ANNEX J

TRANSCRIPT OF THE PANEL'S JOINT MEETING WITH SCIENTIFIC EXPERTS OF 17 AND 18 FEBRUARY 2005

Chairman

1. Good morning. I would like to welcome the parties and the experts, Doctors Andow, Healy, Nutti, Snape, Snow and Squire, to this meeting of the Panel on the European Communities – Measures Affecting the Approval and Marketing of Biotech Products.

2. At the outset, I would like to remind you that the meetings of panels in the WTO are tape-recorded. I would also like to remind you that at today's meeting as well as the meeting of tomorrow, English/Spanish simultaneous interpretation will be provided, as requested by Argentina. So please be sure to use the microphones when addressing the Panel and, above all, speak SLOWLY. I would like to express my sympathy with the interpreters for this meeting, considering it's extremely technical nature. I would like to remind the experts and the parties that there are constraints and difficulties of interpretation and therefore technical jargon will only be properly interpreted if it is delivered at a reasonable pace.

3. May I begin by introducing the Members of the Panel: Mr Mohan Kumar, Professor Akio Shimizu, and myself, Christian Häberli, who will be serving as Chair of the Panel.

4. I would also like to introduce the Secretariat officials who will be assisting the Panel: Mr ***** *****, Secretary to the Panel, Mr ***** *****, Legal Officer, Ms. ***** ***** from Agriculture Division and Ms. ***** ***** from Trade & Environment Division. Finally, I would like to inform the parties of the presence of Mr ***** *****, Junior Economic Affairs Officer from Agriculture Division and Mr ***** *****, an intern with the WTO Legal Affairs Division.

5. I would like the Heads of Delegations to introduce themselves and the other Members of their delegations. If your delegation has not yet done so, it would be appreciated if you could submit a list of your delegation's members to the Panel secretary. In introducing the Members of your delegations, you must indicate any individuals which are NOT authorised to have an access to SCI, if any are present.

Argentina

Delegation of Argentina

Ernesto Martinez Gondra (Head of Delegation)
Minister
Deputy Representative
Permanent Mission in Geneva

José Luis Pérez Gabilondo,
Minister
Director of International
Economic Dispute Settlement
Ministry of Foreign Affairs, International Trade and Worship

Eduardo Tempone,
Minister
Permanent Mission in Geneva

Gustavo Lunazzi,
First Secretary
Permanent Mission in Geneva

Esteban A. Morelli,
First Secretary
Ministry of Foreign Affairs, International Trade and Worship

Gustavo H. Méndez,
Second Secretary
Ministry of Foreign Affairs, International Trade and Worship

Dr Roxana Blasetti,
Secretariat of Agriculture, Livestock, Fisheries and Food

Dr Maximiliano Moreno,
Secretariat of Agriculture, Livestock, Fisheries and Food

Dr Moisés Burachik,
Office of Biotechnology
Secretariat of Agriculture, Livestock, Fisheries and Food

Mr Martín Lema,
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Secretariat of Agriculture, Livestock, Fisheries and Food

Canada

Delegation of Canada

Mr Torsten Ström (Head of delegation)
Senior Counsel, Trade Law Bureau
International Trade Canada/Department of Justice

Mr Kevin Thompson
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Ms. Chris Moran
Senior Trade Policy Officer, Technical Barriers and Regulations Division
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Ms. Jodi Robinson
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Ms. Elizabeth Macaulay
Paralegal, Trade Law Bureau
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Ms. Chantal Sicotte
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Ms. Nora Lee
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Health Canada

Mr Phil Macdonald
National Manager, Environment Release Assessments, Plant Bio-safety Office
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Ms. Kathleen Mackay
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Permanent Mission of Canada to the European Union

Mr Rambod Behboodi
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Permanent Mission of Canada, Geneva

Mr Vasken Khabayan
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Permanent Mission of Canada, Geneva

United States

Delegation of the United States

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Dr Eric Flamm
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United States Mission to the European Union

Kristina Kvien
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European Communities

Delegation of the European Communities

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Eric White, Legal Adviser of the Legal Service

James Flett, Member of the Legal Service

Sybilla Fries, Member of Legal Service

Elisabetta Righini, Member of Legal Service

Eric Schoonejans, Member of Legal Service

Luis Portero Sanchez, DG Trade

Jean Ferriere, DG Trade

Andreas Klepsch, DG Sanco

Paivi Mannerkorpi, DG Sanco

Sylvie Mestdagh, DG Environment

Barbara Weber, DG Environment

Stephen Langrell, JRC (17 & 18)

Philippe Sands, External consultant

Experts

Gijs Kleter (17-18)

Angelika Hilbeck (17-18)

Nicholas Birch (17-18)

Jeremy Sweet (17-18)

Arne Holst-Jensen (17-18)

Philippe Sands

Sue Hartley (17-18)

G. Fandan Aider, Joint Research Centre

Geneva

Raimund Raith, Minister-Counsellor/Legal Adviser

Lars Berner, First Secretary

Franz-Rudolf Schloeder, Counsellor

Marie-Pierre Nicora, Attaché

Member States

France

Cédric Pene, Counsellor, Agriculture

Germany

Ursula Holzhauser, Counsellor

Malte Hauschild, First Secretary

Tobias Maass, Intern

Italy

Dario Ciccarelli

Finland

Jukka Pesola, Counsellor

Chairman

6. Thank you EC. I believe Argentina has not responded to my question on strictly confidential information. Would you care to respond? Thank you

Argentina

7. I confirm that they are all authorized.

Chairman

8. I am turning to the establishment of the Panel's terms of reference. I wish to recall that at its meeting on 29 August 2003 the Dispute Settlement Body has decided in accordance with Article 6 of the DSU to establish a panel pursuant to a request of the US, Canada and Argentina, documents referring are WT/DS291/23, WT/DS292/17, WT/DS293/17. I recall that the Panel held the first substantive meeting with the parties on 2 and 3 June 2004. Both the Panel and the parties recognized the need for the Panel to consult with experts possessing specialized and scientific expertise on the issues arising in the dispute. In consultation with the parties the Panel agreed working procedures for its consultations with scientific and technical experts. These working procedures were communicated to the parties on 13 August 2004.

9. We have consulted with six international organizations such as the CODEX Alimentarius, FAO, WHO, IPPC, OIE and the Convention on Biological Diversity and having received the views of the parties the Panel has appointed Dr Andow, Dr Healy, Dr Nutti, Dr Snape, Dr Snow and Dr Squire to serve as scientific experts in this dispute. Initially only Dr Andow, Dr Nutti, Dr Snow and Dr Dr Squire were appointed, but it turned out that there are two issues which cannot be covered by any of the four experts which are detection methods and molecular characterization. The Panel, after having had the views of the parties, therefore appointed Dr Snape and Healy. Dr Snape was invited to answer questions concerning molecular characterization only. Dr Healy was invited to do so concerning molecular characterization and detection methods only. This applies for this meeting as well.

10. In accordance with the working procedures and after comment by the parties, the Panel, communicated questions to the experts, the experts were requested to reply in writing by 5 January and these replies were communicated to the parties. Comments received from the parties on the expert replies were circulated to the experts. The purpose of today's meeting is for the Panel to meet the experts to discuss their written responses to the questions and to provide further clarification as appropriate. The parties will also be given an opportunity to discuss these responses by the experts to the questions.

11. This is a two day meeting and it will proceed in the following manner. First I will give the experts an opportunity to make introductory or general remarks. The experts may wish in particular to address any point where they believe further clarification is needed in the light of the parties' comments on an earlier response to a question. Then I will give the parties a brief opportunity no more than 15 minutes for any general introductory remarks they may wish to make. Note has already been taken of the remarks they have expressed in writing. Then for each issue I will open the floor to

the parties to ask questions. The Panel will also ask questions of the experts. Finally when we have concluded with each issue I shall allow the experts time to make closing remarks should they so wish.

12. Concerning the questions by the parties to the experts the Panel will proceed as follows. For each issue the Panel will first give the complaining parties a period of time within which to ask their questions of the experts. The complaining parties would ask their questions in alphabetical order. Thereafter the EC will be given approximately equal periods of time to ask their questions to the parties including any follow-up questions to those asked by the complaining parties. After the EC has exhausted its time the complaining parties will be given again a very short opportunity to ask specific follow-up questions on their own. Subsequently the Panel will address its own questions to the experts.

13. In making their remarks both the parties and the experts are requested to minimize redundancy with what they have already submitted to the Panel in writing. We can take it that the Panel has read your submissions, your remarks, and your questions so there is no need to repeat them. With regard to the issues to be considered as requested by the EC the Panel would like to proceed as follows. On this first day the meeting will address the general questions and then move on to Issue 2 (safeguard measures) and Issue 3 (comparison of biotech products to other types of products). This we expect will take the whole day and will probably move into Issues 2 and 3 only in the afternoon depending on how it goes this morning. Tomorrow on the second day we will start again at 10 and start with Issue 1 that is the all product specific questions and then if necessary any remaining time can be used for discussing further on any of the issues addressed today before moving to closing remarks by the experts.

14. I should further remind the parties and the experts that the proceedings of this Panel are confidential as provided for in Article 18 of the DSU. I would like to request the parties and the experts to state in advance if they are going to refer to the SCI information when they do so. This is important to ensure the proper handling of this information including in the preparation and the transcript of this meeting. The experts may want to refer to various documents including the parties' submissions and exhibits. These documents are either filed in the binders placed on the cart over there or in the CD ROMs which can be opened and viewed in the laptop computers which are near your seats. The Secretariat staff is ready to help you locate these documents if you wish so. Unless there are any comments or questions on this procedure we can now proceed to hear the experts' introductory remarks. There are no questions from the floor. I will therefore suggest that we hear from the experts in alphabetical order starting with Dr Andow. You have the floor.

Dr Andow

15. Thank you very much Mr Chairman. I would like to make just a few very short comments. The first is to indicate my very great pleasure at being able to serve at the Panel's request as an expert to the Panel on this important issue and I greatly appreciate the opportunity. Second, I would like to address the parties and say that I was quite pleased to read all the comments on all the experts' replies and was very interested to see how these comments have developed the issues. I hope that through the questioning that occurs today we can clarify some of these issues further. On that point I would like to start with a bit of an apology regarding the clarity and language in some of my comments. It is clear from some of the comments that I read that - let me put it this way - as the Panel Chair told us this morning there is WTO language and there is biotech language. It is pretty clear that many of my questions/answers were written more in biotech language. I will try my best to make the translation more clear so that my point is clear to the various parties. That is my introductory piece.

16. Let me say a little bit about myself. I was trained as an ecologist at Cornell University with my PhD in ecology with a minor emphasis in evolutionary biology. My training is an environmental science. I tried as much as possible to emphasize the environmental aspects in terms of the answers my responses to the questions from the Panel. I would simply like to say in the 25 years since taking my PhD I have been involved in many of the environmental issues associated with biotech issues starting primarily with the USEPA and some of their work. I then assisted the USDA in an advisory panel to the Secretary of Agriculture. More recently I have been doing work associated with international dimensions of these issues. I am pleased to be able to be here and I am looking forward to interacting with you all. Thank you very much.

Dr Healy

17. Thank you Mr Chairman. I also would like to thank the Panel for inviting me to contribute to this process. I found it both interesting but also very challenging even though I have had a more narrow focus than some of the other experts. Now having read the responses of all the experts and the comments that have been provided by the countries there quite clearly appears to have been different approaches adopted by the different experts to answering the questions. I think this comes out especially in relation to the product-specific questions. I want to make a few comments on how I approach the task and in doing so to raise some of the issues that I think are pertinent to the interpretation and perhaps the intent of the questions and the subsequent responses. A number of the questions that I addressed around molecular characterization identified a particular request for information and asked if it was necessary to ensure the safety of the product. The approach that I took to this task was to review all the relevant information up until the time of the request that was identified in the questions.

18. I considered the molecular characterization information in the context of all the relevant available information up until this time. I point out that this approach is consistent with the current international standard as well as the long standing practice and consensus around the world. But what I did not do was a retrospective analysis of information that had been provided after the date identified in the question. Differences in approach to handling information have lead to confusing responses by different experts to the questions and commentaries coming from the countries.

19. In addressing questions I considered if the additional information was likely to have an impact on the safety assessment. There are also critical differences of approach in the criteria that are used for assessing safety. The criteria that I used are generally those set out in the Codex documents. However, it has to be recognized that those Codex documents in relation to food were adopted in 2003, while many of the discussions of the data requirements in the questions were referring in the late 1990s as well as in the early 2000s. The question of the criteria by which to judge safety is quite an important point. Nonetheless, in terms of using the Codex documents I think it is a reasonable approach. While the agreement of Codex was reached only in 2003 there was a general view in the years prior to that about how to approach this issue. The Codex documents are actually using those principles.

20. Another point relating to the judgement of the data comes to whether we should judge the data by today's standards or by the standards that were in place at the time. This is particularly important in the case of the molecular characterization because the technologies have changed considerably through the period that we are talking. This was a question on my mind at the time of answering the questions. Often I decided that I would place greater emphasis on the state of knowledge at the time the discussion was happening and when various data requests were coming into play. That is another point of difference that comes through in some of the replies of experts, as well as some of the commentary from the different countries.

21. Different types of molecular techniques are available in common practice today. The standard of molecular characterization that you might expect in response to a question asked today is quite different to that which would have been expected at the time the questions were actually asked. I want to summarize the principles that I adopted in addressing the product-specific questions. Firstly I took a case-by-case approach and examined all the available information for each of the products in relation to the question that was being asked. I considered the totality of the information also taking into account what information was missing. I want to put some emphasis again on this totality of information approach.

22. I also took a weight of evidence approach. Thinking about what position the weight of evidence supported, recognizing that there are possibilities of other effects. I focused on addressing the question whether the additional requested information was necessary to ensure the safety assessment. It is important to recognize that a view about the safety assessment is not necessarily a view about the technical excellence of the information that is provided. The information has to be obviously sound but there are quite clearly some technical deficiencies at various places. This relates to the issue of considering the totality of the information and the weight of the information.

23. The final point I want to raise is that there was some commentary in the country comments about the fact that I worked for a government agency. I want to highlight that this is a matter of record. In relation to food this has been the case since 1998. It was certainly in my CV. However, in the capacity which I have been undertaking these activities I have been providing independent advice to the Panel as was required and in fact for the majority of the time that I have worked on the written responses I stood aside from my government position or was undertaking the work over the Christmas period. This is true aside from several days from the beginning of January, the 4th and 5th of January. I need to point out in turn that in attending this meeting I am also here as an independent expert and not as a government representative and so my comments will be confined to those matters that the Panel has asked me to comment on. Thank you.

Dr Nutti

24. Thank you. I also would like to say that I am glad to be an expert in this Panel and that it was a unique opportunity to be in contact with all the documents that were submitted to us. I would like to tell a little bit about my background because I asked to answer about food safety and nutrition. I am a food engineer with a background in nutrition. I work for the Brazilian Research Agriculture Corporation where I am responsible for the bio-safety of GMOs project. We are a network of 120 scientists that are evaluating the safety of the GMOs being developed in Brazil. I don't work for the government, I work for a research centre that is linked to the government. I am here as an independent expert. In the beginning I pointed out to the Panel that I was not going to address any issue related to environmental and molecular characterization. As far as detection matters were concerned I would try to find some literature to help with the answers but not given any conclusions on that because even that was not my field of expertise.

25. With respect to some of the comments that the countries sent I would like to point out that although there might be some misunderstanding about substantial equivalence we use it as a step for risk assessment and not for the risk assessment itself. In my responses I was looking at the composition as the first step and not as a conclusion. It is the first step that you need to take into account. After the compositional analysis you go to the toxicological and animal feeding studies. I have been in the Codex these last ten years and also in the WHO, FAO expert consultations as one of the roster of experts. I will be happy to answer your questions. Thank you.

Dr Snape

26. Good morning ladies and gentlemen. My background is in crop genetics. I have extensive experience of research in cereals and cereal biotechnology and the handling of molecular analysis of transgenic wheat, barley, rice and bananas. But my remit for the Panel has been fairly restricted and my comments and conclusions are restricted only to the molecular characterization and the answers to questions 12, 16, 18 and 25.

27. I should add that I found this a rather complex task given the amount and complexity of the information that was presented. However, in my evidence I have tried to compile together all the molecular information for each product to assess whether this is sufficient for the assessment of safety and as Dr Healy alluded to, I have considered each product independently and all the information independently for each product. In interpreting the information my main objective was to assess whether a comprehensive characterization of the information had been provided and also whether this information that had been presented - the molecular information - had been correctly interpreted in its submission. This was the basis of my conclusions. My interpretation is based on a number of technical issues concerning the size and copy number of the transgenic sequences, the organization of those sequences, the organization of flanking and any backbone sequences in the transgenic plants. This is the information which I tried to draw conclusions based on the scientific evidence to suggest whether it is required for the safety assessment. I will conclude with those very brief remarks and I will be happy to answer any questions on the molecular characterization of the products and my interpretation.

Dr Snow

28. Thank you I am Alison Snow, Professor of Biology at Ohio State University. I am pleased to be here and I could echo many of the comments that have been made already. As you know my answers refer primarily to environmental questions about these products and that is my training as an ecologist. I have been involved in looking at the environmental effects of biotech products for many years now.

29. One of the big challenges I think of doing this kind of work is taking evaluations from one country and applying them to another when the environments are very different, the crops are very different, the weeds are different and also the way that people perceive environmental problems differs among countries. In preparing my answers I looked particularly at what the EC had listed as their concerns, and I am sure you are all aware of this, they may be different than the other countries. I found that to be very challenging and I was trying to take that into account.

30. We are mainly looking at problems that might affect weed problems, for example the effects of the crops that might exacerbate a weed problem, effects on other organisms that we call non-target organisms and effects that might change herbicide and insecticide use in a way that could be damaging to the environment. Those were the kinds of things that I was considering. In my answers I stuck close to my area of expertise as much as possible. You will see that I was mainly addressing questions that dealt with gene flow and gene flow and its consequences. One of my major points was that if gene flow doesn't have any biological consequences I don't think you can consider it caused environmental problems. From reading all the different responses I found that my answers were understood and interpreted correctly and I would be happy to clarify any of them later on in the day. Thank you very much.

Dr Squire

31. Thank you. I endorse the comments from the other experts about the opportunity provided by yourselves to be here. I wanted to not refer to any particular point made by or rather queried on my answers but to explain how I have developed my approach to these subjects. Previously I had worked on crops and environment about equally. I do not see that we have to look at one against the other. They are both part of the same thing because environment sustains the crops that feed us. I have done this in several parts of the world, in Africa, fairly extensively, and Asia; more recently in the UK and parts of Europe. My view is coloured by my experience in these areas. Also I have worked on arable land, grassland, woodland, a wide range of systems. Again, this experience colours my views.

32. This brings me to the point that I think has been brought up once or twice. That is: is there a difference between natural ecosystems and highly managed agroecosystems? My view is that the essential processes are the same in both. The way soil is formed, the way organisms that make the soil, the way plants grow, the way plants sustain the food web are essentially the same whatever the system. Agroecosystems are different because they are highly disturbed but they are also very similar to other forms of ecosystem. Now this brings me to my final point, which is to build on what Professor Snow said. Compared to parts of Africa, where there are vast expanses of savannah or certain types of woodland, some of the countries in Europe are largely composed of arable ecosystems. There is not much else left. What is left is also highly affected by man's activity. Is it not the case throughout the European countries that in many of them arable land is their ecosystem? We have to be responsive to that and consider that in this debate. That is all I have to say at this stage. There have been several questions supporting and contending my answers but I can deal with those during the day I hope. Thank you.

Chairman

33. Thank you Dr Squire. I would now on behalf of the Panel and the whole Members of the Secretariat put on record my appreciation to all of you, to all of the six experts for the monumental task you have been taking upon yourselves. Your contribution and your inputs are all the more valuable as you have had to work under extreme time pressure - something academics are even more loathe to than trade diplomats - and also the amount and order of presentation of the documentation was such that your task was all the more difficult. Thank you very much for your work and presence today. I would now like to give the parties a brief opportunity to make general introductory remarks if they so wish in alphabetical orders. Argentina you have the floor.

Argentina

34. Thank you Mr Chairman. Argentina would like to take this opportunity to thank the Panel, the experts and the Secretariat for the hard work in this case. We appreciate the opportunity to offer further comments on the experts' replies. However, in light of the time constraints adhered to the Panel in its letter dated 7 February 2005 at this juncture Argentina prefers to focus on the questions to the experts. We have a number of questions we would like to pose to the experts Dr Andow and Dr Squire which were provided to the Panel last Monday. We are ready to do it at a time and under the conditions laid down in the Panel's letter dated yesterday. Thank you very much.

Canada

35. Thank you. Canada doesn't have a lengthy opening statement to make. Like Argentina, given the limited amount of time available to us, we are anxious to get right into the questions for the experts. However, before we do so we would like to take this opportunity to express our appreciation

to the experts for all the hard work in responding to the Panel's questions and for making themselves available to assist the Panel and the parties with respect to the issues raised in the replies to those questions. Canada would also like to thank you Mr Chairman, the Panel and the Secretariat for all their efforts over the last eight months. It is Canada's sincere hope that the meeting with the experts will help the Panel sort through the scientific evidence and other information and give it a clear view of the relevance of this evidence and other information to the legal arguments that have been presented and will be presented in these proceedings.

36. As the Panel will note, Canada has distributed questions in writing this morning. Canada's questions focus largely on the responses of the experts to the general questions. Canada considers that many of the issues raised by these questions run through the questions found in the other three issue areas. To the extent that we are able to address satisfactorily these issues during the discussion of the general questions Canada does not intend to return to them during the discussion of the other issue areas.

37. Also Canada wishes to note that these questions are not necessarily all of Canada's questions nor will Canada necessarily ask all of these questions during the meeting. In part that will depend on the time available to us. It will also depend on the direction the discussion takes. Canada reserves its right to raise additional questions as the discussion moves forward during the meeting. In particular Canada may submit questions relating to product-specific applications in writing tomorrow morning. Thank you.

United States

38. Mr Chairman, Members of the Panel, good morning. We would like to thank you and of course the Secretariat for your ongoing hard work in this dispute. Given that today's session is intended to allow for the Panel and the parties to hear from the experts and that the United States has already submitted written comments on the experts' responses, we would just like to make two brief comments.

39. First, on behalf of the United States, I would like to thank each of the experts for your decision to accept the Panel's invitation to serve as experts and for the remarkable job you have done to review all the materials and provide written responses in such a short time. We appreciate the input you have provided. We look forward to the discussions during the following two days of meetings. Second in our submission on Monday we explained that we expected that most questions from the United States would be in the form of brief follow-up questions depending on the experts' opening statements and responses to other questions. Our submission on Monday also included a short list of questions which for the sake of convenience we have attached to this statement. Finally we have attached a second page with a small number of additional questions.

40. We have one procedural question. Will a transcript of this session be typed up and circulated at some point to the parties? I understand that has been done in other expert sessions.

Chairman

41. The answer is yes. Thank you United States. The EC has asked to make an introductory remark here. You have the floor.

European Communities

42. I think a copy of our statement is being distributed now. There is also a copy of our questions relating to the issues to be discussed today. Like Canada our questions on product-specific issues, that is issue 1, are not yet formulated. They will be distributed tomorrow.

43. The EC welcomes this meeting and will be brief. Our objective today is to discuss the issues with the scientists and to benefit from their expertise. We need to say a few words about the role of the experts, but first it is appropriate to recall the function of the Panel. As the Appellate Body made clear in *EC – Hormones*, Article 11 of the DSU requires a Panel to make an objective assessment of the matter before it including an objective assessment of the facts. That means in the view of the EC that the Panel must take into account all the scientific advice that has been placed before it by the independent scientific experts it has appointed even if divergent. The Panel is not called upon to prefer one scientific conclusion and disregard another. It is not the function of the Panel to attempt to hand down once and for all a definitive statement on scientific issues surrounding GMOs. Rather the views of the independent experts are relevant to assess the justification for time taken to process the product applications and the provisional measures taken by the EC. In that regard it is of singular importance to recall the words of the Appellate Body in paragraph 194 of the *Hormones* Case when it stated and I quote: "The very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty". In the present case the independent scientific experts have expressed divergent views and that plainly indicates that there is considerable uncertainty that was even greater in the past. It is equally important to recall that the Appellate Body in the same passage from Hormones made the following point: "Sometimes the divergence may indicate a roughly equal balance of scientific opinions which may itself be a form of scientific uncertainty". In most cases responsible and representative governments tend to base their legislative and administrative measures on mainstream scientific opinion. In other cases equally responsible and representative governments may act in good faith on the basis of what at a given time may be a divergent opinion coming from qualified and respected sources."

44. The purpose of the expert advice is to assist the Panel in understanding the scientific and technical issues in particular so as to appreciate whether the requests made by competent authorities, the objections raised by several EC member States in the context of the EC approval procedures, and the continuing provisional concerns underlying the safeguard measures adopted by some EC member States have a sufficient scientific or technical basis. As we have just said the Panel does not need to decide which of several competing interpretations of science is correct. It has to determine whether the views were legitimately held and supported by science. The EC further recalls that the role of the experts is not to judge on the appropriateness of the EC regulatory requirements governing GMOs, as the complainants in this dispute are not challenging the EC regulations. The experts can, however, assist the Panel in ascertaining whether a given information request was necessary to meet the EC requirements. Finally, it is not the responsibility of the experts to express a view, still less to decide on questions, such as whether any delays were undue or whether any such delays support an allegation that the EC was operating a moratorium.

45. I come now to talk about the advice. The EC would first like to reiterate its thanks to the experts for the quality of their advice delivered in a remarkably short time.

Chairman

46. Excuse me, the US has a point of order.

United States

47. Mr Chairman we do not have copies of the EC statement. We were wondering if we could get copies to follow along. Thank you.

Chairman

48. The same goes for Canada and Argentina?

European Communities

49. Apologies to the US. The EC would first like to reiterate its thanks to the experts for the quality of their advice delivered in a remarkably short time. As you said, Chairman, it was a monumental task. The EC has already made quite lengthy comments on this advice. This was necessary in particular because it did not cover all the questions put by the Panel. For some questions, the Panel received opinions from only one expert and there were instances where the EC felt that the advice given to the Panel was based on a misunderstanding of the question or was incomplete or misleading in some other way. This made our comments longer than we would have hoped and we apologize for this but hope that you have all been able to digest them. The experts' answers clearly show that the over simplistic, generalized, black and white scientific debate as depicted by the complainants is far from corresponding to reality. The Panel is now better equipped to assess under the WTO Agreement the actions of the EC authorities during a period of complex scientific debates and new developments. In order to do so when approaching the scientific issues that we will discuss today and tomorrow the Panel should try to stand in the shoes of regulator in a time of scientific and technological change and face with the clear differences of opinion among qualified and respected scientists. The EC will not attempt to summarise, still less to add to, the views expressed in its comments on the experts' answers to the Panel. It need only comment briefly on those of the complainants. The EC would find a great deal to say about the flaws in the complainants comments but we believe that our time could better be spent in other ways especially since there will be a further opportunity to submit such comments. The EC will limit itself to the time-being to some general comments on differences of attitude between the complainants and the EC on the issues relating to GMOs.

50. First on biodiversity, the EC would like to underline the striking misunderstanding of the importance of farmland biodiversity between the complainants and the EC. On the one hand Canada considers that the very purpose of agriculture is to reduce biodiversity. While on the other hand from the EC's perspective agriculture is about the management of biodiversity and not its reduction.

51. It is therefore not surprising to see that the EC concerns about biodiversity are treated as being entirely without merit by the complainants simply because they consider that farmland biodiversity does not deserve protection. This difference is in fact acknowledged by Dr Snow who notes that the conservation of farmland biodiversity in Europe is a much bigger social and ecological issue than in the US and Canada. It is instructive also to contrast the approaches of the complainants to that of the EC when confronted with lack of evidence concerning a risk. For example, paragraph 03.01 of his advice, Dr Andow states that: "In answer to this question I will concentrate on Bt maize and Bt cotton, yes there is some scientific evidence to support the hypothesis that the widespread cultivation of Bt crops adversely affect non-target organisms which may be exposed to such crops under typical agricultural practice. However this evidence is insufficient to establish the hypothesis that such adverse effects are expected to occur." The US takes this to be supportive of its case because it assumes that it means the product should be authorized. And if a problem arises risk management can be used to mitigate and control it. The EC with its more cautious approach takes

Dr Andow's comment to support its view that the real potential risk resulting from the scientific evidence of hazard needed to be studied before a specific product is authorized or any specific management measure could be usefully designed. The US considers that in such cases it was incumbent upon the EC to analyse the risk management options available to mitigate or avoid entirely such effects and to make a decision on the application accordingly.

