and prevalence so there are some relevant points to make in these sections. But before I make some comments, I would like to thank the Panel for the opportunity to address them and also I hope so far my answers have proved useful to them in their understanding of the background to the case. I personally found it a fascinating exercise which at times for me has been both difficult and frustrating. Not necessarily because of the nature of the problem but certainly the 20 kilos or so of paper which arrived on my doorstep to evaluate and assess, which is almost one kilo for each year of the dispute, which is not too bad going really.

17. My own answers to the questions posed for the experts have tried to clarify any contentious points, if you like, within which is a very complex scenario. I have also tried to be non-technical where at all possible using fact to support my own personal opinion, which again, I hope has helped the Panel so far. Consequently, I think my answers and possibly those of the other experts should be taken as a whole and not taken out of context and dissected down into phrases because as I say it is a very complex situation we find ourselves in but, having said that, I recognise that in certain cases it is almost inevitable that phrases are taken out of context. With hindsight, I particularly enjoyed answering questions such as eight and fourteen because at the end of the day both parties seem to agree that my answers were supportive of their own particular stances so that puts me in a better position today.

18. I will try to summarize the answers that I have already given by making some general comments related to selected relevant points, as I see them, perhaps some of the more important points, while at the same time responding to the supplementary questions which were sent to us some weeks ago. Although I will not necessarily name the supplementary questions by number. The original sections were divided -the original questions rather - were divided into three sections, those related to risk assessment procedures, fish diseases, transmission and prevalence, and also the OIE procedures. I will deal with them in traditional reverse order because I did not attempt to answer the OIE section at all, because I did not really have

enough working knowledge of the OIE to comment. I also do not propose to dwell too much on the section concerning fish diseases because the responses from the parties were largely in agreement with some, what I would call minor, exceptions, although they themselves may not agree that the exceptions were minor.

19. Essentially though, what I would say about the disease section is that the most accurate up to date information concerning disease prevalence in an exporting country is usually held by the exporting country itself, providing that country is of course recognised as a competent authority. In this case of course, Canada has a well respected monitoring system in place for this type of situation. The degree of scientific confidence in disease detection with existing methods relies really on the lowest limits of detection of each particular test, or series of identification methods. However, this can lead to difficulties in isolating certain fish viral pathogens and also certain bacterial strains. In addition there is a cut off sensitivity point for most diagnostic methods which leads to the carrier state in particular being difficult to detect, except with the most sensitive methods that are available. Nevertheless, any deficiencies in sensitivity for existing methods are generally accepted by the scientific community both in terms of the supportive science and also by the legislative policies that actually stipulate their use in regular surveillance programmes. It is also true to say that regularly tested stocks are normally considered as a lesser risk than occasionally or untested stocks, since regular monitoring will provide a background database if you like, of information over time. However, post harvesting testing for disease in fish, tested for human consumption is very rarely undertaken at all.

20. As far as actual disease transmission is concerned, this of course combines many biological, behavioural and environmental factors which are interrelated - we cannot get away from that fact. As such, the epidemiological factors relevant to disease transmission would not necessarily be the same for each disease since they are complex and numerous, although the general aspects would be common. Perhaps the most relevant factor to my mind, in this particular case is the introduction of potential pathogens into an already stable environment. Since the natural balance of an indigenous fish population could be altered perhaps irreversibly, this is one factor which perhaps is overriding in this particular case of transmission. However, having said that, there is a generally accepted lack of information about the occurrence of fish diseases in wild fish and the potential interactions between wild fish and the mechanisms of disease introduction themselves.

21. The question of evisceration is also relevant here obviously. I think that we are all in agreement generally that it is an effective means of reducing the level of risk although the level of reduction would largely depend on tissue location of the disease-causing agent and the effectiveness of the evisceration process. Nevertheless, we do not know of any specific cases where fish diseases have been transmitted from one area to another by imported eviscerated salmonids, or in fact any other species of eviscerated fish.

22. Also the post-harvest organoleptic examination for grading purposes should remove unsightly looking fish such as those which may have ulcers or extensive haemorrhaging or some sort of superficial damage. These conditions could occur as a result of disease, although again, carrier subclinically infected fish could still remain after such an examination.

23. Now, I do not propose to comment any further on the consequences of disease entry because I think in general again we are in agreement as to which main step-wise criteria need to be fulfilled for this to happen. However, we should bear in mind that early detection of disease entry and subsequent eradication following any disease establishment would be very difficult in any country. The only supplementary question which does not fall easily within the three main sections that the original questions were divided into was directed specifically at myself, which basically asks what is "steelhead trout" or "rainbow trout", so if I may I will deal with it at this point before I move on to the risk assessment section. Essentially steelhead trout and rainbow trout are salmonids *not* salmon and they are the same species, that is they are *Oncorhynchus mykiss*). There are some salmon within the same genus of *Oncorhynchus* but they are true salmon such as coho salmon and sockeye salmon. The main difference between steelheads and rainbows is their ability to migrate. The steelhead trout is the *anadromous*, migrating fish compared to the rainbow trout which is the non-*anadromous*, non-migrating equivalent. These fish were originally

placed in the genus *Salmo* as the Atlantic salmon still are, but rising taxonomic evidence, if you like, in 1989 led to the change being made because these fish were considered more closely related to the *Oncorhynchus* genus than the *Salmo* genus which contains more Atlantic European species, and at that time all specific drainage trout were placed into the genus *Oncorhynchus*.

24. That brings me to the final section, which is perhaps for us as experts the most contentious section on risk assessment procedures, and in particular, the comparison between the two reports as presented to us. For me the 1996 Final Report is generally less specific than the 1995 Draft Report. It is also more confusing in layout but includes the product of a communication exercise which the Draft Report does not. In fact, we are led to believe it was never within the original remit of the Draft Report to contain a risk communication exercise. Neither report can be classified as a quantitative risk assessment exercise, but the Draft Report, for me, is a clear qualitative assessment of importation risks. Although both reports largely rely on interpretation of the same risk assessment data, the Final Report reaches a different risk analysis conclusion which is a result, for me, of public consultation. In general, the 1995 Draft Report is acceptable for me and meets the minimum requirements as a qualitative risk assessment.

25. As far as the 1996 Final Report is concerned, of course it is based on the earlier Draft Report, that was the intention, and also includes the results of a risk communication exercise which should make it equally acceptable. I think we have the luxury, if you like, of being able to compare the two reports and when you do, there does, for me, appear to be something lacking in the Final Report which is surprising because, following the 1995 Report it should have all the basic elements in place. This missing element seems specifically related to its clarity and its detail and the underlying methodology which almost appears to be a straight forward literature review without conclusion.

26. To be honest, I got completely lost in the Final Report looking for sections which were possibly out of place and this, in my opinion, makes it less transparent then the original Draft Report. It assesses risks on a disease-by-disease basis but in a textural form and does not assign any probabilities that would be needed to reach a conclusion. In this respect, therefore, I think, it possibly does fall short of determining any probability based on the information available. This concept of probability is embodied in OIE guidelines which indicate that the risk factors should be used to estimate the probability of an adverse event occurring with point estimates of probability distributions, employed to represent the values either quantitatively or qualitatively.

27. Therefore, taken alone without reference to the Draft Report, it is probably not acceptable overall as a risk assessment exercise, although it does include more components. There seems to have been a change in style, content and approach in the Final Report following the risk communication step. I personally think this has devalued the report as a whole, which is after all supposed to be the published face of the whole analysis process.

28. If you are concerned with several diseases, effectively the risks are identified by drawing up a list of the potential diseases of concern that would be associated with the importation of a particular fish product, followed by an examination of the consequences of their entry and establishment. Now, although many risk factors are common between different diseases, each disease may have unique factors to consider and each of these will have a variable quality and quantitative of available data that will need to be dealt with separately, which does make it necessary to assess risks on a disease-by-disease basis. But following on from what David Burmaster said, of course you might be able to analyze a higher risk disease in order to arrive at an answer, rather then having actually to look at every individual disease in turn.

29. So where does all that leave us? I got a little confused, and its probably relevant at this point to make an overall summary, purely from a scientific point of view, as I see it. This means effectively that we can now bring in the 1997 risk assessment which was submitted by Canada, that uses a quantitative method to consider the data already available in 1995 for the two most serious diseases of concern, namely those caused by *Aeromonas salmonicida* and *Renibacterium salmoninarum*. To illustrate the point, we fortunately do not have to look, in my mind, into greater depth at the report because we could be here until tomorrow, but rather look at the overall conclusions of the various reports following the various risk assessment components. Here I will read, I am sorry, I will have to quote from the various reports.

30. In the 1995 Draft Report AQIS concludes that "wild, ocean-caught Pacific salmon from Canada and the USA that have been eviscerated and had their heads removed, when consumed in the domestic or restaurant setting, are considered to present a negligible risk of disease introduction and establishment". It also states that "it is considered extremely unlikely that the importation of headless, eviscerated, wild, ocean-caught Pacific salmon would introduce infection into Australian fish populations" (and here it is referring to *Aeromonas salmonicida* in particular), and that "the risk of disease introduction is acceptably low, having regard to the potential serious consequences of such an event".

31. In the 1996 Final Report there is a reference which says "there are risks of exotic disease agents occurring in salmon products; however, the risk of establishment of an exotic disease is low if suitable risk management interventions are made".

32. In the 1997 Canadian Risk Assessment (the so-called Vose Assessment), there is a statement which says "the risk of native salmonid infection with *Aeromonas salmonicida* or *Renibacterium salmoninarum* from Canadian salmon is exceedingly small" and that "the information available to Australia at the time of writing their reports was sufficient to enable them to conclude that the furunculosis and BKD risk posed by Canadian salmon must be considered negligibly small" there is also a final statement which says "head-on and heads-off, chilled and frozen eviscerated Canadian ocean-caught Pacific salmon all present negligible risk of disease introduction".

33. Now for me, I take it to mean that all these reports actually reach a similar scientific conclusion, unless negligible in one report refers to a different level of risk in another report, which is quite possible, I do not know whether Marion Wooldridge or David Burmaster can comment at a later stage on the difference between phrases such as "negligible", "extremely unlikely", "acceptably low", "low", "exceedingly small" and "negligibly small". The interesting thing is that both the original qualitative 1995 AQIS Draft Report and the quantitative 1997 Vose Assessment use the same concluding phrase, "negligible risk". What neither of them have is risk communication.

34. The problem for me seems to be the change in emphasis and conclusion in the 1996 Final Report, which seems to consider the scientific advice but then reaches a political decision, following public consultation, as I have said. Now the OIE revised guidelines state that the importing countries shall decide whether the risk determined in the import analysis is acceptable or not, but that the importing country must be prepared to justify their decision. The question of scientific advice versus final political decision, for me, is a very difficult one to address, since the existence of risk, irrespective of the level, may be ultimately unacceptable.

35. The SPS agreement includes the requirement to undertake a risk assessment in these circumstances by stating "the measure be based on a risk assessment, as appropriate to those circumstances, and that the risk assessment takes into account the techniques developed by the relevant international organizations", which for aquatic animal health, is the OIE. In their relevant recommendations at no time is there a requirement to undertake a quantitative exercise. The OIE state that "a risk analysis must be able to deal with the complexities of real life situations and that no single method is applicable in all cases. For this reason, countries wanting to conduct import risk analysis may find it necessary to design their own methodology or their own process for carrying out such an exercise".

36. In summary, from a purely scientific point of view, I agree personally with the AQIS recommendation in the 1995 Draft Report based on a qualitative exercise. I also agree with the disease summaries of the BRS Review and the most recently commissioned quantitative exercise from Canada, which taken together accept that there is a risk and that risk is "low", "exceedingly small" or "negligible" which ever phrase you want to use. There appears to be no argument that a risk exists, none at all. But the key fact for me, is *not* whether the risk assessment exercises should be qualitative or quantitative, or even whether one report is better than another, because at the end of the day, using similar phrases they all reach a similar conclusion. For me, the key fact is what you do with that information that identifies a certain level of risk, the next step if you like, which in this case, identifies a negligible level of risk. The final decision, after a risk communication exercise which considers additional factors, is going to be a political decision, not a scientific decision. That decision can agree or not with the scientific advice, which

identifies as I have said a certain level of risk. Whether that risk is then acceptable, following socio-economic and internal political considerations (to which, fortunately, in this case I am not a party), is not really for me today to say. What I would say though is that additional fears about the acceptability of such a low level of risk should be allayed by considering a series of risk reduction factors. But those risk reduction factors should be accepted by both parties. In this way, the application of such a series of measures may demonstrate that the extent to which risk is reduced is sufficiently great that an accurate assessment of the initial unrestricted risk is unnecessary and here again I quote from the OIE manual. For me, risk assessment is a piece of the process that helps decision makers arrive at a final conclusion, is not an answer in itself.

37. That is all I would like to say except to finally conclude by congratulating both parties on their presentations because analysing and finding the necessary scientific information for this exercise is not easy. I know from experience how difficult it can be, and I would make a plea if you like for them, as the New Zealanders have done to a certain extent, to make that information available following the Panel decision, irrespective of what that decision is, for everybody, because it is extremely valuable information that should be used, possibly through the auspices of the OIE in some way, for anybody else coming after to help support subsequent risk assessment exercises. Thank you Mr. Chairman.

Chairman

38. Well thank you very much Dr. Rodgers, perhaps I could continue now with the order and turn the floor over to Dr. Winton. You have the floor.

Dr. Winton

39. Well I would like to begin by thanking the Panel for the invitation to attend, I have found this a very interesting exercise. I would also like to state that both parties in this dispute, I regard as friends and I have scientific colleagues in both countries and the amount of effort and time that has been expended is substantial and I second Dr. Rodgers comments that a lot of very good information has been generated in this exercise. I tried to restrict my comments to that of the OIE Fish Diseases Commission for two reasons: partly because I consider this to be a dispute among friends and not to take sides, but secondly because Dr. Blancou the Director-General of the OIE, feels that the OIE should be impartial in these matters and so I have tried to restrict my comments pretty much to areas in which I believe the Fish Diseases Commission has some role.

40. First of all, the Fish Diseases Commission of the OIE and the OIE itself is not necessarily the repository of all information or all judgement on these things. We do not, in fact, sit in judgement, we gather information to the best of our ability through a network of colleagues, reference laboratories and friends, but much of the information generated by both parties and by Dr. Rodgers has been useful to us and we are in the process of learning about this ourselves. We found several of these exercises to really be quite in advance on what we estimated risk assessments might be in the areas of fish diseases, because the Fish Diseases Commission has adopted very much the risk assessment approaches drafted by the OIE itself for large animals and Dr. Wooldridge can comment more about that. But it is an evolving area, it is an area where new scientific information is required in order to develop quantitative assessments, if you do not know survival curves of pathogens, it is difficult to estimate some of the factors that have to go into a quantitative risk assessment, and certainly the OIE recognizes that.

41. The Fish Diseases Commission has, as I said, adopted the approach of the OIE and that is that a risk assessment should be the method by which disputes can be resolved between parties, particularly in the case here of the fish disease. We generally had imagined that such risk assessments would be quantitative to maximum extent possible, and I think, as Dr. Rodgers and Dr. Burmaster have indicated, this is possible. I think the New Zealand and to some extent the Australian and certainly the more recent Canadian reports have gone a long ways towards showing what can be done in the areas of risk assessment.

42. The Fish Diseases Commission has not tried to address every possible disease risk between any possible trading partners because virtually every case has unique elements. Those unique elements have to do with the species in the exporting and the importing countries, the volume of trade, the type of product that might be in trade, etc. But what the Fish Diseases Commission has tried to do is to establish a group of diseases for which there is general agreement that these are significant diseases in worldwide trade. The Fish Diseases Commission has also imagined that the most significant areas of risk involve live fish, live gametes and secondly, uneviscerated products.

43. The OIE Fish Diseases Commission has not considered eviscerated fish to represent a significant risk. But I agree with Dr. Rodgers that probably there is no trade that has zero risk. I think as Dr. Burmaster and Dr. Wooldridge have pointed out, you have a balance between benefits and risks, the only no risk option is no trade. So if there is going to be trade, you can always construct some scenario by which some agent might pass. In an effort to balance this, the Fish Diseases Commission has created a list of Notifiable Diseases which we believe there is general agreement on and a method, or set of standard protocols by which certifications can be obtained for international trade to proceed, primarily in the case of aquaculture products. Outside of that sphere, is a huge grey area which includes the dispute here in question, wild fish or eviscerated fish. For that the OIE Fish Diseases Commission has really not much to say other than, in our view, as a series of experts and based on our evaluation of the scientific literature, we do not find scientific evidence that such eviscerated products have constituted a risk in the past. Should such scientific data be forthcoming, we would perhaps modify the types of products or the types of diseases and it is a very dynamic process, and we probably will never get it completely right.

44. In response to some of the questions then about the Fish Diseases Commission and detailed minutes, etc., and how this body works there are five elected members of the Fish Diseases Commission. We are often joined by one of two experts, Dr. Beers for example attended, I think two years ago one of the sessions and we appreciated his input at that time. We try to invite experts periodically to provide input in areas in which we think we are weak. We are admittedly weak in areas of risk assessment and we rely on the OIE and other authorities such as we have here with us to provide guidance in that area. We are also somewhat weak in areas of crustacean and shellfish diseases and we will invite experts to assist us in some of these areas. But we do have a large network of reference laboratories and colleagues to provide that information. We do not keep detailed minutes of our debates and consultations, they are essentially a consensus agreement, if the five members do not agree, we simply do not do anything for a while until we do agree or we get new information. The minutes that we do provide are somewhat summary in nature and are presented to the general session at which each member country has a voting delegate. So we serve really as a technical body to the OIE itself.