52. The EC would reply that regulators should indeed analyse risk management options provided that they have been sufficiently identified and developed either by the applicant company or other persons. Indeed one of the problems that the EC has faced over the past years, which in some cases is still an issue of concern, has been the absence of appropriate risk management strategies. The experts have confirmed that at present the situation is substantially different from the situation in 1998. The EC has contributed through its financing for research to the current better knowledge on environmental effects and management strategies. The complainants tend to react to uncertainty by saying, "So what. Let's press on". The EC reacts by saying, "Let's take our time and try to reduce the uncertainty".

53. When a new GMO is presented for authorization and scientific knowledge about the product and its possible effects remains incomplete, reputable scientists are entitled to pose reasonable questions aimed at gathering the information and evidence reasonably necessary to meet the concerns of the legislator even if this takes some additional time and/or implies the use of some additional resources. Let me be clear on one point. We are not speaking here about theoretical risks or residual scientific uncertainty, but about a situation in which reputable scientists raise entirely valid questions pointing to the existence of potential risks that in their views should be assessed. As is clear from the files before you, the EC approach is to seek more evidence to establish whether or not there is a risk inconsistent with the level of protection sought by the legislator, in order to make a definitive decision on the basis of full information even if that takes more time. The complainants however consider that such an absence of evidence should lead immediately to an authorization. By insisting that their approach is the only correct one the complainants are in effect trying to impose upon the EC their chosen level of protection which reflects the complainants' specific circumstances and the complainants' specific policy choices including their choices about the appropriate balance between commercial interests and health and environmental issues.

54. That is not something that the complainants are entitled to do under the WTO Agreement. Unlike the complainants, the EC does not choose to rush into actions that are ill considered and have potentially irreversible consequences. The EC chooses to take the time necessary to reach prudent decisions which adequately reflect the concerns of the legislator. In the short history of GMOs we have had limited occasions to explore in detail the effects of such organisms on ecosystems. Clearly the situation regarding GMOs can hardly be compared with cases involving traditional products with a long history of safe use. There is a lot of difference between the cases before you today and disputes over issues like fire blight in apples. The EC is of the view that the potential of GMOs for agricultural improvement among other things justifies taking limited risks provided that sufficient *ex ante* and *ex post* controls are put in place. That is why the EC has approved a number of GMOs and GM food for marketing and use within the EC.

55. Other WTO Members may adopt more liberal or more restrictive approaches depending on their priorities. That is their right. The EC does not challenge those other approaches and it would have expected the complainants to abide by the same principle. In the view of the EC the purpose of expert advice is to shed light on all of the scientific and technical issues that have been raised by the parties in support of their claims. This is especially true for scientific or technical issues that are inextricably linked to legislative requirements in the EC. Requirements, let me stress again, that have not been challenged by the complainants. The legal characterisation of any such scientific or

technical issues under WTO rules, for instance whether it's an SPS or TBT issue is not a matter for this meeting. It is a completely different matter and will surely be addressed next week. To give a specific example, some experts, for example Dr Nutti and Dr Healy, assume that detection methods are not a necessary component of risk assessment. It is nevertheless clear that such methods are indispensable for risk management measures, as well as communication measures such as labelling which are legislative requirements in the EC and which have not been challenged.

56. Mr Chairman, Members of the Panel, the EC is conscious that time like the environment is a precious resource. They are both irrecoverable once lost so let us stop here and let us have more time to devote to our discussion with the experts. Thank you for your attention.

Chairman

57. Thank you EC. I take it that part of your statement allow us to gain time for next week's meeting with the parties. In view of the fact that we are already behind schedule I note that the EC prefers to devote the longer proportion of its time to those general comments. Without further ado I would like to invite the complainants to ask questions to the experts on general issues. I will start with Argentina. You have the floor.

Argentina

58. Thank you Mr Chairman. On the issue of the general questions we start with questions for Dr Squire. We will refer to the document called "measures affecting the approval and marketing of biotech products, notes on ecological and environmental standards" by Dr Squire. Referring to paragraph 13 please comment on our observations which were advanced as question 1 - Farm-Scale Evaluation trials in the UK, does the expert agree with our comments? If not, why not?

59. The other questions to Dr Squire refer to his responses to questions 3-5. Referring to response 3, potential for ecosystem effects of Bt maize on non-targe organisms: does the expert agree with Argentina's statement? If not, why not? What scientific facts have already established that at all molecular, atomic and physiological levels Bt toxins are highly specific to some insect orders?

60. In the same line, does the expert agree with Argentina's statement: "because of the mechanism of action which starts by binding specific receptors in susceptible insects' mid-gut Bt toxins are very unlikely to have harmful effects on other organisms"? If not, why not?

61. Referring to the title "mitigation", the expert says, "However if Bt maize was found to harm the infield biodiversity it should be feasible to reverse". Would the expert agree with this statement insofar as there is no scientific evidence that Bt maize is harmful for the infield biodiversity? If not, why not?

62. I continue with questions for Dr Andow. We will refer to document responses to questions submitted by Dr Andow. To question 69 containing an explicit reference to SCI. Question 4, in connection with response to paragraph 03-01, does the expert agree that there is no solid evidence to support the fact that the organism will actually incur negative effects through exposure to Bt crops? With reference to paragraph 03-03, please comment on Argentina's observations. Does the expert agree with them? If not why not? In connection with paragraph 03-04, does the expert agree that there is no confirmed hazard to earthworms which can be deduced from the scientific findings of EC 150?

63. With reference to paragraph 03-05 does the "possibility that unanticipated effects might be identified" in any way refute the statement that there are no documented adverse effects of Bt maize? Given the last sentence in the paragraph 03-11 in his response, does the expert agree with the statement that there are no proven adverse effects on non-target species in the US experience? Referring to paragraph 03-12, does the expert agree with the statement that the toxin, given its widely known form of action, cannot exert its characteristic toxic effect on mammals since it only can act on certain insects?

64. Referring to paragraph 03-13, please explain in which way your assertion that "it is likely that if the analysis is completed that there will be a documented risk". Is a conclusion of any scientific finding mentioned by you in the preceding point? How can it be recognized as a scientifically based argument instead of an anticipated judgement? Does the expert agree that there are no proven cases of Bt maize?

65. Referring to his response to paragraph 06-02, could the expert please clarify the expression "degree of release of the trait"?

66. With reference to paragraph 07-03 please comment on our observation advanced as question 9. Next question, does the expert agree with them? If not why not?

67. In connection with your response in paragraph 07-06, could it be said also that "the absence of information does not imply the process of effects"? Would the expert agree with such a statement? It is possible that evidence of such an effect had been looked for but not found. Therefore no report with enough merit to be included in scientific literature has been issued.

68. Referring to the response to paragraph 07-12, does the expert agree with the argument that the increase scale actually reinforced our argument in the sense that significant special scale of use effects had still not been found?

Dr Squire

69. I think I need some clarification. Where you say "Referring to paragraph 13 in the document. Please comment on our observations advanced as question 1", I am uncertain what question 1 refers to. In the documentation here or the documentation sent by e-mail I don't seem to have a question 1. Am I looking at the wrong thing?

Argentina

70. Shall I read for you the question 1? We are referring to paragraph 13 and the Farm-Scale Evaluation trials in the UK.

Dr Squire

71. It wasn't given as question 1 in the document I have, but I understand now. I am sorry I still don't have something called question 1.

Argentina

72. Question 1 refers to paragraph 13. Paragraph 13 refers to the Farm-Scale Evaluation trials in the UK.

Dr Squire

73. It is one of the topics in that paragraph and there is an answer from yourself here with some parts of it in bold.

Argentina

74. Let me clarify, when we say "advanced as question 1", we refer to the question advanced on February 14th. That is the original numeration. We had to make the new order because of the EC's question. This is the new order.

Dr Squire

75. So you are referring to your comment "we believe these studies do not apply and quoting them here is taken out of context"?

Argentina

76. What I am referring to is that the herbicide spraying regime but not the genetic modification is the root of the problem.

Dr Squire

77. Yes, it was the herbicide spraying that was generally considered to be the cause of the issue.

Argentina

78. So it's not dependent of the GM or non-GM nature of the crop. That is the first point. The second point is that the results of the Farm-Scale Evaluation trials are likely to make it politically impossible for the British Government to licence transgenic crops. The political issue affects the scientific question.

Dr Squire

79. That is an important point that you raised. We have to distinguish between the conduct of a scientific experiment, which I must tell the Panel that I was very much involved in, and the presentation of the results of that experiment. The presentation of results was peer reviewed excessively and published in a scientific journal of very high repute, with very measured, carefully weighed results and conclusions.

80. It is impossible for those involved in that trial to affect or strongly influence the way the media or the government interpreted those experiments. So while I stand by the experiments, I cannot be in any way responsible for the interpretation put over to the British people by the media. Whether or not that is going to influence UK's acceptance of GM permanently is another matter. I suspect over time it will fade. It is beyond science to do anything about it at the present time. Our results were quite clear and measured. I don't know what science can do about certain newspapers and certain TV channels. It may have influenced the way the public in the UK perceive GM but experimenters, I, can do nothing about that.

Argentina

81. Yes I understand. But I am not quoting the media or magazines, I am quoting *Nature*. And in these experiments one of the conductors of these experiments, Dr Fairbank stressed that it is the herbicide spraying regime not the genetic modification that is the root of the problem. Herbicide resistant crops are engineered to resist broad spectrum weed killers that remove almost all weeds from a field. The results of the Farm-Scale Evaluation trials are expected from this spray regime of the herbicides.

Dr Squire

82. I am not sure they were expected but the issue again goes to the root of how we value ecology and food webs in managed systems. You have to put this in the context of where the UK puts its weed control efforts. Weeds in the UK typically occupy 1 or 2 per cent of the total energy absorption and nutrient uptake in the infield system.

83. We have already reduced them to a very small fraction of the system, yet these weeds as we call them have a dual function. They have an additional function of supporting a very wide range of organisms, typically ten times as many as the crop. The question that was put by the government was: would bringing in herbicide tolerant crops that can be targeted at the last vestige of the weed flora make a big difference to this last remaining bit of the food web? The answer was that in some cases it would make a difference, positive or negative depending on the existing regime. It was quite a legitimate question to ask if you consider that a crop field is more than simply a crop. The UK's agricultural ecosystem has been here for 2,000 or 3,000 years and we wish to extend that for several thousand years. If that is the case, then we have to accept that diversity in the food web is essential. Given that, I don't see that there is anything wrong with the main conclusion of the experiment. What the media or other commentators made of it is their business. I think the experiment is valid. You are right in that the main effects appear to be through herbicide use and not the GM plant. But it is still important to show that the effect was there at that time in the UK arable ecosystem. The effect is valid. The result is valid and I think the government should have acted on it one way or the other.

Argentina

84. Do you think that the same conclusion would be found if instead the GM crop non biotech crop would be used?

Dr Squire

85. I think the same conclusion would apply. It is the issue of managing the food web that is important.

Argentina

86. I would like the Panel to take note that these same results would be obtained whether the GM crop or not GM crop would be used in experiments.

Dr Squire

87. If there was a non-GM crop with broad spectrum herbicide capability and had the same kind of effect then the same issues would arise.

Argentina

88. I would like this to be stressed.

Dr Squire

89. It has been stressed in our writings.

Chairman

90. These records are typed and will be written down. Dr Squire would you like to continue.

Dr Squire

91. That presumably covers your case in question 1, so I can move onto question 3 which refers to my responses.

Chairman

92. Sorry Dr Squire, the US has a point of order.

United States

93. I just want to make sure we all have the documents in front of us. It will save time in the long run. Does the Panel and Secretariat know exactly which document we are talking about? I apologize, but I don't know which one we are working with here.

Chairman

94. As I understand it, Argentina has given two documents of questions addressed to both Dr Squire and Dr Andow. Those are the two documents being discussed right now. I believe all delegations have received those two documents.

United States

95. Right, but which document 1 refers to paragraph 13 of which document?

Argentina

96. We refer to our comments made to the expert responses. Each time we got the responses by the experts we jut put our comments immediately after the response so it would be easier to read for the experts. We believe everybody has got our comments. Our questions arise from our comments.

Dr Squire

97. The e-mail version of your comments which I read and was working to is slightly different from this. Referring to response 3, I am not as competent on the detailed effects of Bt crops as Dr Andow. He has developed this area of research in detail. Argentina is right to bring up the point that the various effects of Bt toxins are highly specific. Indeed there are a number of different types of Bt toxin that are specific. But, as has been mentioned elsewhere in the written evidence, even if the toxins are specific to a particular insect or order or classification there are potentially a wide range of

organisms in that classification that might be affected by the toxin. There has been little detailed information from the areas where Bt has been grown widely about what those effects might be. Largely because they haven't been looked for. There are issues of specificity, i.e. that the toxin has a narrow range of things it might attack but within that range what it might attack has often not been carefully defined. I agree partly with Argentina's statement but not entirely. I do believe that things haven't been looked for and until they have been looked for in a proper and systematic way the question remains open as to what Bt toxins might do. This leads on to 2a, in a way. Unlike broad spectrum herbicides, Bt crops may have effects and these effects have not been thoroughly and properly looked at. While there is specificity and narrowness there is still depth within the regions concerned. I think there is cause for doubt here. Point 3 referring to the title mitigation.

Argentina

98. May I make a comment? You were saying in other words that in every case that the specificity was studied did one find that there is specificity?

Dr Squire

99. In practice impacts on wider things have rarely been looked at. The main programme of research in Europe on this issue, looking at the potential wider effects of Bt toxins in Bt maize for example, has only very recently started to yield results. Because there have been very few attempts to look at any wider effects of Bt toxins in fields, the question at the present time cannot be answered. Theoretically there should be a narrow range of specificity but in reality we don't know whether that is true in terms of the effects, for example, on soil organisms. There is uncertainty in that.

Argentina

100. In other words you are saying that we don't know yet something that can modify a decision taken five years ago.

Dr Squire

101. We don't know yet. That is correct. I think that in Europe this project and one or two others are looking at this. The scientific community will get clear results in the next year or two what the signals are showing. It isn't my role to say whether we should wait for that. All I can say is that within a year or two having kept very carefully abreast of that project I expect results to be forthcoming. Whether or not they confirm your question I am not able to say.

Chairman

102. Sorry to interrupt this but we have a problem of time. I would ask Dr Squire to complete Argentina's question in three more minutes. Then we will turn to Dr Andow for a very short reply.

Dr Squire

103. Again, question 3 very briefly in less than three minutes. Unless you look for effects where Bt has been grown widely you cannot say that infield effects will not occur. There is no question that effects on the infield biodiversity where Bt has been grown widely have not been looked for. I am not saying that they will necessarily be found but they haven't really been looked for. I have to make these cautionary comments. Thank you.

Chairman

104. Thank you Dr Squire. There is no need to repeat what you have written already because that is on record. Dr Andow.

Dr Andow

105. There are a lot of questions here. With respect to question 3 in particular I would like to note that your questions referred to my response to the first part of question 3 from the Panel. I am referring to the question from the Panel which is: "Is there any scientific evidence to support the hypothesis that widespread cultivation of Bt crops adversely affects non-target organisms that may be exposed to such crops under typical agricultural practice"? Before I get into the details of your question I would like to just say a couple of things about how I viewed this question. In doing that I may be able to explain more generally some of the apparent issues that you bring to this.

106. First the Panel asked: Is there any scientific evidence? I took that to mean I am supposed to look to see if scientific evidence exists. The question is not asking me to weigh this evidence but rather to identify this evidence. Some of your questions are related to how one might weigh this evidence. I am not addressing that. I am simply pointing out what the evidence is if it exists. The second point the question addresses relates to adverse effects. Following the risk assessment literature, I took that to be different from the question "is there a risk?" I did confuse the issue a bit in my answer because I should have continued to refer to adverse effects rather than risk but since the second part of the question does introduce the word risk I didn't want to address that in the first part of the question as well.

107. To consider risk I would have to see evidence of some probability that the adverse effects could occur given the exposure. That is why in a lot of my responses I confuse things by saying things in highlight and bold and paragraph 03-02 that there is a possible hazard of adverse effects to collembola. But I think I am quite clear in saying there is a potential risk to *Chrysoperla carnea.* But given what I know about *Chrysoperla carnea* in maize I think the actual risk to *Chrysoperla carnea* will be rather subtle. But the evidence available does say that one has to consider that as a potential risk. That is how I viewed these questions. In connection to your questions 03-01 I would say that this has to do with the distinction we are just making that one can find evidence for that adverse effects are possible in the agricultural environment.

108. However, whether or not it translates into a risk is still an open question. In moving onto paragraph 03-03, my writing is not entirely clear. I begin this paragraph by noting the 14 field studies emphasizing that six of these used large plot sizes. My next sentence says that it is important to use large plot sizes. What I meant was those six studies are better scientific studies because they had large plot sizes. Then I went on to consider these various studies. I guess I could go through every little detail here. I think that my general conclusion is that these studies don't enable an evaluation of the risk to *Chrysoperla carnea* which is foreshadowing my comments and the second part of this question. I can go into the detail. But my guess is that you really don't want to dispute that conclusion?

Chairman

109. Argentina I am very sorry you do not have the floor right now. This is prime time for each party. We have to allocate among the parties in an equal matter so please do not repeat statements. Do not put on record what you have already put in record. Thank you. Dr Andow, please conclude.

Dr Andow

110. Your comments on my paragraph 03-04 note that they are confusing with an approval sentence followed by disapproval sentence. I must apologize for this confusion. This was one of the reasons I tried to highlight the points in bold that summarized paragraphs. The study in exhibit EC-150 allows one to conclude there is a possible hazard to earthworms but that is only related to the fact that the adults were 20 per cent smaller with Bt litter than non-Bt litter at 200 days. This leads me to conclude that there is insufficient evidence to conclude that this is a potential risk to earthworms. Again I should have used the phrase "possible adverse effect" and I have confused the answer by using the term hazard.

111. Paragraph 05 refers to a paper showing that the Bt toxin can be exuded somehow from living maize roots. I understand that you have confusion with this paragraph but again the summary is that this paper simply documents that there is a potential for exposure and does not examine where there is an adverse effect from such movement of the Bt toxin out of the roots. I would just like to leave it at that unless you would like to follow up with questions on that point.

112. Paragraph 3-11 in some ways foreshadows one of your other questions related to the extent of increased scale of use. This would be a comment of question 14 in response to my paragraph 07-12. If Bt maize and the large scale plantings of Bt maize and Bt cotton were being examined for adverse effects to non-target organisms, it would certainly be the case that information from such a monitoring system would support your point of view that there are no proven adverse effects on non-target species. In the absence of such a system what can be concluded is that any large effects which would be evident without looking for them are not occurring. That doesn't preclude that there could be other more subtle effects. I couldn't agree with your conclusion that there are no adverse effects based upon this large scale use of Bt maize and Bt cotton not only in the US but other places in the world. To narrow it down to proven adverse effects seems to me to miss the point of the original question which is what relates to the existence of scientific evidence.

Chairman

113. Thank you Dr Andow. I am afraid we have to move onto Canada. The time is very limited. We may come back to some of the questions raised by Argentina but I would now move onto Canada. You have the floor.

Canada

114. Thank you Mr Chairman. I would just like to ask whether you would prefer us to ask one question at a time or whether you would prefer us to ask all of the questions and wait for the experts response.

Chairman

115. I think it is not necessary for you to read out your questions because the experts have been given those questions.

Canada

116. First you will see from our questions that we distributed earlier today that the bulk of our questions under General Questions relate to herbicide tolerant crops. Given time constraints we will not deal with all of these questions at this point. We will save some of them for the product specific

or safeguard measures. Our questions are grouped under several themes. One relates to the management of controlling volunteers or in-crop volunteers. Another relates to the development of weed resistance, gene flow persistence and finally persistence and evasiveness. My first question is for Dr Snow and possibly Dr Squire and Dr Andow if he would like to respond.

117. Several experts have indicated that the introduction of HT crops derived through biotechnology could make the control of oilseed rape volunteers a major problem. The EC has suggested that the evidence of Dr Snow confirms that volunteers resistant to multiple herbicides prove extremely difficult to manage. My first question for Dr Snow is: what methods, both chemical or herbicide and non-chemical, are currently used to control conventional oilseed rape volunteers in the managed environment.

Dr Snow

118. Are you referring to Canada, the US, Europe or the whole world in your question?

Canada

119. Let's start with the whole world and then we'll narrow it down from there. Or perhaps we could just speak generally.

Dr Snow

120. Sorry I am being a little facetious. It is difficult to say in any one country what the best method is, what is being used now, or what would be used in the future. It's obvious there are many methods for controlling volunteers, including tilling or different types of herbicides that are rotated. These were addressed in my answers to the questions from the Panel. There are methods for controlling volunteers that are effective at this time, that people have decided work. They come at a cost because sometimes they involve using additional herbicides which may or may not be desirable depending on which country you are talking about.

Canada

121. Would these methods of controlling herbicide tolerant oilseed crops that are derived through biotechnology be any different from the methods of controlling herbicide tolerant oilseed rape that had been developed through mutagenesis.

Dr Snow

122. With regard to the volunteers, I think the same methods could be used. The only difference is that the herbicide tolerant volunteers that are transgenic. You have to think about which herbicides we are talking about. Glyphosate is one of them. Many, many farmers want to use glyphosate on a lot of different crops. If volunteers become resistant to glyphosate that limits the farmers' options. There are some issues about how difficult they might be to control. Also the gene could spread possibly more easily if it's a single transgene. It depends on the genetic basis of the trait how fast it would spread to other plants and to weedy relatives. In general I would say the same principles apply I am just giving you a few caveats here.

Canada

123. The ability to manage these volunteers would be dependent on the herbicide to which the volunteers would be tolerant. What are your views in relation to the difference between controlling volunteers using the immizolones - which I will call the immis - and controlling volunteers using glufosinate ammonium. If the volunteers were tolerant to one of those herbicides as oppose to glyphosate, would the issues be the same as between glufosinate ammonium and the immis?

Dr Snow

124. I think the issues would be the same.

Canada

125. Over 80 per cent of oilseed rape that is cultivated is composed of three herbicide tolerant varieties: the glyphosate, glufosinate ammonium and the immis. Given the widespread use of oilseed rape in Canada, the availability of alternative methods for controlling oilseed rape volunteers and the lack of reported problems: what is the scientific basis for concluding that the herbicide tolerant oilseed rapes may prove extremely difficult to manage?

Dr Snow

126. Is the phrase, "the extremely difficult to manage", a quote from me or from the EC?

Canada

127. Sorry that is a quote from the EC.

Dr Snow

128. I think that is their opinion. I don't want to try to justify that. But I would like to mention is that I have read a number of reports that do say that there are problems managing herbicide tolerant volunteers. I cite several of them. One of them is Simard *et al*. in Weed Technology, a paper that came out in 2002 and was submitted in 2001. By 2001 this had become an issue and a topic sentence of the abstract is relevant here. They say "the presence of volunteer canola is becoming a significant agro-ecological concern given the large scale use of herbicide tolerant varieties in some areas. They don't distinguish between transgenic or non-transgenic. Two are transgenic and one is non-transgenic. Herbicide tolerance is reported as a problem. This supports your statement that the immis may be as much of a problem as the others but because glyphosate is used so widely and is associated with the transgenic crop, it is blamed for this problem.

Canada

129. You also say in an article by Linda Hall, who reviews the emergence of multiple resistance herbicides. In that article she indicates that producers have not reported this because they are controlling these multiple resistant herbicides or controlling canola HT volunteers using other methods?

Dr Snow

130. That could be one explanation. That paper was published in 2000 so we don't know if she would say the same thing in a similar paper now. But I found it very difficult to nail down how big a problem this is in Canada. I think you are suggesting Canada has been able to manage it; it is not considered a problem. It could be different in different countries but people don't tend to highlight that it is a problem in some of these publications. It may not be a large problem but it is hard to get to the bottom of that.

Canada

131. I would like to move now to development of weed resistance. Dr Andow, you say there is an abundance of evidence that the repeated use of a given biotech herbicide tolerant crop would likely result in the evolution of resistance in weeds to this herbicide. I would like to ask you whether it is true that there have been numerous reported cases of weeds resistant to the immis, the herbicide used in conjunction with HT crops derived through mutagenesis.

Dr Andow

132. I didn't address that in my answer to my questions but I did note that Dr Snow addressed it. Her answers to the questions indicated that there was such evidence.

Canada

133. Of resistance to the immis? [Dr Andow replies yes].

134. Are you aware of any reported cases of the evolution of resistance in weeds to glufosinate ammonium?

Dr Andow

135. Not to glufosinate ammonium. Certainly to glyphosate. I think one of the broader issues here is that glyphosate is widely recognized as one of the safer herbicides that can be used in crops. This has been one of the reasons why the glyphosate tolerant varieties have been widely accepted in addition to their ease of use. Weed scientists, and other scientist interested in the evolution of resistance like myself, recognize that whenever there is such widespread use there is likely to be resistance even if it has not been reported. Whether or not there are reports is not the main point in terms of resistance risk. It is how much is being used and how many weeds are being exposed. The fact is, at least I understand in Australia, there are some reports beginning to occur of additional cases of glyphosate resistance in weeds.

Canada

136. Now would this be through the use of HT crops or the use of glyphosate generally?

Dr Andow

137. This is HT crops in Australia.

Canada

138. Is glufosinate ammonium used to the same extent as glyphosate in other areas?

Dr Andow

139. For a number of reasons, basically the spectrum of toxicity to weeds, glufosinate ammonium has not gained as widespread acceptance as the glyphosate tolerant plants.

Canada

140. So would your concerns about glyphosate herbicide tolerant crops be different than concerns about glufosinate ammonium crops?

Dr Andow

141. I think that would depend on the crop. For example in maize as long as we have both glufosinate ammonium resistance and glyphosate resistance it is likely that the glyphosate resistance would end up being used more. The resistance risk would be higher with glyphosate resistance crop such as in soybean. But in other crops it may be that the glufosinate ammonium would be a superior product than the glyphosate. In which case it would be used more. The degree of use is what determines the higher level of risk.

Canada

142. In terms of the loss of benefit of using the alternative herbicides, you mentioned that glyphosate is used in a number of different applications and therefore the introduction of glyphosate tolerant crops may pose a problem. Would those same issues apply to the introduction of glufosinate ammonium herbicide tolerant crops given that glufosinate ammonium is not used as extensively?

Dr Andow

143. Yes, I think that it depends on the crop.

Canada

144. I would just like to move onto gene flow. Some experts have indicated over the past five years there has been some additional evidence that outcrossing amongst oilseed rape is more prevalent than previously anticipated. First I would like to ask Dr Squire or Dr Snow: is the potential for outcrossing also a concern for herbicide tolerant crops developed through mutagenesis? Then, in light of this the new evidence of potentially broader outcrossing in oilseed rape, are the experts aware of any measures that have been taken in the EC to minimize the outcrossing of HT crops derived through mutagenesis?

Dr Squire

145. The evidence in Europe of greater outcrossing has arisen because experiments have increased the size of the donor crop in relation to the recipient crop. I think detection techniques have improved to some extent. Now we have a much better appreciation that gene flow goes farther, with potentially higher frequency and possibly to more species than was thought five or six years ago. But in principle there is no difference between the process of gene flow unless there is a difference attached to the

GM-ness through the male fertility or male sterility of the donor itself or the recipient. As far as I can see there is no essential difference in the mechanism other than that. Now, clearly outcrossing has occurred in non-GM oilseed rape for a long time. There hasn't been that much herbicide tolerance derived through mutagenesis in Europe so we don't have the same kind of records in Europe. In general Europe has not put in place any consistent measures to minimize crossing from new kinds of oilseed rape, largely because these products are treated the same as traditional varieties. So even if a farmer over there gives his crop's genes to one over there, it is about the same. They can sell the material.

146. There are exceptions to that. The exceptions concern oilseed rape destined for particular markets - varieties for an industrial market for example containing different concentrations of some of the oils. In those cases there are some measures put in place to do with the localization of those kinds of fields and the non-harvest of any oilseed rape very, very close to the fields, but beyond that there is not much information on the distance over which genes might move from these industrial oils to other fields. The actual criteria are quite lax - the percentage of industrial oil allowed in non-industrial oilseed rape is relatively high. It is a few per cent. Gene flow will have occurred but nobody will have bothered about it very much. That seems to be the case for Europe. Dr Snow do you want to comment?

Dr Snow

147. The only thing I would add is that I really don't know the answer to your question no. 9 about whether the EC has taken measures to minimize outcrossing from non-transgenic crops. I suspect not, but I don't really know for sure.

Dr Squire

148. It has not been a major issue. These kinds of crops have not been brought in a major way.

Chairman

149. A point of order. I suggest we have Canada until 12.20 then we will have the US until 12.40. We will have the EC until 1pm, and after lunch from 3 to 3.30 when we will have follow-up questions from the complainants for half an hour until 4pm. Then we will ask the Panel questions until 4.30. After that we will see how it goes. Canada, please continue.

Canada

150. Thank you Mr Chairman. I will then move to some of the other questions. In terms of question 7, would you agree that there is general scientific consensus that there is no difference in the types or kinds of risks posed by biotech HT crops compared with their non-biotech counterparts? I'll direct that to Dr Squire, Dr Snow and Dr Andow.

Dr Squire

151. In general terms as regards ecological risk, the answer is, with minor qualifications, there is no difference. Generally I would agree with that.

Dr Snow

152. Yes, I always get uncomfortable when people group all HT biotech crops together and all non-biotech. I think many people have said we should look at these case by case. For me it is very difficult to group them all together and say the kinds of risk and the types of risk are the same.

153. I pointed out in my answer to the question that came from the Panel that there are certain characteristics of the biotech crops that cannot be found in the non-biotech crop. For example, a Bt transgene is not available to introduce either through mutagenesis or breeding with a relative. These are specific cases where I think the biotech crop is different from the non-biotech and the same thing with the glyphosate resistant trait. But those are characteristics of specific biotech crops. In terms of generalizing, I don't think you could say there are major differences between these two large groups. You have to look case by case and see whether it's attributable to being a biotech crop or not.

Canada

154. Ok, given this has there been any reported incidence of glyphosate resistance that has been developed through mutagenesis?

Dr Snow

155. I am not sure about that. There has been a single gene for a very valuable trait to biotech companies. The reason why Monsanto has made so much money on this is they developed it first. Your question is: could it be developed through mutagenesis? Several weed species have spontaneously become resistant to this herbicide so there is a way that it can happen. Another company was able to get it from bacteria through a process called directed evolution from bacteria. They have the right to put it into a crop but I am not aware that it has been available to biotech companies in any other way than through a transgene.

Canada

156. But if it did become available so that you had an oilseed rape herbicide crop that was resistant to glyphosate, would that pose the same sort of ecological issues or concerns as the biotech crop that is resistant to glyphosate?

Dr Snow

157. If it is a single dominant gene, just like the transgene, I don't see any difference.

Canada

158. I have a question about genetic diversity. Dr Andow, you have indicated that gene flow from a GM HT crop can reduce genetic diversity. Can you explain how the integration of a single gene conferring herbicide tolerance then affects the genetic diversity of oilseed rape?

Dr Andow

159. It wouldn't be a single gene. There would be effects on genetic diversity through scale effects similar to what Dr Squire was referring to. If a large amount of a particular genotype is planted then the hybridization between the two means that all the hybrids have half of the genes of the one variety and half of the other variety. If there is a lot of the one variety introduced then that puts pressure to

move more than just the one gene from that crop into the other varieties. In fact there is pressure to move lots of genes. That is how the genetic diversity is affected. It is the rapidity and scale of use that influences the loss in genetic diversity.

Canada

160. Then would you agree that in the impact on biodiversity would be the same if there was a HT crop developed through mutagenesis that had the same repeated use and scale elements?

Dr Andow

161. At this time there is no non-transgenic glyphosate tolerant crop, so it is still a hypothetical question.

Canada

162. But your comment is if there is greater scale of use this could have an impact. It's related to how popular the crop becomes?

Dr Andow

163. Yes, it is related to scale and rapidity of use.

Canada

164. In terms of biodiversity I just have one comment. I would like to clarify a statement that was made in the EC opening address. Dr Squire, would you agree that in fact agriculture by its very nature has an impact on biodiversity. In fact the purpose of agriculture is to reduce the range of species within a managed environment so as to favour a particular cultivated species and to eliminate those species which compete for soil nutrients, moisture, etc?

Dr Squire

165. I think this is a very important philosophical point that will determine the future of mankind. Because yes, but we have to channel resources through single species for efficiency. We have been doing that for a long time. But to work harder and harder to eliminate the last vestiges of biodiversity, because it competes with crop production, will in fact end up destroying the system that sustains it. We have to be very careful about this. The managed arable or agricultural environment may be classed as being unnatural but you would have to class humans as unnatural as part of that system. If humans are animals, and we are all to some extent natural, then the arable environment is another example of a natural ecosystem. It's just that we control it to a degree. These systems might have replaced a kind of forest or steppe vegetation with something else but that something else is not ecologically non-diverse. It can contain a very large number of organisms - plants, and invertebrates. It can be the main habitat for some kinds of organisms, like certain types of beetles or spiders. We have to live with this, make it work for us and not obliterate it. I think we should channel a lot of resource into the crop but not everything.

Canada

166. Apart from the debate on GMHT crops and biotechnology are there instances in the context of conventional agriculture where farmers are either encouraged or regulated to reduce the effectiveness of weed control measures? To allow more weeds?

Dr Squire

167. I think it's a matter of balance, of where you are in the world, and of where you are in the development of a cropping system.

168. In much of Europe, but not all of it, we have largely succeeded in managing weeds. The benefits of changing weed control over a factor of 1.5 are not very great. We are already there. There are instances in parts of the UK where the food web is purposely stimulated. People were paid to let fields lay fallow for some time. There are examples already in place where weed management is encouraged rather than the total obliteration of the weed flora.

Chairman

169. Thank you. Canada your time is up.

United States

170. Yes I will take one of my 20 minutes to confer to reduce any duplication.

Chairman

171. United States, when you ask your questions please refer to the number of the question that would be helpful.

United States

172. This is a follow-up question to Question 3 in the middle of the page. Can the regulator or the scientist assess the effects of Bt toxins on non-target species without identifying all potentially exposed non-target organisms? If you can do that, please describe how one might do that.

Dr Andow

173. There are many different procedures that can be used to assess non-target effects. The different procedures have different data requirements and give different degrees of confidence in the assessment. With pesticides, for example, one common procedure is to use indicator species. A relatively small number of indicator species are supposed to give some indication of possible environmental effects. If you see adverse effects on those species it triggers additional environmental testing. It takes a little bit of time to get there.

United States

174. This question, for Dr Andow, is from our second page of additional questions. It is on Bt risks. Dr Andow had mentioned there could be subtle potential non-target risks. Could one design a field study to address potential subtle non-target risks associated with Bt crops?

Dr Andow

175. I am going to treat it as a two-part question. There is the question related to subtle effects and then there is the experimental design. To some extent getting at subtle effects requires a staged process rather than a direct process because subtle effects are, by definition, hard to detect. What you want to do is to determine what are likely ways in which such things could occur. You would do some experiments to try to determine what possible mechanism could explain the effects. For example, as I mentioned in my response to question 3, there is a possible risk to *Chrysoperla carnea*. I predicted it would be a subtle effect. Using that as an example how would one go about investigating that effect?

176. You could have started those experiments in 1999 to get at part of your answer. Since it is known that any effects would result from what the *Chrysoperla carnea* feeds on I think the first study would be to investigate in a field situation under what circumstances could *Chrysoperla carnea* actually encounter the foods that could adversely affect it. The study would first define whether there are circumstances where it would be able to encounter these foods in large quantities. That experiment would not require any transgenic crop to do and could be done on a small scale because you would focus on the feeding behaviour, rather than at the population biology and survival rates. Through that process one can start to identify the conditions under which that risk could actually be manifested. Depending on what you find it would lead to the design of an experiment that could detect the subtle effects. In contrast, if you just went out and planted a field and then counted *Chrysoperla carnea* you may find that there are more *Chrysoperla carnea* or less *Chrysoperla carnea* with Bt crops. Even if there were less *Chrysoperla carnea* with Bt crops that would not necessarily let you say the reason for that Bt crops caused this effect. You have to get into the mechanism that causes this effect. My feeling is that you can approach the mechanism first rather than later.

United States

177. Now I am going to question 1 which refers to the studies that were cited regarding Bt's mechanism of toxicity and spectrum of activity. In light of subsequent studies that have called these results into question, could you summarize the data, positive or negative, on the topic? Is there any reason to believe this mechanism of toxicity and spectrum of activity would vary across different environments?

Dr Andow

178. Are you referring to the experiments associated with lacewings specifically? Because I interpreted the question differently. Let me rephrase what I understand the question is. A series of studies looked at effects of Cry toxins on lacewings. The first studies that were published on this were in 1998. Those were a series of two or three studies - two are quite prominent in my mind - that suggested that when green lacewing larvae were fed caterpillars that had eaten Bt crop that there were higher mortality rates in these larvae. After these studies, a series of follow-up studies then confirmed the first studies, but also suggested that when you feed green lacewing larvae mites fed on Bt crops there were not higher mortality rates on *Chrysoperla carnea* despite the fact that the mites contained the Cry toxin.

179. The final study, which I think both Canada and Argentina referred to, was an experiment in which the investigators incorporated the Cry toxin into the water that the lacewing larvae drink. Then they exposed those lacewing larvae for a series of short periods in their life to this water. (Lacewing larvae cannot live only on water so you have to feed them food at some point in order to get them to grow. Otherwise you can't determine mortality rates and they will die.) They incorporated very high

concentrations of Cry toxins in water and they found no significant differences in mortality rates in the larvae. The key conclusion of last experiment is that there is no evidence of acute toxicity of Cry toxin to lacewings. It doesn't entirely contradict the first set of experiments in which lacewings were given long-term exposure over their entire life. Whether or not there is chronic effects on lacewing is still a question.

180. To get back to the original question, it wouldn't have been predicted that the Cry toxins would have any effect on lacewings, because the Cry toxin that was used, Cry1Ab, is one which had been considered to be specific only to Lepidopterans (moths and butterflies). Given that lacewing are less genetically related to Lepidopterans than fish are to humans, people thought that this Cry toxin should only kill moths and butterflies. It was surprising that it had any effects at all on lacewings.

181. In my view that is probably one of the more significant issues. How can that happen? It suggests that there might be other ways in which these proteins exert effects on insects. I think that is still an unknown. There is unpublished evidence that the way that toxicity normally acts on Lepidoptera is not how it acts in lacewings. That is unpublished information, but exactly how it acts is still uncertain. Now the data has been interpreted both ways. Some people say this proves that there are no effects of Cry toxins on lacewings and others say there are still major effects. My personal assessment has been that any effects are going to be subtle.

182. When I say any effects are going to be subtle I am not saying that there are going to be effects. I am saying if there are going to be effects they will be subtle. That is in response to a point that Argentina was raising earlier.

United States

183. Thank you. I think you may have answered this question, but just to clarify. Is there a reason to believe that the Bt toxin is likely to be the source of the chronic concern that was potentially identified in the original studies or is there a potential likelihood that the effects could be traceable to the kind of food or the kind of prey that was available to the lacewings at the time?

Dr Andow

184. There is a lot of comment in the literature on this question. My assessment of what that evidence suggests is that there could be food effects associated with this but it is probably not purely a food effect because one of the experiments had an artificial diet with and without Cry toxins in it. The effects were seen in that circumstance and it is hard to explain why using food effects as the only explanation. We should say that the data are not entirely consistent with each other, which means there must be something else happening that we haven't explained yet. So I am not willing to say that I know the answer to that question. I think that something to do with food is possibly part of the explanation but I am not yet prepared to believe that it is all of the explanation.

Chairman

185. Congratulations US. The EC has the floor.

European Communities

186. Thank you Chairman. By my calculations the complaining parties have spoken for 1 hour and 20 minutes on general issues so the EC will expect to speak for the same length of time especially

since we also have to deal in our time with follow-up questions whereas the complaining parties will get a short period of time later on for follow-up questions. Is that correct?

Chairman

187. I ask you to do your best and I note that we have not received your questions in writing.

European Communities

188. The questions in writing, or at least a draft of them, are available and will be distributed now. I am told they have already been distributed, but if anyone does not have a copy we have some more. The experts in particular should have a copy.

Chairman

189. Before you take the floor, EC, I would say this is not exactly a matter of minutes but I do take in account that you have spoken longer than the other parties on the introductory statement. We will try to stick to the 3.30 limit for your delegation.

European Communities

190. I agree it's not a question of minutes but a question of opportunity. Our first question relates to question 1 and 2 from the Panel to the scientific experts. These questions related to the presence of antibiotic resistance marker genes in genetically modified organisms - or some of them. Our first question is therefore to Dr Nutti who commented on this. I will read out the question since you've not had it so much time in advance.

191. We assume, Dr Nutti, you are aware now of the studies demonstrating transfer *in vivo* of plant antibiotic resistance marker genes to bacteria by the group of scientists led by Simonet *et al.* published between 2000 and 2004 which was mentioned in paragraph 78 of our comments. We wanted to ask you how you reconcile the results obtained in these studies with the view you expressed in your reply to question 1 that, I quote, "to date there are no reports that markers genes and plant DNA transfer to these cells".

Dr Nutti

192. When I answered that question I listed the literature that I was consulting at that time. I didn't have the Simonet *et al*. I only received your comments last week so I will be happy to look at this. I didn't have time to look at them.

European Communities

193. I hope you will have an opportunity to complete your answer taking into account those studies. We can now move onto the next question. It will be delivered by Mr Flett.

194. I would like to ask a question about Bt toxin and non-target effects specifically to Dr Andow and to Dr Squire. You already have some written questions from us on this matter, however in the light of what has already been said this morning I would like to slightly reformulate those questions and put them to you as one general question designed to get at what may be the essential point here. The question is quite long but the sense of the question is sufficiently clear.

195. We recall in particular Dr Andow's comments this morning about the distinction between a potential adverse effect and a possible risk. Dr Squire echoed this distinction on this issue of Bt toxin and non-target organisms. This is the distinction between the first step when the scope of possible further scientific enquiry is set and the second step when one considers whether or not the scientific knowledge within that defined scope is sufficient for taking a view on whether or not there is a risk. Now it seems to us that this may go to the heart of the difference between the parties on this point. It seems to us that the complainants sometimes set this scope relatively narrowly whilst the EC sometimes sets this scope more widely.

196. We would like to ask you Dr Andow and Dr Squire how, as scientists, you go about setting this scope with particular reference to Bt toxin and non-target organisms. How do you decide as scientists what you need time to look at, what you need time to think about? How do you decide what the relevant context might be? Do you, for example, draw on your knowledge and experience in relation to different crops, different regions, different natural or agroecosystems, and different receiving environments? Do you believe that your approach to setting this scope, either narrowly or widely, reflects conventional wisdom within the scientific community? Are there divergent views on this issue within the scientific community? Please feel free in your answers if you find it helpful to refer to the specific questions that we have already submitted in writing. Thank you.

Dr Andow

197. Thank you. When you say "set the scope", are you referring to the different possible ways of investigating non-target effects? It is a little unclear what you are referring to when setting the scope. Would you be so kind as to help me with that?

European Communities

198. We would like you to talk specifically on the areas in which you might think that more time and resources could be spent by scientists analysing anything relevant to the issue of the Bt toxin and non-target organisms. If this scope is set in an extremely narrow way then you might, as the complainants, look at the landscape with almost no helicopter vision and declare: "There is no evidence of a problem". If, on the other hand, you have some reasonable degree of helicopter vision, and you want to put the problem in context and look at a wider landscape, you might say: "I would like to know a little bit more about this issue before I take a definitive view in relation to the specific product application that is before me". I am trying to get at this issue of how you set the scope of possible relevant future enquiry as a scientist before you feel able to take a view on the absence or presence of a possible risk. Is the question sufficiently clear?

Dr Andow

199. First of all, as a scientist, I am not a risk assessor. I am not in a position to make these decisions as to when we have enough information. What I'll address instead follows from the US question: how do you actually do these assessments and are there ways in which you procede that may require more scientific work and give you more information? Especially in the area of non-target effects the challenge has been that there are so many different species and so many different possible ecosystem functions, biogeochemical cycles, ways in which nutrients are cycled through the environment, etc., that could possibly be affected. It is simply not possible to study them all. Any procedure has to figure out a way to focus. The one that I mentioned in my response to the US question is focusing on a few indicator species under the presumption that they can tell you something about the environments.

200. This has been an approach that has been used for toxic chemicals because the chemicals aren't restricted to particular environments. In contrast, most of the transgenic products are in the crop environment. It may be possible to think about how to evaluate non-targets in a different way than through indicator species because you have a particular environment of concern. Certainly for gene flow it could go to other environments but the main environment is going to be the crop environment. One can ask what kind of non-target effects would there be in that crop environment. In that sense then there are other ways to focus things than trying to look at indicator species. One could select species out of that environment for testing, for example.

201. I have also previously commented on how things have changed over the last ten years. This relates to this question too and I'd like to amplify it in this context. Since around 1998 there have been non-target studies associated with transgenic crops focussing on actual things that could happen in that agricultural environment rather than things that could happen in some general environment. For example, some of the Cry3 Bt toxins that are currently being assessed are supposed to kill beetles, so the focus has been on other beetles in that system. Rather than selecting any non-target species the idea is to focus more on things that could actually happen. In that respect a change is occurring, in different degrees, in the way in which non-target risks are being assessed around the world. The assessments are looking more at what could happen within that receiving environment. With this approach you cannot use one indicator species applied to lots of different environments. It does mean that you have to do more tests. It also means that a test done in China on Bt cotton may not be the same kind of test one would do in Spain on Bt cotton.

European Communities

202. I understand that what you need to look at may depend on what you're focusing on and this has been changing during the period that we're looking at. I just wondered if Dr Squire might like to also comment on the question.

Dr Squire

203. I agree in general with the sentiments. I think scientists have to be aware of what makes a soil, or an ecosystem work, and to be able to answer a question or approach questions like the one on Bt that was presented. There are numerous organisms, bacteria, fungi, etc., that are absolutely essential for the working of the system. By looking at the processes they mediate, for example the transformations of compounds, we get a feel for what should be there and how it might be affected. Quite a bit of that work is in place in various parts of the world. In the institute where I work there are groups looking at those processes, not with Bt in mind. When the issue of Bt came up and some of the first results in containers showing potential chronic or small cumulative effects came up, the question was raised whether these effects would potentially be different from something else that we have experienced so far. Would they be important and would they shift any of these organisms or processes in a certain way that was beneficial or detrimental? Prior knowledge and awareness is essential for the process. The question is: Is there any possibility that over long periods of time, over larger areas of land these small effects might multiply and cause some major effect on the essential organisms and processes. In the case of Bt there are some legitimate queries. Because it exists throughout the plant it might well have influences on parts of the system that other chemicals cannot reach.

204. It is not catastrophic. The effects would be known by now if they were catastrophic, but they are potentially there. The next stage then is to see if we can predict those effects at that scale from present knowledge. How could we scale up? What is the next feasible step to test whether these potential effects on our known system are realized or not? That would need to be a gradual process.

At the present time that information isn't available or transferable to an European context from work elsewhere. So there would be need, in this particular case, to consider these upscaling effects. You would need to do field scale experiments for a few years in the first instance. My understanding is that such experiments are in place in Europe. That is the way that I and colleagues would approach this kind of problem.

European Communities

205. I think that brings us nicely to question 9 and your comments about transferability. Questions 9 and 10, again to Dr Andow. Could you indicate to us whether or not in your opinion there is a consensus on the design and implementation of insect resistant management programmes in the US? Are these designs directly applicable in Europe? And question 10: What factors in your opinion might affect the efficacy of resistant management in Europe?

Dr Andow

206. Thank you. With respect to the design and implementation of insect resistant management in the US there is a fairly strong consensus on some issues. For other issues there is still discussion about how to design and implement the IRM.

207. There is quite strong consensus when the crop expresses what is referred to technically as a "high dose". In those circumstances the consensus has been that a structured refuge is a reasonable approach to IRM. The refuge is specified as land which is usually about 20 per cent of the total land area and within a certain distance, usually between a half mile to a mile or so, of the crop. The area where I am sure consensus will be reached over the next few years is related to low-dose events. The issue under discussion is what refuge size is needed for low dose events. Currently at the rate at which they are being used in the US the idea has been to use the same refuge requirements (20%) and then adjust them if necessary. Are these designs directly applicable to Europe? I would say, in principle, yes. But the specifics of how one implements them in Europe are not as clear. For example the implementation in the US is in part related to the legal authorities of the regulatory agency. My understanding is that the legal authority, in this case EPA, is a little different from the legal authority that is granted in the EU. It is very likely that the details of implementation will be different in the two areas in terms of where liabilities lie. Those are legal issues. In the US the main point in terms of the science is that each individual farmer is responsible for resistant management. Whether or not Europe will decide to go in a similar direction or whether they will take a different perspective because there are more small fields that will require communities to get together and cooperate is still an open question. While those are not necessarily points of biological science, they would certainly be important points in social science in terms of how one actually implements successful IRM.

208. I will go now to question 10 and the factors that will affect the efficacy of resistance management in Europe. There are similar factors that are going to affect the efficacy of resistance management in the US. If the people that are supposed to implement it, actually are the ones to implement it, then it will probably be efficacious. If they are unwilling to implement it then will not be efficacious. That is one of the scientific issues that we have to deal with. Certainly it would be better to have larger refuge in the US. Economic analysis of that question suggests that there would be resistance on the part of US farmers to implement it. Then you get a lot more violations from what you want which would affect the efficacy of resistance management. Again these issues are not necessarily purely subjects of biological science. They are issues of biological science entwined with the economics of farmer behaviour that influence how the efficacy of resistance management works.

European Communities

209. To follow-up on some of the specific issues in the context of the community, is it your view that there are divergent opinions in terms of how the scaling up might take place? How long it would take? Second, also specifically on science, could you say a few words on what is and what is not a high dose. Does it depend in your view of the target pest. For example, is the high dose the same for all target pests in Europe for Bt maize, or is it different? In other words, does this depend on the receiving environment?

Dr Andow

210. The scientific component of scaling up has to do with when the resistance management should be implemented in order for it to be effective. Most people agree that the earlier a particular refuge strategy is implemented the more likely it is to be effective because people are used to it from the beginning. But it is also possible to adapt management as scaling up occurs. There are trade-offs between the two that are recognized on scaling up. There are different preferences for how to approach that.

211. In terms of high dose if you look at Bt maize, the targets for Bt maize in Europe are what we call in the US European corn borer. I think even in Europe they call it European corn borer. We know that the toxicity spectrum is similar between European corn borers in US and Europe. In the context of the Bt maize plants considered for Europe, the management strategies are likely to be high dose in Europe. I have less to say on *Sesamia* because I cannot remember exactly what the toxicity results are for *Sesamia*. Frequently that family has a lower toxicity spectrum. I do know that the toxicity varies from life stage to life stage. The older life stages are fairly tolerant of the Bt crop, unlike the European corn borer. We also get into issues of timing. Whether or not there are alternative posts they can switch from to becomes an issue in terms of design of resistance management for that species. This would be a concern primarily in Spain and Greece.

Chairman

212. Thank you Dr Andow I suggest we now interrupt the EC's time on the questions to the experts. Before we break for lunch I have two announcements to make. The first is organizational. We think that it might be difficult to finish issues 2 and 3 this afternoon. Given the fact that some of the EC's experts will not be available tomorrow the Panel is ready to sit an additional session this evening from 6.30 to 8.30. That is under the assumptions that the experts are paid by the day and not by the hour and that Argentina will accept that we will not have interpretation this evening. That is not possible. The second announcement is that during the lunchtime this room is going to be locked. This means you can leave everything you want in this room until we come back at 3pm and please be here at 3pm Swiss time not Geneva time. This meeting is adjourned.

United States

213. Mr Chairman, we have been talking to our Geneva delegation who covers these things. It is really not the norm for the defending party to have the same amount of time as the complaining parties. In a very recent case in fact the EC argued vigorously against the US having as much time as the other eight parties in an Appellate Body context and the EC largely prevailed in its position. So it is a little bit ironic for the EC to insist that that's the way it has to be. That said, we don't have objections to EC asking questions. I just want you to be aware that it can't be considered the norm. That's not the EC's position in other disputes.

Chairman

214. Thank you. Madame Fries you have the floor.

European Communities

215. Thank you Chairman. We have three questions on detection methods which we hope will not take too much time to answer. Dr Nutti, I would like to ask you whether you agree that a detection or identification method is required (1) to distinguish between authorized and non-authorized products and (2) to assist in the withdrawal of authorized products in the unlikely event that hazards are observed after authorization. Thank you.

Dr Nutti

216. Yes, I agree. When I answered in my written replies I pointed out that there were two kinds of detection methods and that they are mostly used in the context of labelling requirements.

European Communities

217. Your response leads us onto the next question. Do you agree that DNA-based event specific methods would consistently possess the ability to uniquely identify a product?

Dr Nutti

218. As I pointed out in my answer I am not an expert in detection methods. I tried to collect all the information for this. I am not sure if DNA event-specific methods possess the ability to uniquely identify a product, because you can have two events with the same trait. I would like to ask other people with more experience in the field of molecular characterization to help on that. Maybe Dr Healy could help me.

Chairman

219. Would you like Dr Healy to take the floor?

European Communities

220. Yes, I want someone to comment on it.

Dr Healy

221. Thank you. I was also going to go back to the first question on the detection methods because the ability to distinguish between products is going to depend on the type of the detection method and the type of product. For example if you have DNA or protein-based detection methods but your product is a highly refined oil that does not have DNA or protein present, then the ability of the detection method is limited. If the product has the DNA or protein in it and it can be extracted then the detection methods have that ability to distinguish between authorized and non-authorized products.

222. In terms of the second question: do the DNA based event-specific methods consistently identify a product? If the methods are event-specific then they do have the ability to identify products

providing that the DNA is present in the product and the DNA can be extracted from the product. Thank you.

European Communities

223. Thank you Dr Healy. May I also put the third question to you because it is connected to the second. Would you agree that other DNA based or protein based methods would not always possess the ability to uniquely identify a product?

Dr Healy

224. Certainly if the DNA based method is using DNA sequences or primers that are common to a number of products then the ability to detect will not be unique. That is also true for the protein based methods. For example, if your protein based methods relate to the detection of something like the Bt protein and it is an antibody based method then of course your antibody is going to detect Bt regardless of the product assuming that the protein is present and extractable.

European Communities

225. Thank you Dr Healy. I think we can move onto the questions on molecular characterization. We would like to put this question to Dr Snape. Dr Snape, if there is not exact correspondence between the description of the GM in the dossier and a complete sequence based characterization could these effectively mean that the dossier does not describe the GM accurately?

Dr Snape

226. I was not specifically asked to comment on question 9 because I will dealing with specific products questions 12, 16, 18, and 25. I am happy to answer that question if the Chairman wishes me to do so. Also in the question I wouldn't necessarily use the word accurate in terms of describing molecular characterization. I think a more appropriate word would be "complete" or "sufficient" in terms of the molecular characterization. Molecular characterization is necessary because it indicates the number and the complexity of the transgenic insertions. Therefore it is necessary to know the complexity of the locus, the flanking transgene sequences and also the presence of any backbone sequences since this can determine target and non-target effects of the transgene.

European Communities

227. So Dr Snape, you objected to the use of the word accurately and replaced it by a complete or sufficient manner. If we replace it by this do you agree with the question?

Dr Snape

228. Yes, I think it has to be based on a product-by-product characterization. And are you referring to oilseed rape Falcon in respect to this question?

European Communities

229. It's a general question.

Dr Snape

230. In a general question then yes. You have to have a description that is complete and sufficient to describe the target and non-target effects of the transgene.

European Communities

231. If the sequence does not correspond to the data in the dossier is the risk assessment valid in your opinion?

Dr Snape

232. It depends on the type because we need to consider this on a case-by-case basis in terms of the transgene and its non-target effects. The likelihood of any non-target effects of the transgene could affect the safety assessment if it is not complete and sufficient.