45. I think that ... understand that the OIE Fish Diseases Commission as a subgroup of the OIE is developing essentially as we go and I think this dispute actually has been very informative to us. The OIE code and manual for terrestrial animals and animal diseases has been around for quite a while. Over twenty years ago this approach was imagined to be extended to aquatic animals for which trade was increasing and the Fish Diseases Commission was created. Until the GATT Treaty, the Uruguay Round of GATT, the OIE was not given as much authority in these issues. But following the Uruguay Round of GATT OIE was seen to some extent as a reference body and the Fish Diseases Commission was increased to five members to increase its geographic distribution and to some extent its expertise. We do not represent geographic areas per se and certainly not countries, but we assemble information on the epidemiological situation in various parts of the world and for that some geographic input is important. Certainly we could use experts from other areas of the world including Australia or New Zealand. Presumably our network of reference laboratories, of which we have two in Australia, are important sources of information.

46. I think that I can comment on one or two of the additional questions that the Panel has raised. Dr. Rodgers has expertly answered the question on salmon and steelhead. This is an areas that is of a little bit of debate, the geneticist will tell you that all members of the genus *Oncorhynchus* are probably closely related, but by convention Pacific salmon are really those traditional species of Pacific salmon that migrate to the ocean and that the rainbow trout, the *anadromous* form, the steelhead, is seen as a trout, to some extent, so it is in fact a salmonid but perhaps not a Pacific salmon in most people's general agreement.

47. To the other questions, most of which involve risk assessment, I would certainly defer to Dr. Wooldridge or Dr. Burmaster. The 1996 Final Report of Australia, in many ways took into account some of the risk assessment techniques developed by the OIE in that this is an evolving process. We imagined that a risk assessment might be necessary, but in fact the OIE right now is moving along and refining and adapting its techniques, and in fact I think has gone quite a ways farther then some of us who are not familiar with risk assessment methods might have imagined. To that extent, the 1996 Final Report, as Dr. Rodgers I think mentioned, falls short of a quantitative assessment, one that Dr. Burmaster perhaps had argued for. Yet I certainly acknowledge the fact that there are large gaps in the scientific information by which a quantitative risk assessment can be fully done. But I think that the New Zealand Report and perhaps some others have made a good effort given the existing scientific information of trying to quantify those risks, and whether the probability is one in a hundred thousand tones or one in fifty thousand tones, I am sure there is some margin of error. But the idea at least that you can begin to assess probability estimates, I think is important and I think that all of us will be looking towards that approach in the future. At that point I think that will conclude my comments.

Chairman

48. Thank you very much Dr. Winton. Perhaps I could now invite Dr. Wooldridge to take the floor.

Dr. Wooldridge

49. Good morning, thank you very much for inviting me here. I would like to just first of all say I think I have got friends in both parties here, so I reiterate some of Jim Winton's comments. What I have tried to do is look at this with an unbiased approach and actually look at the methodology that has been used. So first of all I am going to go through a few comments, a brief summary of what I think about this, and then I am going to specifically focus on the questions, the additional questions after that.

50. First of all I must apologise for having labelled my written answer to question 17 as an answer to question 16. However, it appears that this was realized by all parties and therefore caused no major problems.

51. I then spoke about the terminology in my original written report and I think that what David Burmaster has said does show that there are different terminologies in use. But I will just reiterate the terminology which I am coming from again, which is that a risk analysis comprises hazard identification, risk assessment, risk management and risk communication. A risk assessment may, in my opinion, be a either qualitative or quantitative, but either way the essential components are: identified and defined hazards and identified and defined unwanted outcomes, a clearly set out and biologically feasible pathway or sequence of events from the hazard of interest to the unwanted outcome for which the risk is being assessed, and information to assess the *probability* of the steps in the pathway occurring, from which can then be assessed the overall probability of the outcome occurring. In addition, all information must be referenced, and the whole assessment transparent.

52. In my opinion, it is not simply enough to demonstrate the *possibility* of an outcome occurring, as I said in my written report and as Jim also reiterated, I think you can always find a feasible way in this question, at any rate, of the possibility occurring and that I do not believe is enough.

53. Just a few words here on the OIE guidelines, which I did in fact refer to, I did mention in one of my answers, which I think was to question 29. They are currently undergoing a rewrite as many of you will probably know, and because I was actually involved in that rewriting, it was a little bit difficult for me to separate out what the original guideline said and what I knew was going to come up very soon. There are in fact, many areas which are similar and one is that quantitative assessments are not required in either the original or the new guidelines and that once you have assessed the risk then the acceptability of that risk does depend upon local factors which then need to be highlighted and brought out when trying to decide what the appropriate risk management strategies are. Basically, the draft guidelines for risk analysis and risk assessment coming out from the OIE hope to reflect the best methodology currently available, which means that it will always be to a certain extent out of date unless it is rewritten all the time

and my own personal feeling is that we do not and should not use outdated technology and methodologies simply because they are in older guidelines if we can actually demonstrate an improvement on those methodologies and that would be in fact, an argument for changing the guidelines, which is what is happening.

54. Anyway, to go back to the question in hand here, in my opinion, the Draft 1995 Report fulfils these requirements of qualitative risk assessment. It contains a clearly set out and transparent qualitative risk assessment. The Final Report is the result of the process of risk communication. In my opinion, the process of risk communication has two major functions relevant here: (i) to uncover errors in the factual information used, and (ii) to gather opinions on the level of acceptable risk amongst all those concerned. Factual changes may affect the assessed or scientific risk, that is the probability of something actually happening. Opinions will not - or at least they should not, in a well executed risk analysis -affect the assessed risk, they should be used only in management decisions as to whether assessed risk is accepted or not, and that is a value judgement depending upon local requirements and conditions. The two issues should be clearly separated, so that the accepted risk can be agreed - or challenged, if necessary - and the issues relevant to the locally acceptable risk level can be understood, and modified be negotiation, if necessary.

55. In my opinion, the Final Report, also qualitative in nature, is far less clear or transparent than the Draft. Like Dr. Rodgers, I had difficulty in differentiating between the various parts in it, in particular between assessed and acceptable risk, and the effect risk communication had on these two different things. In particular, the Final Report does not make clear where any factual errors in the Draft may have occurred which may have altered the assessed risks. And since it came to the opposite conclusion to that in the Draft, this clarity for any factual changes is essential. It is very difficult to see from this whether different conclusions to an adequate assessment would be valid. However, since it looks only at the possibility of the unwanted outcomes of infection and disease importation, rather than the probability, in my opinion, it does not in any event fulfil the essential requirements of a risk assessment. As I said in my written report, I am not a fish pathologist or a fish expert in any way and so I am unable to assess whether the data given to assess the risks is accurate and complete. As I stated, this will affect the final outcome and the final conclusions from either assessment and this is where Dr. Rodgers and Dr. Winton actually have a far greater input.

56. I initially stated that a risk assessment may be qualitative or quantitative and that a quantitative assessment is often initially undertaken. Now, and I also said that frequently you can not do a quantitative assessment based on two reasons. Partly the fact that often you would not have the data to actually complete it satisfactorily, but I also put the corollary on that, that when you start doing one you often find that there is a lot more data around then you initially thought. Secondly, very often because time constraints and requirements for action dictate that in the given circumstances a qualitative assessment, which is generally much quicker, is the thing that is required or the only thing that can be done. There is a third reason too, and that is that if you actually do a qualitative assessment more rapidly, and everybody agrees with the result, there is actually no point in carrying on and doing a quantitative assessment, and mainly this is where, if one concludes that an assessed risk is negligible, from a qualitative assessment, and this assessment is agreed as being correct, and if, in addition, all concerned also agree that this negligible level is acceptable, then there is unlikely to be a requirement for a quantitative assessment. Now, from this point of view, it really does not matter what people mean by negligible if everybody says "yes it is negligible and we are happy with that" then fine - nobody is arguing, there is no dispute and there is no problem. The problem, of course, does come when there is a dispute and people do wonder what is meant by 'negligible', and yes, it does mean at lot of different things to a lot of people which is why, when I get to my summary, I actually advise that one way around that is to carry on with a quantitative assessment.

57. Anyway, where it is not the case that everybody has actually agreed on a decision that there are negligible risks, or where further demonstration of a low level of probability is required, as I say, a quantitative assessment is in my opinion the next obvious process to attempt. This is what New Zealand have done, and I cannot actually see any reason Australia did not *attempt* to undertake the same kind of assessment - selecting the disease which, qualitatively they assessed as the most risky in their Draft Report. In my opinion, as I have stated in my written evidence, the basic New Zealand method and much of the

data is equally applicable. In addition, and more importantly the attempt to undertake a quantitative assessment, whether you get all the data or not, and whether you can in fact feed everything into to the model and come out with a quantitative answer, clarifies your thought processes, and will, as a result, highlight those specific data inadequacies if and where they exist. This also helps to remove the subjectivity of a qualitative assessment and separate clearly the issue of assessed risk from acceptable risk.

58. In summary, I do not accept Australia's contention that it is impossible to attempt to undertake a quantitative assessment in this situation. In my opinion this is the obvious way forward. The specific method used to estimate the probability of the unwanted outcome can then be examined completely separately from the issue of whether that probability is acceptable or not. One example of this is the David Vose risk assessment, one could do a separate risk assessment if that was felt appropriate. It seems to me that it is the obvious way to go forward when any dispute of this sort arises, is to attempt to actually clarify everything through stages by doing this quantitative assessment, which I would say is the next obvious step.

59. I will just now go through the answers to the specific questions that came up this last week. Questions 1, 2 and 3 on that paper were either not addressed to me or not in my field. Question 4: Section 2 of the 1996 Final Report describes, with references, the diseases it considers relevant on a disease-by-disease basis, with a summary of the information given. However, in my opinion these summaries do not attempt to estimate the probability of importation of infectional disease. They therefore do not meet my minimum requirements for a risk assessment.

60. The individual diseases are also considered in the Final Report in Risk Analysis Factors, Section 1.4.2, page 37. This format seems unnecessarily repetitive and confusing - well I was confused anyway - re-iterating much of the same information that was given in section 2 but this time unreferenced. For 19 of the 25 organisms listed, the conclusion after considering the disease and some potential safeguards is worded along the following lines: "Because of gaps in the information base, there remains some uncertainty about how effective this (or these) treatments would be in practice." Again, this does not meet my minimum requirements for a risk assessment (see my original answers: that in my opinion is not enough to demonstrate only the possibility of an unwanted outcome).

61. In my opinion, therefore, the Final Report has not assessed the risks on a disease-by-disease basis, although it has categorized information on a disease-by-disease basis. Just to illustrate the difference between the disease-by-disease sections in the Draft (May 1995) and the Final Report in December 1996, I will just compare the sections on *Renibacterium salmoninarum* . The Consideration (Section 4.2.8, page 75) in the Draft concludes that: ".... it is very unlikely that titres of bacteria present would be sufficient to cause a disease outbreak". I cannot find any comparable conclusions in the Final Report Summary (Section 2.4.9, page 162) nor in the Risk Analysis Factors Section on *Renibacterium salmoninarum* (Section 1.4.2, pages 41-42) either agreeing or disagreeing with that conclusion. I cannot actually find a conclusion based on the information at all, not in the obvious places to look.

62. However, just to highlight the subjectivity and the problem with a qualitative assessment, I would like to just make another little point which compares two parts - the Draft and the Final Report. There is an interesting and important difference in the wording on environmental survival of the particular bacterium Renibacterium salmoninarum. The Draft Consideration states that: "Renibacterium salmoninarum does not survive well in the environment..." whereas the Final Report Summary states that: "The organism (Renibacterium salmoninarum) has potential to survive in the environment for significant periods." Checking the data and the reference given, these conclusions in both cases appear to be derived from the same reference: Austin and Rayment (1985), Journal of Fish Diseases Volume 8, pages 505-509. I think this illustrates as well as anything, the potential problems with, and potentially subjective nature of a qualitative risk assessment. The bottom line there is: if you do a qualitative assessment and you cannot get to an agreement, I think you are then forced to proceed down the route of attempting a quantitative assessment.

63. Question 5. This question appears to be asking whether, in an import risk analysis, there is a requirement to assess risks using each of the different potential risk management option being considered.

Risk management options generally involve the putting in place of risk reduction measures, otherwise called safeguards. The baseline risk assessment would be one with no safeguards, and it is sometimes appropriate to assess this risk. Often however, some safeguards are integral to the initial risk assessment as they are either already in place (for example, existing legally required testing regimes), or would be incorporated automatically into the risk pathway in question (for example, the safeguard of cooking, if estimating a risk from a cooked product only).

64. In an import risk analysis, if the assessed baseline risk, or the risk with current regulatory or "usual" safeguards in place was considered acceptable to the importing country, there would be no requirement or need to assess any further scenario. Only if this baseline or initial risk is unacceptable would one need to go further. If, in such a case, there are additional safeguards identified which are considered practicable to employ, then in my opinion, it would be necessary for the importing country to assess the risks with the most stringent practical combination of these in place, and demonstrate that the risk were still unacceptable, in order to refuse imports. Whether it is necessary to assess intermediate combinations of safeguards separately depends on the precise problem being addressed.

65. For example, suppose import-risks of fresh whole unchilled unprocessed uncooked carcases of animal X into country Y are assessed and the result considered to represent an unacceptable risk. Then it may be that the removal of offals would be adequate to lower the risk to an acceptable level. But if offal removal is *always*, and here I mean always undertaken, for example, in conjunction with deboning and smoking then there is no point in assessing the effect of offal removal in isolation (unless you are actually testing out a risk with a new product). An assessment with the three processes included would be the appropriate one here, but, if more than one completely separate sets of safeguard options are available, practicable and mutually exclusive then in my opinion an assessment of all those sets of options is necessary in order to demonstrate that there is no method of reducing import risks to an acceptable level.

66. Question 6 was not actually addressed to me but I will just comment on the wording of the question. In my opinion the OIE has advised that certain risk assessment techniques are used, however, these techniques were developed by others rather than the OIE developing the techniques itself, they are more concerned with publishing and collating those techniques. That is all I have to say at the moment. Thank you.

Chairman

67. Thank you very much. I think before I invite the parties to participate, perhaps it would be useful if I could just invite the experts again to, well, let me ask them if they wish to respond or follow-up on anything that has been said so far. There were one or two specific points that were put to each other, for example, Dr. Rodgers on "negligibility", which has already been responded to by Dr. Wooldridge, but I think it was also addressed to Dr. Burmaster, so I do not know whether any of you want to say anything more to develop any points or to respond in any way at this stage. Dr. Burmaster.

Dr. Burmaster

68. I have no further comments now.

Chairman

69. Right, then in that case lets go on to the parties and, as I said earlier, we will start first with Canada and I would ask that in putting your questions or comments that you do identify the speaker at the beginning. Canada, you have the floor.

Canada (Ms. Valery Hughes)

70. Thank you Mr. Chairman, my name is Valery Hughes and I am the General Counsel of the Trade Law Division of the Department of Foreign Affairs in International Trade. If I may just start by expressing on behalf of my delegation and the Government of Canada, my thanks to the experts for agreeing to

participate in this process and for all the work that they have done so far. We very much appreciate their taking time out of their other duties and responsibilities to be with us here today. We have had an opportunity to comment on the responses provided by the experts to the questions put to them by the Panel and therefore, much of what Canada has to say has already been said and we need not repeat it here. I wonder, Mr. Chairman, if you might give, perhaps, me five minutes with my delegation just to confer about what we have just heard so that I can determine whether or not we have other things to mention at this time.

Chairman

71. OK, well let us just have a short break at this stage, we will reconvene here in ten minutes time, so those who want to go down and have a coffee can do so.

[Break]

Chairman

72. Well lets resume now and I would give the floor to Canada for questions and comments to the experts, Canada.

Canada (Ms. Valery Hughes)

73. Thank you Mr. Chairman, I at this time would like to thank the experts for the additional comments and information they provided to us this morning and very useful and helpful, [microphone problem]. As I was saying, if I could thank the experts for their further interventions this morning and the clarifications that they provided, they have been most helpful to us. I do not have any further questions to put to the experts at this time although I would like to reserve the right to do so later if, in the course of the day, other matters are raised that we have questions about. I do have a brief question for you Mr. Chairman, if I may in terms of process and the transcript. I was wondering if that would be made available to the parties today, this evening, tomorrow or ever.

Chairman

74. I am afraid the production of the transcript can be, depending on how long the meeting goes, it can be quite a long process, all we can say is that they will issue it as soon as they have completed the task. If there is a lot of material it can really take a matter of weeks. So I am sorry about that but it is just a fact of life. But we will get it out as soon as possible and it will be verbatim so there should not need to be any question of commenting on it or confirming anything that you have said here in writing.

75. Well in that case, perhaps I could turn to Australia and ask if you have any questions or comments for the experts, you have the floor.

Australia (Mr. Ric Wells)

76. Thank you Mr. Chairman, I am Rick Wells, the Deputy Permanent Representative at the Australian Mission in Geneva. Mr. Chairman, I would like your guidance, we do have an overview statement with regard to issues that have come up in this experts' discussion and we would like to make that statement at some point.

Chairman

77. Well, as long as it is related to the issues under discussion here with the experts then by all means it comes under the rubric of comments and if it contains questions, fine, but if it does not we will still give the experts the opportunity to respond to anything you say in it, so please continue.

Australia (Mr. Ric Wells)

78. Thank you Mr. Chairman. First of all, Australia does not propose to go into WTO legal issues at this point and our comments are without prejudice to our legal position on certain questions, responses and evidence. First of all, we would like to thank the experts for their participation in these hearings and for the time and effort that they have taken in responding to the Panel's questions.

79. The basic science examined and evaluated in the Final Report has not been challenged by the experts or by Canada, nor has any new evidence been provided to Australia that would warrant a revision of its assessment and risks. However, I would like to note, Mr. Chairman, that the experts themselves have underlined at the point that the science and the methodology are dynamic and evolving, a point which of course we have made in our submissions. I would note however, that the one thing that is not changing, is Australia's appropriate level of protection. Australia has adopted a structured approach to the development of quarantine policies, including the assessment and management of risk. The third component of risk analysis, risk communication, is a very important and integral part of Australian Import Risk Analysis. This is often lead to a series of consultations with consequent revision of Draft documents and reassessment of the risks to ensure that the decision is consistent with Australia's appropriate level of protection.