European Communities

233. Thank you. Probably or maybe we will come back to this tomorrow in the product-specific questions. Another question on molecular characterization: Is it possible that a detailed molecular characterization could predict an unintended effect that would not be detected in the absence of detailed sequence characterization?

Dr Snape

234. Yes, because unless you understand the complexity of the locus you cannot predict its total effects. For example if the locus is complex then it is possible to have interspersed genomic sequences which might have an effect which you couldn't predict from not knowing the sequence.

European Communities

235. Thank you. Since this was very clear and complete we might just skip to question 3. Dr Andow, could you explain how this debate relates to unintended environmental effects.

Dr Andow

236. I think I described that fairly thoroughly in my response to question 9. Was there something specific that you wanted to follow up on with respect to that?

European Communities

237. No we just wanted you to summarize or give in bullet points what can be the unintended environmental effects.

Dr Andow

238. Again, I would refer you to the written record in the event that I leave something out here. The characterization of the genotype is important because it allows prediction of phenotype. If we have the information on genotype we can make predictions about what the expected phenotype is. When we can predict the expected physical characteristics of a product a number of things go from unexpected to expected and this indicates what we should look for. We need to have good

descriptions of the phenotype in order to characterize exactly how the phenotype could be exposed to the non-target species. That would be a non-target effect. With respect to resistance issues we need to know enough information about the expression patterns in order to determine how the organisms that could become resistant to the transgene product would be subject to selection. Those are the two major pieces relating to actual environmental effects.

European Communities

239. Thank you. The last question on molecular characterization goes to Dr Healy. Could a complete sequencing of the transformed and inserted sequence have been done with application of standard molecular techniques in 1995?

Dr Healy

240. The short answer is yes. Certainly by that stage the qualification would be around the rapidity with which sequencing could be done. By that stage we were starting to see automated sequencing and the introduction of polymerase chain reaction. These types of techniques were starting to accelerate the ability to sequence. But even without those techniques the sequences could have been chained out and sequenced more traditionally.

European Communities

241. Dr Snape, would you agree with this?

Dr Snape

242. Yes, with the caveat that some of the technology for getting at flanking sequences were not available in 1995.

European Communities

243. Thank you Dr Snape, we would like to move to question 111. It is part of the general questions. These are questions relating to approaches to safety assessment. We have a few questions for Dr Nutti. In case of incomplete molecular characterization could a whole food feeding study provide assurance of no adverse unintended effects?

Dr Nutti

244. Usually one study complements the other. We need the molecular characterization and the others. If one is incomplete you need to get the information through another means.

European Communities

245. Thank you Dr Nutti. Is targeted compositional analysis enough to completely preclude unintended effects?

Dr Nutti

246. It depends. For instance under CODEX guidelines we have the compositional analysis for the first step, but we never stop the analysis after only completing compositional analysis. We continue with the 90 days study, with the protein study, the oral toxicity study, and at least one animal study.

European Communities

247. Thank you. Third question: Do you believe that feed safety, animal health, plant health and environmental safety or other environmental impacts are fully covered by the approach that are in paragraphs 128-133 of the US supplementary rebuttal submission and that you supported in your reply to question 111?

Dr Nutti

248. My reply to 111 was related to food and feed safety and not to ecological or other impacts. I made that very clear in my answer.

European Communities

249. Thank you for confirming. Our last question is: are simulated gastric fluid studies for purified proteins a true model for *in vivo* digestion given that Bt toxin has been detected in animal faeces?

Dr Nutti

250. Again, we never use only one model. We would not rely only on the gastric fluid study. This is one of the tests that you are going to use but it is not the only one. You need to have different tests.

European Communities

251. Thank you Dr Nutti,. We are going back to HT crop questions and I will hand over to my colleague Mr Flett.

Mr Flett

252. We would like to ask Dr Squire our question 11. What information do we have from European or Japanese studies that oilseed rape can be spilled and can become established along a transport route? Could you tell us a little bit about that please?

Dr Squire

253. Yes, this happens visibly in many parts of Europe. There have been three major, almost parallel, studies in Europe: in northern Germany, central France and in parts of Scotland. The results of these studies mostly agree that spillage occurs frequently, that plants along roadsides and field margins can become established and that they can persist for several years. In many cases they may disappear but grow back from buried seed. They eventually die out but they keep being replenished by new seed. To my knowledge the longest established record of a population in one spot is about 10 or 12 years. They are becoming quite well established in some areas. These three studies, with supporting work from Denmark and elsewhere in Germany, confirm this phenomenon. They differ to some extent from studies around motorways in the south of England which is a different environment and probably not one that is as relevant to agriculture. The interesting point is in how these three studies differ. In particular the one in central France shows a much higher density of wayside, or feral, populations than the one in Scotland. There are uncertainties relating to why some persist longer than others and why they persist at a different density. They can exchange genes with crops. They can also hold genes from crops for some time. But they are a fairly small pollen source compared to the crops themselves.

Mr Flett

254. Thank you. Next we have a question for Dr Snow. Question 12. Could you tell us from your experiences in Europe what do you think the impact of GM herbicide tolerant oilseed rape will have on the management of conventional oilseed rape?

Dr Snow

255. Could you clarify what you mean when you say the management of conventional oilseed rape? Are you referring to problems with labelling and thresholds or possibly weed problems?

Mr Flett

256. Thresholds and weeds.

Dr Snow

257. Both? If you are thinking about the thresholds that would be established in terms of labelling, it would be very difficult to continue to grow conventional oilseed rape side by side with herbicide tolerant rape because of all the gene flow issues that we have discussed with pollen movement and seed movement and seeds persisting in the soil and the types of crop rotations that would be needed. It makes it difficult to grow a non-GM crop in the same region. It could be grown in some other region. That has to do with thresholds and labelling. Otherwise the management of conventional oilseed rape may not be that much affected by GM herbicide tolerant oilseed rape. I could imagine that if the gene moved into a weedy relative that would become a common problem where that herbicide was used but it doesn't seem like a large problem in the short term. That is why I was a little confused about this question. Maybe Dr Squire could elaborate on that if you are ready for him?

Dr Squire

258. Yes. Our direct experience is fairly recent and it follows GM field trials in the UK. This experience coupled with general knowledge of gene flow and persistence in the environment would indicate that growing conventional or non-GM in a field would be difficult if there was a need to keep it to a threshold of 0.9 per cent because of the persistence of volunteers. It is feasible under our present calculations to grow it in separate fields where one was always GM and the other non-GM with reasonable aggregation in a region. Farmers would need to cooperate to concentrate GM in one area and conventional in another. That is the current thinking in the UK. The biggest defect is the time effect that would make rotations impracticable if you were growing GM and non-GM in the same holding sequentially.

Mr Flett

259. Thank you. So I do understand from your answer that when it comes to controlling GM rape and related weeds in a conventional oilseed rape environment that that could well induce changes in the herbicide regime previously operated in that environment. Is that understanding correct?

Dr Squire

260. It is possible, but the biggest effect would be that the farmer wouldn't be able to sell the conventional rape under present regulations if it contained GM above the threshold. It would depend upon how the regulations developed. I suspect the desire to achieve that if it was essential to do so,

(i.e. a GM field going to non-GM) would mean probably more stringent controls for broadleaf weeds, including the oilseed rape, than were implemented at present. But that is one of several possibilities.

Mr Flett

261. Thank you very much.

Mr White

262. Chairman, we are thinking of asking several follow-up questions on the basis of what was said this morning, but I think they are not yet sufficiently in a collate form. Perhaps it is better if we can ask those questions later on and move on to issue one if you wish.

Chairman

263. You would have three more minutes. But now we will go to the complainants for short follow-up questions taking a maximum 30 minutes altogether. Then the Panel will ask their questions and we will see how time goes. Perhaps we can get you a small slot for follow-up as well. Would the complainants like to ask follow-up questions in any order from what was said this morning by the experts and what was now said by the EC on general issues. Argentina you have the floor.

Argentina

264. Thank you. We had a time limitation this morning and also a misunderstanding on regarding protocol. There are a couple of questions we would like to ask which we didn't have the opportunity to ask this morning. Three of them are in our opinion very important for the Panel. Three of them refer to Dr Andow's response for the translators. Our question 10 will refer to paragraph 03.13 in Dr Andow's answer. It is question 7 in the original.

Chairman

265. Dr Andow you have the floor on the original question 7.

Dr Andow

266. To clarify is this the question with reference to paragraph 03.05.

Chairman

267. It is question 7, referring to paragraph 03.13.

Dr Andow

268. My argument is based on my close examination of many of the papers that were submitted in the original materials and also resubmitted recently by Canada. There is a series of papers, perhaps five or six, in the *Proceedings of the National Academy of Sciences, USA* on monarch butterflies. There are also some recent papers in the last year in, I think, *Environmental Entomology*, by Dively *et al*. and Anderson *et al*. In my examination of those papers I note there is an incomplete analysis of event 176. The analyses of event MON 810 and Bt 11 will stand the test of scrutiny. Even if you add an analysis of the variance associated with the primary parameter estimates there is just not enough exposure and enough toxicity associated with the pollen of those events to change that conclusion.

But I do believe that if one were actually to carry through the calculations that are published in those papers on event 176, and carry them out with respect to the new information (Dively *et al* and Anderson *et al.*), one would have a potential effect on monarchs that would be significantly larger than is claimed for MON 810 and Bt 11.

Argentina

269. In other words, you are not using the information established but you are anticipating research results that would be obtained in the future?

Dr Andow

270. No. I am looking at the results that they published in those studies. They simply did not analyse the event 176 problem as thoroughly as they analysed the MON 810.

Argentina

271. Anyway, you have an opinion on that uncompleted study.

Dr Andow

272. Based on the data that they published in those papers, the analysis that they did was for the Bt 11 and Mon 810 events. They didn't carry through a similar analysis on the event 176. They made a similar conclusion for event 176 but if you look at the paper, the analysis of the event 176 is incomplete. I am not using anticipatory information.

Argentina

273. I asked this question because I find in many of the questions, you often use expressions like "may be exposed", "no solid evidence", "opens the possibility that", "a possible hazard". For instance the conclusion points in 3.13 say "has been identified as a potential risk, however, it cannot be concluded that an actual non-target risk of Bt maize or Bt cotton has been fully characterized". You first talk about possible hazards that have been identified, potential risks that are evident, and at the end you say it cannot be concluded that an actual risk. I find it difficult to understand the logic of this kind of statement.

Dr Andow

274. I will apologize for the lack of clarity here. I have probably confused things by introducing the term hazard when the question was really associated with adverse effect. I think that the data suggest that there are possible adverse effects identified. That is to say that there is some endpoint that could be evaluated that would be considered to be adverse. When I say that potential risks are evident I am referring particularly to the *Chrysoperla* study. I am also referring to my judgement about event 176, that we just discussed, as potential non-target risks, rather than saying actual non-target risks. I probably should have just said the risk has not been fully characterized. In other words, the exact amount of exposure and the probability that the adverse effect would occur have not been fully characterized for those two issues.

Argentina

275. Are you aware that 176 is phased out. Are you aware of that?

Dr Andow

276. It is phased out in the US because it no longer has a registration. My understanding is it is still planted in Europe.

Argentina

277. Ok, going back to the questions. I am now referring to the response in 7.12 about the scale situation. My question is the 14th question which was advanced as question 11.

Dr Andow

278. I believe I answered this question in response to Canada or the US this morning. To summarize, any large-scale (magnitude) environmental impact due to the large scale use of these Bt crops in part of the US and other parts of the world is very unlikely. However, unless we have some way of looking for smaller scale (magnitude) effects we cannot make the same conclusion. I cannot agree completely with your statement but I can agree with it in part.

Argentina

279. Next, we would like to look at number 13, which is question 10 in the advanced document. When you say that the absence of information does not imply the absence of effect, as a scientist, could you see the opposite statement - like the absence of information does not imply the presence of effects?

Dr Andow

280. Certainly that would be true. Usually though the conclusion has been that there is no effect. So I was guarding more against that mistake than the other. But yes you are right it would be also a mistake if you have no evidence to assume there is an effect.

Argentina

281. Can I make a very quick remark on one of the questions to Dr Nutti. The EC said that there is a phenomenon observed that HGT marker genes transferred from plants to bacteria. The papers that were quoted were papers by Simonet *et al.* I would like to clarify to the Panel that these experiments were made without treated bacteria prepared to eliminate the possibility of recombination. The strains used were strains prepared especially to be recombinant for analogous DNA sequences coming from the plant. If you do that, obviously you will find recombination because there is a forced phenomenon. But I don't know of any other recent evidence that gene transfer from plant to bacteria occurs under natural conditions with natural bacteria.

Dr Nutti

282. As I said in response to EC questions, I didn't know this paper. I didn't have the chance to read it, so I cannot judge anything about that. In the papers I listed there was no evidence of the transfer.

Chairman

283. US. You have 10 minutes. Sorry there is a point of order. EC?

European Communities

284. Just to put on record, Mr Chairman, that what Argentina said just then was not a question. It was a comment. A scientific statement, a statement with which we disagree. We are sure we will have an opportunity to explain the science at some other point in time. It was not something which is coming from the expert but scientific opinion coming from Argentina. We are also in a position to give you scientific opinions from our side and trust that we will have an opportunity to do so later on.

Chairman

285. The Argentine delegation did announce it as a comment on a statement made this morning. For more comments we will have ample time on Monday and Tuesday. US you have the floor.

United States

286. We have one follow-up question. We were all put in a difficult position on this question, which refers to a paper that was included on a CD that I received on Monday or Tuesday. We actually printed out over lunch two papers and took a quick look at them. Dr Flamm from the Food and Drug Administration will have a follow-up question.

United States (Dr Flamm)

287. This is to Dr Nutti. We recognize that you have not had the chance to read the studies of Simonet *et al.* on DNA transfer from transgenic plants to microbes in the soil, but we would like to ask a follow-up question nevertheless. Given the existing widespread resistance in soil microbes to the antibiotics at issue and their relatively limited clinical utility, would studies showing potential transfer of plant DNA to soil microbes in the environment affect your conclusions in general answer 1?

Chairman

288. Dr Nutti before you answer this material was submitted after the time fixed for submission and you have not had a chance to see. So you may or may not answer the question as you wish.

Dr Nutti

289. I was able to answer the question according to the papers that I read. I cannot give any other comment on that because I did not have the chance of reading this paper. The papers that I saw and listed showed that there is not a possibility of this transfer.

United States

290. I just want to thank Dr Nutti. We've finished our follow-up questions for now. Thank you.

Canada

291. Thank you. We have several follow-up questions. One for Dr Squire in relation to EC question No. 11. What information do we have from EC or Japanese studies that oilseed rape can be spilled and established along transport routes? You indicated that there were three studies. Could you clarify whether these studies involved the transportation of oilseed rape seeds from the field to the

processing plant or whether these studies involved the importation of seeds to processing facilities located in port areas?

Dr Squire

292. It was very largely transportation within an agricultural region to grain silos or plants or between farms: it is essentially transfer of a harvested product from fields around the countryside. In one case there was transfer to a port but that was transfer of harvested seed to a port area. These were the three main studies I mentioned. The oilseed rape came mainly from recently harvested seed within the country.

Canada

293. Yes, thank you. Second question in relation to EC question No. 12 to Dr Snow and Dr Squire. This relates to the broader issue of coexistence and agronomic practice issues or changes in the use of herbicides. If you could clarify whether the impact is primarily an impact because of co-existence issues or whether the impact relates to changes in agricultural practice because of a greater incidence of weeds for instance.

Dr Snow

294. I think we could address each of those independently. There is definitely a threshold issue as we both discussed. I think the confusion may be related to what are the other effects of introducing herbicide tolerant canola into a region where you are growing conventional canola and how that might affect the weeds. I had a hard time with that question. If you start growing herbicide tolerant canola, in a region that hadn't been using it, then the only impact would be that those herbicides would not work on the volunteers that come up from that crop or on any related weeds that spread from that crop. I am confused about what direct impact there would be on the local production of conventional canola other than the threshold issues.

Dr Squire

295. I would support that. The main issue would be if a threshold of GM in non-GM was imposed then that would be the most difficult thing to handle. There would be a change in the way oilseed rape was managed in those fields that grew GM but it would not be a massive change. It would be a change in herbicide type and use, but it wouldn't be a massive change. The most difficult issue is coexistence.

Canada

296. Yes, thank you. Just one last question to Dr Healy. This question follows up on the European questions related to molecular characterization. The question is a variation of question 22 found in Canada's list of questions. Would you agree that molecular characterization is one tool to inform the risk assessment and that the risk assessment also considers a wide range of other elements such as the generation of agronomic data, nutrient, anti-nutrient and other compositional analysis, amino-chemistry of the expressed protein, the nature of the expressed protein including any allergenicity and toxicity issues? In light of all of the other elements included in the risk assessment to what extent can a risk assessment be considered to be an accurate and sufficient, to use Dr Snape's words, characterization of the product?

Dr Healy

297. I would agree that molecular characterization is one tool that you would use in a risk assessment or safety assessment. I am restricting my comments to the food context where I am more familiar. The CODEX principles and guidelines documents clearly talk about incorporating a number of elements into a safety assessment, including molecular characterization, analysis of the protein or substances from the genes that have been introduced, and a compositional analysis. The extent to which the molecular characterization becomes important is a little bit dependent upon what you might find in that molecular characterization. It also is dependent upon the extent of the information available from the other sources. I find it hard to be quantitative about it but it's certainly a judgement about the quality of the studies undertaken from each of those steps and also the type of information that is revealed from some of those steps.

Chairman

298. EC you have a point of order.

European Communities

299. Chairman, the EC is very pleased that Argentina and the US are waking up to the scientific evidence that we put on the record on 28 January when we referred to the studies by a group of scientists led by Simonet. We referred to those studies as I said on 28 January and we were not aware that only scientific literature and articles that are actually produced and copied to the Panel can be taken into consideration as scientific evidence. We assume that at least in respect of published works and unpublished works where the source is given, simply a citation would be sufficient. So this evidence has been on the table since 28 January. It is only now over lunch that the US has decided to go and look it up. To get to my point of order, could you please confirm that it is only scientific literature that has been submitted to the Panel in some form or another that can be taken into consideration?

Chairman

300. On this very point do the other parties wish to make a comment? On the assumption that only material submitted to the Panel in time is now before the Panel and the experts?

European Communities

301. It is not so much a question of time. To put the problem squarely on the table for you. Argentina and US have not provided you with copies of the scientific literature to which they have referred. Canada has done so and then made the objection that some of the literature to which we were referring had not been provided as exhibits to the Panel. Some people say we have provided a lot of information late but we consider it to be voluntary provision of information to the Panel. If this is inadmissible then so are all of the arguments of Argentina and US when they have not provided copies of the literature to which they refer.

Chairman

302. This would be the Chair's understanding but I give the US the floor for comment.

United States

303. First of all, the 2004 study that we are talking about was unpublished. The issue is what's before the experts and what the experts can be expected to look at. I don't think we expect, when an expert cites a study, that the experts can provide a copy of that document. But the parties normally do provide copies of their documents when they expect people to look at them. If the EC is missing some document that they believe we have cited we will be happy to provide it.

Canada

304. Thank you Mr Chairman. Our concern is well-known we expressed it in the letter. Certainly we feel that at a minimum, if materials are to be taken into account by the experts, those materials should be made available prior to the meeting. As for the larger question as to whether materials not submitted as exhibits should be taken into account I think we would want to reserve on that for now. Thank you.

United States

305. First of all let me say that we recognize that organizing and managing this meeting has posed and will continue to pose a number of challenges to you and to the Panel. We want to thank you for your efforts and assure you of our continuing support as this goes forward. I think there are two separate questions. One is how the Panel should organize this meeting and take advantage of its rights under Article 13 to obtain evidence it needs from experts. The question of how that is organized and what information the experts have and whether it is on paper or not are entirely separate questions from the question of what it is the Panel should take into account in writing its final report. To the extent the EC is pressing that latter point I would suggest that that is not something we should take time with today or tomorrow. Should they wish to press it again on Monday or Tuesday we would be happy to revert to it then. Thank you.

Chairman

306. Whatever is in front of the experts in time for them to reasonably look at and upon which they wish to comment, is before the Panel and is part of these proceedings for this expert hearings. As for the question on what material is before the Panel without the experts we can revert to that on the substantive meeting on Monday and Tuesday.

307. Now while I have the floor I would like to straighten out one thing with regard to this question of time management. As you know all the questions were formulated with the consultation and consent of all parties. To my knowledge there is not one of those for which now there is no time for the experts to comment, which were at that time rejected for inclusion in our questionnaire. Secondly, the format for this two day meeting has been agreed also in consultation with the parties. We have agreed on spending two days on this part of the process of the Panel work so we need to stay on track. In other words, time limitations will continue to be applied by the Chair. We now move to the next stage which is the Panel's questions. We have a number of follow-up questions. Point of order only.

European Communities

308. Just to remind you Chairman, we said earlier on that we were in the process of finalizing our follow-up questions and it wouldn't take very long. Just before we leave the general issues we would like to complete our questioning with some follow-up questions.

Chairman

309. Yes, and you will remember I said that you might get a chance after the Panel has its chance so we will stick to that. The questions from the Panel were given to the parties and to the experts this morning. I will not read them out for purposes of saving time but I will ask the experts to try to respond on the questions that were either asked to them specifically or to the experts in general. We have three general issues addressed to anyone and then we have some questions addressed to some of the experts. Who would like to start on the general issues questions and we take 30 minutes for the whole two pages. Dr Snow?

Dr Snow

310. I will comment on biogeochemical cycle, what that is and how it might be relevant. The biogeochemical cycle refers to the cycling of nutrients and carbon in any type of ecosystem including a farmer's field. People are asking questions about whether the biotech crop might affect nutrients that come out of the dead materials from the crop and are recycled into the soil. It could affect soil fertility and things like that and or the rate at which nutrients are cycled locally. Biogeochemical is nutrients and carbon cycling in the form of organic matter and then coming back to their original components in an ecosystem. People have been asking whether there is some GM product that would interfere with this process and cause some bad consequence that we need to know about. We haven't really addressed it very much and I avoid it because I don't know of any problems that I could identify. I have been hearing from a lot of people who study soil processes, but basically the variation within agriculture in the way the soil is treated is so great and so extreme that the impact of a biotech crop compared to a non-biotech crop would be insignificant. There are differences among crops and agricultural practices but the effects of the biotech product would not be that great. People are asking me these questions and that is my sense of the consensus, but it is outside my area of expertise.

Chairman

311. Who would like to come in on *nptII* that is question 2?

Dr Snape

312. *NptII* is a gene which confers resistance to the antibiotics kanamycin and neomycin. This is used as a marker gene to select transformed cells and therefore to produce your genetically modified plant.

Chairman

313. Who would like to answer the third question on the vector backbone?

Dr Snape

314. To introduce the target gene into the transformed plant, it is necessary to put this DNA into a piece of bacterial DNA, termed a plasmid, and the plasmid is inserted into the cells. Sometimes the vector backbone, that is sequences outside of the region that contains the transgene, are or can be transferred into the genetically modified plant. Both of these issues relate to safety issues concerning the use of antibiotic resistance genes present in the transformed plant.

Chairman

315. Unless any other expert disagrees I will ask Dr Snow to continue with the question 4. Argentina?

Argentina

316. Two questions. For a backbone of plasmid or bacteria to be expressed in a plant two very stringent conditions should be met. One is that the backbone should have an operating frame with an appropriate promoter. The other one is that the governed usage of the backbone should be similar or coincident with the plant's usage.

Chairman

317. Is there disagreement among our experts?

Dr Snape

318. No I think the issue is not so much about the expression in the plant but the possibilities that these could be transferred to other bacteria in the soil or in the gut bacteria when these products are eaten.

Chairman

319. We move to the next question. I see the EC wants to take the floor.

European Communities

320. Since Argentina is busy adding to the advice to the Panel in relation to the general issues we also would have a follow-up comment or question on one of these issues which are probably more convenient to take now.

321. Chairman, this is related to the biogeochemical cycles so we address it to Dr Snow. There is new evidence that Bt crop decompose slower than conventional counterparts. I am referring to a study that was published in soil biology and biochemistry in 2005 it is by Floris and Stotzky. Is that kind of evidence relevant for biogeochemical cycling?

Chairman

322. Sorry, it is an unpublished study. I would not want to go into details about it.

Dr Andow

323. I don't mind saying that I don't think it's a big issue whether it decomposes more slowly or not, because this is a reversible problem. If it turns out to be a big problem people could stop planting that.

Chairman

324. Ok, we move to question 4. Who of the five experts would like to comment on Dr Snow's comments?

Dr Squire

325. This is an outcome of some of the repeated requests for information and responses. What we need for each of these issues is some indication of when we are almost there when is a reasonable level of certainty achieved. This is often a two way issue. It requires consensus almost before a product is discussed concerning what constitutes adequate safety. I don't think on the environmental side of things we have that agreement. We may have it in other areas. I suspect that when we have satisfied our need to know then we are there. Defining what we need to know is really quite difficult to do.

Chairman

326. Question 5. Who would like to comment on Dr Andow's statement?

Dr Squire

327. The standard for what was an appropriate environmental risk is not static. I think it has evolved because we know more about the issues to do with GM cropping and wider issues. The ecological environmental standards have certainly changed over that period. I would endorse his statement.

Chairman

328. Thank you. I am being reminded we must turn off our microphones at the end of statements. It reduces the quality for the interpreters. Dr Squire you have broken the ice on 4. Break the ice on 6 and 7.

Dr Andow

329. The unintended consequences that Dr Snow refers to are abnormal growth and development which are typically evaluated during the agronomic evaluation of any crop. Such traits are unlikely to have effects that are ecologically significant. As I pointed out in another answer, we begin with the introduction of genetic variation and then seek to develop a variety with good agronomic characteristics. This development of the good variety will eliminate traits that are of poor agronomic character. These issues Dr Snow is particularly referring to are ones that with poor agronomic character. Those would be eliminated. Therefore I would agree with that statement.

Chairman

330. Thank you. Would you like to continue with question 7?

Dr Andow

331. This is where there may be a slight difference and this is where my points about the scale of use coming into play. While I think I would agree with Dr Snow that it would be wrong to characterize it as biotech versus non-biotech, certainly the scale of use of a crop would be very important in determining whether or not there is influence on genetic diversity. In the cases that are in front of us with respect to, say, the glyphosate resistance trait itself, is quite advantageous to production. So these crops have increased tremendously in scale of use. In the US perhaps their production has increased faster than the production of any other agricultural technology.

Chairman

332. Thank you. Question 8 with three sub-questions. Who wants to have a go?

Dr Andow

333. I would say that it relates to my previous number five statement. I agree that absolutely safe is not really the issue. However what is the benchmark by which ecological safety can be judged? I believe that that benchmark has been changing and that's what is making it so difficult In some countries the benchmark has been changing, but evaluations were continuing to be made. For example in the US the benchmarks have been evolving over the same period of time but the US has been continuing to make decisions on products. That is partly because changes are being introduced slowly over time. In contrast with respect to the benchmarks that we're referring to in the EU regulations some of them have had to be worked out quite rapidly.

Chairman

334. Any other views. Replica from Dr Squire?

Dr Squire

335. What I was getting at here was that it is not impossible to envisage a set of criteria that defines what a soil ought to do to keep it operating properly and what a complex food web ought to do to keep it operating properly, including the production of crops. My point was that so far those criteria have not been agreed upon and universally established. Even though people do make decisions very often, it is not against independent criteria.

Chairman

336. Thank you. Dr Nutti

Dr Nutti

337. I would like to comment on Item B of the EC's statement which also applies to food safety concerns. For food safety, we have the CODEX guideline which is a generally accepted standard. It is different for environmental issues. Maybe we need a step by step guideline, like the CODEX guideline, for environmental assessments. Even when we have the statement that no product can be assessed as absolutely safe, we could at least try to say "as safe as when we were going to the food safety assessment".

Chairman

338. Question 9 about healthy population. Would you, Dr Andow care to respond?

Dr Andow

339. I would agree with Dr Squire's point that there are no reference objective criteria. However I am not sure I completely agree with his point that it is possible to develop those objective criteria at this time. I think there are some criteria that can be established, but the debates relating to what it means to be able to sustain agriculture into the future are still relatively unresolved. Part of those

objective criteria would have to include some recognition that these are not yet resolved and it's not clear when they would be resolvable.

Chairman

340. Would you agree Dr Squire?

Dr Squire

341. Yes, in principle I would agree with that. It's a very complex issue. I would also say that we could make progress in some areas, if the scientific establishment set its mind to it. But I accept the point that there are some very complex issues that will be very hard to resolve.

Dr Snow

342. This question relates back to the previous one about what the benchmark would be for ecological safety. By talking about sustainable agriculture we are getting into the academic issues. If we think back to what regulators are facing when they need a benchmark it is usually a reference which reflects what is accepted within that country as being healthy enough for the environment. It could be related to what that is trying to attain in terms of environmental harms and benefits. It's important to distinguish what is an academic goal and what is practical in the present or especially 1998-2003. What were people thinking at the time?

Chairman

343. Questions 10 and 11 go to all experts on a first-come-first-served basis.

Dr Healy

344. I was actually going to ask for clarification, because the term up-coming evidence is not a term with which I am familiar and seek clarification from perhaps the EC about what they intended by that term?

European Communities

345. Chairman the up-coming evidence was a new molecular characterization which was submitted into the dossier.

Chairman

346. Dr Healy? If you are not familiar with this term then may be you don't want to answer this one.

Dr Healy

347. What I understand from the response is that upcoming evidence is in this case referred to new information that was inserted into the dossier for consideration. In that case, if information is included in the dossier then of course it should be taken into account in the overall assessment of the product.

Chairman

348. We will move to question 11. Dr Nutti?

Dr Nutti

349. My answer is related to this case. I believe that first of all we need to have the risk assessment of the product without the herbicide use. We have the levels of the herbicide determined by the FAO joint committees. We don't need to assess the herbicides together. We need first to assess the GMO and the non-GMO and then maybe if we still have doubts then go further to assess the safety with the herbicide. This is what I pointed out in my answers also.

Chairman

350. Thank you. That seems to cover the subject. The next question goes to Dr Snape.

Dr Snape

351. This goes back to the answer that I gave to question 3, insofar as the backbone is there for the introduction of the DNA into the plant. There is a possibility of the introduction of antibiotic genes that are used in maintaining the transgene in the bacteria. The environmental and health safety assessments relate to the transfer of these genes to gut or soil bacteria and the general concerns of antibiotic resistance genes.

Chairman

352. Dr Healy. Question 13?

Dr Healy

353. In responding to question 9 I included this caveat that I was talking about safety assessments. The reason for making that caveat was that the product-specific questions related to safety assessments and question 9 related to risk assessments. I did not know whether there was an intentional difference in the use of those terms. A conventional risk assessment in relation to foods would be considered to have four steps: identification of the hazard, characterization of the hazard, an assessment of the exposure to the hazard and then ultimately a risk characterization. A safety assessment is essentially a modified form of a hazard identification. It is asking whether there is a hazard associated with this product. The CODEX document, the principles for risk analysis of foods derived from modern biotechnology, has a definition which says: a safety assessment is characterized by an assessment of a whole food, or a component thereof, relative to the appropriate conventional counterpart (a) taking into account both intended and unintended effects, (b) identifying new or altered hazards, (c) identifying changes relative to human health in key nutrients. The intent of a safety assessment is to identify, if there are any hazards over and above what you would see in the conventional counterpart. If you do find hazards, they would then be subjected to a conventional risk assessment.

Chairman

354. Thank you Dr Healy. Our last question goes to Dr Nutti. It is a very long one on toxic allergens.

Dr Nutti

355. We use the CODEX guideline for the conduct of food safety assessment of food derived from common DNA plants as a reference. According to this guideline, when we assess possible toxicity, it is clear that we need to treat toxins and allergens in different way. For the assessment of the possible toxicity the new substances we are assessing can be proteins, fats, carbohydrates, vitamins and new metabolites but they are new substances. This is why we have to have the assessment of possible toxicity. The assessment of the allergenicity should be done separately because it has a special procedure. In addition the possible allergens are always proteins and so we are free to use different methods. This is why the CODEX guidelines treat allergens differently from the toxins and also why the EC SCF distinguishes between toxins and allergens.

Chairman

356. Thank you. This covers the Panel's questions to the experts. Thank you very much for giving us your replies. I will now re-open the window on follow-up questions and this until 4.40. The EC you have the floor.

European Communities

357. Thank you Chairman. We have just a few follow-up questions. Since it is topical and related to what we've been discussing just now I wanted to ask a question briefly to Dr Snape. In view of the fact that backbone DNA can affect the transformed plant in many ways, for example, increasing the probability of unintended recombination and the creation of undesired open reading frames, do you not agree that the presence of backbone DNA in a transgenic plant is undesirable and that a detailed molecular characterization is needed to determine its presence or absence?

Dr Snape

358. I am not aware of what evidence you are quoting to say that it increases recombination or that it affects recombination. Perhaps you can enlighten me on that?

European Communities

359. It is the fact that bacterial DNA present in the genome facilitates the copying of that genome by other bacteria, and its integration into the DNA of other bacteria.

Dr Snape

360. I still don't understand your question.

European Communities

361. I think, I am going to ask Dr Kleter to explain to you, because I am sure he can do it much better than I can.

Dr Kleter

362. As you correctly noted this pertains to horizontal gene transfer.

Dr Snape

363. Horizontal transfer refers to the fact that the backbone will have antibiotic resistance genes. I am not sure how you think that affects recombination within the transgenic plant.

Dr Kleter

364. It is recombination with other bacterial sequences.

Dr Snape

365. This means that it would occur when this was eaten or coming into association with soil bacteria not affecting recombination between the plant DNA. That I can't comment upon. This refers to an environmental issue rather than a molecular characterization issue about the transfer of bacteria of genes between transgenic plants and bacteria. I am not competent to answer that.

European Communities

366. Are any of the experts competent to answer that question? If not, I will move quickly to the next follow-up question which is in fact a follow-up question to Dr Andow in relation to clarify the Panel's question No. 6. The question is about the unintended effects arising from the creation of transgenic plants. The question of the Panel spoke specifically about effects such as abnormal growth or development. Can there be other unintended effects than those mentioned? That is other than growth and development, for example, long-term environmental effects? Dr Andow?

Dr Andow

367. Thank you. In theory, the short answer is yes. With respect to the products that were at issue here, any long-term or indirect or unintended effects of these products are hypothetical. The only way we would know, whether anything like that would happen, would be because we were looking for something in particular. It creates a bit of a quandary in terms of how one actually does it, because you have to look for something particular and know what you are looking for. Whatever monitoring system you have has got be match the harmful effect. With respect to how one might manage an effect associated with decomposition rates, all we know right now is that there could be differences in decomposition rates. We still have not made the link to what could be the adverse effect from that difference in decomposition rate. Changes in decomposition rates could be changing biogeochemical cycle, but we still have to specify and figure out what is the adverse affect associated with that.

European Communities

368. I would like to pose my next question to Dr Andow and Dr Squire. This is in the context of risk management strategies for non-target effects and HT crops: How can the fact that small farms, meaning farms that have less than 10 hectares which are frequent in the EU, obviously effect risk management strategies for Bt and Ht crops.

Dr Andow

369. The risk, as I have made it clear, as established for both Bt and HT crops is that adverse target pests can involve resistance either to the Bt plant or to the herbicide. I would rather talk about risk management of something that I believe to be an actual risk rather than something that is a hypothetical risk. I'll focus specifically on the Bt crops, because I have thought considerably more

about this in a small farm context: I believe when you have large farms you can argue that you can internalise the cost of risk management and have individual farmers be responsible for it. When you have smaller farms it may be more difficult to get acceptance to do that. So one approach that has been suggested is to organize local communities to be able to manage risks. In countries such as those in Europe that would seem to be a potentially feasible approach, depending on the farm size. I am thinking of farms that are as small as a few hectares per field. It does become more difficult to figure out how to do this in such a way that it is acceptable to the farmers themselves.

Dr Squire

370. I agree with that opinion. There are two issues: the management of the ecological effects over a region and the management of coexistence. Both would need agreement and cooperation among the farmers involved. This would be an additional thing to achieve beyond what many communities in Europe presently achieve. They would need to actively manage their region among themselves. The effects on biodiversity or food webs would be less because there would be inherent diversity in small farms anyway. The greatest difficulty would be managing coexistence. For example, if a small farm did not want to grow or market GM crops, or vice versa and if that farm had neighbours who did grow GM crops then there would be difficulties. If those crops were open pollinated and left seed residues, farmers would have to organize their joint machinery in a certain way. They would have to organize the proximity of flowering crops. The smaller the farm and the more heterogeneous the farming community, then the more difficult it would be to accommodate coexistence. It hasn't been done in Europe yet on any big scale.

European Communities

371. We have a question for Dr Healy regarding in the context of detection methods. Before the establishment of the community reference laboratory on 18 April 2004, did there exist any body or infrastructure capable of organizing and completing a high quality collaborative trial validation of a quantitative events specific detection method in less than 12 months?

Dr Healy

372. I am not a developer of detection methods, so I cannot answer that with any accuracy. I would note that the joint European laboratories in ISPRA have been organizing collaborative, world wide, ring trials over some period of time. I would not be able to comment on whether those ring trials occurred within less than 12 months though.

European Communities

373. Another question to you Dr Healy, relating to the comments you made to the Canadian follow-up question. How can you test the safety of the new protein as part of the complete safety assessment if, as had often happened with GM plants, some new proteins had not been identified in the molecular characterization?

Dr Healy

374. Again, there is a totality of information approach that can be taken and is clearly outlined in the CODEX process, whereby you would look at the molecular characterization, the properties of the protein that you intended to insert and then the compositional changes. Of course the protein analysis, the middle step that I have just referred to talks about the protein that you intended to insert. What the molecular characterization can give you is identification of open reading frames which you may not

have known were present. Detecting an open reading frame doesn't necessarily mean that a protein is going to be made.

375. The impact of those open reading frames is then the next question. The ability to determine the impact of those open reading frames on human health is quite problematic. Nonetheless, the examination, particularly of the compositional information, is very important in giving you an indicator of unintended effects which may be biologically important.

Chairman

376. Thank you. Now, as you know, we had foreseen to break at six and resume at six thirty but there are two reasons why I want to suggest a little change. One is that we need five minutes to work out the new time allocation for issues 2 and 3. The other one is that the cafeteria downstairs closes at 5.30. I suggest that we take a break until five o clock so that you can refresh yourselves and come back here at five sharp so that we can continue but then we will work through until we finish the agenda for today. Thank you. [Pause.]

Chairman

377. We have worked out a timeframe for the issue 2. The proposal is that we would give the complainants half an hour, that means 10 minutes each starting with the US this time in reverse order and then Canada and Argentina, followed by the EC with half an hour, followed by the complainants or the EC at the later stage with another half an hour. That would take us to 6.45 for issue 2. We have interpretation until 6 pm. The Argentinean delegation has courageously agreed to do without interpretation after that. So we start with issue 2 and I give the floor to the US.

United States

378. Thank you Mr Chairman. We have no initial questions and any questions we will ask in follow up. Thank you.

Chairman

379. Thank you. Canada?

Canada

380. Thank you Mr Chairman. We have a series of questions in relation to the Panel's questions 59 and 60 to the experts. This relates to the safeguard measure adopted by France in relation to MS1 RF1 and this can be found under issue 2 on page 5 of Canada's questions starting at question 26.

381. I would just like to preface these questions with a statement that here we are talking about a crop that has been modified to be resistant to glufosinate ammonium and not one that has been resistant to glyphosate. I apologize if we have gone over some of this material earlier in the day. Is there a distinction between the methods for controlling glufosinate ammonium tolerant oilseed rape derived through transgenesis compared to oilseed rape that is tolerant to the immis in terms of controlling crop volunteers in subsequent years. Suppose you plant canola one year and the next year you plant something else, but you have canola volunteers. In scenario (a) these canola volunteers are tolerant to glufosinate ammonium. In scenario (b) the canola volunteers are tolerant to one of the immis. Do the management practices of controlling the volunteers differ?

Dr Snow

382. I don't think there would be a difference. All my other qualifications are in what I have written which is on record, but I don't think there is a difference here between these two.

Canada

383. Would there be a difference if the comparison was between the glufosinate ammonium herbicide tolerant crops and conventional oilseed rape, conventional meaning non-herbicide tolerant oilseed rape. For example, in the field you are planting oilseed rape one year and the next year you decide to plant beet.

Dr Snow

384. If you wanted to use the same herbicide on the subsequent crop and the volunteers are resistant to that herbicide then the volunteers would be more difficult to manage.

Canada

385. What is the likelihood that you would use glufosinate ammonium as a means of controlling volunteers in subsequent years?

Dr Snow

386. It may be quite low at the present time.

Canada

387. Which would be in comparison to glyphosate where you might use glyphosate to control these volunteers?

Dr Snow

388. Correct**.**

Canada

389. Dr Squire would you have anything to add?

Dr Squire

390. No, I would agree with that statement. With the proviso that there has been very little experimental comparison in Europe on that issue.

Canada

391. Thank you. The next question is for Dr Andow. At paragraph 59.05 of his answers of comments on the Panel questions he states that there may be years when certain fields of GMHT oilseed rape are not harvested at all and the entire crop goes to seed since this happens occasionally with non-transgenic oilseed rape. Subsequent problems with *Brassica* weeds may require exceptional agricultural practices to bring the field under control. Such possibilities were not considered by the

SCP and France may be concerned about such scenarios. In light of the fact that there are other available management measures to control oilseed rape volunteers or weeds could you clarify your statement here?

Dr Andow

392. There are other management practices for controlling these things, but the issue with respect to, for the example of controlling GMHT oilseed rape, rather than directly controlling them, one could make sure that the management systems were in place to ensure that they would actually be controlled in the way that we would want it to be controlled. In other words, there may be a requirement, incentives, or a management system that would need to be in place in order to accomplish that particular piece. It is not in place for the conventional practice.

Canada

393. Perhaps we can just build on this point. If the non-herbicide tolerant oilseed rape was planted in a field and the farmer let that field go to seed but then in subsequent years decided to plant beet or they needed to clear the field, there are several options that are available. You could spray glyphosate as a preseason burn off, you could till or you could use phenoxy. This would be used in conventional practice. How would this differ if the oilseed rape was tolerant to glufosinate ammonium?

Dr Andow

394. The specific herbicide and perhaps the way the equipment used may not be different, but needing to make sure that the farmer actually followed the management practices would be a new requirement.

Canada

395. What would make you expect that the farmer wouldn't anticipate then that the canola volunteers would be tolerant to glufosinate ammonium and then just not use that herbicide, but use something else like glyphosate or till. Isn't this something that farmers do all the time?.

Dr Andow

396. The reason I brought up the going to seed part was that there is a lot more seed that enters the seed pool so then there is a longer term process that is involved in terms of the management. Certainly a farmer may know that these seeds will be coming up, but depending on the crop that is going in it may be difficult to control the oilseed rape. It could end up restricting the management options. If they have to control the glufosinate ammonium oilseed rape for these purposes that may come at a cost. Then the farmer will adjust by changing their management practices and it might not result in the suppression of the particular GMHT oilseed rape in a way that prevents the movement of the gene out to other areas.

Canada

397. If you are not using the glyphosate ammonium to clean the fields of weeds, why would this matter?

Dr Andow

398. It's a question as to whether or not the oilseed rape would be sufficiently controlled. Controlling it to reduce competition is one level, but controlling it sufficiently to minimize the potential adverse environmental impacts associated with GMHT crops is likely entail a different threshold of control. A farmer may be willing to tolerate more in their field, because they always have dealt with volunteers and there is some level of tolerance of volunteers. They are not eliminating all of them, they are eliminating enough to have economic control from the perspective of the subsequent crop production.

Canada

399. And would your acceptance level of weeds within your field be the same regardless of whether you are growing HT or glufosinate ammonium tolerant and regular canola?

Dr Andow

400. The farmer's acceptance level probably would be the same, but the point would be that with the conventional weeds or the conventional volunteers the concern about gene flow from that field to other fields is not an issue, whereas the gene flow from the GMHT fields may occur at densities lower than the economic thresholds that merit the control by the herbicide. If there are many volunteers that next year, meaning they are not back to some economically insignificant level, but are still at a high population density, these other issues could arise.

Canada

401. When you say that there may be an issue with gene flow can you just explain why the conventional farmer would not be worried about gene flow, whereas the GMHT farmer would be worried about gene flow? Is this the coexistence issue?

Dr Andow

402. That is the one that most immediately comes to mind.

Canada

403. Thank you. Those are all of our questions for the safeguard measures issue no. 2.

Chairman

404. Thank you Canada and the experts. Argentina you have the floor.

Argentina

405. Concerning the second issue I will ask a few questions from our long questions. My first question, number 16 in our questionnaire, refers to the paragraph 69.09 which was advanced as question 13. It concerns Bt-176 maize in Austria. The question has to do with exposure to toxin in the field as compared with spray or the presence of the Bt producing bacteria. Dr Andow?

Dr Andow

406. You want to know if the resistance risk in this case with 176 is potentially higher or lower than the resistance risk associated with another insecticide. I understood the Panel's question to mean: is there any reason to believe that there is scientific evidence that would not permit it (the EC) to undertake the appropriate assessment? And in considering that, I was not convinced that the relative risk of resistance compared to any other insecticide was necessarily relevant to answering that particular question.

Argentina

407. So you don't agree with the report that was in your answer that "a Colorado potato beetle population 100-fold resistant to a Cry3A- containing *B. thuringiensis* spray could not survive on potato plants expressing the same protein"?

Dr Andow

408. One would have to say that European corn borers that express 60 to 74 resistance can't survive on Bt maize either but that doesn't necessarily mean that there isn't anything that will become resistant. For example, colleagues have found colonies of potato beetles that could survive on the potato that you are referring to. We have not yet found any colonies of European corn borer that can survive any of the transgenic Bt crops at this time. We do not yet have any evidence of resistance in any European corn borer population that we have been able to bring into the lab. Now we have colonies with several hundred fold resistance in the laboratory and none of them can survive on the Bt plants. It suggests that the amount of resistance that has to be in the insect is probably on the order of a thousand fold or even higher levels before we can expect to see resistance.

Argentina

409. Were you talking about the special levels of the Bt toxin in the plant or the continuity of the expression of the Bt toxin in the plant?

Dr Andow

410. I am not really referring to either. I am referring to the susceptibility in the target insect itself. We measure the susceptibility in the target insect and conduct laboratory bioassay associated with the toxin. Then we find how resistant it is. We put it on the transgenic plant and even those with quite high levels of tolerance to toxin in the laboratory cannot survive on the plant.

Argentina

411. How does this compare with the chemical insecticides?

Dr Andow

412. I am not convinced that that comparison is relevant to this question.

Argentina

413. But what is the alternative under current agronomic practices?

Dr Andow

414. In the US, about 12 per cent of the maize is sprayed with an insecticide for European corn borers. Essentially current agricultural practices do not spray at all.

Argentina

415. My second question is number 19 referring to 69.11 point (b) and was advanced as question 16. Did the committee address the issue of resistance as an environmental risk. My contention is that if the committee addressed the environmental related issues like toxin presence persistence in soil effects on agricultural practices they were really addressing the issue of environmental effects.

Dr Andow

416. The committee considered some aspects of environmental risk but not the totality.

Argentina

417. I wonder if it is possible to consider all environmental effects, even effects that we don't know about today.

Dr Andow

418. At the time I particularly referenced my comment to things that were known to be of concern at the time the committee made their evaluation. They did not consider the totality of environmental risks that were known to be of concern at that time.

Argentina

419. Our next question is 21(a) referring to paragraph 69.14, part 1 in your answer, and was also advanced as our question 18(a). This question refers to the new knowledge about transformation, which you claim would be reason for the EC to postpone this issue. As science evolves continuously, we can say that any decision could be postponed indefinitely because new knowledge will come out and will require the revision of previous decisions.

Dr Andow

420. In comments on the experts from some of the other parties there is recognition that these were possibilities that Austria could have made at that time but they did not make these points. They could have made these points at that time but they did not make these points. Because the question was: is there any information before the Panel that would indicate at that time that the evidence associated with Austria was not sufficient for them to make a decision. Tthis was evidence in front of the Panel that we received. It is information that was available at that time. They could have used it, but they didn't.

Argentina

421. Any evidence means evidence obtained after the decision of the committee?

Dr Andow

422. I took the timeframe to be at the time Austria made their decision, which was February of 1997. Then there was another decision that was made in 2003, I believe. Those were the two timeframes I was looking at.

Argentina

423. [blank from face 8]… modify whatever decision the committee has recommended to take.

Dr Andow

424. I don't think I can answer that specific question in terms of what the committee would do.

Argentina

425. Dr Andow I am asking this question to you.

Dr Andow

426. For event 176 the point is that there was some information that has become available. Unfortunately this is not information before the Panel because event 176 is not one of the cases. But sufficient information (for Event 176) has become available to say that: had Austria made the request they could have gotten the information and they probably would have been satisfied with the information on the molecular characterization. For example with maize, because they said in the initial reports that there were only so many insertions and had they done the additional work to fully establish that, they would have been able to prove that there were only those many insertions and no other silent ones. Then they would have been able to continue.

Argentina

427. So in your opinion, after the decision of the committee, any evidence on molecular characterization would have required the revision of the decision.

Dr Andow

428. My point is summarized in 69.16, which is in 1997. I judged the information that was in front of Austria to be insufficient, but by 2003 there remained some uncertainties. They probably could have had the information to make a decision by 2003, had they pursued those uncertainties.

Argentina

429. They didn't have the information in 1997?

Dr Andow

430. That is my point.

Argentina

431. The last question is 20 with reference to 69.12, which was submitted as advanced question 17. It considers answers to the paragraph 69.06 and it concerns three points, the beta-lactamase (BLA) gene, the Cry1Ab toxin, and if there is an environmental risk for targeting insects with resistance that would require resistance management measures. Was there evidence for point 1 to be disregarded as a risk? Is there evidence of low or high probability of Bt entomotoxins to be toxic to other non-target organisms. Since the development of resistance is an essential phenomenon in evolution - so it is something that is expected to occur - it is also managed by the strategies like the high-dose/refugia strategy**.** Did these three reasons support Austria's decision to ban commercialization of Bt event?

Dr Andow

432. In my response I did not consider point no. 1 about the BLA gene. I concentrated my response to the points concerning non-target risks and the resistance for Cry1Ab toxin. My opinion is that they didn't consider all of the non-target risks that were available, that were of concern at that time. I will just refer you to my comments, because I think that they are clearer on these points than anything I can say at this time.

Argentina

433. So resistance was known to be an environmental possibility. How can Austria raise this point, when it is a natural evolutionary process and there are some means to avoid this risk?

Dr Andow

434. In terms of the resistance risk - and this is quoting then from the SCI scientific committee document - the scientific committee did believe that resistance risks were not environmental risks. They didn't consider it to be under their purview. Despite this they still made a recommendation that resistance management should be considered. This is quite different from a recommendation based on what they consider to be their remit on which they could have based a requirement for resistance management.

Chairman

435. Last question from Argentina? Thank you. The EC.

European Communities

436. Thank you Mr Chairman. The first question is a slightly more general question. Then we have briefly some more specific questions on the safeguard measures picking up specific points in relation to specific safeguard measures. The first question for Dr Snape and Dr Andow, although may be Dr Squire would also like to comment, is about the issue of molecular characterization. We would like to invite the experts to answer the following question: given the absence of a complete molecular characterization in the periods preceding the adoption of the Members' safeguard measures and the consequent need for Member States with specific concerns to pose further questions, are you supportive of today's generally more stringent requirements regarding molecular characterization?

437. We very much appreciated the experts' attention to placing their advice on these matters in temporal contexts. We should not forget that we are looking at the science at that time. And also that

the experts have by and large taken care, notwithstanding the leading questions on occasion put by the complainants, to limit themselves to scientific issues and not to legal issues which are for next week

Dr Snape

438. I wouldn't necessarily describe them as more stringent but I would make the point that I think a complete characterization helps everyone in the risk assessment process of GM crops. Characterization should take into account three levels of molecular characterization. The first is the transgenic locus complexity, which refers to the intended effects of the transformation, in terms of the copy number, in terms of the sequence and organization of the transgene insertion. The second is the information on flanking sequences, which can refer to unintended effects of the transformation. This refers to gene disruption and unintended effects or proteins that might be expressed or might be absent that could have unintended effects. The third is the presence of any possible backbone sequences which again can influence the risk assessment process.

European Communities

439. I understand that you are supportive of the more current arrangements?

Dr Snape

440. I am believe that a complete characterization helps everyone in assessing what the transgenic is doing.

European Communities

441. Thank you. I wonder if Dr Andow would also like to comment on that?

Dr Andow

442. Nothing more.

European Communities

443. Dr Squire, do you agree?

Dr Squire

444. In my written responses I commented that for some ecological assessment you didn't need to know in detail the full sequence. I don't want this to be misinterpreted. I agree with what Dr Snape has said. But for certain kinds of ecological assessment, for example, the comparison of herbicide tolerant crops with conventional, the design of the experiment, the detailed running of it, the things that you measure, the target organisms that you look at - all that can be done without detailed knowledge of the entire transgene. Other aspects of characterization such as for example gene flow, the kinds of segregants that are in the populations following gene flow, would need fuller characterization. For a completely detailed knowledge of what the transgene might be and do then you would need sort of detail that Dr Snape has spoken about.

European Communities

445. Thank you. Our next question, number 24, relates specifically to the provisional measure put in place by France in relation to MS1 RF1. It is just a question to Dr Snow at least in the first place. You conclude in your advice to the Panel at page 21 that France had a valid reason to follow the advice of its biomolecular engineering committee, of course at the time, to carry out more research to supplement existing scientific knowledge and validate methods for managing the cultivation of genetically modified oilseed rape. Now in your opinion and taking into account the specific climate and agricultural structures in France: do you think that the estimated extent of gene flow and the need for an agreed design for a monitoring programme were areas that could reasonably have been the subject of further research?

Dr Snow

446. Yes. I explained that in my written documents, but the reasons for my conclusion are that the scientific committee on plants had identified concerns about the spread of herbicide resistance to volunteer weeds and that they had underestimated the extent of gene flow. So back in 1998 one of the quotes that I have in my document here about the extent of gene flow was that it was unlikely to happen. Basically the hybrids that would be formed would have low viability and the transgene would not spread. That was back in 1998. Between 1998 and 2003 a lot more information was coming out about where the genes would move and how rapidly. If France wanted to monitor this process, you could argue that they had valid reasons for getting more research because it was still coming out at the time. This research included farm scale evaluations published in 2003 and an article that I cite showing the extent of contamination of non-GM seed by GM seed. There are just a lot of questions that France had at that time.

European Communities

447. Thank you. It would be correct, presumably, to say that in relation to the large populations of *Brassica Rapa* in France as well as in other regions in the community; but at the time there was an open question of what one would do in terms of management in the event that such plants became HT?

Dr Snow

448. Yes. I agree.

European Communities

449. We move onto the next safeguard measure in relation to oilseed rape Topas 19/2. Here there were provisional measures adopted by France and Greece. We wanted to clarify this point but I think it has already been clarified by Dr Nutti that she did not intend to provide the Panel with advice in relation to the environmental issues in relation to these two provisional measures.

Dr Nutti

450. When I was reading these questions, I looked for the food safety issues. When I answered on question 63, I was looking at the documents about the food safety. I don't want to talk about environmental issues, as this is not my expertise. I checked all the documents that were submitted to the Panel. I may have misunderstood because I thought that I was supposed to check all the documents, as well as the opinion of the scientific committee. This is why I checked the documents,

but I am not an expert on environmental issues. I stated that there were no reasons related specifically to food safety.

European Communities

451. Thank you, Dr Nutti for that helpful clarification. I think that brings us to the next product which is maize Bt 176. Here again there were some provisional measures adopted by Austria, Germany and Luxembourg. The question is to Dr Andow. In your advice to the Panel on page 94 you conclude that when Austria adopted its safeguard measures the evidence on risks to non-target organisms was insufficient for the conduct of a full risk assessment at least for Austria. On this point we take note of Dr Andow's observation that the question refers to the information before the Panel. I think this is really touching on a legal issue which is for next week. For the time being Dr Andow has correctly, in our view, offered scientific advice on the basis of the information that was essentially in the public domain at a time when Austria for example adopted these measures as well as the other Member States. And the question is: could you briefly recap for us what considerations support your conclusion regarding non-target organisms and Austria?