80. I would like to emphasize here that the Final Report, as we have said before, includes all considerations covered in the 1995 Draft Report and all of the scientific papers that are referenced in the Draft Report. I would note too, that consequences are an integral part of Risk Analysis as much as Risk Evaluation. The very favourable health status of animals, in particular aquatic animals in Australia is generally higher then in many other countries, underpins in a very significant way the cost efficiency of Australian primary industries and the wide acceptability of products, both in Australia and internationally. Consequently, successive Australian Governments have adopted a very conservative approach to Risk Management with the objective of preserving the advantages derived from avoiding production loss due to these diseases to help maintain export markets and to protect the environment.

81. In practice, Australia is willing to accept only a low likelihood of the entry establishment or spread of diseases of quarantine concern, if the consequences from the entry of a pest or disease are expected to be significant. When through the lack of important epidemiological information there could be no reasonable assurance that disease will not enter, establish or spread, then due caution is used throughout the risk assessment and appropriately conservative risk management measures are taken.

82. Australia has undertaken a comprehensive risk analysis, including a risk assessment that, in its judgement, used a methodology appropriate to the circumstances. The risk assessment factors identified in the SPS Agreement and by the OIE's International Aquatic Animal Health Code, were all considered in the Final Report. The International Aquatic Animal Health Code is under continuing development and is subject to ongoing refinement. There are important issues that remain to be resolved, including the criteria by which diseases are listed. The code provides voluntary minimum guidelines that should be applied in international trade by importing and exporting countries.

83. The most immediately apparent feature of the Final Report is the large number of disease agents potentially present in Canadian Pacific salmon that have not been found in Australia. For these agents, there are many gaps in the information base, including the infectious dose and root of infection, prevalence in the source populations, numbers found in the various tissues of the host and the agent's ability when subject to various physio-chemical treatments. All of these factors could have a significant impact on the level of risk.

84. In the following, Australia would like to cover three main issues, namely: Risk Analysis, International Standards, and Fish Diseases. It is clear from the expert responses to the question of what constitutes an appropriate risk analysis that there is a variety of acceptable analyses, ranging from the purely quantitative as advocated by Dr. Burmaster, to the more qualitative approach of Doctors Wooldridge and Rodgers. The Australian Final Report is a risk analysis falling within the latter range of descriptions, one that has taken into account the guidelines recommended by the OIE. It is important to

note that the SPS Agreement does not prescribe risk assessment methodology but rather requires that whatever approach is taken it should be appropriate to the circumstances. The variety of expert comment on this issue testifies to the highly subjective nature of what is appropriate in terms of the risk assessment, and the impact that the particular circumstances can have on the judgement to be made, and we would note that the experts appear to acknowledge that there is no obligation to undertake a quantitative risk analysis. Paramount in deciding on the type of risk assessment most appropriate to the circumstances, is an examination and evaluation of the available data. There may be legitimate differences of views between experts as to whether a quantitative or qualitative approach is preferable depending on individual perspective on issues, such as the value of applying qualitative methods where little empirical information is available. The judgement by New Zealand, for example, that it was appropriate in its circumstances to perform a quantitative risk assessment on salmon imports has no direct relevance to Australia's situation. For these same reasons one cannot use outcomes derived from other countries as an indicator of how Australia should have undertaken a risk assessment on Canadian salmon.

85. In its Final Report, Australia took full account of all available knowledge and determined that there was insufficient data to undertake a quantitative analysis, particularly in view of the conservative approach of Australian quarantine policy and the high level of uncertainty involved. The risk assessment conducted by Australia was both comprehensive and intensive. It was the most thorough risk assessment feasible in the circumstances. By world standards, as judged by the risk assessments published by the other countries, Australia's risk assessment is exceptionally thorough, rigorous and transparent. It considered all the relevant scientific information and the gaps and found the probability of pathogene establishment to be low. However, given the uncertainty inherent in this assessment, for example, because of the limited amount of data on infectious dose, prevalence and rate of transmission, and the very severe potential consequences, the report concluded that the risk posed was inconsistent with Australia's appropriate level of protection. I would note here that the experts appear to acknowledge that it is up to Australia to take a decision on the acceptability of risk, and I would repeat again that Australia did take that decision based on its appropriate level of protection.

86. Moving to international standards, given that the IAAHC has been identified as that most approaching international model, we welcome the participation of a member of the Fish Diseases Commission, Dr. Winton in these hearings, and the insight into the workings of the FDC that he brings to these discussions. During these proceedings, Australia has raised some concerns about the lack of ability to determine OIE-FDC opinion or intent with regard to the Code's guideline, as no minutes are kept of meetings, and the balance of global representation in the Fish Diseases Commission, particularly its impact on disease listing. Australia has detailed in its responses to questions, in page 22 of the October 1997 rebuttal, questions the process by which the current OIE notifiable and other significant diseases were selected. Australia would also emphasise that the IAAHC is in its developmental stage and is subject to ongoing review. Further it provides only minimum voluntary guidelines. In other words the IAAHC is a work in progress not a finished document. I would note here that Dr. Winton has acknowledged the usefulness of input that is now being provided on conditions in Australia and New Zealand.

87. This view that I have just given is supported by the current Director General of the OIE and I quote: "The OIE Aquatic Code and Manual are by no means carved on tablets of stone but are fully expect to be revised and refined on a regular basis as countries follow and gain experience of the guidelines", - end of quote which is drawn from the preface to the Scientific and Technical Review of the OIE, 15th of June 1996, page 378.

88. Australia has also raised concerns about the way the OIE implements the definitions used for the categorization of diseases and the resulting exclusion of diseases that may be of very significant concern to some countries. For example, although diseases notifiable to the OIE is a list of transmissible diseases which are considered to be of socio-economic and/or public health importance within countries, and which are significant in international trade of aquatic animals and aquatic animal products, nevertheless a disease is not listed if it has a broad geographical range. Furunculosis is one of the most significant diseases of salmonids, particularly Atlantic salmon, however, it is not listed by the OIE, presumably because it is endemic in most salmonid producing countries. In contrast, terrestrial diseases which have a broad geographic range and which have significant impact are listed in the OIE Animal Health Code.

89. The SPS Agreement allows a WTO Member to decide whether the OIE minimum recommendations can be an adequate basis for achieving its appropriate level of protection. It is not the role of any international organization to determine the appropriate level of protection for a sovereign country. The minimum voluntary guidelines provided by the OIE are one option that importing countries should consider in the addressing the risk of disease entry. Whether these guidelines are sufficient in themselves to make the countries appropriate level of protection is for the importing country to ascertain through a risk analysis.

90. I will move now to "diseases". Evisceration alone would not meet Australia's appropriate level of protection. Other factors will impact on level of risk, including the fact that disease agent may be found in flesh and blood. A more detailed evaluation of this issue is presented in Australia's October 1997 response to question 13 which identified muscle, remnant kidney tissue, bone, guilds, skin and appendages, head with its specialised organs and blood, especially in remnants of major blood vessels, highly vascularized areas and capillary beds as the main tissues potentially harbouring disease agents after evisceration. The FDC has taken an apparent stance without any form of risk assessment that evisceration is an adequate treatment of fin fish to reduce the presence of any pathogen to acceptable levels.

91. In contrast to terrestrial animals, there are no definitive proven instances of the spread of fish diseases via product for human consumption. However, as previously stressed in Australia's first submission, this must be seen in the context of the prevailing situation in most of world, where many or all of the diseases of concern occur endemically so that there is little chance of proving the source of outbreaks of salmonid diseases. Indeed, once a disease becomes established, the high costs in terms of scientific research to determine the source and pathway of its entry, may be a lower priority as compared to alternative use of government budgets for disease management. Diseases of salmonids have continued to spread throughout the northern hemisphere with significant production losses and economic consequences despite the OIE guidelines that were designed to reduce the risk of disease spread. It is Australia's contention that in time there will be definitive proof of the spread of aquatic animal diseases via product for human consumption. Thank you Mr. Chairman. I would like however to foreshadow that we will have some additional questions with respect to the experts responses.

Chairman

92. Thank you very much, do you have that statement you have just given, in writing. Whilst it is not necessary for the record, it might be helpful to the experts in trying to respond to have the text to refer to because there was so much in it. If so, perhaps we could have it copied.

Australia (Mr. Ric Wells)

93. We will be able to provide a final version of this shortly, Mr. Chairman.

Chairman

94. I think perhaps it would be helpful to have that before we ask the experts to attempt to respond.

Australia (Mr. Ric Wells)

95. We can provide an unedited version now.

Chairman

96. Fine, perhaps the Secretariat could arrange some quick copying. I assume the experts would prefer to wait until they have got the document before responding. If you are ready to say something right away, then we can go right into it.

Dr. Winton

97. I am not going to comment on the areas of risk assessment but there are two areas that I think Mr. Wells has raised that do go to the OIE Fish Diseases Commission's areas of interest. The OIE Fish Diseases Commission is certainly a work in progress and we rely on a number of experts around the world and also from input of the member countries: Australia, New Zealand, Canada, Sweden and several other countries have been very diligent in providing comments on both, the Code and the manual to the Fish Diseases Commission. These are discussed at the annual meetings of the Fish Diseases Commission and many of these recommendations are in fact adopted. Many of them are matters of technical precision, changes in language that we find very helpful.

98. Occasionally there are matters where even countries disagree, one country may wish to add a disease, another can make an argument to remove a disease and in this case we try to use scientific weight. But I even brought with me an example of Australian comments that were discussed at the last version and largely we have found these very helpful and the arguments well constructed. So we do appreciate the comments and the great amount of effort that Australia, Canada and other countries have put into this process through the OIE delegate.

99. I also feel that the OIE's list of transmissible diseases, while it varies somewhat from the terrestrial diseases in its focus, is a minimum agreeable standard and as the OIE has said that bilateral negotiations or even the process we are here today, may be required for those situations not covered by the OIE. But that in general the OIE Fish Diseases Commission has used both the lack of documented evidence of transmission by eviscerated products, some personal experience and in fact some unpublished studies to regard the use of evisceration as a method by which risks could be reduced to levels that took it out of the generally agreed upon category such as the Notifiable Diseases in live fish.

100. Now, I do not think anyone can imagine that there are not cases of possibility with transmission of fish or other animal diseases in a variety of situations. But the Fish Diseases Commission at least, in the absence of scientific evidence to the contrary, has viewed evisceration as a way to approach this or to actually remove it from the purview of the OIE's process. There are certainly cases where pathogens could be expected to be in filets or eviscerated product. I do not disagree that certain pathogens could be expected to be found in these, but, given the total sum of risks involved, i.e., is it transmitted with the product? Does it find its way to a susceptible host? etc. The total risk may in fact ultimately be exceedingly low, and we have many examples where fish diseases have been transmitted with the movement of live fish or even gametes, and a few cases where it has been transmitted with uneviscerated fish, particularly those used in aquaculture. Two examples that Dr. Rodgers raised are, I think, particularly relevant, where marine fish species are now seen as a major risk for movement of fish diseases when used in feeding aquaculture species. Australia is certainly familiar with the Pilchard epizootic that occurred in Australia and, while I do not think scientifically it has been proven and Dr. Barry Munday and others can comment perhaps more effectively then I can, there seems to be at least some supposition that that agent may have been introduced by the use of raw marine fish from the southern hemisphere, in South America.

101. Similarly, viral haemorrhagic septicaemia was introduce into the United Kingdom where it was formerly free by extensive sample efforts - probably also by the use of marine fish. So there are many cases where uneviscerated fish, particularly those fed directly to a susceptible species and where fish and gametes has transmitted fish diseases. But in the absence of such information for the eviscerated products, the Fish Diseases Commission has simply not chosen to address those issues. I do not mean to imply that the Fish Diseases Commission thinks that there is a zero risk option in evisceration, there is not a zero risk option perhaps in ballast water, certainly not in live ornamental fish and certainly not in marine fish that are uneviscerated. Relatively, the Fish Diseases Commission has assumed that that was a quite low if not zero level of risk. Thank you.

Chairman

102. Thank you very much, perhaps I could ask Dr. Wooldridge if she would like to respond to Australia.

Dr. Wooldridge

103. OK, I have got one or two areas to talk about which I think all fall within the broad area of risk assessment and risk analysis methodology. I noted the comment that the type of risk assessment most appropriate depends on an examination of the data. I would suggest that actually, well, in my opinion that is not the appropriate way to view it. I would suggest that one normally undertakes the qualitative risk assessment first and then, if necessary, follows up with an attempt to undertake a quantitative risk assessment, and this does not depend upon an examination at the initial stage of the data to decide which type of assessment one wishes to undertake. I think a qualitative assessment gathers the information and categorizes it and orders it and comes up with a qualitative assessment. Leaving aside the meanings of the words, this may be things like high, low, negligible - and if everybody agrees that the risk is too high from this basis to be acceptable, we do not have a problem; if everybody agrees that the risk is negligible, we do not have a problem, and it does not matter what those words mean at that stage.

104. When you have a dispute, I would maintain again - there may be other occasions - but particularly when you have a dispute, I would maintain that the most appropriate way to then follow it up to try and get further on the matter is a quantitative assessment. I would here like to reiterate the point I made earlier in my written evidence that the basis of a quantitative risk assessment is the putting together of a model into which you feed data and the whether or not you have the data, you can still put together a model and put dummy-data to actually clarify the pathways by which you think your identified hazard may become the unwanted outcome that you are attempting to assess. I think the big value of this is that it does clarify the pathways required and the data that you need, and if you say "I do not think I have got the data to do a quantitative risk assessment" without actually attempting to make the model required for that quantitative risk assessment, I do not believe you can categorically state you do not have that data. That is my theoretical point. From a practical view point I would say that when you do try and put together a quantitative risk assessment you almost always do find that you have got a lot more data of appropriate type than you initially anticipated that you would have. So I would say that you cannot tell whether you have got the data to do a quantitative risk assessment until you try and do one.

105. I think, following on from that I would like to say I am afraid I did not find the Final Report transparent. I think there is a quote or a comment that the final version was transparent. I personally found it far less transparent than the draft and difficult to find the information for which I was looking, sometimes I found it, sometimes I did not. It did not appear to me to be set out in a way which made it easy to find the information and to differentiate between what is the assessed risk and the acceptable risk.

106. Having said that, I would like to reiterate and I agree with Australia's contention here that it is up to the country or a local area or the particular place in question to decide what is an acceptable risk for them, and therefore whatever came out of Australia's Draft or Final Report as far as the assessed risk is concerned and whether I believe that was done well or badly is immaterial in this instance, it is up to them to say that is an acceptable or not acceptable risk. However, I think international guidelines would suggest that if they come to the conclusion it is not acceptable, they have to be able to justify it at a meeting such as this.

107. A word about diseases themselves, not specific diseases but which diseases are appropriate to include in a risk assessment and how this interacts with Notifiable Diseases and standard lists of diseases and so forth. We had many discussions on which information it was valid to include in an international risk assessment, when we were redrafting the OIE Risk Analysis Code Guidelines. There were opinions that the only diseases which could be included from a given source were those which had been notified and there were opinions that said "no, you need to be able to include any disease for which you have reason to suspect, or knowledge to backup, that it might be in the product which you are considering". That was my opinion and it was actually the final opinion of the working party, that those diseases which one may legitimately look at are any that one has evidence could be in the product, and that might not simply be the information notified to the OIE, but it might be from a literature search or personal reports or communications. The rational for this was that one wishes when one is doing an import risk analysis and risk assessment to have the best, the most appropriate, the fullest data available and that is not necessarily

only the data that has officially notified to OIE or any other body. I think those are my only comments at the moment. Thank you.

Chairman

108. Thank you very much. Turning to the other table, can I ask Dr. Burmaster? You have the Floor.

Dr. Burmaster

109. Well I have a couple comments in response to this overview statement from Australia. Risk assessments, at least the way I use the word, are always anticipatory of some future event. So by definition, if some group of people are thinking of doing, changing a policy or taking a new action in the future, by definition we *never* have enough data to describe it. A risk assessment is always lacking some data which someone, somewhere thinks are important. It is part of the process, we are looking ahead, and by definition we are missing some part of it. Nonetheless, I would agree with Dr. Wooldridge that by putting together a model has very beneficial results. It sharpens the thinking. By this I mean a quantitative model, a mathematical model, whereby we can put in numbers or put in distributions and make calculations about what if, what if this were true? what if that were true? what if we did this? what evidence do we have? But we will never have - I am not aware of any situation where risk assessment has ever been conducted in any field, at any time, for any purpose, where they had perfect data. The concept of perfect data does not exist in risk assessment or, for that matter, may not exist in all of science.

110. Nevertheless, there are ways working with the model to use a combination of data and a combination of expert opinion and expert evidence and evidence from other fields to come up with calculations which somehow give a numerical value to the proposed action. It can also highlight where data is missing, where to go looking for data. That would then show where the data are most missing and could most beneficially help (this is called the value of information approach). Now this is still in risk assessment, this is still trying to ascertain what risks may occur in the future. Then comes a separate step called risk management, is this risk that we have calculated acceptable or not? I strongly separate risk assessment from risk management. Let me stop here.