Dr Andow

452. Yes, I could recap. But in the interest of time I will simply refer again to my text and again with some apologies to Argentina for not being clear on certain words. I would say my conclusions would stand even if I were to respond fully to those comments.

European Communities

453. Thank you very much. I think we can move directly to question 31 since I think question 30 has already been the subject of some discussion this morning. This is in relation to maize T25 and the provisional measures adopted by Austria and Italy and the question is to Dr Andow. Is it your view that secondary ecological effects need to be assessed for each member state under regionally appropriate conditions?

Dr Andow

454. This is certainly a difficult question from a scientific perspective. It is clear from one level that one needs to identify and evaluate things under regionally appropriate conditions. But what is not resolved scientifically is what is the appropriate region? For example in some work that I have done associated with the Bt maize in Kenya we can identify different cropping regions within Kenya. Some of the risks seem to be associated with these specific regions and others probably are specific more to all of East Africa. I doubt that one could get it down to the individual cantons of Switzerland, but there certainly is an issue associated with this. I would say that there is no consensus as to how much regional specificity is needed. Even if you get down to all of North America it is still not clear how much transfers from North America to Europe and how much is specific.

European Communities

455. Thank you. So if I understand your answer correctly it would be appropriate and even unsurprising for an authority considering whether or not to go forward with a definitive decision on authorization or whether provisionally to pose further questions or look for conduct of further research to take those kinds of issues into account, depending of course on the region for which that authority was responsible.

Dr Andow

456. Yes. I raised issues associated with butterflies and the Bt maize. There was a recent paper that I referred to in which butterflies were of conservation concern and identified as being associated with maize. I believe it was in Hungary or some part of eastern Europe. When we are dealing with issues of conversation concern there is likely to be some specificity because most species of conservation concern don't have a very large geographic range. I bring that up merely to emphasize that there were such issues I guess at the same time - what I didn't emphasize is that this issue comes up around 1998. A logical approach would be to compile a list of all the known species of conversation concern and start to do some research to determine which ones were associated with maize and knowing that this sort of evaluation would be necessary.

European Communities

457. Thank you. I wonder if any of the experts disagree with Dr Andow's comments. Otherwise we will move directly to our final question. In that case, our final question on the provisional measures adopted by the Member States relates to maize MON809, where a provisional measure was adopted by Italy. The question is to Dr Nutti in the first place: would you agree with the Italian competent authority that the term substantial equivalence involves a significant degree of ambiguity and as a scientist, do you think such ambiguity would have consequences for the conduct of a risk assessment?

Dr Nutti

458. As I wrote in my written comments, I do not agree with the opinion of the Italian competent authorities, because this was defined in the FAO, WHO expert consultations in 1996, 2000, 2001 and Codex Alimentarius. You say that the consultation talked about concerns about the substantial equivalence. I would like to read a little bit of this paragraph of the conclusions, if it is possible. "The consultation was of the view that there were presently no alternative strategies that would provide a better assurance of safety of genetically modified foods than their appropriate use of the concept of the substantial equivalence. Nevertheless it was agreed that some aspects of the steps of the status assessment process could be refined to keep abreast of developments in genetic modification technology. The concept of the substantial equivalence was developed as a practical modification technology approach to the safety assessment of genetically modified food. It should be seen as a key step in the safety assessment process although it is not a safety assessment in itself." So I would like to emphasize that it's a tool. It is a key step, it is not the complete safety assessment. In your comments you always pointed out that this consultation was not in agreement but, in fact, it was.

Chairman

459. Dr Nutti can you tell us at what step this procedure stands if it is a Codex document you are referring to?

Dr Nutti

460. This is in the consultation phase and also in the Codex Commission. But the consultation was earlier. When the EC refers to the consultations they only refer to a paper of Millstone that was complaining about the substantial equivalent. They never refer to the conclusions of the consultations. The conclusions of the consultations were also important, because we had discussed all the papers that were presented for three days. The conclusions were that we needed to use the substantial equivalence as a first step, and after that we should go to other tests that are needed.

European Communities

461. Thank you very much for that clarification. Of course we need to look at everything which has been said, all of the information, even if it is divergent. We just wanted to clarify the relationship between some of the conclusions and some of the statements in the paragraphs leading to those conclusions. We were particularly struck by the statement on page 64 of your advice to the Panel. The first phrase of the penultimate paragraph where you say: "I do agree with the opinion of the Italian competent authority regarding the ambiguity of the term substantial equivalence and we just wanted to clarify."

Dr Nutti

462. I do not agree. If you look at the other comments you see that I wrote in previous responses that I do not agree.. May be in this one I forgot to add the "not". But I do not agree.

European Communities

463. That is important. So we may understand that as a typographical error and we should have the word not. It should read "I do not agree" rather than "I agree".

Dr Nutti

464. English is not my first language and I checked the answers a lot before sending but sometimes I did have some typos.

Chairman

465. Do I take it the EC has come to the end of its questions and follow-up questions?

European Communities

466. Mr Chairman we have certainly finished for the time being our questions and I suspect that we may have exhausted our follow-up questions. But I would just like to have a few moments as the proceedings progress to consult with my colleagues in order to make sure that is indeed the case. But I don't want to stop the proceedings progressing in the meantime.

Chairman

467. While we wait for your answer on the eventual follow-up questions I will now go back to the complainants to see whether they have follow-up questions. Then you will get another chance. So I turn to the complainants for the possibility to ask follow-up questions on issue 2 and to the experts. Canada?

Canada

468. I'd first like to clarify with Dr Andow your discussion regarding secondary ecological effects and the necessity to create an inventory of potentially affected species. Are you referring to the possible effects on these very species as a result of Bt maize?

Dr Andow

469. In the context of my previous answer with respect to Bt maize, yes.

Canada

470. The maize T25, which is the maize that was subject to the Austrian safeguard measure, was actually a maize that was tolerant to glufosinate ammonium and not to Bt. So in that way I wonder whether that affects your response?

Dr Andow

471. Yes it would. I think the question, as it was posed to me, it was listed by the EC under maize T25. I did not understand their question to be restricted to maize T25. That is why I expanded in that way. I would have to consult again with my answers particularly for maize T25 before I could provide you with a response.

Canada

472. That's fine. I have a question for Dr Healy. Is it possible to do a molecular characterization for a product that had been derived through either mutagenesis or any other form of plant breeding? My second question is: is it not true that molecular characterization or the requirement to provide molecular characterization is in part a function of the fact that this information can be generated, and that as technology progresses, the extent to which the detail that is required in a molecular characterization, will likely increase?

Dr Healy

473. Can I just ask that you repeat the first question?

Canada

474. Is it possible to do a molecular characterization for products that had been developed through mutagenesis or any other form of plant breeding?

Dr Healy

475. It may be possible in certain circumstances, particularly for the trait that has been looked at. If the gene for the trait has been identified, then it will be possible. What it probably will not be possible to do is a molecular analysis of the whole genome and of course when you're doing mutagenesis, you're going to have random DNA breakages or other changes to the DNA at a range of sites. This contrasts to the situation with GM where you are often able to identify those and any additional sites or the sites for insertion. This type of specific identification is not necessarily possible with mutagenesis. To summarize, it would be possible to do part of the molecular characterization but it may not be possible to do a whole molecular characterization.

Dr Snape

476. Could I supplement in fact that some of the herbicide resistance genes, for example some of the immis resistance genes generated by mutagenesis, have been in fact sequenced. The nature of the

changes have been demonstrated. So it is possible. It is happening where you have a major mutant gene that is cloned and sequenced and the changes described.

Dr Healy

477. The second question then which relates to whether other requirements for molecular characterization increase as the capability increases. I think that's probably true. Certainly the changes in the technology have been highly significant over the last decade, over the last five to eight years. So that sequencing ability has improved certainly in terms of the speed and a whole range of other techniques have come into play. The requirements have increased as the technology has changed and one is able to get a much more complete characterization of the molecular characterization of genes and of the surrounding regions then previously was possible.

478. Sometimes there is a difficulty in interpreting what those changes mean in a biological context. Sometimes you can see what's happened at the molecular level but the understanding the impact of any changes at that molecular level in terms of its biological impact and in terms of health impact is less developed.

Canada

479. If one was concerned about the possible health effects of a plant that has been developed through mutagenesis, given the fact that it's not possible in some cases to do a complete molecular characterization, would it nonetheless still be possible to conduct a risk assessment on that particular food?

Dr Healy

480. Yes indeed. I guess we have the evidence that many of our crops have been developed through mutagenesis type techniques, have been successfully released into the environment and have successfully entered our food supply.

Canada

481. Just one last question for Dr Snow. You have indicated that France had concerns regarding gene flow to *Brassica rapa*. Why would the gene flow to *Brassica rapa* matter if the trait or the gene conferring tolerance to the herbicide is conferring tolerance to a herbicide that is not used in the control of *Brassica rapa* weeds? Here we talking about glufosinate ammonium. If glufosinate ammonium is not used to control *Brassica rapa* weeds, why would there be a concern about the transfer of this gene to weedy *Brassica rapa*?

Dr Snow

482. In framing my answer I was looking exactly through what France's concerns. I don't know if that was even one of the major concerns. It isn't mentioned but they speak of contamination and then in EC 161 attachment 4 they talk about, I am quoting from my page 23,: "the main undesirable effects of this herbicide tolerant oilseed rape would be agronomic and commercial". They namely want more research on gene flow. You are asking what are the consequences of gene flow and why would they be worried about *Brassica rapa*? I don't know enough about the frequency of *Brassica rapa* in France and whether there is a concern that it might increase in frequency the more glufosinate ammonium is used, and whether this would be an advantage to a weed that is maybe minor right now.

I don't know enough about the current and future herbicide use in France to be able to answer your question.

Canada

483. Thank you.

Chairman

484. I'll go back to the EC.

European Communities

485. We have one follow-up question. We have been listening to discussion of molecular characterization. I think it is uncontroversial that the technology was developing very rapidly even accelerating at the time. If you find yourself operating in an area where you need to look at dozens of different complex areas, so that you need different experts for different fields, and you know that the science is developing very rapidly or even accelerating in one or more of those areas, are there any of the experts here, who think that it would be inappropriate or irrelevant for an authorizing authority to take that circumstance into account when considering whether or not the time was right for a definitive yes or no on authorization. From a purely scientific point of view, is it relevant as a scientist, if you find yourself in that kind of environment? Would anybody disagree with the proposition that it was appropriate to take the fact that the science was dynamic into account? I suppose not, but I'll put the question. Thank you.

Chairman

486. I am not sure these are questions for scientists, but if anyone wishes to go on the ice you are free.

Argentina

487. May I? Thank you Mr Chairman. I would say the progress of science is such that if we consider everything that may be known in the future as a reason to disbelieve current science, we would be paralyzed. If we were revising all this information every two months, we would be paralyzed by the progress of science. In this situation, progress, the very thing that science is for, is used as a justification not to move forward. I don't think we can justify not taking a decision in order to wait for something new to appear that could support or not support any decision that we might have taken today. It's a philosophical question. I don't think I will agree with that.

Chairman

488. I will not qualify the question anymore, but I suggest we wait for Monday until we continue this particular discussion. The Panel has one follow up question on its own. Basically to Dr Squire and Dr Andow. In terms of the EC's questions on the need for complete molecular characterization in order to fully analyse transgenes, when was this need for complete molecular characterization identified and when was the necessary technology available to undertake this complete molecular characterization for the specific products at issue?

Dr Squire

489. The answer is difficult to give. Dr Snape would be better (or Dr Healy) to answer the question precisely when because knowledge has increased so rapidly on this particular topic. The question of whether it is essential is a really complex question. Without full molecular characterization a lot can still be done in the way of assessing and developing experiments on ecological and environmental risk. You can still do a lot if you know something. And again, you will probably be able to get a better assessment the more you know. As an example, one very interesting aspect of some of the herbicide-tolerant varieties is the range of progeny that you get, because they are constructed from a number of different sources. If you take something like the glufosinate ammonium oilseed rape, you get nine different types of progeny from crossing, because of various number of copies and combinations of male sterility and male fertility which come out. Now, if you did not know that, and did not know what was behind it, you would not be able to formulate very clear hypotheses about that particular issue. But you could still look at the issue of the effect of herbicide-tolerance on the ecosystem. The more you know about molecular characterization the more you can do to assess the benefits and potential harms of the product. My answer can't be definitive. I will defer to others on the issue of when it became available.

Chairman

490. Dr Andow, then Dr Snape.

Dr Andow

491. I will address it primarily from the context of the environmental risk. In that area I would say that in 1992 it was technically feasible to sequence a transgene in a plant. However, it was difficult to do. In my role as Advisor to the USDA Secretary of Agriculture I heard multiple testimonies saying that "while it was technically feasible it was not practically feasible to implement in a regulatory context in 1992". By the year 2000 I was involved in a committee with the National Research Council at which point the discussion was more about whether, since it was technically feasible, it should be a regulatory requirement. Improvements in technical capacity affected how we were viewing environmental risks, and that in turn affected the regulatory context.

Chairman

492. Thank you. Dr Snape?

Dr Snape

493. I think it's been technically possible for some time, since before 2000, to look at the stability and the inheritance and the sequence of a transgene insertion in a crop plant. In terms of flanking sequences, I think, the technology is still developing. That is possible but it's still a developing technology.

Chairman

494. Do I see Argentina with a follow up question?

Argentina

495. I would agree with Dr Snape, when he says that molecular characterization is something that is evolving very rapidly. It may not be available in a practical way in 1992, like Dr Andow was saying. But in Argentina molecular characterization has been a regulatory requirement since 1998. In 1991, when we developed the first regulatory system for GMOs in Argentina, we asked about the complete genetic authorization of the insert. A few years afterwards, we were requiring the complete sequence, and also the flanking sequences. We require the applicant to analyse the nucleotide sequence against the amino acid sequences of databanks of toxins and allergens. I think that this technology has been available from at least from 1995 or 1996. I would imagine that any developer of GM crops would be doing this molecular characterization very early in the development of the GM crop. Because if he happens to find any sequence which has some homology with toxins or allergens, I don't think he would spend more money going ahead with the development. If they find any homology, a complete sequence characterization from the beginning would be necessary.

Chairman

496. Thank you, Argentina. I believe this brings us now to the end of issue number two. I suggest we break for five minutes and then we start with issue number three. [Pause]

497. Complainants will have a maximum of 30 minutes to ask questions, followed by an equal maximum amount of time for the EC, followed by an equal maximum of 30 minutes of follow up question from the complainants. Who, from the complainants, would like to start? Canada?

Canada

498. Thank you, Mr Chairman. My first question is for Dr Andow. I am now reading from page six of Canada's questions under issue three, and its paragraph 30. Under question 102. Is mutagenesis also a process to introduce genetic variation?

Dr Andow

499. The answer is, yes.

Canada

500. I wonder if you could just briefly describe what mutagenesis is, or the techniques involved in mutagenesis.

Dr Andow

501. There are lots of different techniques to do this, but the overall idea is to use a technique to introduce a mutation in the genome, in this case of the plant.

Canada

502. Through the use of either chemical mutagens or gamma rays or x-rays. Is it true that you have a series of seeds, you shoot them with gamma rays or x-rays and then you plant them to determine whether or not the seeds have either survived or display or present the phenotype that you are looking for? Is that a rough description of the process.

Dr Andow

503. I will grant you that rough description, yes.

Canada

504. Rather unscientific, I know.

Dr Andow

505. It's a good rough description of the process. It is not always seeds. It is not always how you actually do the screening. Of course it's quite complicated.

Canada

506. You indicate that insertional mutagenesis is another outcome of transgenesis that is new to breeding. And then you later state – at paragraph 102.11 of your report – that the magnitude of insertional mutagenesis, introduced by transgenesis, is higher than that introduced by recombination of adapted material. Perhaps you could describe what adapted material is.

Dr Andow

507. By adapted material I mean material that has already been selected for use for agronomic purposes.

Canada

508. When you say that the magnitude of insertional mutagenesis is higher than that of recombination of adapted material, are you implying then that insertional mutagenesis can occur with the recombination of adapted material? Corn, for example.

Dr Andow

509. We are increasingly more aware of the complexity of normal recombination. So, I guess, I would have to say, yes, it is possible.

Canada

510. So it is possible. If it is possible then, how can insertional mutagenesis, as an outcome of transgenesis, be considered a new risk, if it is possible with the recombination of adapted material.

Dr Andow

511. I knew you were heading there.

Canada

512. Sorry, I was trying to be a little bit more oblique.

Dr Andow

513. You are implying that it is inappropriate to say that the whole idea is absolutely new. But I would say that the frequency of insertional mutagenesis would be higher, which is newly considered for transgenesis.

Canada

514. You state that the magnitude of open reading frames (ORFs) introduced by transgenesis may be higher than deliberate or spontaneous mutation in cell culture, although this is not certain. Is there any scientific evidence to suggest that the magnitude of open reading frames is any greater for transgenesis than for mutagenesis.

Dr Andow

515. That, I am not prepared to say one way or the other.

Canada

516. So, you are not aware of any scientific evidence, or, the scientific evidence is inconclusive or there are no studies, or..?

Dr Andow

517. I would say I am not able to answer your question.

Canada

518. Okay. I wonder if one of the other experts would be able to answer that question.

Dr Snape

519. I am sorry, I don't understand what is meant by magnitude of open reading frame. I don't know that that refers to anything I am familiar with.

Dr Andow

520. I was referring to the rate of induction.

Canada

521. I could rephrase the question as: is there scientific evidence to suggest that the likelihood or possibility of open reading frames is any greater for transgenesis than for mutagenesis? Dr Snape?

Dr Snape

522. It depends on the type of mutagenesis, because mutagenesis isn't one type of process. It depends on the mutagene that you use. If you use x-rays or gamma rays you tend to induce deletions, which tend to be knock-outs in terms of gene function. Whereas, if you use chemical mutagenesis you generally tend to create base substitutions and therefore you create novel proteins by base-substitution and changes in amino acid sequence.

Canada

523. Then how does that effect then the likelihood or possibility of open reading frames?

Dr Snape

524. Transgenesis would be form of mutagenesis similar to deletion mutagenesis, because it generally tends to be knocking out the function of a protein rather than creating a new type of protein, depending on the type of construct you put in, and whether it is a promoter-less construct or a promoter on its own that will actually stimulate the expression of a gene that's possibly silent.

Canada

525. Would the likelihood be the same?

Dr Snape

526. It is difficult to say because it's comparing apples and pears.

Canada

527. Now I think we a getting to metaphors we can all understand. Is the possibility of having a gene silenced or disrupted any greater or any less in the context of mutagenesis.

Dr Snape

528. That would depend on the construct that is used for the insertional mutagenesis.

Canada

529. But it is possible that there are some forms of mutagenesis that may lead to a greater likelihood of open reading frames.

Dr Snape

530. I can't comment. I don't have the data for that.

Canada

531. I'll move on to the next question. This is for Dr Healy or Dr Snape orDr Andow. Is it true that all eukaryotic cells, that is cells that have a nucleus, possess non-transcribed putative ORFs? These cells contain nucleotide sequences which appear to be ORFs but are not transcribed in the messenger RNA. That's the first question.

Dr Snape

532. Yes.

Canada

533. Thank you. Is it also true that eukaryotic cells routinely produce transitory and unstable messenger RNA that is not translated into a protein.

Dr Snape

534. Yes.

Canada

535. From a safety perspective, would you agree that the important issue is not so much the presence of an open reading frame but whether these are transcribed and translated into a protein - whether they affect the phenotype?

Dr Snape

536. They don't necessarily have to be transcribed into a protein to have a regulatory effect on the genome.

Canada

537. Could you elaborate on that? Would you agree from a safety perspective that the important issue is not so much the presence of the open reading frame but the effect that that open reading frame has, either in the production of a protein or the regulation of the plant metabolism.

Dr Snape

538. Yes, whether a gene works or doesn't work would affect whether or not it has an effect.

Canada

539. Dr Andow, you state that unanticipated effects could arise from a transgene by any of the following mechanisms, and you state that there is a whole series of possible sources of unanticipated effects. I won't read. If any of these unanticipated effects result in a serious disruption to the plants metabolism, would they be expected to present themselves in the phenotype, for example in agronomic performance, or in compositional analysis. This question relates to unanticipated effects that result in the serious disruption of the plants metabolism.

Dr Andow

540. I'm going to back up, since you did ask if I had a response to 33. Relating to that last part, it may be not just related to the expression genetically. Really it has to do with whether or not the open reading frame would result in any particular risk. One doesn't necessarily have to go to the trouble of showing that it is expressed. You could just say "let's presume it's expressed". We know that if it's expressed it will have this type of protein structure and that kind of protein structure doesn't have any allergenicity risk or any other food safety risk that we can think of. Then we can avoid the whole problem of determining whether or not there is expression of that gene worth examining, and do the risk assessment directly from that information. It is important to realize that we don't have to go through all those other steps necessarily. In some cases, it would be necessary. That's why I have

listed it as one possible source, because from a risk assessment perspective one doesn't necessarily need all the molecular information.

541. Then again, you have limited the question to "serious disruptions". It would have to be said that such serious disruptions– if you define serious disruptions as ones that affected plant growth and development - would be the kinds of serious disruptions that would be screened out in the selection process. That's not to say that all changes that would occur, due to any of the effects, would be serious disruptions.

Chairman

542. Argentina, you have the floor.

Argentina

543. Thank you, Mr Chairman. I have only three questions. The first one is to Dr Andow and Dr Snow. It refers to Dr Squire's statement. Do they agree with Dr Squire's statement on question no. 103, when Dr Squire says "there is no reason to suppose that biotech crops confer different degrees of genetic impurity compared with crops produced from, say, induced mutagenesis"?

Dr Snow

544. Yes, I am going to go first, while he looks something up. Dr Squire, could you remind me what you meant by impurity.

Dr Squire

545. Yes, there are about 20 lines there. In 103 what I was saying was that many crops have impurities in them: we can ignore these in some cases, and in others we can manage them. I cite the issue of high erucic (?) oilseed rape, for example. The potential of the crop to convey an impurity isn't the same for all varieties. It differs depending on a number of issues in its physiology and gene flow. What I am saying is that the ability to confer impurity should not be affected by the GM-ness of the plant, but it would be caused by other characteristics. The only caveat is that, if a conventional type of variety was contained within another type, it might not be considered an impurity, whereas a GM one might. It's the physiology of conferring that impurity that need not be different, depending on the way the crop was developed.

Dr Snow

546. So you are referring to the uniformity of the seed source. If it is impure it includes other seeds of unwanted types.

Dr Squire

547. Yes. The seed source and the seed yield. The seed that goes into the field and the seed that comes out of the field.

Dr Snow

548. I would agree with that. We are talking about contamination and whether you are any more likely to get contamination from a GM crop compared to a non-GM crop. Contamination is related to gene flow, which is the same for all genes, no matter what kind of crop they come from.

Dr Andow

549. If the question is restricted to the issue of, say, the rate of gene flow then yes, we will have to agree that there is no difference. Except as you pointed out earlier, if the GM crop has been modified to have altered pollen viability or reproductive rates, then that certainly could affect it. The other thing that I think you are raising here is related whether you have different goals associated with the levels of contamination, which may change the significance of that level of contamination. Seed purity standards may be different in one case than another.

Argentina

550. Thank you for your answers. I would like, though, to say that I don't agree with impurity or contamination wording. I would rather talk about advantageous presence, which is a better idea to convey to the Panel, because of the pejorative value of the word "contamination".

551. My second question is to Dr Andow and Dr Squire, and refers to a statement by Dr Snow. Dr Snow's statement was that another way to answer this question is to focus on the characteristics of biotech products - the phenotypes - rather than the male presence of transgene. This is more appropriate if the goal is to avoid direct or indirect harms to human, plants or animal health, or the environment. This is Dr Snow's response to question 103 . I would ask Dr Andow and Dr Squire if they agree, or if they have observations to this statement?

Dr Squire

552. In the context of that original question, yes I agree, the issue is of contamination or adventitious presence, or whatever, there's the presence and the effect, they have to be looked at differently. Something might have a presence but no real effect. In the case of some GM crops, in Europe, for example, that might be the case. The presence isn't wanted, even though there's no effect of that GM in the yield known. In other cases, the presence may well be divorced from the actual effect. I think you have to look at both or concentrate on one depending on the circumstances. In relation to the overall question, in which Dr Snow talks about presence and effect, I agree, but maybe qualify it with the fact that the concentration on presence and phenotype or effect might differ with the particular question or particular circumstances.

Dr Andow

553. I would agree with Dr Squire and also add that, as I point out in my answer to question 103, scale issues can also influence some of these concerns.

Argentina

554. This is to all experts. Does anyone have any information on experiments done with to compare the turn-on of genes by micro array techniques, for instance, comparing GM crops versus crops obtained by breeding?

Chairman

555. Can I ask the experts to indicate in their reply whether this material if before them, has been given to them?

Argentina

556. No. It has not been given to them. It's a completely new question.

Chairman

557. Yes, I understand, but the experts should tell us whether the experiment, they are going to refer to, has been on the table of this proceeding.

Argentina

558. I don't think so.

Dr Snape

559. I know of unpublished information but I don't know of any published information on either using micro arrays or Massively Parallel Sequencing or SAGE techniques to look at and compare GM with non-GM. There is unpublished information of a project in the UK from the Food Standards Agency. It will be in the public domain hopefully later this year.

Chairman

560. Dr Snow.

Dr Snow

561. If you're wondering why this question is being asked, I think the reason is you're asking if there might be more unanticipated effects from one type of breeding than another. The way you would detect these is this new method called micro arrays. It's a way of getting at unanticipated effects, but we don't have any good data on that. Several review committees like the National Research Council have requested that more studies like that be done so we could answer that question. We don't have any good answers.

Argentina

562. Thank you.

Chairman

563. I see six minutes to the credit of complainants, maybe Canada wants to have one more question.

Canada

564. One question to all the experts: is there any reason to believe that the unanticipated effects that could be produced through mutagenesis are any more likely than the unanticipated effects produced through transgenesis or RDNA technology?

Dr Snape

565. I'm not aware of any data on this and so I'll have to present an opinion. My view is that transgenesis is introducing completely foreign DNA into the genome, whereas mutagenesis is not introducing foreign DNA into the genome. It is either disrupting the DNA that's already there, or it's creating base substitutions, which might occur naturally in the process of evolution anyway. And therefore I think that the processes are not directly comparable.

Canada

566. Would any of the other experts like to comment?

Dr Healy

567. I would agree that in transgenesis you may be introducing DNA from another organism. That's not true in all cases, of course. In some cases you may be silencing a gene. In some cases you may be transferring a gene from a different variety of a particular crop into another variety. It's not always the case that you would be introducing novel DNA. When you're thinking about whether you're introducing novel DNA, another aspect that has to come into the consideration is the level of similarity between genes across species. We know quite a lot about that now, with the various sequencing projects. In my mind it's not as simple as saying it's from a different species. That's not always the case and in some cases, certainly, the genes may be similar even if they are from different species. It was certainly one of the concerns in the early days. We are starting now to get some empirical experience with these kinds of changes. Some of those concerns were the basis for proceeding slowly at the beginning. I might add that the familiarity and empirical experience is the basis for some of the approaches adopted with conventional crops as well. There is an increasing degree of familiarity at least in a subset of changes that have occurred within various crops.

Chairman

568. Thank you. Dr Nutti.

Dr Nutti

569. In Brazil the problem that we have is that crops that are obtained by mutagenesis are not submitted to any food safety assessment at all. You can have rice that was bred from mutagenesis and then it goes to the market without being submitted to any toxicological or any allergenicity testing. When I answered these questions, on the perspective of food safety, my concern was that I think all the new products should be assessed step-by-step and not only once.

Chairman

570. Thank you. One minute for Canada. Dr Andow ...

Dr Andow

571. I agree with that perspective. First Dr Snape suggested that because a lot of mutagenesis is introducing variation in a plant that has probably already been tried. It's not clear that that's true because there is a significant amount of genetic variation in any organism. If you start to calculate how many different individuals you'd have to evaluate to actually try them all, often times it ends up that the number of genotypes that you'd have is more than the number of atoms in the universe. It's really not possible to evaluate all possible genotypes. Part of my answer was emphasizing that there is a scale issue here. For a crop like maize, mutagenesis is simply not used that much in conventional plant breeding, whereas the transgenic techniques are used quite a bit.