Chairman

111. Thank you very much. Can I ask if Dr. Rodgers would like to respond to Australia? You have the floor.

Dr. Rodgers

112. Thank you Mr. Chairman. One of the beauties of coming last is that you do not have much to say providing the other experts have said it for you and in this case to a certain extent that it is true. So I will be brief. At the last European Association of Fish Pathology International Biannual Meeting, in Edinburgh, in September of last year, we organized a workshop on risk assessment for aquatic animal health. In a room of 120 seats there was standing room only. It was freely available meeting for anyone that was present at the main conference. We addressed many of the issues which have been raised by both parties in their submissions. What came out of the meeting was not only a sense of relief because somebody had actually got people together to talk about this subject, but that there was a lack of data in certain important areas in aquatic animal health for use in either qualitative or quantitative risk assessment. These areas are particularly related to species susceptibility, diagnostic techniques, survival parameters of the pathogens themselves in the fish, particularly after harvest, and pathogen inactivation.

113. Now I would think that there is a real need for risk assessment in aquatic animal health but this is already leading to a parallel need for basic epidemiological studies to be carried out to support the data gaps, if you like. I personally have not known this situation before as a scientist because, what normally happens in this sort of situation, is you generate data through research projects which then lead to a need for something else, like risk assessment. This has been driven the other way around, it is coming down from the top and it is being led by agreements such as the SPS Agreement, in my opinion, which says you

must use this technique. It is new, it is evolving okay, but at the end of the day it is pointing out where the data gaps are occurring and that is something which David Burmaster has just eluded to. I think that also one of the most important things at the moment for risk assessment is that it can drive research projects because it does show you where the missing information is. But at the same time sometimes we do seem to be standing on thin ice because we are looking for information, some of which is there, but most of the time it is not there. Where the information is not there, there is a need for expert opinion. I think this has not yet been addressed sufficiently in aquatic animal health. Nobody has actually got experts together other than in this sort of forum, where they can actually give their opinion about missing data. In risk assessment and statistical terms this is acceptable for supporting risk analysis. The beauty of the technique is that the experts do not need to agree either, in fact it is probably better if they do not agree, because you end up then with a range of probability, a range of distribution, a probability distribution - Dr. X would say "there is a one in a million chance of that happening" and Dr. Y will say "no it could happen tomorrow". That is useful and I do not believe that it has yet been done for aquatic animal health. I have no further comments to make on that.

Chairman

114. Thank you very much. Can I ask ... any further questions or comments for the experts? Australia.

Australia (Mr. Ric Wells)

115. Thank you Mr. Chairman. Yes we do have some questions for the experts, I wonder however, whether we could have the indulgence of five minutes among ourselves just before we ask those questions?

Chairman

116. We will have five minutes in that case.

[Break]

Chairman

117. If we can now resume, perhaps I can put the question to Australia again if they have any further questions or comments for the experts please feel free to give them now. Australia you have the floor, Mr. Wells.

Australia (Mr. Ric Wells)

118. Mr. Chairman, I will ask Dr. Gardner Murray, the Australian chief veterinary officer to ask questions. Thank you.

Australia (Mr. Gardner Murray)

119. Thank you Mr. Chairman, I am Gardner Murray, Australia, despite the Scottish accent. We have a number of questions. I suppose the first question I would like to pose relates to consequences. I think only one of the experts talked about consequences this morning, the potential consequences of irreversibility of disease, should enter Australia. My question is this: how can one best resolve the issue of the low probability of establishment of a disease with the high socio-economic consequences that could result should such a disease enter a country? Because this is the point that is made in the Australian submission, low probability but very high consequence. Thank you.

Chairman

120. Thank you. Is that addressed to all the experts or to anyone in particular? Dr. Burmaster.

Dr. Burmaster

121. Well, perhaps I can shed some light on that, certainly that is a key issue in this dispute between the two countries, but it is a common feature of many, many, many risk assessments. For example, people do risk assessments of large earthquakes in Los Angeles, California, in the United States. Now if a low probability earthquake occurs in Los Angeles, California, there could be hundreds or thousands of deaths along with property damage valued in the hundreds of millions of dollars or more. So this is not the first time, I do not want to be deflected into thinking that this is the first time that anyone, anywhere has ever thought about low probability high consequence events. It is a very standard question that occurs many times in many risk assessments and I will stop there for the moment.

Chairman

122. Thank you. Other responses? Dr. Rodgers.

Dr. Rodgers

123. Yes, the only thing I would say in answer to that is that you can reduce the low probability to an even lower risk, if you like, by addressing certain risk reduction factors, as I mentioned this morning. Providing those risk reduction factors were agreed to by both parties, I do not see that there would be a problem. Obviously you do need to consider the high consequences of disease introduction although even that may not reduce the level of risk to an acceptable level for Australia in this case.

Chairman

124. Dr. Burmaster.

Dr. Burmaster

125. Yes, I guess I can go back to it now and say that it is precisely in the situations of low probability and high consequences where numbers help. If we thought that an even might recur in hydrology, with floods and so on, people talk about storms of a certain magnitude, and they talk about a storm that may recur every hundred year, a storm so large that a storm of comparable size might occur only once every hundred year on average, or once every five hundred years, or once every ten thousand years, different sizes of floods. It is important to begin to talk about those numerically, rather than just saying "well it is a big flood". Different people have completely different interpretations of what "big" means, there is no common definition. I think if you posed to people in this room "what is a low probability?" we would have no agreement here in this room, even amongst the Australian delegation, or just amongst the Canadian delegation. If I describe something as a low and each of you wrote down on a piece of paper what you think that might be, there would be orders of magnitude, differences of opinion here. I am using one word, I am saying "low probability", yet amongst the audience here today, there would be orders of magnitude, differences of opinion as to what that word meant in that context on the spoken day. So without numbers we are engaged in an exercise that cannot converge. The English language was not designed to handle this, but mathematics was designed to handle this kind of question. It gives us the tools that we need to try to resolve this kind of dispute and to find out what we know and to find out what we do not know. What we know is important, what we do not know is important. Both of those have to be brought up in a way where we can talk about them and understand what each other means. Thank you.

Chairman

126. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

127. Yes, I think I am more or less concurring with what Dave Burmaster says here but I will just go through it and put it the way I see it. I think what we need to do is decide first what we are talking about in

terms of consequences and work through similarly to hazard identification listing each of the consequences about which we are worried. These can be simple consequences or very complex consequences. For example, we are talking about the probability of the import of disease, and that is perhaps the simplest consequence that we can envisage in this case. So importing disease is a consequence. We then might think about another consequence perhaps, whether one consequence is an epidemic of that disease. Now the import of disease may or may not lead to an epidemic of that disease. So there are various different consequences resultant upon the previous consequence, some of which may happen, some of which may not, and if you are talking about a quantitative model you can actually model that as the next part in your model pathway, so you can work out the probability of the import of disease, then you can work out the probability of an epidemic of that disease in a given species or in all species or whatever you are interested in. You may also have on your list of consequences that you are worried about and that you have categorized, the loss of a certain amount of economic good in some way. I am not an economist and I do not plan to try and describe this in any more detail - I have just written down loss of X pounds of money due to this epidemic occurring. You can in fact add that onto your model and work out the probability of that given loss, albeit all these probabilities will probably have very wide uncertainty limits on them.

128. So quantitatively, with each of your high impact consequences, you can work out your probability of it happening. You have assessed that risk, you have assessed the loss of that amount of money. What you then got, assuming everybody agrees with the methodology and that is the probability of loss of that amount of money or the probability of that epidemic occurring or whatever - you have then got a risk management decision, "is that acceptable?" This is quite different from your risk assessment. You have actually included your high impact consequences in your risk assessment by calculating this probability of each happening. So then, are we prepared to accept this probability of this epidemic happening? Are we prepared to accept these particular series of consequences? That is very difficult to make a decision on but one potential way is actually to do something similar to a risk assessment, but a cost benefit analysis. That can also be done quantitatively if you are actually in a position where you have something which has a low probability of happening, you can actually look at the benefits that might accrue by letting the process go ahead and then compare the two - as I say, a cost benefit analysis, which can be done in a similar methodological way to a risk assessment in that you can put uncertainties into your benefits as well as your potential for disease importation. So that is perhaps the most straightforward way I can see of actually judging this particular kind of problem. But I accept it is a difficult problem and of course different people from different areas with different backgrounds and different perceptions, and different cultures will view different risks in a different way with regard to their acceptability all over the world. So as I say, I would recommend something along the lines of a cost benefit analysis, which again is lengthy and difficult and time consuming but there we are.

Chairman

129. Thank you very much. Dr. Winton?

Dr. Winton

130. Just maybe a brief comment, Dr. Murray is certainly correct in that the consequences of certain introductions of certain diseases can be quite high in some cases but certainly not all cases. The range can be from nearly not effect or to a manageable level. For example when VHS virus was introduced by, presumably, uneviscerated marine fish into turbot culture in the UK, United Kingdom lost its VHS free status, but that disease was able to be quarantined and was eradicated and the UK has now regained its status as a VHS free zone. So, while there was potentially a very large impact, that impact was contained and managed. Certainly Australia has seen in wild fish, the impact of an introduction for example in the Pilchard mortality which I think by most agreement is probably the largest fish kill ever recorded on the planet occurred in a wild fish. Once a disease is introduced into wild stock it becomes much more difficult to eradicate. In the case of whirling disease in the United States, is an example, where introduced from Europe, this disease has proven virtually impossible to eradicate from large areas due to its presence in wild fish.

131. The consequences can also range from biological which may be losses of natural stocks of fish to economic, which are generally those in aquaculture. So I certainly support Dr. Wooldridge's contention that a risk assessment can also include, for example, those range of consequences and perhaps try to quantify those.

132. Earlier, Mr. Wells talked about Furunculosis as an example of a disease that is not on the OIE notifiable list presumably because it is broad spread. It is also because that disease is manageable in context of aquaculture now through the use of therapeutents or vaccines to an extent that makes it of less concern to the aquaculture industry. Australia also has a strain of Furunculosis that is certainly not virulent in its own right, and so Furunculosis is certainly an example of a disease which might be more concern in certain areas or less in others, but I do not think that its absence in Australia, and its presence in other parts of the world, argues that it could be used for example as a special case. I think there are a lot of cases of diseases that are either present in other areas in the world, or even strains of diseases which are already present in Australia that might be significant in some ways. So both the range of probability of import go from nearly zero to very high, but the consequences also can go from very minor to relatively high depending on where it is introduced and what pathogen into what species of fish. It is virtually impossible for the OIE Fish Diseases Commission or perhaps any group of experts to foresee all of these various permutations. That is where I think the strength of these risk assessments comes in, in that you can then begin to then estimate those probabilities and those consequences in a more quantitative manner that can be discussed more clearly. Thank you.

Chairman

133. Thank you. Well that is the responses to the Australian question. It is now five minutes to one and this is probably a good moment to break for lunch. But before I actually adjourn, can I ask if there are further questions coming from the parties? Certainly from Australia, Canada too perhaps.

Canada (Ms. Valery Hughes)

134. Not at this time.

Chairman

135. So there will be further questions coming from Australia this afternoon. Well lets resume at three o'clock in this room, we have this room at - Mr. Wells.

Australia (Dr. Gardner Murray)

136. Mr. Chairman, Gardner Murray, I do not have a question at this point but I would just like to make an observation on one of Dr. Winton's comments. That was in relation to Pilchard mortalities. It is our view and also the view of New Zealand that in fact the causual organism Herpesvirus is endemic to Oceania, and we could find no relationship between the importation of feed stuff and the event, in particular, as it started first in New Zealand. But that is an opinion that we have and others have different views of course. Thank you.

Chairman

137. Dr. Winton.

Dr. Winton

138. Yes, I appreciate that clarification and I think earlier I had mentioned that while scientifically Koch's Postulates had not been fulfilled and I do not think that epizootic is clearly understood, I appreciate that clarification and perhaps it is not a very good example of an imported disease in that case if that is in fact the case. I do not know, is there an explanation for the sudden appearance of such a large loss, is it an environmental issue in addition then? What is the other explanation?

Australia (Dr. Gardner Murray)

139. The explanation, and they come in large part from New Zealand as well as Australia, is that the virus in question, Herpesvirus occurs in Pilchards but when stressed disease can manifest. The stressors in this case appear to have been a sudden drop in temperature, Pilchards are very sensitive to sudden temperature drops, plus probable physiological changes, hormonal changes at that time of the year. That is the explanation of stressors. Thank you.

Chairman

140. Can I just clarify, is that the only remaining question from Australia or are there going to be others? There are going to be others. So lets resume at three o'clock in this room and we will take the further questions at that time. Before we leave the room, the Panel does have questions which will be putting in later to the experts. We will circulate those in writing right now, so before you depart, if you would like to pick up a copy of that. It will be available in about five minutes time, we are just going to finalize the questions.

Chairman

141. Let me start by inviting Australia to continue. Australia you have the floor.

Australia (Dr. Gardner Murray)

142. Thank you Mr. Chairman, Gardner Murray. Now this first question is to those experts who care to answer: To the best of your knowledge, is it the exception or the norm for countries to base their import policies on purely quantitative risk assessments?

Chairman

143. Dr. Wooldridge.

Dr. Wooldridge

144. I think at the moment it is probably still the exception but I think there are quite a lot of us who think that it is probably the way forward that things are going to go.

Chairman

145. Any other, Dr. Burmaster.

Dr. Burmaster

146. Well I guess I do not know the worldwide answer, but it certainly is the way for the future and this is how these kinds of disputes and disagreements will be settled, I think starting in the last year of two and proceeding into the future.

Dr. Rodgers

147. If I can only say that I agree with Marion, since I do not think there are too many examples of any legislation in aquatic animal health being based on a quantitative risk assessment exercise or any risk assessment exercise. I am thinking in particular of the EU directives which now govern the movements of fish into and out of the Community and I think that was done simply by negotiation, based on expertise rather than a fully functioning risk assessment exercise.

Chairman

148. Thank you. Next question.

Australia (Dr. Gardner Murray)

149. Thank you Mr. Chairman. This again deals with quantitative risk assessment: Assuming one has conducted a quantitative risk assessment, is it not then still a matter of judgement as to how this relates to a country's acceptable level of protection?

Chairman

150. Dr. Wooldridge.

Dr. Wooldridge

151. Yes.

Chairman

152. Dr. Burmaster.

Dr. Burmaster

153. Well, I will say yes also, with the 'but'. I guess I will take my examples from another area where risk assessment is performed, and this might be with pesticides residues in foods - not the topic of discussion here. The notion of risk assessment is partly comparative in nature: you want to compare the risks of one activity compared to a different activity, and if a risk assessment finds, or as the fields develop and it is found, that there is great differentials in two different activities that result in two different levels of risk, that is an insight, that is what we are thinking about and trying to understand how that differential arose - is it really intended? Do people wish to maintain that differential policy? Or is there some desire upon viewing this differential to change policies and practices to bring the two risks to be more commensurate - by either raising one risk or lowering another risk? So the purpose of risk assessment is partly specific and partly general.

Chairman

154. Thank you. I think that is the response unless anybody wants to say anything more to that. Thank you.

Australia (Dr. Gardner Murray)

155. As far as Australia is concerned, we contend we have conducted a probability risk assessment. But having said that, how can one distinguish between a low probability and a possibility? Is not assessing risk as low or small a statement of probability?

Chairman

156. Dr. Burmaster.

Dr. Burmaster

157. Well it is a statement in the English language to say that something is a small probability. But again I would go back to the example I raised this morning, if we were to conduct a quiz in this room, and I said: I am thinking of a certain activity that has associated with a low probability; and then I asked each of you to write down on a card what you do you think Dr. Burmaster might be thinking of? What could

possibly constitute a low probability? I think we would get back answers ranging over several orders of magnitude, such that in my view, let me just continue on that thing, I think that therefore the phrase, low probability is essentially meaningless, it has no meaning. It has no consistently agreed upon meaning even in this room, even in a ten minute interval. By the time you step outside of this room, and by the time you step into different times and locals and different places and speak with different people, many of whom may not have any education beyond high school, and so on, that the word "low probability" becomes a meaningless phrase. It is an absolutely meaningless phrase. So if we wish to proceed, if you wish to do something that is rational, if that is your goal, if your goal is to do something rational - maybe it is not - but if your goal is to do something rational, I think you have to attach numbers or ranges of numbers or probability distributions in order to make any kind of sensible discussion.

Chairman

158. Thank you. Dr. Wooldridge.

Dr. Wooldridge

159. I think I more or less agree with Dr. Burmaster. It is a problem and I think partly it is a pragmatic problem in that if you, theoretically I think, if you are talking about the pathway for a given disease to get into a particular country, you can always sort out a pathway which makes that possible. You can always make the most unlikely, and therefore improbable assumptions, about a given part of that pathway to say something is *possible*. But from the point of view of actually doing a risk assessment on whether something really will get in, and if you have come up with the answer that you say it is a low probability, obviously, you are also saying it is a possibility. If you say something is a possibility, you are not necessarily saying it is a low probability, you could also be saying it is high probability or any other probability. I mean, if you look up the words in the English language, they are different in meaning, but from the point of view of really being helpful to distinguish in terms of a risk analysis or risk assessment, I think it is a pragmatic thing; if you have come to the conclusion that you have something that you are calling a low probability, and you need to go on from there, I think the only way you can advance, if somebody is not happy with that, and is not prepared to accept that as is, is to try and make it into a quantitative assessment. So in the end, what one is saying I feel, in my own opinion, if you left in that position that you have a dispute over what "low probability" or "negligible probability" actually means, you have got to go down the quantitative road, that is my opinion.

Chairman

160. Dr. Burmaster.

Dr. Burmaster

161. If I could pick up on further elaboration of the problems with not just the English language, this language is not unique, the semantic problems are not unique to English, I would imagine that they occur in French and in Spanish and in many other languages as well - the problem is even more profound. The problem, - one of the things scientists like to be able to do, the first most elementary scientific activity in risk assessment is trying to rank two things, you have two alternatives, and you are simply trying to say which is more likely to occur, and which is less likely to occur. You just want to be able to take two things and compare them without attaching an absolute magnitude to their occurrence, you are simply trying to rank and say "this one I think is more likely", "I think it is more likely today that the sun will set". I do, I believe it is more likely today that the sun will set, that than we are going to be struck with an earthquake in the next ten minutes and we are all going to spend the afternoon in the lake. Now, both of those are possibilities. It is possible today that the sun could set, that is a possibility. It is also possible that we could have an earthquake in the next ten minutes and we could all be swimming for our lives out of the lake, those are both possibilities. I happen to believe that it is more likely - the ranking - it is more likely the sun is going to set and less likely that we are going to swim out of the lake together. But that is my own personal ranking, some of you may have different rankings on those two possibilities. The problem with English is that if I say, event A (skip those two examples), if I say one activity I personally rank is "a

low probability" and another situation I rank is "unlikely". You do not have any way to compare those. You do not know which I am thinking of is the greater probability and which is the lesser. The semantic problems are severe. The only way out, I maintain, of this semantic debacle is to start to attach numbers or probabilities or probability distributions to those things. Then we can have a consistent conversation. If we cannot have a consistent conversation, we are just running in circles.

Chairman

162. Thank you. Dr. Rodgers.

Dr. Rodgers

163. Thank you Dr. Wooldridge and Dr. Burmaster because really effectively you have just answered question 2, which is exactly what I wanted to say, but they have done it for me. You can get confused with terminology, since there is always a possibility of something happening, but if you can attach a probability to it, it is more understandable. I did not mean to confuse the Panel in any way in my written answers. What I would say only, I would add, is that even with a probability distribution, or an estimation, you still have to backtrack and attach a textual phrase, if you like, to qualify that statement for the non-experts. Because at the end of the day, a zero point thirteen noughts one probability, is something which most people cannot understand - it is just not something they can tangibly get hold of. So you still have to use phraseology such a "negligible risk" or "low" or "high" or whatever the terminology. That was all I had to say.

Chairman

164. Thank you. So you have helped to shorten our subsequent process. Any further questions from Australia.

Australia (Dr. Gardner Murray)

165. Yes. What we were just discussing, and I apologize, what we should follow-up on some of the answers given. I suppose there are many lines we could take. The fact that using, for example the term "low probability" is meaningless - in fact most countries in the world deal in these kind of terms, really. It does not all look very well, in some ways, for practices in place. But a question I would like to ask, and this is dealing with acceptable risk of quarantines, or acceptable level of protection, and I think I know the answers, but, - is it the exception or the norm to express acceptable risk and quantitative terms?

Chairman

166. Dr. Burmaster.

Dr. Burmaster

167. In my experience, practising risk assessment in the United States as I do, I have not seen, - How do I express this? I have only seen quantitative risk assessments done. So I was quite surprised when I first was asked to join this Panel and read through the background materials. I was really taken by surprise that the, in my view, that the materials prepared had all been qualitative. That struck me as highly unusual.

Chairman

168. Dr. Wooldridge.

Dr. Wooldridge

169. The answer is, I think is, sort of again I would agree with Dr. Burmaster, - in some fields I think it usual to actually look at the quantitative risk and decide whether that is acceptable or not. Some of those are not fields with which I am particularly familiar, but I mean, for the agricultural import exports, veterinary kind of field, which I am more familiar, I think up until now or up until very recently, an acceptable risk has much more often been by negotiation on words than actually mathematical numbers and an agreement on those. Again I would go back to a comment I made earlier, that I think things are beginning to change, and I think it would make for clearer basis for negotiation and challenge and/or agreement or disagreement if one did have a numerical value to work around. Because you could get your numerical value, you could agree or disagree that the method had been done correctly, and if you disagreed, one could go back and look at the individual parts of the model and agree it. Then we would all be talking about the same thing: "yes we agree this is the assessed risk", "we do not actually find that acceptable" or "we agree it is the assessed risk, we do find that acceptable". I think that would make a part of the negotiation process much easier. But it would not give you an answer as to whether it was acceptable or not, as we have said before.

Chairman

170. Thank you. Australia.

Australia (Dr. Gardner Murray)

171. Thank you. This is again a question to any expert who may care to answer: Transmission of disease through product for human consumption is well known for many terrestrial animal diseases. Do you think that there is a scientific reason to assume that this could not occur in aquatic animals?

Chairman

172. Dr. Rodgers.

Dr. Rodgers

173. You are talking about a human disease or an animal disease? An animal disease. Because certainly Cholera is one disease which is possible to be transmitted from fish to humans, but I am not familiar with the terrestrial side. Sorry I was thinking out loud.

Chairman

174. Dr. Wooldridge, would you like to carry on from that.

Dr. Wooldridge

175. A quick comment. I think, in terms of risk assessment, when one is actually starting out on this process, in part of this hazard identification step of this, you need to consider whether these are possibly transmitted diseases through the product for human consumption. As I said before, I think you can put together a number of pathways that show the possibility of that happening. Whether there is any scientific evidence to say whether that would or would not happen, would depend partly on the available state of evidence, but also if it had been shown to have happened in a particular instance, there you have got your evidence. If not, then if you actually did follow your pathways through and had done a quantitative assessment, again you would come up with a probability of that happening, albeit that if your data was not very full, it would be a probability with very wide uncertainties.

Chairman

176. Thank you. Dr. Burmaster.

Dr. Burmaster

177. I guess, at the most general level I work in a profession where - this sounds like a contradiction in terms - but there is no such thing as a zero probability. There is always a risk of something. There is always some - even for rare events - there is some small, finite probability greater than zero, that the undesirable consequence might occur. For example, in under the laws of statistical physics (this example has been around for fifty years and it is in many textbooks), there is a small chance that all of us in this room are going to suffocate to death in the next minute. How could this occur? How can we start to discuss it? Well, through the statistical mechanics of the air molecules and the oxygen and nitrogen molecules that are in this room right now, there is a small chance greater than zero that all of those molecules are going to end up in that corner of the room sometime in the next minute and stay there for a long enough time, just a normal fluctuation, that we will all die. Is there a zero probability of that? No. Well, how big is the probability? It is kind of small, it is probably so small that we would have a hard time in calculating it. But it is not zero. So back to this question: "is there a chance that some disease might be introduced from country Number One into country Number Two?" Can we rule it out and say that there is a zero probability? No. We can never say there is a zero probability. But it might be small, it might be large, we have to do the numbers to find out.

Chairman

178. Dr. Winton.

Dr. Winton

179. Probability and numbers aside, and I have specifically tried to stay away from this, and if you saw my scores in mathematics as a graduate student you would understand why. From a more fish disease perspective, the answer and it is largely opinion, is that probability is relative to other sources of introduction of fish diseases in the case aquatic diseases, is relatively low with human products. You are correct that in the case of [hams ?] for example and Foot and Mouth Disease, and other products, African Swine Fever - there have been estimates that those contain risk; that products for human consumption do carry risks of animal diseases. But there is such a large body of scientific evidence associating movements of live fish and eggs with diseases, and the *absence* of scientific data associating any other products for human consumption that the preponderance of data seem to be that the risk is quite low. In addition, as I said in my comments, there are some unpublished studies of people who have actively looked for diseases in products destined for human consumption and been unable to find them, at least using standard methods. I do not think anyone would say it cannot happen, but at least I think it is my view, that probability is quite low relative to perhaps other sources of risk - those might be ships or tourists or other import products, all of which are not a zero risk option. Until proven otherwise, I think, the risk is estimated to be quite low.

Chairman

180. Australia.

Australia (Dr. Gardner Murray)

181. Thank you. I think the answers to that question more or less indicate that in fact salmonid product could contain exotic agents, in terms of product. On relative terms, as Dr. Winton said, well, gametes and all the rest pose greater risk, but, nevertheless, it can happen. But just to follow on from that, Mr. Chairman, I have got a fairly long kind of list of questions here, and, please accept my apologies, but it kind of deals a bit with the absence of evidence issue that you raised. What does a country do if there is no evidence? Does it wait until the problem happens - and then says "Oh, Hallelujah, we have got evidence

now!", or does it take action, the Australia approach? I apologize if I am long and convoluted today, if I could get some sort of answers I would appreciate it. Given the high cost of investigating disease outbreaks, in cases where the cause is not immediately apparent, determining the cause of an outbreak may be a low priority compared to implementing disease control measures. In countries where many or all of the diseases of concern occur endemically, it is likely that the cause of all new outbreaks of any of these endemic diseases would be investigated with sufficient thoroughness to determine the origin. Could outbreaks of endemic disease cause by products imported for human consumption occur and not be recognized? Could outbreaks of endemic diseases caused by newly introduced strains occur and not be recognized?

Chairman

182. Dr. Winton.

Dr. Winton

183. Certainly it is possible that it would be difficult or impossible to see very low level of introductions in the background of a number of cases. Your are correct, some of these are expensive to investigate. In a few cases, some investigations have been undertaken and our laboratories, using some molecular tools now to begin to trace some of the epidemiology of some outbreaks. This kind of approach I think will help in this regard, but yes, I do not think anyone would say, "no, of all of the cases of Furunculosis in North America, could some of those actually have come by imported Atlantic salmon from Norway and not be an endemic disease problem?" We would not know that. So your assumption is correct. However, unusual outbreaks, for example, when viral haemorrhagic septicaemia was first found in North America, tremendous amount of effort went into that. In our laboratory, we investigated those strains at the molecular level, we have since developed ways to identify those strains uniquely, and we now have a surveillance mechanism in place to be able to differentiate between a European strain and a North American. So at least for this particular disease and in this particular case, such work was done and we know that all of the isolation of VHS in North America, every single one has been typed in our laboratory and they are all of North American origin. So, in some cases we know that. But in the background of large numbers of cases, no, we would not - or for lower priority conditions.

Chairman

184. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

185. Just another very quick comment about a completely different disease. I can say from personal experience of attempting to differentiate between the various different sources of a particular disease with similar clinical and pathological manifestations, that actually, even when you know what different sources you are looking for, it can be actually very difficult to decide whether you have got a different disease from a different source or whether it is another endemic outbreak. Nothing to do with fish, in that particular practical instance I am talking about.

Chairman

186. Thank you. Dr. Rodgers.

Dr. Rodgers

187. I would just like to echo what Jim Winton said. I would just like to add also that it is very much easier to characterise and identify disease causal agent in a clinical outbreak than it would be in, for instance, a routine monitoring programme. When you are doing routine monitoring, unless you are selecting fish, in this case which are diseased looking or sick or dying, to actually weight your sample towards finding something, then you are really looking at the limits of your detection tests, which is

something I have mentioned this morning. Routine monitoring nearly always brings you around to a negative result, if you like, but based on the limits of the detection tests.

Chairman

188. Thank you very much. Dr. Winton.

Dr. Winton

189. Maybe one additional comment too, that in the face of this is a compounding factor as well. At some point today I wanted to mention this and this is as good a time as any. That is as detection methods improve there always appear now to be cases that you have missed before or low level sub-clinical carriers and disease agents, not all of those of course are introductions but they are first-findings. I think in many times we have difficulty even distinguishing between what is in fact an introduction and what is in fact a discovery because of improved methods in diagnostic methodology. Many times the first case of a disease in a country is assumed at first to be an import until proven otherwise. But I think that we have some experience now suggesting that many of these are simply better detection methods and more observation. In the case of Canada and Australia, the distributions of all of the diseases that have even been mentioned, I do not think are know with certainty at this particular instance. That will become more clear over the next decade of centuries.

Chairman

190. Thank you. While you have got the floor, Dr. Winton, I wonder if could just help the Panel by explaining what the term "gametes" means. We have heard it used a couple of times but we are not very clear on what it is.

Dr. Winton

191. Gametes, are the sperm or eggs and they are often imported separately to fertilize eggs in a country or to use just the eggs or just the sperm as opposed to eggs or fertilized eggs, which is the other term. Gametes would simply be the seed stock. Many pathogens, particularly viral pathogens and a couple of bacteria can be transmitted with gametes themselves as they can with fertilized eggs or live fish.

Chairman

192. Thank you for that clarification. Dr. Rodgers.

Dr. Rodgers

193. Yes, I would just like to make one comment, not on gametes, but following on from disease identification and characterization. I do not know, perhaps Jim can correct me if I am wrong, but I do not know of any national legislation anywhere that would, on the finding of a disease causal agent, unless that disease causal agent was isolated and fulfilled Koch's Postulates you would not act, for instance, on a molecular technique which pointed to the fact that you had detected VHS but that you could not isolate it in culture. I think most monitoring programmes and most national legislation is based on the understanding that to take action you must actually isolate the organism itself.

Chairman

194. Dr. Winton.

Dr. Winton

195. I think that is generally true and I think that is going to run into some problems as some of the molecular techniques are more wildly adopted because we now have techniques that, as you say, can find

evidence of agents in the absence of the infectious dose or even sometimes viable agents themselves, just genomes or killed organisms. So this is going to be a problem but not just obviously in fish.

Chairman

196. Australia.

Australia (Dr. Gardner Murray)

197. Just on that last comment. There are occasions and circumstances in Australia where we might take action without insolating the organism, particularly in emergency situations.

Chairman

198. Before you go on to another subject, would Canada like to come in on that point?

Canada (Ms. Valery Hughes)

199. I am certainly not going to comment on the science. I wonder if I just might seek a clarification as the questions are piling up and as they seem to be getting longer it is more and more difficult for us to follow them and I wondered if we could have a copy of those questions. It would certainly facilitate things for us.

Australia (Dr. Gardner Murray)

200. Yes, well the good news is there are only two questions to go. I suppose the bad news is that they are both fairly long, so I apologize. We had to make a number of modifications to these questions over lunch which is why did not have a chance to type them up and give them to you. I apologize.

201. The second last question is to Dr. Winton, and I think you have covered it a bit this morning, but I would just like a bit more clarification. Dr. Winton, you have stated that the Fish Diseases Commission was unanimous in its belief that evisceration is an effective measure to reduce greatly the risk of transmission of notifiable diseases. What are your views on the efficacy of evisceration as a measure with respect to the other significant diseases such as epizootic ulcerative syndrome and viral encephalopathy and retinopathy. Does this apply in the case of fish harvested from emergency slaughter, that is evisceration? Or would evisceration of Canadian salmon result in an equal degree of reduction of infectivity for all of the pathogens identified in the Final Report?

Chairman

202. Dr. Winton.

Dr. Winton

203. Well that is a difficult question. I think first of all, I should say that it is not entirely correct to say that the Fish Diseases Commission felt that evisceration would, *per se*, reduce Notifiable Diseases and was therefore somehow thought to be a measure that was recommended. To a large extent, and I think that it is important to clarify, the Fish Diseases Commission was unanimous in its feeling that eviscerated products, by themselves, represented a low enough risk that they were not really within the purview of the Fish Diseases Commission to consider. We were more concerned with the aquaculture products, and particularly live fish and eggs moving international shipment. As several countries have done, there was a presumption that if the product was eviscerated, whether it came from a wild source or even from an aquaculture facility - even from an aquaculture facility at which a disease outbreak was occurring - that evisceration removed that product from the purview of the OIE recommendations. So we do not necessarily have an opinion, *per se*, about evisceration other than the fact that it seemed to reduce the risk significantly such that it was no longer of interest to us at that particular point. If the scientific evidence is

such that eviscerated products are a risk, then perhaps, we would reverse that opinion. We have considered for example, uneviscerated bait fish and whether or not we should include these as a source of discussion, but we currently do not discuss them either.

204. In addition to saying that evisceration of fish was thought to reduce notifiable diseases, you are correct that evisceration would probably be more effective for some diseases than others. More stable agents, and particularly agents that might be found in the flesh of the animal, as opposed to viscera, might well be expected to survive longer in such product and therefore perhaps be of slightly higher risk. We are not able to carry out such an analysis because we do not have the survival curves of all of the potential pathogens in such products. But I think it is safe to say that for both the Notifiable and the Other Diseases, we assume that evisceration significantly reduced the risk to a level that we no longer were concerned about.

Chairman

205. Thank you. Dr. Murray.

Australia (Dr. Gardner Murray)

206. One final question to Dr. Winton. Dr. Winton, is it anomalous that a disease occurring in the Southern Hemisphere, EHN, is made notifiable, but one occurring exclusively in the Northern Hemisphere, for example ISA, is not - especially when the later is much more devastating then the former? What implication does this have for the application of the Code?

Chairman

207. Dr. Winton.

Dr. Winton

208. Well, you raise a point that has behind it a suggestion that somehow Australia is being treated unfairly in the case of EHN versus ISA. Diseases are so called listed diseases by the Fish Diseases Commission not only on the basis of their geographic distribution. In the case of ISA it is now know to be confined to Norway and to Canada. EHN, initially, was believed to be only in Australia. But the second thing and third things that we consider are how treatable they are. In this case neither one is treatable being viral. The last thing is how robust are the diagnostic and certification methods. In the case of EHN, good, robust cell culture detection in serological identification were in place, such that you could in fact certify a population of fish as free of EHN virus such that it could be moved. That was not the case of ISA for which, until the last month or so, no standard diagnostic method had been available, except clinical signs. It was impossible, literally, to certify a population as free of ISA.

209. Now the Fish Diseases Commission may well, based on the findings of ISA in Canada and the now improved diagnostic methods, including a cell line which will replicate the virus and a molecular method - may well choose to add ISA. The second point is that EHN is now seen as part of a much larger pool of iridoviruses of fish. Our biggest problem on the Fish Diseases Commission in the next year is how to define this group. I can almost guarantee you that this group will expand from being simply an iridovirus in Australia, primarily of Redfin Perch to a pool of viruses, and the noda virus in the marine environment are going to represent the same difficulty. It is a pool of strains of very closely related viruses which can have devastating effects for which there is a limited geographic distribution but a fairly wide species distribution. We are going to have some troubles trying to decide how to define this new thing. I have asked for example, Dr. Ron Hedrick (on the Fish Disease Commission) to help us define these iridoviruses of fish. It is as you said, a work in progress and we will make some adjustments accordingly. But I would say, and you only have to believe me on this, I guess, but there is no bias against the situation in Australia regards to ISA versus EHN virus.