Chairman

572. Thank you. I believe we now go to the EC for their questions on issue number 3.

European Communities

573. The scientific issues have been fully clarified. They were made clear in a general way earlier on. We don't think it's necessary to ask those questions and we'd much prefer to use the time to go away and properly prepare for tomorrow's meeting which we think will be very important.

Chairman

574. I open the floor for follow-up questions from the complainant's side, if there is a wish, since we have not exhausted fully our allocated time. Would anyone like to come back? This is not the case. EC wants to come back.

European Communities

575. Just to say that since we don't ask any questions and the Panel hasn't asked any questions, we thought that would mean that they're couldn't be any follow-up questions.

Chairman

576. I take note of your statement. Canada to one point.

Canada

577. Just two small follow-up questions. One related to the use of the term "contamination". Is there any scientific justification for why the mixture of biotech herbicide tolerant seeds with conventional seeds is referred to as contamination while the admixture of HT seeds derived through other forms of breeding, is not? Is contamination here being used in a scientific manner or is it being used more in a colloquial manner?

Chairman

578. Dr Squire.

Dr Squire

579. It's used variously in the UK. Adventitious presence, impurity, contamination. I get the impression that people are not too politically correct. They use it generally. They would use it to mean the unwanted presence of one thing in another, whatever it was and however it got there and whatever its type was. We don't use it as an emotive term or an anti-biotech term. I would say that high oleic oilseed rape in non-high oleic oilseed rape, was contamination or impurity or adventitious presence. It's not colloquial. It's a correct and useful description, if the party buying the oilseed rape, or selling it, doesn't want that particular thing in its product. Sometimes those who have perhaps most to lose on this, try and make us not use such words as impurity and contamination in their right context.

Dr Andow

580. The term arises a lot in seed purity standards.

Chairman

581. Ladies and Gentlemen, as you know we have reserved one full day of tomorrow for the remaining issue, number 1, as well as probably some wind-up questions which may be necessary to make full use of the experts presence tomorrow.

582. There are some points I wish to raise in this context so you may reflect over them this evening. The first is that one of the experts, that's Dr Snape, will only be with us in the morning session.

583. Secondly, the Panel is not quite sure to which cases the questions from the Parties are referring. It would help us to get some information from the Parties on this account. We ask you to send an email by 9am tomorrow morning, to indicate where according to the EC chronology you would have questions. We will then group those questions together according to the cases identified for further discussion with the Panel's experts, taking into account that priority will have to be given to molecular characterization. The procedure tomorrow might be a little bit different from today in the sense that we would go by the cases where all of the Parties have indicated that they will have questions. And at 10 'o' clock when we convene we will then give you the order of proceeding as we see fit in this context, given these circumstances. Of course, it goes without saying that we will seek to ensure equivalent time for both sides. We also would like you in your mail to indicate any products where the questions may be in particular be addressed to Dr Snape.

584. Is the request from the Panel clear to the Parties? Argentina.

Argentina

585. Just to get a clarification. I believe we already circulated questions for the meeting for tomorrow and in our paper there is a reference to a specific product. This covers the request of the Panel in the sense that our allocated questions related to the specific products. Do we need to send an email repeating that?

Chairman

586. We have noted your written questions on the table. In case you have additional questions on the basis of today's discussion you should then come back with a mail. If we do not hear from Argentina that means we know which questions you will raise and in which cases they are located.

587. Other clarifications required?

European Communities

588. Chairman, you're only talking about the questions for tomorrow, not the existing questions, of course. You'd like each of them to indicate the product to which it relates and the scientist to whom it is addressed?

Chairman

589. Actually we don't even need the precise formulation of the question. Wed' like to know to in which cases, relating to EC chronologies, you have questions, and which of those you would want to ask specifically to Dr Snape.

590. If there are no other questions, I would like to close the meeting by thanking you for your endurance, especially also our cherished and valued experts. I ask you, in order to make full use of the Panel's time and the interpretation time, to be in your seats tomorrow by 10am. Thank you. The meeting is interrupted. [Pause]

Chairman

591. As envisaged yesterday, we will start with issue number 1- which are all product-specific questions. Then, if necessary, the available remaining time can be used for discussing further any of the issues addressed yesterday. Finally, we 'll move to closing remarks by the experts.

592. I would also like to remind the parties that Dr Snape, as announced, will only be available in the morning session. According to our feedback and our own questions, there is only one question addressed to Dr Snape which is further down the chronology line – that's 94. Therefore, I suggest we take the issues according to the EC chronology, starting with 62. Then, briefly before 1.00 o'clock, if we haven't got there by then, we will take item 94 which has a question addressed to Dr Snape. This will allow us not to jump back and forth from one case to the next and make full use of the presence of Dr Snape at the same time.

593. For each issue or group of applications we would first have the convening parties in alphabetical order and give them time for their questions to the experts. Then the EC will be given an approximately equal period of time for their questions to the experts, per subject, and including any follow up question to the complaining parties' time. I do not at this time propose to make any allocations by minutes or hours but if we take more time than available today then I may have to revert to a more clockwise attribution like we did yesterday. So, for the time being, let's see if we can do without strictly timing everybody's interventions.

594. The Panel will also have questions and will address them on its own, also within each group of questions of cases. In this context, I wish to remind the parties that they should limit themselves during this meeting to ask questions of the Panel's experts. Should the parties have any comments on the experts' replies, those comments should be made in the context of the second substantive meeting

starting next Monday. We do not propose to have comments and discussions between parties in this meeting today.

595. Finally, the experts themselves are requested to answer the questions from parties and the Panel and should refrain from offering any view on the legal implications before the Panel, including, for example, whether any delays that might have occurred were due or undue within the meaning of the SPS Agreement. So, without further ado, I suggest we start with the case no. 62. Unless you have questions on the procedure? No? Argentina, you have the floor.

Argentina

596. Mr Chairman – just a clarification. May we have a chance when we address a particular product to get the name of the product. This will help my delegation, because we prepare the questions by making reference to the expert and the problem. I presume 62 should be a question to Dr Snape. We don't have questions to Dr Snape, but it would help very much if, at the moment, when you trigger a particular exercise, we have a chance to have in our mind the product.

Chairman

597. That's okay. The EC?

European Communities

598. Thank you Mr Chairman. If I understood you correctly while shuffling my papers, you said that you would take questions to Dr Snape first. You didn't?

Chairman

599. No, the idea is to go in chronological order and before we get to one o'clock we will see that all questions to Dr Snape have been put forward. On our line, on the feedback you gave to us, there is only one which goes after 74 and that is in 94. So, we will see how time goes. Before one o'clock we may come to 94 or we will have to come to the question addressed to Dr Snape in case 94.

European Communities

600. Just to be clear Mr Chairman. There is also EC 62 and EC 74.

Chairman

601. To make it very clear, we have questions to Dr Snape. According to our information these are 62, 63, 74 and 94. Those are the ones announced and that seems to allow us to go in chronological order without having to jump back and forth in order to take the presence of Dr Snape into account.

Chairman

602. On 62 we have questions from the EC but I will first turn to the complainants to see whether they have questions on case 62. Nobody? EC you have the floor. You have questions to Dr Healy and Dr Snow?

European Communities

603. Our first question on oilseed rape Falcon is to Dr Snow. In your reply to question 11, you indicated that the widespread adoption of glufosinate tolerate oilseed rape could have implications on biodiversity in farmland habitats. Would this, in your view, justify the requests for more information (as made by the Italian competent authority) and would a rigorous post event monitoring (as requested by the German competent authority) provide that information?

Dr Snow

604. I would say, yes. This is one of the issues that I pointed out. That early on, there was no information about possible effects on farmland biodiversity. Would monitoring be enough to answer your questions? It will certainly be a step in the right direction if that's a concern to the German and the Italian competent authorities. I think that this is a valid concern, and the question is – how do you answer these difficult scientific questions?

European Communities

605. Thanks. So we understand that these questions were actually justified.

Dr Snow

606. I think so. Yes.

European Communities

607. Thank you very much. I move on to a question to Dr Snape, that relates also to oilseed rape Falcon, but to Question 12 from the Panel. You conclude in your answer, that for a formal accurate characterisation to satisfy all regulatory requirements, the experts would suggest that more information is still required. Dr Healy, on the other hand, concludes that additional molecular characterisation requested by the lead CA is unlikely to affect the conclusions of the safety assessment and was not necessary to ensure that the conclusions of the safety assessment were valid. We would very much welcome your comments.

Dr Snape

608. My analysis of the documentation showed that there are two loci in this particular product. One locus had been sequenced and well characterised. The other locus which was a complex locus – EE2 – which had not been fully sequenced. I suggest that the sequence of that locus is required for a full safety assessment.

European Communities

609. I think this concludes our questions on 62.

Chairman

610. Then I come to the Panel question on Falcon G7 GS40 and the first question is to Dr Snape. The first one to Dr Snape. Further to your reply to Question 12 on bio oilseed rape, you indicated that there was a need for a study on the progeny of the biotech plants. When was the technology to do this type of study commercially available? And b) You indicated that you examined the information

requested relative to the EFSA-Q-2003/005 guidance document produced by the scientific panel on GMO's. When was this guidance document adopted? Please explain how this document is relevant to the request from Germany in April 2002.

Dr Snape

611. The technology for studying the inheritance and stability of transgenic loci has been around for a long time. It's one of the first analysis that would be done with a transgenic plant. The guidance that I used is the 2003 guidance document. It is relevant to the request from Germany, in so far as the totality of the information required for the full characterisation is summarized in that document, which I think would have been good practice.

Chairman

612. Dr Snape. I think we want to have the exact date of that document. Otherwise I will ask the Communities.

Dr Snape

613. I don't have the exact date.

Chairman

614. Communities – do you have the date?

European Communities

615. We will look for it and give it to you in a second.

Chairman

616. Then I will turn to Dr Healy with a question. What is the significance for the safety assessment of this product, after the subsequent identification of additional DNS fragments in Round-Up Ready soybeans?

Dr Healy

617. The Round-Up Ready Soybean example, provides an interesting example in a different product, where the molecular characterisation which is carried out using the southern blotting techniques do not necessarily give you all the information that a sequence analysis would give you. But it also is an interesting example in that it demonstrates that despite the fact that there is additional sequence present, it does not affect the safety or the safety assessment of the product because the other elements of the safety assessment provide that additional assurance. So, it's quite analogous to the situation that we find with the Falcon product.

Chairman

618. Last question from the Panel to Dr Healy and Dr Snape. Could you please explain why you have different views regarding the necessity of the additional information on molecular characterisation requested by Germany?

Dr Healy

619. Can I just clarify that that is the request in Attachment 106. It's the attachment that's referenced in the actual questions. Yes. I think this relates to the approach that I took. As I said in my introductory remarks yesterday I examined the molecular characterisation information in the context of the other elements of the information that were available for the safety assessment. In this particular case, there was a reasonable amount of molecular characterisation. There was a characterisation at the protein level as well as at the compositional level. Taking account of the totality of the information and the method of transformation, in my judgement, additional information which was around the DNA sequence for the inserts as well as the junction regions, was unlikely to have an impact on the safety assessment.

Chairman

620. Dr Snape.

Dr Snape

621. In my view, when you have complex transgenic loci, it is necessary to have sequence information to understand the inherence and the stability of that transgenic locus. Therefore, I thought that sequence information was required for the safety assessment.

Chairman

622. Thank you. Follow-up questions from Canada?

Canada

623. Yes, we have a follow-up question for Dr Snow. Can you indicate whether or not the widespread adoption of any herbicide tolerate oilseed rape could have implications on biodiversity in farmland habitats?

Dr Snow

624. In other words: Does it matter if it's transgenic or not?

Canada

625. Yes.

Dr Snow

626. No. It doesn't matter if it's transgenic or not in that context. It just matters if there is a very effective gene for herbicide resistance and herbicide is used and has greater effect on the weed flora, as people have hypothesised might be the case. Then there could be an effect on farmland diversity regardless of the source of the gene, whether it was a transgene or not.

Chairman

627. Thank you. I believe we can go to Case 63. That's biohybrid oilseed rape. The EC has a point on 62.

European Communities

628. We would like to reply to your question on the date. If your allow me, I will give the floor to one of our experts who is one of the authors of that document.

European Communities (Mr Sweet)

629. Thank you, Mr Chairman. This is just to confirm that the EFSA guidance – that's the European Food Safety Authority guidance document on the risk assessment of genetically modified plants and food and feed – was adopted on 24 September 2004. That was after the date in your Question 15b to Dr Snape.

Chairman

630. Thank you. That's helpful. The US on 62.

United States

631. A question to Dr Snow. I wanted to clarify your response to the first EC question. It talks about whether this additional information is required and there is a parenthetical in the question related to a request from the Italian competent authority. Were you, Dr Snow, opining on whether or not, in fact, the Italian authority asked for that information? Or, was that sort of an assumption of the question?

Dr Snow

632. Actually, I would like to see that information again. I was trying to look it up just now because I don't recall the exact wording of it. I avoided the answer, since I haven't seen it recently. If anyone could show it to me recently, I could answer the question better.

Chairman

633. We will ask the US to provide it or to see in the laptop...In the meantime the EC would like to clarify?

European Communities

634. Chairman, if you would like I can read out the Italian request in Attachment 10 referring to the conclusion of the last meeting of the Regulatory Committee of the EC. "Italy would be very pleased to receive from the notifier more information concerning the assessment of the effect of the genic product on the biogeochemical cycles and on the food chain, and on the spreading of the gene due to the possibility of crossing between the PGM and wild species". We are referring to the last bit of the sentence.

Dr Snow

635. The part that is relevant to the farmland diversity issue is the reference to the food chain. They are asking for more information about food chains which refers to: whether the weeds are being controlled to such an extent that there is no longer a food supply for some of the endangered farmland birds.

Chairman

636. Is there any question to Dr Snow, or to an expert, left? EC still on 62?

European Communities

637. Our answer on the EFTA guidelines was in part missing. It is true the document is from 2004 but it is based on a previous consolidated guidance. It actually only consolidated good practices that were there from well before the date of its adoption. Therefore, we concur definitely with what your expert said that this document is relevant also for your request from 2002, insofar as it was only a consolidation of good practices in the field.

European Communities (Mr Sweet)

638. Previous to that, the guidance was coming from the EU Scientific Committee on Plants. That committee terminated in 2003 with the formation of EFSA, and the Committee that took over the regulation of GMO's and risk assessment was the EFSA GMO Panel. They took up the guidance document produced by the Scientific Committee on Plants and reissued it in September 2004.

Chairman

639. Can I ask Dr Snape if you are aware of any major changes having taken place between the good practice and the consolidated good practice.

Dr Snape

640. No.

Chairman

641. Thank you. Canada?

Canada

642. My question is to Dr Andow. This is in relation to your comments concerning the Italian request at EC 63 Attachment 95. You stated in paragraph 1013 of your report that "while a request for additional clear assessment of the possible effects on the environment can be readily justified, such a request itself must be clear and specific". In your view, was this request clear and specific?

Dr Andow

643. The reason I said that is because the request was simply for – as it quotes here – concerning the assessment of the effect of the genic product on biogeochemicals and on food chain. It is three things. The request on biogeochemical cycles is just two words and gives very little guidance as to how to think about that request. The short answer to your question is yes.

Chairman

644. This takes us to the end of 62. On 63 we have question from Canada, the EC and from the Panel. I do see the EC wants to have the floor.

European Communities

645. One follow up question to Dr Snow. But you would concur that gene flow to wild relative is a valid concern for Europe and the competent authorities?

Dr Snow

646. Yes, they also mentioned gene flow.

European Communities

647. Can we therefore conclude that although a bit formulated in generic terms, the request from the Italian authority contained concerns that can be shared by the experts?

Chairman

648. I am not sure that that is a scientific question.

European Communities

649. It is in a sense that although formulated in general terms it contains scientific concerns. I think the experts can reply, if they wish.

Chairman

650. Dr Snow. Do you wish to reply?

Dr Snow

651. I agree that it is vague and not very specific but it's a valid point that was raised. These food chain effects were just coming. The Scientific Committee on Plant did not iodentify that this might become an issue and it later did. This is an example of developing science and questions during the time that these products were being put forward.

Chairman

652. On the same point, Dr Andow.

Dr Andow

653. To elaborate. The other part of the reason for my concern about this particular request is the timing. It is in 2000. It's before the promulgation of the 2001 regulation. This is the test period and it would seem that it is appropriate to give some guidance in trying to implement the test, when you are working through a test period.

Chairman

654. Thank you. We take note.

European Communities

655. I guess that is not a scientific comment but a regulatory comment.

Chairman

656. We take note. Canada we have floor on 63.

Canada

657. My first question is to Dr Nutti. The question is 15, which is paragraph 3 on page 1 of Canada's questions. Dr Nutti, you state in your report that, "the low levels of PAT protein and the weight of evidence available concerning the safety leads the Committee to conclude that there is no significant risk to humans or livestock following the ingestion of the gene product". You then conclude that you agree with the overall SEP's assessment. The Europeans criticize your assessment in the following terms: "The experts speak of weight of evidence available elsewhere concerning safety. However, the evidence is misleading. No references are provided". They later state "however, when researching for the weight of evidence, one finds more often than not, that this evidence is actually meagre, unpublished, informal, containing grey literature or notification, a notifier documentation". That is at paragraph 328 of the European comments. I would just like to read to you a statement by the Scientific Committee on Plants. Their opinion issued in May 1998 - found in EC63 Attachment 54 - on the bottom of page 4 the scientific committee states "low levels of PAT protein and the weight of evidence available elsewhere concerning the safety of PAT leads the Committee to conclude that there is no significant risk to humans or livestocks following the ingestion of the gene product. Is the weight of evidence that you were referring to "meagre, unpublished, informal and contained in grey literature"?

Dr Nutti

658. No. I have checked all the information that was here and also the references that were on files. Also, the codex. That was my basis for evaluating this.

Canada

659. So, the weight of evidence that you are relying on in part, is that the same weight of evidence that was relied on by the European Scientific Committee on Plants?

Dr Nutti

660. Yes. I used all the documents that were presented by the Scientific Committee. Then I made it very clear that I was in agreement with the European Scientific Committee. I used the same material that was given to them.

Canada

661. My next question to Dr Nutti is in relation to potential allergenicity and toxicity of the rival nuclease of MS8/RF3. Considering that these rival nucleases are only expressed in the anthers – that is the male flowering parts of the plant – and only for a short period of time, and that humans do not eat the anthers or the flowers, and that even if they are expressed elsewhere in the plant there is extremely little protein in the oil consumed by humans, what would be your conclusion about the risks to human health of these enzymes?

Dr Nutti

662. My conclusion was that there was a very low possibility for a problem for humans. All the questions related to human health and human were going to ingest the oil and not the flower. So, in this case, my conclusion was the same as the Committee's: that there was no problem for human health.

Chairman

663. Canada satisfied? Other complainants? That's not the case. The EC.

European Communities

664. Dr Nutti. A follow up question. Are you aware that this application was not about food and, therefore, did not concern human health as you assessed. But it was about feed and, therefore, it concerned animal health. Are you aware that animals are fed a protein-rich by-product of oilseed processing and that this is called cake?

Dr Nutti

665. When I assessed the documentation, I was looking for human health. If this is supposed to go for cake, then you have to look at the proteins and it is a different evaluation.

European Communities

666. Thank you very much. You also briefly touched in your answer on issues related to molecular characterisation. Would you agree that molecular characterisation is important for animal feed safety?

Dr Nutti

667. As I mentioned yesterday, we need to have an integrated approach. We need the molecular characterisation to help in the overall characterisation. There will be times that we need the molecular characterisation. In all my answers I pointed out that the Codex put the molecular characterisation as the first step to be done.

European Communities

668. One point you make on this is that although detection methods were commercially available, the detection method that is at stake here had not been validated. What it means that a method has not been validated? What is the implication?

Dr Nutti

669. To my knowledge, after you develop a method you need to validate it. To validate the method, is to take steps to ensure that the method can be duplicated in different labs. Sometimes you have a method which is not validated. The method can be validated through *inter-laboratorium*, or you can submit it to the Codex CCMS in order to have it recognized. In this case, I looked at all the information and, my understanding was that the method was available. But the method had not been validated. Validated in my understanding is that the method should be internationally recognized and used in different labs. For the same method then, different labs will have the same answers.

European Communities

670. Can we therefore conclude that the further request by the lead competent authorities on this issue of animal feed and molecular characterisation was therefore valid?

Dr Nutti

671. It was not clear for me. Maybe if you could read again the question from the competent authority, because I thought they were assessing for risks to humans. Maybe this is the difference on our understanding. I don't have the question from the authority in front of me now, but my understanding when I was doing all of this, was that it was related to human health. As you can see when Canada asked this there was a lot of stress on human health risks associated with oil. Was the request specific for animal feeding?

European Communities

672. I will look for it and we will revert to you.

Dr Nutti

673. Maybe you could take the SCP, because as far as I could remember, they emphasized human health. Humans and not feed.

European Communities

674. The problem is that the authorization was requested for animal feed, so the whole analysis of this product was done in that context. What is important for us is that to your knowledge it was not invalid to have these concerns with regard to oilseed rape when fed to animals, because this was the end use that this product was going to fulfil once on the market.

Dr Nutti

675. We need to pay attention to whether or not the feed contains the proteins. Therefore to the whole composition. Because in the oil, proteins are not included.

European Communities

676. So it was not invalid, in fact, for animal feed?

Dr Nutti

677. It was not invalid but the question for me is that this product was for humans. Maybe, we should check this.

Chairman

678. I think we will go on and refrain from further comments on validity or non-validity of applications in terms of regulators. Canada, on this point.

Canada

679. If I could be of some assistance. In the opinion of the Scientific Committee on Plants -issued in May 1999- it was asked whether or not, for the purposes used, does the product cause any adverse effects on human health and the environment. The Committee at the time did indicate that they were looking at both the risks to humans or livestock following the ingestion of the gene product.

European Communities

680. I think this confirms our point of checking the document. The questions are not qualified for human health or animal health. The issue here is that the legislation under which this product was requested authorization, concerned only animal feed. If it had been food it would have been under the novel food regulations and not under the environment legislation. So, although the SCP was looking also at these other effects on humans because it was a wider concern, the scope of this product authorization was animal feed. For the same product there have often been, in fact, two notifications. One under the environment directive and another under the novel food regulations. You have the same product dealt with twice in this case. So, EC-63 and the application that was called C/BE/9601 referred to animal feed.

Canada

681. In any event, Dr Nutti, considering that protein is only expressed in the anthers – that is the flower of the canola – and not in the oilseed, and that the oilseed is processed, would this have an effect on the safety of the seeds for livestock?

Dr Nutti

682. No it does not. If it is in the flower, it will not be on the seed. But I wonder if whether in the processing you could have a contamination. This would be the only problem. But the proteins are not supposed to be in the seed, because they are only in the anthers. There is a very limited possibility they are going to import the seed and the seed will not have the protein.

United States

683. We have a little trouble procedurally with questions that start with new facts and then ask experts to comment on new facts. First, we have new facts about what "cake is". My people who know "cake" say cake only has seeds and not anthers. The SCP opinion clearly says the proposed use is for food, feed and industrial uses. It says food and feed, both. The SCP says food and Dr Nutti answers on human health. I don't know what good it is to present new facts and then try to ask additional questions that way.

Chairman

684. I am not sure whether these are new facts or old facts. So I will not stop this discussion. Unless we need a definition for the term of cake. But I think this is almost common knowledge.

Dr Nutti

685. I am a food engineer; I know the term very well. The cake would not have the flower, because the cake is supposed to have only the seed.

Chairman

686. That is quite clear. Yesterday we decided that contamination and adventitious presence was synonymous. For the purposes of this hearing.

European Communities

687. Can I give the floor to one of our experts to try to clarify what is in this cake that can be of damage.

Chairman

688. Actually, I would like to have only questions to our experts.

European Communities

689. Yes. It will be in the form of a question.

Chairman

690. Please try.

European Communities

691. It is stated here that the PAT protein would only be expressed in flowers, correct? Given that the crop is glufosinate tolerant, it should be at least expressed in the green parts. Because otherwise it would simply die after application. So, do you agree that it would also be expressed outside the flower.

Dr Nutti

692. I don't agree.

Chairman

693. EC, one more question.

European Communities

694. Yes. But before, you agreed that the animals are fed a protein which is rich in by-products of oilseed processing.

Dr Nutti

695. When I gave my answer to you, I tried to clarify that all my answers were focused on human feed concerns. If it was about animals we would have to check the protein. But in this case, if the protein is the same that was analysed for the seed, there is no difference. The problem is that it was analysed, and the small difference is on the flowers. That is not going to go in the seed or in the cake.

Chairman

696. I think we should move on. OK, the Panel is satisfied with the question and answers to this point. The EC had another question, I believe, to Dr Healy? EC you have the floor. Canada, on this one?

Canada

697. We had several other questions in relations to MS8/RF3. I was wondering if we were going to go through the complainants and have an opportunity to address the questions to the experts on MS8/RF3 before the Europeans, or whether we will have some opportunity afterwards.

Chairman

698. Canada, you can continue with your questions to the experts.

Canada

699. My question is to Dr Andow. This is question number one or the question in paragraph one. You indicate that the SCP did not consider that contamination of conventional varieties was an injury to plants in your report in paragraph 1401. This is in relation to the determination of whether or not MS8/RF3 could constitute a pest. Can you confirm whether you are referring to the adventitious presence of biotech seeds in non-biotech seeds or some other form of injury to plants?

Dr Andow

700. I agree with what Dr Snow has written in her determination of the pest status here. I simply looked at the information associated with what the SCP actually said and used that information in trying to make this determination. But the short answer to your first question is yes, and that should be clear from my answer to question 6, which is the more general answer.

Canada

701. So, either a question to Dr Snow or Dr Andow. Is the economic harm that potentially arises from the loss of an ability to sell a product as GM-free an injury to plant life or health within the meaning of ISPM No. 11?

Dr Snow

702. I was not interpreting this in terms of economic harm to farmers but more as the creation of a weed that is more difficult to control. I was very literally looking at the wording - which I quoted - about what are the possible definitions of weeds. That's very early on in question 6, lets just turn to that page-. Definition of a pest. Indirectly affecting plants, such as weeds or invasive plants. Annex three mentions animos with increased potential to spread due to "pesticide resistance including herbicides", so that was what I was basing my answer on.

Chairman

703. OK, thank you.

Dr Andow

704. I came to slightly different perspective based on the same reading, although I wasn't considering the weed side of it. As I read in the SCP, they determined that there wasn't going to be higher survival or out-crossing. So the weed issue, according to the SCP was not an issue. Then I turned to the issue of contamination. Here there is some issue as to whether or not the contamination certainly could have the effect of the farmer not being able to sell the seed. It could also have the effect of the farmer not being able to use the seed. It could also have the effect of the farmer believing that those seeds are no good. In other words, those seeds are in the farmer's perspective "harmed". I did not make a determination as to whether any of those were applicable. But I did not want to simply say that it could or could not be a pest, because that point had not been clarified.

Canada

705. I would like to move on to question 19. Dr Snow, can you elaborate on what data, requested by the competent Belgian authorities, seemed unnecessary in their October 2003 request?

Dr Snow

706. This is a bit similar to that previous one we were talking about, where the words were biogeochemicals, cycles and food chains. Only here there is more. The competent authority asked about effects on "farmland diversity (macro fauna, weed flora and microbial soil ecosystem, food web integrity, trophic structure, population dynamics of key species, life cycles, etc.,)". By having that etcetera it seems all encompassing. When I first read it I thought that they were asking for everything and that it was really vague. Although it seems to ask for too much unnecessary information, what I really think they were getting at is this question about ecological effects of intensive herbicide use on food chains. Because it seems all-encompassing, it's a difficult one to respond to.

707. If you think about what regulators are faced with, there is a certain amount they need to know. There are some things that would be nice to know and there are other questions that may or may not be possible to know. There are things that scientists just may not be able to answer. So, the second paragraph of the next part of my answer goes into how difficult it is to prove that there is going to be no effect on farmland biodiversity. This is a philosophical question. Can scientists answer this question? The Farm-Scale Evaluations are an attempt to begin to answer that question and I think we should talk about that more. I know you have questions for Dr Squire about what is the value of those Farm-Scale Evaluations. I am assuming the intent is to ask a serious valid questions about farmland biodiversity.