Chairman

210. Just for the benefit of the Panel, I wonder if you could just clarify what EHN and ISA are.

Dr. Winton

211. Ok, is an iridoviral disease, initially found in Redfin Perch and we have experts here that can tell us a lot more about it than I can. It was formally thought to be confined to mainland Australia, and it now appears related to a series of viruses from Sheatfish and Catfish in Europe and the United States, that are very difficult to differentiate from each other, and are somewhat related to a frog virus and amphibian virus, and this particular disease, so called Epizootic Haemorrhagic Necrosis was first described in Australia. ISA, *Infectious salmonid anaemia* was first described in Norway, and that is now know to be caused by an orthomyxovirus.

Chairman

212. Thank you very much, sorry for that diversion. Another question?

Australia (Dr. Gardner Murray)

213. No, I have - we have kind of finished. I would like to, in finishing, thank the experts very much for the effort they have put into this exercise and answering my questions so frankly and honestly. Thank you very much.

Chairman

214. Thank you very much. Can I take it that we have come to the end of the parties questions? Does Canada have anything to add at this stage? You have the floor.

Canada (Ms. Valery Hughes)

215. Thank you Mr. Chairman, I wonder - I realise that the day is getting long - but I wonder if you might give me five minutes just to check with the experts that I brought with me because there is of course a lot of information that has been raised since we have returned?

Chairman

216. Ok, five minutes.

Canada (Ms. Valery Hughes)

217. Thank you.

[Break]

Chairman

218. Well thank you for observing five minutes more or less exactly. You have the floor Canada.

Canada (Ms. Valery Hughes)

219. Thank you Mr. Chairman, and thank you for giving us that time. We have no questions at this time.

Chairman

220. Right, well in that case that seems to bring us to the end of that stage of the meeting. Perhaps we could now turn to the questions from the Panel[*] that were tabled just before lunch. I am going to ask the experts if they would address these questions. I will give the experts the floor one-by-one and ask them to run through the whole list. I think in the light of the discussion we have had this afternoon, that some of them actually fall away and do not need to be addressed further; I am thinking particularly of 1, 2 and 6, which I think we have covered. But by all means feel free to add something if you want to, but I think we have dealt with those this afternoon. We would like to change the order to bring number 17 up to number 1, if you would. Also, I have something to add to question 15. We have had some discussion on evisceration and we want to put a rather specific addition to that question which is as follows: What is the effectiveness of evisceration in reducing risk from *Renibacterium salmoninarum*, IHNV, Salmon leukaemia virus, and *Henneguya salminicola*, that is just for those four diseases - so that is an addition to question 15. If that is clear perhaps I could start by offering the floor in alphabetical order. Perhaps start with Dr. Burmaster, if you would be kind enough to address the questions.

[Dr. Rodgers took the floor first]

Dr. Rodgers

221. Could you clarify whether you want to run through them as they are or do you want each expert to go through all of the questions one by one.

Chairman

222. Well, I will offer floor to each expert and ask each one to run through them and address those questions which you feel you can, - no, perhaps that is - Let us take them question-by-question. Yes, sorry, I am confusing the issue. Let us take them question-by-question and let us start with question 1 which is now 17, renumbered 1 and on the sheet 1, 2 and 6 have disappeared.

Dr. Burmaster

223. I am, question 17 now renumbered to become Number 1. I do not fully understand the question, so it might be better if we went in reverse alphabetical order for a moment. I am sorry.

Dr. Wooldridge

224. I have to say I think I know what the question means but I am not quite sure either. So I wonder if it is possible to clarify the question at all.

The Secretariat (Mr. Joost Pauwelyn)

225. Well the question relates to the third requirements invoked by Canada; the idea that you should assess the SPS measures you, upfront, want to consider. So if you think this is a requirement, do you think it is enough to just assess each option separately? Or do you have to - once you have made such an assessment - do you have to compare the different options? Do you have to compare and examine the relative risks related to each of these options? And, in the end do you have to justify the option you finally choose, as to whether this option reduces your risk appropriately?

Dr. Wooldridge

226. Starting somewhere in the middle of that question first - if you actually undertake a quantitative risk assessment for each of the options under consideration, your answers will automatically give you a comparison of the different options. Therefore, if you have undertaken a quantitative assessment, I think

[*] See Attachment of Annex 2.

the question is redundant, or at least the central part of the question is redundant. I suspect, with regard to giving a rational explanation as to why you have chosen those measures, if they are measures that are acceptable to whoever else is involved in the question under consideration, you will not need to give a rational explanation because they will be accepted without any explanation. If they are not accepted then you would have to give rational explanation if you wished to persuade somebody to accept them. So again I cannot quite see that there is a question there, the answer is almost automatic. If there are - and I think I have sort of answered this morning when I answered the questions that were put additionally to the original questions - but, if there are several different options that one can undertake, then if you are going to say that the risks are unacceptable in importing a particular product, then you do have to have looked at the most stringent feasible combination of safeguards and concluded that the risk is still unacceptable in order to adequately demonstrate your position in denying imports. Is that clear? Have I answered the question? Well I have done my best at answering the question, anyway.

Chairman

227. That is helpful, thank you. Dr. Burmaster do you want to say something on this subject.

Dr. Burmaster

228. Well having heard that answer, I have nothing to add.

Chairman

229. Thank you. Can I just clarify whether - right, yes. Well, I think unless anybody else want to address that question perhaps we can go on to the one that is numbered 3. Now this is primarily for Dr. Rodgers, but it also relates to something that has come from Canada so perhaps we can start with Dr. Rodgers.

Dr. Rodgers

230. Yes, thank you Mr. Chairman. I did not mean to confuse anybody with my non-inclusion of the citations from the public literature. I was, for the sake of completeness, trying to answer the question which says "which disease agents" it does not actually say "which disease agents from the Australian list", it just says "which disease agents", so I was trying to be complete. I will agree that flexibacteriosis is probably ubiquitous as is *Kudoa*, and is probably not of concern. However, there are references in the scientific literature to *Kudoa* appearing in Canadian salmon, whether the Canadians are aware of it or not I do not know. There is for instance a reference by Kabata and Whitaker in 1989 which says that all species of returning adult salmon in British Columbia, Pacific salmonids, except Chum salmon and Sockeye salmon had *Kudoa*, isolated from cardiac muscle and I believe it was also reported at a *Kudoa* workshop in Nanaimo in 1994. But, as I say, *Kudoa* is ubiquitous and I would agree if is probably of no concern now, specifically as it has been taken off the list by Australia. As far as the other one is concerned - *Parvicapsula*, there is a report in 1992 by Kent which says that wild Sockeye salmon, did have an isolation of *Parvicapsula* and they occurred off the coast of British Columbia which I assume was in shore, I do not know, - I assume in Canadian waters. There is a very recent publication by Kent *et al* in 1997 which says that adult Sockeye salmon recently returned to the Weaver Creek from the Pacific Ocean, have had what has been identified as a new species of *Parvicapsula*, isolated from them. So there are references, as far as I am concerned as a scientist, in the literature to both these species - both these disease causal agents rather. But I would agree that they are not of overriding concern for us today. Does that answer the question? I thought there was another aspect to it. Oh, PKD. PKD I believe has not been found in adult Pacific salmon, it does occur in juveniles and with previous exposure to PKD as a juvenile, most adult salmon would become resistant anyway to subsequent exposure. But I believe it has not been reported from adult salmon. That is true.

Chairman

231. Thank you very much. I do not know whether Canada wants to come in on that at all. Yes, Canada.

Canada (Ms. Valery Hughes)

232. Mr. Chairman, I would just remind the Panel that Canada has commented on this previously in the comments filed on December 18th, and we stand by the response provided to question 2, on October the 7th. I think that Dr. Rodgers has confirmed that point. Thank you.

Chairman

233. Thank you very much. Perhaps we could now go on to question 4, I do not know whether Dr. Rodgers, you would just like to carry on with that one.

Dr. Rodgers

234. Thank you Mr. Chairman. There is a distinction here between dead fish and eviscerated fish, I assume they are one and the same. Because a dead fish which is not eviscerated - well, in fact, a dead fish which has been eviscerated also has autolytic processes which would render some disease agents inactive simply because of the autolytic enzymes which are present as an actual process of decay. Any fish which entered the evisceration process as a carrier fish could still remain with some level of disease agent depending on what that agent was, as we have already heard today, because the evisceration process is not totally efficient at removing all pathogens, particularly those pathogens which occur in the kidney, for instance. The evisceration machine (if the machine is being used) tends to leave some kidney behind in the backbone of the fish and any viral agent, for instance, would remain also in blood - but as to how long for, there are very few studies done on pathogen survival in eviscerated fish, so I could not say at what level they would occur. But as we heard from Jim Winton, evisceration is an effective way of reducing the level, but to what level, and whether that level is acceptable, is another question completely.

Chairman

235. Right, thank you. Dr. Winton.

Dr. Winton

236. One thing is the definitions of carriers and reservoirs. In a general sense, carriers and reservoirs are live species, either the same or in some cases a different species, that serve to maintain those infections. A good example might be Pacific herring which are now known to be an important reservoir and carriers of VHS virus in North America. VHS virus has been introduced into some North American salmonids but primarily from an enzootic pool of these carriers. A dead animal, probably more accurately comes under the definition of a fomites, which is an inanimate object which serves as a potential source of contamination, much as contaminated boots or other items might - the organism does not replicate in such a state and it is really incumbent on the fomite to have been contaminated at some point and then you have a decay curve that goes on depending on the organism, the length of time and the conditions. So a fomites in general, or a dead fish, really is of less concern in a way because it is not replicating the agent in an active state or maintaining it such that it could be expected to have high level at any particular point in time.

Chairman

237. Thank you very much. Unless there is anything else on 4 can we go on to 5. Dr. Rodgers.

Dr. Rodgers

238. Basically, yes. The salmon are quite high up the respective food chain. They would eat scraps of salmon meat. The answer is yes.

Chairman

239. Thank you. Unless anybody else wants to say anything on that. We will skip 6, which we have dealt with, and go strait to 7. Dr. Wooldridge.

Dr. Wooldridge

240. I gather from this question that you were not quite sure what I was trying to say in my answer 2.4.3, is that correct?

Chairman

241. Yes, it is a clarification of that.

Dr. Wooldridge

242. On a theoretical level, the risk assessment that you wish to do depends on the risk that you wish to assess and therefore, on a theoretical level, I have put down in my 2.4.3, two potential questions, and there are many but I have chosen two. The first one being "what is the risk of an exotic disease being introduced with product X", and here you are imagining a situation where somebody wishes to introduce product X and you need to assess *any* risks of *any* diseases potentially in product X. So you need to go through a hazard identification exercise looking at all potential diseases which might be in product X, and in some way assess the risk of each one of those being introduced with that product. However, if your initial question is simply concerning one disease, for some reason, somebody has brought up perhaps the question of *a* particular disease, then you only need to look at that disease because that is the hazard that has been identified as being the requirement that you have been given to do a risk assessment on. So that is the theoretical background as to whether you would do a disease-by-disease or a product-by-product assessment. It very much depends on the question you are trying to answer. But your question number 7

here then goes on to ask "are these two alternative models", well, the final sentence. In a real life situation, if you are actually interested in every possible way in which exotic disease Y, might be introduced, then you would have to consider all the products that could carry exotic disease Y. So you then you would have your disease and your hazard identification will be saying "hazard of this disease in *that* product, this disease in *that* product, this disease in *that* product". So in a practical situation you would then need to broaden it out to look at other products. But the final analysis is that it very much depends on - the way you approach it very much depends on what is the question you are trying to answer. Does that clarify or not?

Chairman

243. Yes, I think that has got to the point, thank you very much. So if there is nothing further on that one, perhaps we can go on to number 8. Dr. Rodgers.

Dr. Rodgers

244. Thank you Mr. Chairman. Basically, I cannot answer question 8 without doing a full quantitative risk analysis. Following what you have heard this morning about terminology, would you like to qualify what you mean by the term very small.

Chairman

245. Negligible.

Dr. Rodgers

246. I think the answer is linked to the sensitivity of your detection method. If you bear that in mind then - yes, you cannot say that the disease will be totally absent if you have not found it, unless you have a background database with time of regular testing, and even then, if you have never found a single fish out of - maybe you have tested thousands - even then, you cannot say the disease is absent. That will give you a probability - thank you, I was just about to say it - a [beta-distribution] which will indicate the level of probability of it being absent. Perhaps Marion would like to elaborate further?

Chairman

247. Thank you. Dr. Wooldridge.

Dr. Wooldridge

248. It think yes - if you do not look for something you will probably not find it. You have a number of different problems here. If a disease has not been found in a category of fish it might simply mean we do not have a test that is able to find it, yet. Or it might mean that we have not actually tested any fish yet, and, so - yes, we are talking about the numbers of fish that one has tested, we are talking about the sensitivity of the test and if you have found no fish in a given number that you have tested then you still have a probability because you may find in the very next fish that you test that you have actually got that disease. You cannot - to say that it is a very small probability, well, again, you are talking about how many you have tested. If you have tested every fish out of two and you have not found it, you are not necessarily talking about a very small probability. If you have tested every fish in ten million and you have not found it, you are probably talking about a very small probability given that you have got a test that will pick it up.

Chairman

249. Thank you. Dr. Burmaster.

Dr. Burmaster

250. I agree with both of the previous statements and I think it is summed up in science as saying that: in science, one can never prove the negative. You can never prove the negative, it just cannot be done in science.

Chairman

251. I am not quite sure how much those answers have already addressed 9 as well but perhaps we could just have a look at that and see whether we have - Dr. Wooldridge.

Dr. Wooldridge

252. I think they have partly addressed 9, but the format of question 9 is slightly different. It is the first sentence: "should this disease nonetheless be considered in a risk assessment of fish from this area?" I think the answer is yes, this disease should be considered in as much as when you do a hazard identification, which should be your first stage, you would start off with thinking about all potential diseases that might be in that particular species of fish and then reduce it down to those - or you might then prioritize - looking next at those diseases which had been found in that species, in that area. So you would consider them, you would not throw them out. What you might then say is, well, if they have not been found, given the things we have already talked about in the previous question, and if something else has been found, then our initial risk assessment, where are perhaps going to get further details and do a quantitative assessment perhaps needs, perhaps, to be prioritized first on the ones that have been found.

253. Given the assumption that you have got equally sensitive tests, and you might not have, and given the assumption that you have tested an equal number of fish for both diseases, which again you might not have, if you have found one disease and not found another, then the probability - or it is likely that you are going to end up with higher risks overall from the one you have found. So if you wish to pursue the quantitative argument and do a quantitative assessment based on the prevalence of the disease you actually have found, and if you find that gives you a risk which is, when you have quantified it out, acceptably low, then it might be considered safe to say (if you agree with the use of the word "safe"), that something with a lower prevalence would have an even lower probability of being imported, therefore that is also acceptable. If you come to the conclusion that the disease which was found, and therefore of probable higher prevalence, has an unacceptably high risk, and there is no safeguard, or mitigating, or disease reduction measures you can put in place and you are left with something that because of this disease you found is unacceptably highly risky, then it does not really matter if the other diseases are there or not because you are not going to have it, because it is too risky for *that* reason. So you consider these things but whether in the last analysis they make a practical difference, depends on the exact circumstances, but you might argue that actually maybe you do not need to worry too much given the proviso, you have tested for it and you have got a sensitive test.

Chairman

254. Thank you. Anything else on that, Dr. Burmaster? No. Unless anyone else wants to add anything on 9 lets go on to 10. I think this was mentioned as an example by one of the experts this morning. I do not know whether you have got anything else to add on the subject of the "Vose Assessment".

Dr. Wooldridge

255. Well in broad terms this would be the kind of way that I would like to see any problem of this sort tackled. I am not talking about the detail of this because I have read through it but I have not actually committed to memory all the details - but in broad terms this is the way I would like to see any dispute of this nature taken forward to the next step. Something along these lines that David Vose has produced. I think it is very relevant.

Chairman

256. Thank you. Dr. Burmaster.

Dr. Burmaster

257. Yes, I agree with Dr. Wooldridge's formulation exactly.

Chairman

258. Thank you. Unless there is anything else on that, lets go on to number 11 which is addressed to Dr. Burmaster.

Dr. Burmaster

259. Well, I continue to agree with my previous answer, which is yes. But I am not sure maybe there is some semantic detail here that I am missing, but let me tell you what I am answering yes to. Let us say there is one bacterium which is responsible for some terrible disease in some stock of fish. And let us say that bacterium could have originated in just two places on the globe. So it might have originated in country A or in country B. Somehow that bacterium got to country C and damaged the fish, it caused fish disease in country C. I think from the fish's perspective, the bacterium is there in country C and it is damaging the population of fish in country C and from the fish's point of view, the fish really do not care whether it came from country A or country B, they are sick fish and they are not liking this experience in any way. I am trying not to be factitious about this, but it is only the humans who really care about where it originates. The humans care a lot about whether it came from A or B because they may want to go back and under some trade treaty or something they may wish to collect monetary damages or something else. But it really the phrase I am sticking here with is "regardless of imported host", and I guessed that is where I stand. Thank you.

Chairman

260. Thank you. Question 12 is addressed to all. Dr. Winton.

Dr. Winton

261. Question 12 is a very difficult question because it might be possible, given enough information around specific disease, to rank these relative risks. In a general sense, fish that have been inspected by a competent inspection set procedure, and which are in a pathogen free water supply, or at least a controlled water supply, represent a rather high level of safety. These are the areas in which the OIE Fish Diseases Commission imagines most trade would occur. In the case of these Canadian fish here, we are talking about ocean-caught Pacific salmon which has its own suite of diseases versus freshwater-caught Pacific salmon, which have a slightly different subset of diseases, versus cultured fish on the Pacific coast which well be inspected but are in an uncontrolled water supply, Atlantic salmon, a different host species. So there could be different subsets - in fact very likely there are different subsets - of pathogens in all of these different groups. So it is difficult to rank them to say that they pose less of a disease risk. If these were wild adult fish that were being moved live, then I think that you might find one set of pathogens. If they are dead fish or eviscerated fish you might see a slightly different set of surviving pathogens. So I think that is a very difficult question to address. But in a general sense, wild ocean-caught Pacific salmon during their ocean phase, would be probably free of several of the disease that might be expected to be either present in freshwater, or present at higher level if the fish were reared in captivity. So that in a general sense, the fresh water fish and the cultured fish, provided they were in an uncontrolled water supply might in fact be somewhat more dangerous product than a wild open ocean fish at that stage of its life. But it really depends a lot on which diseases you are talking about.

Chairman

262. Thank you very much. Dr. Rodgers.

Dr. Rodgers

263. I agree entirely. I would just like to add - if you have a monitoring surveillance programme in place and you are using diagnostic tests which you have faith in, if you then had to rank the expected ranking, if you like, for these groups of fish in increasing risk, it would be the wild ocean-caught at the bottom, the wild fresh water migrating fish in the middle, and the cultured fish at the top (being, as Jim pointed out, the most risky fish). But it may also be that a non-monitored wild population of fish may have normal pathogens which we have not even found anything about yet, we have not even discovered yet which, put into another situation, such as a cultured situation, could cause a lot of damage.

Chairman

264. Thank you. I believe Jeff, you may have a follow-up on that. Yes, perhaps the legal advisor would like to follow up a little bit on that.

The Secretariat (Mr. Jeff Gertler)

265. Thank you Mr. Chairman. This is not directly in this question by I think it something that is of concern to the Panel here. Could you make the same sort of comparison of the relative disease risk of the Canadian salmon, that is wild ocean-caught Pacific salmon, versus risk from live ornamental fish or bait fish.

Chairman

266. Dr. Winton.

Dr. Winton

267. Again, the subsets of pathogens in these different species will be different. Ornamental fish will have their own subset of pathogens. But in a general sense, live fish that are introduced carry probably, in my view, the highest risk of any category. We have documented examples of ornamental fish carrying both Notifiable Diseases of the OIE and non-notifiable other fish diseases in international trade. Second level, might well be those fish used as bait. Again Dr. Rodgers' point is good, we may not have ever sampled them adequately to know, but in an example from the North American coast, for example, number of years ago, everyone assumed that herring were sent around as safe products up and down the coast and used as bait. We now know that Pacific herring, and in fact Atlantic herring in the Baltic and North Sea are probably the major reservoir for viral haemorrhagic septicaemia virus, and probably constitute a much higher risk than a certified population dead salmonids or eviscerated salmonids. So I would put them in the second most risky category. The most safe of the three groups would be uncertified uncontrolled open-ocean salmonids such as I have talked about here.

268. Now there may in fact be even higher levels of safety in a well inspected aquaculture environment where you have, say, a well-water source, the stock has come from a certified disease-free population, it is a single species that has been looked at for years by very good methods. In my view, that might be the safest of all of the possibilities, but of the three you mentioned, I would rank them the live ornamentals the most dangerous, the bait fish second and the open-ocean salmonids third.

Chairman

269. Thank you very much. It might be a sensible precaution Jeff, if you would record that question because I ...

Mr. Gertler

270. Mr. Chairman, - it is just this light that is not working.

Chairman

271. Right, good. That brings us to number 13, which again to any or all experts. Dr. Wooldridge, would you like to start on this one?

Dr. Wooldridge

272. I think this is possibly the most difficult question to date actually. I think, by rolling all the things under consideration into this one sentence, one tends to loose track of what we are actually talking about here. I think one needs to break it down into its constituent parts, because we are talking about uneviscerated bait fish, live fish, eviscerated fish of a different species and we have a number of different things implicit in this sentence which need considering. Most of them have been considered somewhere or another, but I think here we need to be clear about what we are trying to compare. The question is asked, whether you need to do a completely detailed scientific risk assessment for each of these situations, I think.

273. My answer is that you need to take account of all the differences in your risk assessment. You should be able to do that in a quantitative assessment in terms of the models you are using. For example, you can compare directly evisceration and non-evisceration by looking at such things as where the organism localizes in the animal or fish. So you may be able to say that the probability of the organism being in the uneviscerated fish is this, and in the eviscerated fish is that. So then, depending upon which type of fish you are talking about in your risk assessment model, you can put in the probability of whether the organism is present or not. When thinking about whether you are talking about a fish that is intended for human consumption after processing in a particular way or whether it is a live fish that is going into a water-way as bait or whatever, then you are thinking in terms of adjusting your model with a different exposure, and possibly different transmission pathways. So you would need to take account and put in the appropriate pathway for this situation under consideration. When you are talking about different species, you may need to take into account that there might be differences in where an organism may localise or the amount of viable organism that might be present in different species and in different tissues in different species.

274. So my answer is: "Sort of". You can look at all these factors in one risk assessment but it might end up with being - with looking like, or with including, several different models depending on which particular aspect you are looking at. So you may in fact end up as having effectively done a number of different risk assessments in order to compare the differences. So I am not giving a clear yes and I am not giving a clear no to that. Because it really depends, I suppose, to a certain extent, what you call a single risk assessment and how complex you need to get given the data you have got to actually compare the differences.

Chairman

275. Thank you. Would anybody else like to have an answer to that? Claudia, do you want to - ? Please.

Panel (Ms. Claudia Orozco)

276. If I may Chairman. Well thank you for that answer, and not being an expert on risk assessment I am puzzled. Because, somehow, two minutes ago - or trying to clarify an answer for question 12, there was a kind of generalization of what experts seem to understand as different levels of risk of different situations. Now we will try to see if we need a complete risk assessment then we have this full explanation. If we tie this back to question 7, it is not clear to me how far a risk assessment has to go if there is a situation like the one that we are looking at where you have identified several diseases of concern and it seems to be ... several products in types of fish and species of fish that are known to carriers of those

diseases. So, in trying to have a full risk assessment, do you need to incorporate a risk assessment of those other products, because you have identified several diseases of concern? From what you are telling us now it seems that you might need, you can - it is not clear if you can generalize or not that bait fish for example poses a higher risk or not. It seems, from what you are saying, that you might need to have a risk assessment - either complete risk assessment or part of the analysis that you are doing. But then in order to have a complete picture, do you have to expand the scope to your original risk assessment once you have identified several diseases concern and that you know that they are potential carriers out there more than the one product that you have in mind?

Dr. Wooldridge

277. I think this is partly why I said this is probably the most difficult question. I think, all I can really say, and I would like Dave Burmaster's opinion on this as well in a moment, is that it, what you do depends on the particular risk you are trying to assess. That goes back to question 7 and that takes care of varieties of products. If you need to look at the risks - or if you are trying to look at a particular disease X, and it is potentially present in certain products, you would need to do an assessment for each of those products.

278. In this question, what you are trying to do, perhaps, well - if you are trying to actually assess the probability of, say import of a given disease in a given product, and you undertake a quantitative assessment, you actually do not need to worry about the probabilities in a different product if you are only thinking about this one particular product. However, if you are trying to say which is the most risky, then you do need to know something about and possibly do a full assessment for another product. The most likely - if you had full data for your original assessment, you really would not be worried about these other products in that context. But the question, or as the problem comes, when you do not have the data you would perhaps ideally want for your initial risk assessment, and you have to base some parts of that model and the data you put into it, on knowledge from a different source, and you would then say something like, or one might say something like, "well, we have been importing this and" - or, "you have been importing that and it looks riskier so it must be alright". Then if you wish to actually compare them in a proper risk assessment fashion, you would need to actually pick out the bits that were different and show that the one you were saying was riskier, actually *was* riskier in the particular part that you were talking about. For example, if you are trying to compare the eviscerated with the uneviscerated you would want data to show where the organism localized in the fish. If you were trying to compare the *use* of the product, you would want data to compare the exposure pathways for example. I am not aware that actually clarifies things or whether I am making things more confusing. I would like Dave to come in and see if he can put it a different way that perhaps clarifies the issue from a different perspective.

Dr. Burmaster

279. Thank you Mr. Chairman. Let us see, as this question is written (question number 13), the first sentence contains a contention - a very sweeping generalization. It is a very sweeping generalization, and I guess I am sceptical of that generalization as it is written. I do not know enough to prove that it is absolutely true, I could not tell you if it is absolutely true, I cannot tell you it is absolutely false either. I cannot name here a counter-example. One of the things scientists like to do is to find a counter-example of something and say "well here is specific counter-example" and that one counter-example makes the generalization false. So I guess I cannot either support or criticize or condemn, or disagree with the generalizations written. Nonetheless, it may contain sort of the kernel of a truth. I heard one of the previous experts say that there nonetheless maybe a something of a kernel of truth in this, that eviscerated fish - I think, of the list of three that you had earlier - that eviscerated fish was the least risky. Am I correct in that?

Chairman

280. Well I think that is partly where the Panel's confusion has come from because we understood from the earlier discussion that fish put directly into the water course, which are the first two that are mentioned here, the bait fish and the live fish, are likely to be a higher risk than product which is imported solely for

human consumption and is not intended to go in the water course. So is that statement compatible with the answers that we have now heard?

Dr. Winton

281. Yes, for a couple of reasons. One, the fish that go directly in the water course bypass some of the exposure methods that might be imagined, some of which are not so likely that would accompany human consumption products, and, secondly, because some of these fish are known to be carriers of diseases and if they are particularly uncertified or unexamined, could be carrying that disease at a level as high or higher than that of an eviscerated product.

Chairman

282. And you can make that statement without having a scientific risk assessment?

Dr. Winton

283. You can make that statement for certain species of fish in certain areas of the world. I could make that statement with a high level of certainty for Pacific herring in North America. As bait fish those fish contain a significantly and quantifiably higher incidence and prevalence of infection than do Pacific salmon. Thank you.

Chairman

284. Australia, you have a follow-up - ?

Australia (Mr. Gardner Murray)

285. Gardner Murray, Yes, I will just make more of an observation more than anything else. As a sweeping generalization, everyone agrees with these kind of three levels of risk. What Australia is saying is that you have got to do more than that. You have go to do more than sweeping generalizations if you are looking at product which may have a different intended purpose. So therefore, Australia contends that whether ornamental fish, or whether bait fish, we need to do a risk assessment because the source, which are - the country factors, the number of diseases, the intended use, the pathways, the socio-economic consequences, might give you a different equation. So in short, we agree with generalizations, but the specifics are really what we are dealing with.

Chairman

286. Dr. Wooldridge.

Dr. Wooldridge

287. I think actually, that was precisely the point I was trying to get at perhaps when I said that you actually need to be able to have the data for each part where a difference may occur and compare or put into the model those differences. So for example, if you are talking about eviscerated versus uneviscerated you need to have the two parts of information to compare in the model that you are using. If you are talking about a different *use* for fish, for example bait fish as opposed to human consumption, you need to be able specifically to put the data for the different exposure pathways into that model. That is, I think, we are saying something like the same thing there. The question asked whether it would require a complete, detailed scientific risk assessment. The simple answer is, yes - but many parts of that risk assessment, many parts of the model, might already be present in your previous model for one of your other scenarios and that certain parts of that model would need to be altered specifically to take account of each of the differences which are present in the different scenarios which one might be attempting to compare.

Chairman

288. Thank you. I do not want to labour this too much, but if you were going to do a risk assessment in these three areas that are mentioned, would it not be a logical approach to start with what you perceive the highest risk area rather than the one that you perceive to be the lowest risk area. I mean, if you were going to commit resources to a risk assessment at all -

Panel (Mr. Kari Bergholm)

289. My questions goes that, in fact, I think we are here speaking not about risk assessment so much as to hazard identification. You have said that the first stage always must be a hazard identification. We know that the objective of the Australian measure is to protect their domestic salmon stock, that is the aim, the objective of their measure. Then I think the first stage of risk assessment should be hazard identification. What is your opinion as expert, what would pose the most likely hazard, in this case: the eviscerated salmon or the bait fish or the ornamental fish? If you make the hazard identification, where should you then concentrate your risk assessment? Thank you.

Chairman

290. Dr. Wooldridge.

Dr. Wooldridge

291. Yes, the hazard identification is the first step. From there, one would prioritize in whatever seemed the most logical way. I am not, as you know, a fish expert. If I had got the various scenarios suggested in this particular question, I would go and ask a fish expert which was the appropriate order of prioritization to tackle the risk assessment, and that is passing the buck, but that is the best way to do it. There is no point in me, not an expert, deciding which to do. So yes - but, and starting from a completely open beginning, it would be sensible to assess that which you have prioritized initially to have the highest risk first, but, until you have done the risk assessment, you actually cannot be sure you have got that right. So there is a circular argument here, it is a problem, you could get it wrong whatever you do, and you might never know.

Chairman

292. I thank you. Dr. Winton, you have anything to add to that? No. What about Dr. Rodgers, as the fish expert - about hazard identification?

Dr. Rodgers

293. Thank you. I get the distinct impression in this case that we are talking about wild caught Pacific salmon and not ornamental fish, which is why we are here. So the first place where you would start, if that was the premise, would be to do your risk identification, your risk assessment exercise on that group of fish. However, if you were also concerned that there were other potential imports, or existing imports, in another group of fish which had been demonstrated already through the scientific literature to be carriers or to undergo certain clinical disease outbreaks which you confidently believed by monitoring did not exist in your country, then you would almost certainly have to do a risk analysis and a risk assessment on that group as well. So as Marion said, it is a circular argument. If the issue is wild ocean-caught Pacific salmon, there is not much point in starting with ornamental fish, although they may come into the equation.

Chairman

294. But if the issue is measures to protect Australian salmon, then what would your answer be?

Dr. Rodgers

295. That is a political decision. I would have to undertake a scientific risk assessment which would give me an answer as to which was the most risky group and that advice, irrespective of which group that would be, would then be past to my civil service equivalent. I was a civil servant, I was good at saying "Yo". No, you cannot say, without doing the risk analysis, the full risk analysis, which includes risk communication, so -

Chairman

296. I think we have probably had all that we are going to get out of that. Not much point in trying to squeeze the lemon any further. Can we go on to number 14 which is addressed to all? Who would like to start on that one? Yes, Australia, are you still on 13?

Australia (Mr. Gardner Murray)

297. Yes, I was just going to sort of make another observation. One which deals with your logical approach, and second which deals with the issue at hand. The reason we are here is because there has been a request, and so therefore we have conducted a full-blown risk analysis to meet our obligations. On the second issue, that is the logic of the situation, our government has decided that a series of risk assessments need to be carried out on a range of products, and this includes additional staffing, it includes a timetable for those risk assessments. These include ornamental fish, a re-evaluation of our approach on ornamental fish; this includes a re-evaluation of our policy on bait fish. But at the same time, the quarantine service has still got to deal with requests from countries for access so it is an enormous effort. Concurrently you have got to deal with requests from Canada and other countries and do risk assessments while at the same time you have got to look at those areas that you wish to examine because you continually want to protect your fish health status and this is the balancing act that Australia is involved in at the moment.

Chairman

298. Thank you. Right, well, obviously we will no doubt have the opportunity to go into that sort of issue a bit further tomorrow. For now I think perhaps we could pass onto the next question. Which of the experts would like to address number 14? Dr. Burmaster?

Dr. Burmaster

299. Thank you Mr. Chairman. I am unaware of any advances in scientific knowledge that occurred between May of 1995 and 1996 which would justify the changes between those two documents.

Chairman

300. Thank you. I am sorry, could you repeat that answer again please.

Dr. Burmaster

301. Yes, I will repeat it. I am unaware, I am not aware of any advances in scientific knowledge that would justify the changes and conclusions between the May 1995 Draft Report and the 1996 Final Report.

Chairman

302. Dr. Rodgers.

Dr. Rodgers

303. I think all the experts are in agreement.

Chairman

304. Right, well in that case, let us go on to number 15 and this is the one where I had an addition. I suppose you have noted my addition to that, Dr. Winton.

Dr. Winton

305. You have only made the question more difficult but I will attempt to answer it. I think I have already tried to state that evisceration really is seen as a way to reduce the risk, perhaps not just of Notifiable Diseases but of other diseases, but certainly in different levels with respect to the nature of the disease, where the organism might be found and at what levels . For each disease we have some, but perhaps not enough information, to be able to rank them convincingly. Relative to evisceration for *Renibacterium salmoninarum*, IHN virus, salmon leukaemia virus and *Henneguya* it is sort of tough. For example, *Renibacterium salmoninarum*, is generally regarded to be a pathogen exclusively of salmonid fish and, as its name suggests, *Renibacterium* is primarily associated with bacterial kidney disease. It is found in large amounts in the kidney and in other haematopoietic tissues (kidney, spleen) and to that extent would be reduced significantly by evisceration. But foci *Renibacterium salmoninarum* have been found in other places in the fish, maybe less frequently, but behind the eyes is one, occasionally in the muscles. *Renibacterium* is generally vertically transmitted from adult to progeny through the egg, in many cases of Chinook salmon and salmon in the North West, and occasionally by water-borne exposure but the water-borne exposure levels are somewhat lower. But the effectiveness of evisceration for *Renibacterium salmoninarum*, in general, is quite good in that the visceral organs would be the areas in which you would expect to find the highest levels of bacteria. Similarly with IHN virus - this is primarily a virus of the haematopoietic cells - the kidney, the spleen of the fish, and likewise would be found at high levels in the viscera. But examinations of different tissues and organisms, organs of fish, have also revealed levels of IHN virus in the mucus and skin of the surface of the fish and certainly in the blood, so again, evisceration could be judged to provide a substantial, but perhaps not complete level. I am unaware of sufficient data on salmon leukaemia virus to be able to make a judgement but presumably it would be found primarily in the blood cells of the fish and to the extent that evisceration removed the blood which must be 90 some per cent, it could be expected to be somewhat effective there as well. For *Henneguya* I would refer to Dr. Rodgers, a little bit because I am not a parasitologist by training, but *Henneguya* does not survive all that well except on live animals like a lot of parasites. I think it would be tough to judge in my view, and I guess evisceration probably would not make as much difference as it might for the other diseases.

Chairman

306. Thank you. Dr. Rodgers.

Dr. Rodgers

307. I agree, but I am a bacteriologist as well so - No, I agree that it does not survive particularly well outside of the host, and this probably would be an effective method particularly with the washing step included in evisceration.

Chairman

308. Thank you very much. So if there is nothing more on that perhaps we can go onto 16 which is addressed to all. Who would like to start? Dr. Wooldridge.

Dr. Wooldridge

309. We have - and I think I touched upon this in the written answers that I gave you (the extra ones) this morning. With a risk assessment one would normally look at a baseline with either no safeguards in place or the current level of safeguards in place. If that produces an unacceptable risk, then one needs to look at the assessment with various safeguards in place. If you already have quarantine requirements as part of your normal safeguard then I can see no reason why they should not be included in your initial

assessment. If you actually end up by having an assessment result that gives you an acceptably low risk having put in place vast numbers of additional safeguard measures, then, without looking at the intermediate stages, I think that probably is not acceptable. But we do not have that situation here; we have a situation where even putting in place all the safeguard measures, the risk assessment has come out giving an unacceptable level of risk. So the conclusion is to my mind that in order to be acceptable as things stand at the moment to Australia, they would need to be even more safeguards in place which we are not sure what they might be at the moment. So - in *their* terms we have not yet reached the appropriate level of protection. So what I am trying to say is that if we have reached what they consider to be the appropriate level of protection and that perhaps in fact that had been reached at some way prior to putting in all those safeguards, then the appropriate methodology would be to actually go back and look at the problem with fewer safeguards in place. But in their terms we have not reached that point, so that is not, from their point of view, yet an appropriate option. Does that answer the question?

Chairman

310. I think so but I think we may need to provide a bit of clarification. I am going to ask the legal advisor to just say a word or two on that.

The Secretariat (Mr. Jeff Gertler)

311. Thank you Mr. Chairman. Just to point out that the current safeguard as we understood it here what heat treatment and should that be built in? Does that change your - modify your response in any way?

Dr. Wooldridge

312. In as much as heat treatment changes the product, we are then effectively looking at a different scenario so what you are then saying is that - I think logically you should, well, what, - What am I trying to say here? Let me try and get this right. Heat treatment did not even - if the level of protection is acceptable without heat treatment, then any other safeguards, for example, removing offals, de-boning etc., it is acceptable to include them in the methodology. If heat treatment takes you to the stage where you change from unacceptable to acceptable, then you do need to have two different risk assessments, one included and one not, in order to compare the differences and say "this is where we find it acceptable and this is where we find it unacceptable". It would not I think be enough to just do a risk assessment with heat treatment in it, quantitatively, now I am talking about, and say "we need this safeguard". I think it would be necessary to show that without that the risks were unacceptable. Does that clarify the -

Chairman

313. Thank you. Dr. Rodgers.

Dr. Rodgers

314. I would just add that I think what Marion is trying to say is that you can adapt the model, if you like, by putting in and taking out your, in this case risk management measures, your risk reduction factors, to see how it effects the final result. Heat treatment is a potential risk reduction factor, as well as evisceration for instance - but it may be the last one, the most effective, but you would not know until you had incorporated it into the model and seen how it would effect the overall result.

Dr. Wooldridge

315. I think the point of the question, I think, was to try and work out whether simply saying "we need to do that in order to make it acceptable" is good enough. Do we need to actually show that the level below that is unacceptable. I think if you are going to say we need to do that as an extra over and above the normal measures of quarantine or testing that we would take, then you do have to actually do the two

and show the difference. To just go straight in and have a risk assessment that includes heat treatment when heat treatment is not your normal baseline safeguard is not appropriate methodology.

Chairman

316. Thank you. Yes, Jeff.

The Secretariat (Mr. Jeff Gertler)

317. But let us assume, as my understanding of it is to be the case in Australia, that heat treatment is the normal baseline safeguard, is it then appropriate to build it in to your risk assessment or should you still do one with and one without that safeguard?

Dr. Wooldridge

318. Since I think heat treatment effectively changes the product, I mean, if you are looking for muscle meat and you eviscerate and you de-bone, you have not changed the product, you are giving the consumer the product that they think they are getting. If you heat treat that actual muscle you are changing the product, therefore you are effectively importing a different product. Therefore if you are talking about the import of salmon, uncooked, unheat-treated, fresh salmon, then that is not actually a safeguard that you can put in place and still have the same product. So you do need to actually do a risk assessment which does not have that in place to get a level of risk out of that to decide whether that is acceptable or not.

Chairman

319. Thank you. Sorry, go on.

Dr. Burmaster.

320. Okay, thank you Mr. Chairman, that is an interesting answer. It is very difficult to import fresh salmon that had been cooked. I think that is a contradiction in terms. If you are interested in doing a risk assessment on fresh salmon I think you do it on fresh salmon and there is an old adage in computer science I want to bring up, but first let me sort of set the stage. I think that the type of risk assessment that needs to be done in this situation is one that would be done somehow using computers and software to do a simulation. It would have many of the characteristics in the report as prepared by David Vose. This report would be a computer simulation that would consider various risks, various options. Now the adage from computer science, is that the purpose of computation is insight and it seems to me that if there is a contention here in the room about what effect does cooking have, well you could build a computer software to include a toggle switch where you have cooking yes or cooking no and you run the software two different ways, one with the toggle on, you get some results, and one with the toggle off and you get a different set of results and you compare the difference. From that difference you try to figure out what is going on, what is going on in the computer programme and what is going on in the real world. So I guess those are my two thoughts.

Chairman

321. Thank you very much. Does anybody have anything else to add to that? Well, I think that brings us to the end of the list of questions. We have dealt with seventeen. I propose at this stage to invite the experts one by one to make any concluding remarks that they may have, rounding up the discussion and stressing any views and conclusions that they regard as important. Perhaps we can proceed in alphabetical order again. Dr. Burmaster.

Dr. Burmaster

322. Well, at the risk of simply reinforcing what I have stated in my written response, and in my spoken comments here today, I think there is a consistent theme and I may just as well round out the

afternoon by stating it fairly bluntly. To my mind, the documents prepared, both the May, sorry, let me get the dates out here, the two risk assessments, so called, prepared by Australia in 1995 and 1996, do *not* meet what I consider to be the minimal requirements of a risk assessment. So in the last couple of weeks I have posed myself - well, they are long thick documents and there was a great deal of effort put into the preparation of these documents, it was a sincere effort on behalf of Australia to prepare those documents. What could they possibly be? If they are not risk assessments what could those wonderful, those long thick documents be? And I guess I come to the point of view that they are hazard identifications. They are long, and I think thorough, and if I understand Dr. Winton's and Dr. Rodgers's comments, they have really looked at a comprehensive list of the bacterial and viral diseases that could *possibly* be transmitted into fish in Australia. But because there is no quantitation, there are no quantitative arguments, it is for that reason, I believe that these documents prepared by Australia, do not meet my definition of what the minimal requirements for a risk assessment. So I think we have all been reading very thorough hazard identifications and we are yet to read a risk assessment from Australia. Thank you.

Chairman

323. Thank you very much. Dr. Rodgers.

Dr. Rodgers

324. Thank you Mr. Chairman. I really have not got any extra comments and I would not like to sum up the whole day in two minutes. I stand by what I said this morning in my opening 20 minutes. The only point I would like to reiterate from what I said this morning is that I think that everybody is in general agreement that there is a level of risk, and whether that risk is then acceptable or not is the key issue. That level of risk can only be acceptable providing you put in place a risk management procedure which is a risk reduction, a set of risk reduction factors, which are acceptable to both parties. That is the only way you can get some leeway in the situation. But personally I think that looking at the SPS Agreement and the OIE guidelines that it does seem that a country can set its own level of - its own acceptable level of risk, whatever that is. Just coming back to what Marion was talking about now, is that somewhere down the process, somewhere, by building in a set of risk reduction factors, you reach a point where you do find an acceptable level of risk. Now that may be when you have finally put in the last risk reduction factor or it may be in the middle. It is just something which has to be done by risk analysis and also by negotiation if the parties cannot agree on what that acceptable level of risk is.

Chairman

325. Thank you very much. Dr. Winton.

Dr. Winton

326. I only have two comments and I hope they are relatively short. One from the OIE Fish Disease Commission standpoint, in question 6 which we actually ignored, in the last statement is this actually the OIE recommendation, i.e. evisceration or a *de facto* standard. I think I have tried to explain that the OIE Fish Diseases Commission, in the absence of information to the contrary, viewed evisceration as taking that risk to below that would remain in the purview. But to some extent it is also a *de facto* standard in that many salmon-trading countries have viewed evisceration as acceptable for imports, for example regulations in the United States, the entire European Community and in Canada, now allow the importation of eviscerated without inspection regardless of origin. So to some extent, many of the salmon-trading partners have already decided this by themselves and so it is hard to say it is a *de facto* standard but it is not the OIE Fish Disease Commission that is actually pushing this, it is more widely I think understood.

327. Secondly, I think today has pointed out the very great need for additional scientific information. As a researcher I go away from here really with the understanding that we need a lot more information on things like decay curves of pathogens, reservoirs of infection, transmission mechanisms, the basic epidemiology of fish diseases. I think many of these disagreements are partially a reflection of the absence of information, and Australia's coming down in the absence of information with a more conservative

approach; Canada in the absence of the same information with a more trade-orientated approach. But in neither case are all the data available by which to construct the final perfect quantitative risk assessment. For example, as detection methods improve it would not surprise me to find *Renibacterium salmoninarum* in some Chinook salmon in Australia. I cannot predict that for certainty but I would be willing to bet a substantial amount of money on it. The same issue occurred in New Zealand when we developed a new test for *Renibacterium salmoninarum*. We went looking for negative control tissues for our test and we were sent some tissues from New Zealand, and in fact we found low levels of positives, and by exhaustive examination we actually in our laboratory have evidence that very few numbers of those salmon are in fact at that very low sub-clinical level. This is not unexpected given the fact that Chinook salmon were brought to New Zealand from the United States, and that this disease is commonly transmitted with the eggs. So I think that as detection methods and our understanding and our data improve, many of these issues will begin to resolve themselves and I apologize, as a scientist, that we do not have sufficient data that this large exercise has been necessary. I think perhaps had we been better at our jobs a lot of this information would have been available and it would have been easier to make these sorts of decisions. Thank you.

Chairman

328. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

329. I am not sure that there is a lot left to say really, we seem to have said quite a lot already but I would just like to reiterate, restress two points which are very important from my standpoint and the way I see things. The first one is the absolute necessity of differentiating between the assessed and the acceptable risk and I think at the beginning of the day maybe that was not quite so clear. I think we all know now that there is a difference between the two and they both need to be taken into consideration but in different ways. The other point I would like to make is that I see risk assessment as a sort of a fairly pragmatic process, in a way, in that you start at the simplest level with what I would call a qualitative risk assessment, what Dave Burmaster would call a very thorough hazard identification, and if everybody agrees on the results then that is as far as you need to go, bearing in mind things like these are incredibly costly, time-consuming etc.. However, if there is disagreement then you need to go to the next step, and the next step is probably to undertake, or attempt to undertake a quantitative assessment. And if you do that successfully and everybody agrees, fine. But if you find that you do not agree on the data or the data is not available, then you need to go to the next step and put in place the required epidemiological or bacteriological or other studies or experiments to get the evidence in order that you can complete a quantitative risk assessment. So I think you go as far as you need to go until you can get appropriate agreement on the level of risk by all concerned. And when you have got that - that was the easy bit - you then have the difficult bit sorting out what is acceptable. Because we have all discovered that varies, and I think that is actually much harder to agree on and that is really all I have got to say, thank you.

Chairman

330. Well, thank you very much. I think it only remains for me to thank the experts for their very patient and expert answers to our not always very expertly phrased questions. I think at the end of the day it will be clear that your input has been extremely valuable to the work of the panel and we are very grateful to you for participating in this process today and for the written work that you produced before that. So thank you all very much indeed. We will meet tomorrow morning with the parties at 10 o'clock in Room C, downstairs, and continue our process there but as far as the experts are concerned, thank you. That now concludes our session for today and have a safe journey home. Thank you very much.

ATTACHMENT

Questions Posed during the Joint Meeting with Experts, held on 4 February 1998

1. **To Dr. Winton:** With reference to the Panel's initial Question 3, do you believe that a risk assessment must consider the **probability** of risk or is it sufficient to identify the possibility of risk?

2. **To Dr. Rodgers:** We remain somewhat confused regarding your views on probability versus possibility in terms of risk assessment. In some of your written responses, you appear to equate estimates of probability with quantitative risk assessments and conclusions of possibility with qualitative ones. In another response (to initial Question 1), you indicate that the May 1995 Draft Report uses a qualitative risk assessment methodology to identify probabilities to disease introduction. Could you please clarify your views on the differences in these terms in the context of risk assessment.

3. **To Dr. Rodgers/Canada:** With regard to the identification of possible diseases in Canadian salmon, Dr. Rodgers has identified four disease agents not included in Canada's list (*Kudoa thyrsites*, *Parvicapsula* sp., flexibacteriosis and proliferative kidney disease (PKD). Canada argues that these should not be included in the Panel's consideration because the first two disease agents have not been found in adult, wild ocean-caught Pacific salmon and PKD is not known to occur in any of the five categories of adult salmon. Furthermore, Canada notes that Australia does not include *Kudoa thrysites* or flexibacteriosis on its most recent list of diseases of concern. To what extent does Dr. Rodgers believe these diseases are of sufficient concern to be considered in the evaluation of risks?

4. **To Dr. Rodgers and Dr. Winton:** With regard to concerns about "carrier fish" as "reservoirs" of a disease agent, to what extent is this concern applicable to dead fish (rather than live fish)? to eviscerated fish?

5. **To Dr. Rodgers:** Are salmon scavengers? Will they eat scraps of salmon meat?

6. **To Dr. Winton:** The Final Report refers to the "... current international standards for trade in salmon product for human consumption, that is, OIE recommends that product be eviscerated and that no other risk reduction measures need be taken". Is this actually the OIE recommendation, or a de facto standard?

7. **To Dr. Wooldridge:** Could you please clarify whether you believe that a risk assessment should consider risk on both a disease-by-disease and a product-by-product basis, or one basis or the other? Response to 2.4.3 seems to suggest two alternative approaches - what is the risk of exotic disease Y being introduced by product X? or what is the risk of introducing exotic disease Y, independent of the product. Are these two alternative models or once you decide there is evidence or suspicion that exotic disease Y might be in product Z, do you need to broaden the risk analysis for any other product of which you have evidence that carries disease Y?

8. **To Dr. Rodgers:** To the extent that a particular disease has not been found in a category of fish, can one assume that the probability of its existence is very small?

9. **To any/all of the experts:** If a disease has not been found to exist in fish from specific waters/area, should this disease nonetheless be considered in a risk assessment of fish from this area? If several diseases are included in a risk assessment model because there is suspicion that the product in question may be a carrier, and during the analysis evidence does not show that the disease is known to exist in the product in question, i.e. the first event in the chain of events does not occur, should you narrow the analysis to the diseases confirmed to be in the product in question?

10. **To all of the experts:** solicit comments/reactions to the "Vose Assessment" provided by Canada.

11. **To Dr. Burmaster:** In responding to Question 6 regarding the consequences for disease establishment regardless of the imported host, you indicated that you believed the statement was correct

and that you could not think of a counter-example to this principle. Do you believe that this principle is valid in virtually all circumstances? Do you believe that this principle is valid in regard to the fish diseases of concern as identified by Australia?

12. **To any/all of the experts:** Do you believe that adult, wild, ocean-caught Pacific salmon pose less of a disease risk than the other categories of salmon identified by Canada (i.e., (i) adult, wild **freshwater-caught** Pacific salmon; adult, **Pacific** salmon cultured in seawater on the **Pacific coast**; adult, **Atlantic** salmon cultured in seawater on the **Pacific coast**; and, adult, **Atlantic** salmon cultured in seawater on the **Atlantic coast**)?

13. **To any/all of the experts:** Australia contends that the "generalization that uneviscerated baitfish or live fish pose a greater threat than eviscerated fish of a different species cannot be substantiated without reference to a risk analysis including detailed scientific risk assessment." Do you agree with this contention?

14. **To any/all of the experts:** The Panel previously asked (Question 18) if there were any advances in scientific knowledge that would justify a change in the conclusions from the May 1995 Draft Report to the 1996 Final Report? Are you aware of any such new scientific information?

15. **To Dr. Winton:** Australia characterizes your responses with regard to evisceration to be limited to the FDC list of "notifiable" diseases. Do you believe that evisceration provides the same effective reduction of risks for "non-notifiable" diseases?

16. **To any/all of the experts:** Australia indicates that "Options for pre and post entry quarantine conditions on imported product were built in to all stages of the risk analysis and can not be separated out. This includes .... evaluation of measures for reducing risks and consequences in the context of the appropriate level of protection." Is this an appropriate methodology for consideration of various sanitary options for reducing risks to the acceptable level? Article 5.6 of the SPS Agreement requires that

> "... when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."
>
> A footnote to this provision indicates that:
>
> "For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."

17. **To any/all of the experts:** If, in your view, an option-by-option assessment is one of the minimum requirements of a risk assessment, is it enough to "assess" the risks associated with each of the SPS options (i.e. risk reduction measures) a country is considering? Or does one also need to "compare" the risks related to these different options and in the end give a rational explanation, in terms of relative risk, why one option is chosen rather than another?