Canada

708. Would you agree that in addition to being a theoretical concern, it is also a very practical issue, in that a notifier has to respond and provide information?

Dr Snow

709. Yes, and I think maybe an alternative would be to say – if you can't provide this information we won't approve the product. You know, if it is not possible to answer the question. There may be concerns that are strong enough to not approve the product. It is really difficult for me as a scientist to know how to evaluate this.

Canada

710. If it is impossible to know the answer to these question then you just shouldn't approve the products. Would that also apply to any other herbicide tolerant crop?

Dr Snow

711. Regardless of whether it is transgenic?

Canada

712. Yes.

Dr Snow

713. Yes, it would. I am not saying because it's impossible to answer that it's now worth looking at. That's why I wrote in my context all the examples of publications that have actually shed light on important questions, even if they don't answer the regulators' question. I think it's very important to look at these questions.

Canada

714. My next question is for Dr Squire. You indicated that there is a need for a standard or a comparator to evaluate the effects of biotech derived crops. Recognising the importance of ensuring sustainable agriculture and recognising that all agricultural practices have some degree of detrimental impact on biodiversity, would an appropriate standard or comparator be the effects of typical agricultural practices?

Dr Squire

715. Interesting question. Since the bronze and iron ages in Europe, humans have been balancing cereal-based rotations with weeds. Weeds are still here. I think they always will be. I think there is a philosophical point here. You could argue that humans have replaced one form of habitat or biodiversity with another. They have created their own habitat in which to grow crops and that habitat is an essential part of the future of humans on the planet. Now, in some parts of the world, that habitat is potentially sustainable and could be used as a comparator. In other parts of the world there is a general agreement that the typical practice is not a good comparator. In the most intense European agriculture I, and many others, think current practice is not a good comparator. There is general widespread opinion that the use of seven, eight or nine chemical applications per year to a crop is not sustainable. So the answer is, it depends on what your typical practice is. Current intense practice, as carried out in parts of Europe, is not a good comparator.

Canada

716. So, has the type of information then requested by the Belgian competent authority in EC Exhibit 63/At.149 been required, in relation to any other of the forms of conventional agriculture that you have just mentioned?

Dr Squire

717. In general, no. There has been little appreciation -as I indicated in my notes- of the developments in intensive agriculture during the last fifty years. I think the point I made also is that, relying on what I would consider the bad practice in the past, or bad approaches in the past, doesn't mean to say that you can justify the continuation of those for any particular reason. It just happens that the impending introduction of GM cropping into Europe, has coincided with a number of large-scale experiments and changes in philosophy and approach.

Canada

718. Is the same sort of scrutiny - in terms of the impact on this particular agronomic practice on biodiversity - being applied to some of these bad agricultural practices that you have just referred to?

Dr Squire

719. No. I think there are some examples. I think Europe is slow to learn, and I think that in some instances we are not applying the same sort of rigour to our understanding of different types of things. It doesn't mean to say that we shouldn't be applying a certain level of rigour in this case. I take the example of the use of glyphosate as a herbicide in parts of Europe, its rise in the last ten years, and the balance of minimum tillage and deep ploughing for example. Both these occurrences will have large effects on the future and they are taking place without adequate understanding.

Canada

720. As you may know, in the UK, in order to register a new herbicide, the regulations require that the herbicide must control, I believe it is about 95 per cent of weeds. So considering the concerns evaluated in the Farm-Scale Evaluation - that is that the adoption of some GMHT crops could affect biodiversity by being too effective at controlling weeds-, is this not inconsistent with current policies regarding herbicides where the efficacy of the herbicide is, in fact, a precondition to the approval of the use of that herbicide.

Dr Squire

721. In this instance it is not inconsistent. If you consider that typical primary production above ground – that's the production of plant matter in fields in Europe – is around ten tons per hectare, as a general order of magnitude figure. Current estimates suggest that the weed flora is of the order of one per cent of this. It could rise well above that, but in well-managed fields it is around one per cent of that primary production. Since the iron age we have reduced the weeds down to around one per cent, typically. A control of around 95 per cent is well below the level that is currently exercised. That level is a result of long-term repeated use of a range of herbicides. Now, what the Farm-Scale Evaluations were saying regarding those two crops that were found to decrease weeds further was that the effects appear to be - at this stage for those break crops - in excess of what was required to control adequately the weeds for yield. It was over the top. If there is to be a balance between sustaining the food web, the soil organisms, the predators that are beneficial to agriculture, then we don't want to go over the top. We need to find a balance.

722. My own understanding of the agronomy and economics of herbicide use was founded by detailed study of two large-scale, long-term experiments in the 1990's in the UK. These are referred to by acronyms TALISMAN, and SCARAB. They are both government funded. They showed that cutting herbicide use by half from the present intense use gave a moderate increase in the weed flora

and a net improvement in gross margins. There was no detriment to yield worth speaking of and the benefits came through less use of herbicide. So, in the UK and in parts of Europe where agriculture is intensely managed, there is no additional benefit financially in squeezing the last bit of effort into reducing the weed flora at the expense of biodiversity.

Canada

723. In terms of other forms of agricultural practice that you mentioned, some of the bad practices, would you consider that there is a justification or a reason for imposing a much higher level of scrutiny on the introduction of this particular agricultural practice, the HT cropping, with other agricultural practices?

Dr Squire

724. I think it is incumbent upon us to scrutinize those other practices with the same rigour that we are scrutinizing, for example, herbicide-tolerant GM crops in advanced agriculture in Europe. I don't think the option to reduce the rigour of scrutiny of GMHT crops is the way to go. I think we need to be consistent. I agree, we are inconsistent at the present time. But the consistency should be upwards towards appreciation of the ecological aspects of agriculture.

Canada

725. For instance, Dr Squire, in your report you indicate that large-scale autumn-sown cropping in some parts of Europe was not scrutinized with the same rigour. Would your assessment on the impact of farmland biodiversity of not leaving a field to fallow would be in comparison to HT cropping?

Dr Squire

726. I would say it is at least the same order. Autumn-sown cropping has been used for centuries but it rose to predominance in the 1970's in the UK and some other parts of Europe. There have been few systematic and detailed records of the effect of that very major change. It also occurred with a very big change and continuous change in the range and type of herbicides used with that cropping. It is at least as big as any potential effects of GMHT cropping. But again, that in itself, is past. I believe that we should have monitored and regulated that change as appears to be the case for GMHT cropping.

Canada

727. Would you agree that the ability to use zero-till systems with broad spectrum HT crops, as opposed to the more conventional practice of soil incorporated herbicides, be a more sustainable agricultural practice?

Dr Squire

728. Again, it is difficult to generalise. It depends where you are in the world. It is certainly a potential option in the UK and some people are going towards this practice. It is certainly an option. The uncertainty in the soils of the UK is whether zero-till for longish periods would itself cause problems for farmers and for soils. Surprisingly in Europe there is little detailed information on the effects of zero-till. Experiments are now starting, including some that we are looking at ourselves. It's a possibility but it hasn't been demonstrated.

Canada

729. My next question is for Dr Snape. We have passed out -for the Panel's convenience, as well as the experts' convenience- EC - 63, Attachment 105, and these are the Minutes of the Belgian Biosafety Council Scientific Committee transgenic plants. It's the meeting of 7 February 2002. I would like to direct Dr Snape's attention to the back page- at the bottom it's marked 41 under the heading Discussion 1.9.2. It's the second paragraph. The experts had a monumental task. There was an incredible amount of information, as you indicated in your cover letter, Dr Snape. This report or this assessment that had been done by the Belgian Biosafety Council- who admittedly had the file for about five years now.

730. The Minutes read as follows (and I would like to read the full paragraph, if I may):

> "Mr Delouse presented new molecular data submitted by the company. In general, he concluded that the experiments carried out by the notifier were well done and that exact but vague conclusions were made. As a scientist he felt that more could be done. One of the figures suggested a linkage but it was not demonstrated and not claimed, meaning their conclusions were correct. In fact, they proved, as requested by the guideline on molecular characterisation of transgenic plants, that the flanking regions were plant material but not the linkage. It was suggested that either the pictures in figures one would be adapted, or that the results supporting this figure would be added to the document. Next to this some mismatches were found. These data will not have an impact on the risk assessment knowing rearrangements occur frequently."

731. Given the conclusion of the Belgium Biosafety Council in February 2002, again bearing in mind that they have had the file for five years, and obviously you are at a bit of a disadvantage because you had this information over your Christmas break, that additional molecular data will not have an impact on the risk assessment knowing rearrangements occur frequently. And given the totality of the information submitted in the dossier, including the 1998 opinion of the European Scientific Committee on Plants that stated: Based on phenotypic and molecular techniques, it is shown that the genes are stable and follow standard mendelian inheritance. And given as well the statement of the Biosafety Council that the documents related to molecular characterisation are well documented and experiments and results are of a high quality, was the request for additional information in Attachment 107 necessary in order to enable the risk regulators to conduct a risk assessment?

Dr Snape

732. Thank you for that and thank you for the additional document. My assessment of this product with the two components MS8/RF3 is that this is the most complete molecular characterisation that I have seen in the evidence that I was asked to look at. I found that the evidence for the molecular characterisation of MS was complete and that there was adequate information to provide a safety assessment. I had some queries of my own about the inheritance and stability information for RF3 but, again, I concluded overall that the molecular characterisation of this was sufficient for a safety assessment. In the document that presented to me (what you have just read through) I find it difficult to understand the saying that "information. were well done and that exact but vague conclusions were made". I don't understand how those are compatible. I also don't understand how these data will not have an impact on risk assessment knowing rearrangements occur frequently, and I am not sure, without of course discussing it with them, exactly what sort of rearrangement that they are considering. In conclusion, I think that the information on this product is comprehensive and to a

high standard. I wouldn't say that the additional information was necessary in order to conduct the risk assessment.

Canada

733. I missed that last part.

Dr Snape

734. I wouldn't say that additional information was necessary in order to conduct the risk assessment.

Canada

735. So the information was not necessary in order to conduct.

Dr Snape

736. Yes, the information was sufficient, in my view.

Canada

737. We have no more questions on MS8/RF3. Thank you very much.

Chairman

738. Thank you. This goes over now to the EC.

European Communities

739. One final point. Do I understand you correctly, therefore, that with regard to agricultural practices the small structure agriculture of Belgium justified the concerns that its lead competent authority expressed with regard to its request of 2003.

Dr Squire

740. Could you clarify slightly, please, with regard to what explicitly.

European Communities

741. All of the discussion was generated by the review of these requests for further information that the Belgian competent authority addressed to the notifier on farmland diversity (macro-fauna, weed flora and microbial soil ecosystem). So, do I understand correctly from your answer that given the fact that in Europe, unlike in other parts of the world, the agricultural system is structured on a small-scale basis, and that that is very true for Belgium, their concerns, as expressed in that request, were valid.

Dr Squire

742. Yes. I would say in general that they had a valid case for concern, given some of the uncertainties in this issue.

European Communities

743. On another point, because you mentioned that Europe is not fast to learn. Aren't you aware that – maybe not in the UK but in continental Europe –an enormous amount of money is spent on assessing changing agricultural practices to fund large scale projects to increase and maintain farmland biodiversity.

Dr Squire

744. Yes, I think things are improving. In some parts of Europe there are serious considerations given to this broad approach to the future. But, Europe hasn't been quick to learn in the last twenty-five years. So, compared to, say, the early 1990's, the attitude to sustainable agriculture has improved immeasurably in Europe – and it differs between countries. Some are advanced in this respect. Denmark, for example. Others are less so – but things are improving.

European Communities

745. Thanks a lot. We have no follow up questions, thank you.

Chairman

746. Thank you. This leaves the Panel with just one question. Since you have been given the text of our questions I will not read it out again. It is question 19 and goes to Dr Squire.

Dr Squire

747. I think in this instance the argument had come to a position where the request was that information be given on large-scale processes. Given that knowledge could only be imported from other parts of the world with a great uncertainty, the only way to answer this kind of question was to do large-scale experiments. Generally, this is not the way that the development of agriculture has proceeded. If things start to go wrong after the event then good monitoring should detect that. I would say looking back over the past one hundred years in the UK, for example, few developments have gone this way, i.e., that there was a request for large-scale data before general release. At this time there were, in practice, some large-scale experiments either starting or about to start. So, given the uncertainties it was legitimate to ask what the large-scale effects would be. This is where the impasse comes because the country says "give me the evidence" and everyone knows the evidence isn't there. I can't say anymore than that. It isn't usual to do this. But given the concerns in this instance it was done. There was no precedent. It's a very difficult situation.

Chairman

748. You are saying there is no precedent in cases where before there were such question in regard to non-transgenic on crops.

Dr Squire

749. There have rarely been such questions asked in relation to non-transgenic organisms at the time of their potential introduction into agro-ecosystems. The questions haven't been asked before.

Chairman

750. Thank you. I think that that is clear. Any more follow up on 63? The EC?

European Communities

751. To follow up on your answer Dr Squire. Do you think it was either appropriate or reasonable that this information was requested?

Dr Squire

752. In the case of this particular product, it was reasonable to understand the potential risks. How that is done is another matter, but it was reasonable for the country to ask in this instance. That isn't a blanket sort of statement that I would make for all GM crops or any kind of crop. But in this particular instance I would say it is a reasonable request. As an example, if you go back to the introduction of different pesticides, they were tested for their toxic properties on different organisms - often in a laboratory, often in small trials. And then they were deployed quite widely in the field. If there proved to be effects that were consequent on that, then those chemicals might, or would be, withdrawn. But there was no clamour in advance for testing of these chemicals at the field scale, over long periods of time before they were introduced. This is where the difference lies in this case. There was a request for large-scale testing of ecological effects before the product was introduced. Given the uncertainties that have been expressed both to do with gene flow, impacts on biodiversity and persistence, I think these concerns are reasonable.

European Communities

753. Thank you very much Dr Squire. Am I permitted another question, Mr Chairman?

Chairman

754. A scientific question, yes.

European Communities

755. Dr Squire. We have heard a lot about comparisons, perhaps between the experiences in North America and the problems confronting Europe. What would you say are the essential different elements in Europe which have caused the concern amongst the Europeans, in particular amongst the Belgians, in relation to herbicide-tolerant oilseed rape? Bear in mind Europe is a milder climate and we are talking about winter oilseed rape with a higher yield. We are talking about different farming systems and we are also talking about the use of a herbicide which is widely used in fruit production in many parts of Europe.

Dr Squire

756. The salient issues have to do with the landscape, the size and arrangement of fields, the degree of transfer between fields that exists and also the desire of growers, or farmers, to maintain some control or integrity over those fields. The smaller scale and the need to restrict, as far as possible, unwanted movement between units of management is one aspect of it. The arable landscape is fragmented and fairly heterogeneous. The second aspect is that increasingly large numbers of people in Europe regard the arable ecosystem as being of value to them. This particularly applies to land-locked countries without mountain ranges or large forests. One can understand that people wish

to see organisms, often in the form of birds and mammals and visible invertebrates, in these ecosystems. The evidence for this is the massive rise in the past twenty or thirty years of nature conservation in these countries. I would say these were the two main issues that distinguished large scale production where it occurred from the very small, heterogeneous intimate landscapes of parts of Europe. Not all Europe but parts of Europe.

Chairman

757. Thank you. You have already extensively commented on this question in your responses to our questions. I will allow Canada a small question, but not to repeat what Dr Squire has written already.

Canada

758. Dr Squire, you mentioned that pesticide regulation. First of all, are you aware that the Belgian pesticide regulatory authorities have already authorized glufosinate ammonium which is the herbicide to which MS8/RF3 is tolerant, for use with genetically modified herbicide tolerant oilseed rape? And in light of the fact that the pesticide authorities have already authorized the pesticide for this particular use, does it not seem a bit inconsistent that you wouldn't authorize the product – or the seed – because of the potential impacts on biodiversity, when actually the application of the herbicide and the use of the herbicide has already been authorized for that use. And if there was a concern, wouldn't the concern be with the use of the herbicide and the solution would be to modify the conditions under which the herbicide could be used?

European Communities

759. We object to the question as not being scientific, it has to do with our regulatory system. If the Canada has a problem with the way we deal with herbicide regulations and what we authorize and how we authorize products, they should bring a case on that basis.

Chairman

760. I would like to hear Dr Squire on this one.

Dr Squire

761. Thank you. It's not just to do with the herbicide in a small country that wants to keep its units of land management discrete. There are issues of movement of genes by pollen and by seed and the ecological impact of GMHT crops. The only large scale study has been in the UK – Farm-Scale Evaluations and literally one or two other trials. The issue is not the use of the herbicide *per se* in this case, it's the way it can be used with a crop to get at certain aspects of that crop's weed flora that can't be accessed by the herbicide used alone in other circumstances. It's a particular use, the timing of the herbicide application, that was found to be important in the biggest large scale study - Farm-Scale Evaluations. That may not answer your question, but whatever the use of the herbicide there are still issues perceived or otherwise of the movement of a transgenic organism out of the field in which it is grown. It isn't just the use of the herbicide, it's the way the herbicide can be used to target certain organisms where it couldn't be used in the absence of a GMHT crop.

Chairman

762. Thank you. The floor is still open on 63. If there are no more requests for the floor we will pass to the next case which is 64, Round-up fodder beet. And here we have questions only from the Panel, but I will first ask if the complainants or the EC have impromptu questions on this particular case. This does not seem to be the case so the Panel will ask its question. It's our question no. 20 and it goes to Dr Nutti and Dr Andow (the first one). Dr Nutti …

Dr Nutti

763. I'd like to clarify that my answer was related to food safety. When I was checked the information of the SCP in the request, the request was about molecular characterization. I would like to rephrase my answer explaining that regarding concerns about food safety there was no need for more information. This is why there is a difference. Because I focused on the food safety and I was checking all the information according to the codex guideline. Thank you.

Chairman

764. Thank you Dr Nutti. Dr Andow …

Dr Andow

765. I'm going to say almost the direct complement to that. Even though I did, in my answers to questions 21 through 23 include an indication of the clause "human health" in my answers, that was more hypothetical than a necessity, and my focus was more on the environment.

Chairman

766. Thank you. Question 21 goes to Dr Nutti again.

Dr Nutti

767. They presented all the information regarding the substantial equivalence. That one was comparable. But my conclusion on this question is not with regard to the backbone, because this is not my field. My conclusion was with regard to the food safety assessment. I did not understand, if your question is also asking about the Italian CA, or it's only the Dutch? The Dutch CA's question was about molecular characterization so my answer is not related to that. My answer is related to the food safety assessment. And in this case, the notifier has presented all the information necessary for the food safety assessment and the SCP and the Danish authority had agreed with the conclusion.

Chairman

768. It's on Italy.

Dr Nutti

769. It's because their question is about the biogeochemical cycle and this is not related to food safety. This an ecological question.

Chairman

770. Question 22 to Dr Andow.

Dr Andow

771. The documents and chronologies were a little confusing, I hope I got them right. But what I understand is that the Dutch competent authority first made a request for information on the backbone information. The notifier then provided information in two different ways. Then, after that, the UK CA made an almost identical request which the notifier then simply said that they had already provided the information. So that must have been that the UK CA didn't realize that the information had been provided, but that information was necessary, even though it was already provided, so the request was not necessary but the information was. The request by the Italian CA then was to – and this is what wasn't clear – is if the Italian CA was disputing the response of the notifier, because the Italian CA was requesting information that essentially the notifier had already provided. So I understood that request, then, to be unnecessary because the information had already been provided, and I suppose it's a little bit puzzling there …

Chairman

772. Time wise, these informations were on the table, on the record, when the next Italian commission …

Dr Andow

773. My understanding – and, please correct me, someone should correct me if I'm wrong – is that the information that the notifier provided was available at the time the Italian CA made the request.

Chairman

774. Thank you.

775. This is all for the Panel. Would any of the Parties wish to have a follow-up question on 64?

776. EC …

European Communities

777. Chairman, could we have a break for 5 minutes while we discuss whether we have any further questions? Would that be possible?

Chairman

778. I'd prefer to go on to the next case, but if there are no questions for Dr Snape we will revert to this one later today. OK? So we have an open point on 64, possibly. And we turn now to 66.

779. EC has a follow-up right now. Please do.

European Communities

780. Thank you, Mr Chairman. This is a question to Dr Nutti. Do you agree that the use of sugar beet pulp for animal feed justifies a risk assessment for animal feed of Roundup Ready sugar beet?

Dr Nutti

781. I think that that justifies the risk assessment for animal feed, but that you have to take into account what was the assessment that has been done before and check if there is a necessity of complementary analysis. But in my case, I would look at what has been done for the composition and everything, and then look if there is anything else needed. Thank you.

Chairman

782. Thank you. Do I take it the EC has finished or do you want to have a mental reserve on 64? We do go to 66 now, and here we have questions from Argentina and from the Panel, both addressed to Mr Squire. It is on RC 1545 cotton.

783. Argentina you have the floor.

Argentina

784. Thank you, Mr Chairman. As you know we have these three questions and if you allow us, we are going to request Prof. Burachik to put forward our questions and perhaps we are going to have some follow-up in light of the developments.

Chairman

785. Thank you.

Argentina (Prof. Burachik)

786. Thank you, Mr Chairman. We have a few questions for Dr Squire regarding the glyphosate tolerant cotton. First question is, if the expert agrees that the original gene transfer from the GM crop to bacteria is a very unlikely phenomenon, and if it is or if it is not, then why it is, or is not, a very unlikely phenomenon?

787. I think that this subject was touched yesterday at some time and it was the idea in the floor that original gene transfer from plant to bacteria was a very unlikely phenomenon, but I would like very much for Dr Squire to elaborate on this in this particular case of glyphosate tolerant cotton.

Dr Squire

788. I think I should like to qualify some terminology. "Likelihood". "Likely", as opposed to "frequency", because some things are likely to happen but they would do so under extremely low frequency, so it would be a time-dependent issue. Bacteria are known to be fairly free with their genomes, they do take in and give out their genomes to other organisms. It is likely that they will take in genomes or bits of them from plants. Whether this occurs over evolutionary time or over arable time scales of the lifetime of crops and crop species is uncertain, and I know that several studies are underway in Europe to look at the exchange of genes between plants and bacteria. I'm perhaps not the most qualified person to give definitive information on these recent studies, but I would say that in

general I agree with the tone of this question that, even though such exchanges will happen, they will do so under very low frequency.

Argentina (Prof. Burachik)

789. Thank you, Dr Squire. I think actually there are some experiments done in 1995 which were addressed to find this frequency and it's 10/-17 in one particular case, in one study. So I agree with you that it's a very low frequency.

790. You say in your answer to this question that there is now widespread perception that antibiotic resistance should not be introduced through GMHT products, and I would like Dr Squire to clarify this question as to where these perceptions are coming from – scientists? from risk managers? or regulatory agencies? companies? or the media? Yesterday you made some comments about the media, so I would like you to elaborate on this case what is the origin of the perception that antibiotic resistance genes should not be introduced into the GM crops?

Dr Squire

791. From a number of sources now I think, scientists, risk managers, government regulators, would prefer … I've just realized that there is a possible misunderstanding here, in this respect. I was referring to perhaps the unintentional introduction of these products, or their introduction as a result of selection during the transgenic process, not through an intentional introduction. I was talking about antibiotic resistance being in a GM product that was intended for an entirely different purpose. I'll answer the question in relation to that.

792. There is a desire amongst scientists doing this kind of work and regulators and others, to have the GM construct as clean as possible, to have as little extra in there that isn't doing the job that it was intended for. It is partly to satisfy maybe non-scientific concerns, that these products are doing something else. But I think from what Dr Snape has said, and from other more knowledgeable stances than myself, that we can only truly evaluate a transgenic product if what is in it is only the essential bits and that nothing else is in there that might cause issues or difficulties. I'd like to suggest that others on the Panel comment on that. I'll give one particular example. That is during our work on the ecological effects of GMHT crops in the UK, part of the genetic line was found to contain antibiotic resistance. It was there because it hadn't been cleaned out by the company providing the seed. Now my stance on this, for example, was that it was in such low frequency that it had no ecological impact by itself, but it cast doubt in the minds of activist groups and the media on the validity of our measurements. To us it was an entirely unwanted intrusion into a perfectly good scientific experiment. So there are those aspects as well as the potential genetic, or the kind of interrelations that were discussed yesterday.

Argentina (Prof. Burachik)

793. I would like to have a few minutes to examine the question.

Chairman

794. In the meantime the EC has asked for the floor. We can use the time, perhaps.

European Communities

795. Thank you, Chairman. At the invitation of Argentina, Dr Squire just commented on the likelihood of horizontal gene transfer, distinguishing between likelihood and frequency -an entirely valid point- and he qualified his remarks by saying that he's not the best expert on the Panel to respond to this issue, about whether this horizontal gene transfer can take place on an arable time scale, as he put it, or not. But just in order to put his advice in context, please, could I ask Dr Squire if he has looked at the articles, the literature that we put on the record, the studies by Simonet et al., and in particular a paper by Kay and others, and which shows, in our view, the transfer, this horizontal gene transfer taking place. Just a question about whether he's read the study or not, please.

Dr Squire

796. I don't feel familiar enough with this work or competent enough to comment at this time without further detailed study of my own of this particular issue in these papers.

Chairman

797. Thank you. Argentina.

Argentina

798. Yes, in reference to the question that just was in the floor, you said just a few minutes before that you're not familiar with the Simonet work... Would you consider a homology-facilitated unintended combination between genes of plants and bacteria to be a natural phenomenon?

Dr Squire

799. There are examples of that that are natural …

800. Sorry, as far as I understand it, there are examples of that that are natural, but I would have to qualify that very considerably. This is an extremely complicated issue and without further detailed study of these papers and the issue in general I do not want to lead myself into making hasty remarks or drawing conclusions that I may regret.

Argentina (Prof. Burachik)

801. Thank you very much. And I appreciate what you're saying …

802. I go on to the second question then. The third question. Coming back to the perception issue, would you qualify the weight of the perception issue versus the scientific evidence, in terms of which one will override the other one?

Chairman

803. Dr Squire, the Chair is not very comfortable with perception questions, but you may wish to respond.

Dr Squire

804. If we are, as scientists, conducting experiments that are very much in the public eye, that will be scrutinized by scientists and by people who have a vested interest, then it's essential that the plant or invertebrate material that we use is as pure as possible in terms of its genetic construct. So even if there is no major demonstrable scientific effect of a particular impurity -in this case antibiotic resistance- it is still better to be safe, and to ensure that no unwanted impurity lies within the material we are looking at. It isn't just a perception, it is for scientific rigour in comparing one thing with another. I still think there are others who could comment on the scientific issues of the presence of the potential influence of antibiotic resistance genes in transgenic organisms where they're not intended to be there.

Chairman

805. Thank you, Argentina

Argentina (Prof. Burachik)

806. Thank you, Dr Squire. Thank you, Mr Chairman.

Chairman

807. Argentina, you have further questions? Your third question …

Argentina

808. No further questions, thank you.

Chairman

809. Thank you. Let's go to the Panel and then follow-up by the Parties. On 66 the Panel has one question also to Dr Squire. Would you care to respond?

Dr Squire

810. Yes, yes I saw this and quaked. It's like telling a man that he's condemned to death and letting him choose the method of his going.

811. I have been frustrated, I must say, in my deliberations on these issues, by the lack of criteria or a comparator, in many instances, and I have thought, whose responsibility should it be to provide that? It isn't a scientific question, in our sense, and the answer I would give wouldn't be a scientific answer. I suggest it's up to both parties, but as I say, I'd rather not choose the method of my dispatch from this world.

812. So I prefer not to answer a non-scientific question, with respect to the Panel.

Chairman

813. That was clear.

814. This concludes the Panel's question on 66. I open the floor for follow-up questions from Parties.

815. This is not the case, then we move on to case 70. And in 70 we have questions from Canada and from the EC to Dr Nutti and Dr Squire. It's on GT73.

816. Canada you have the floor.

Canada

817. Thank you, Mr Chairman. Canada has a question for Dr Andow, regarding his comments on the Panel's questions.

Chairman

818. You do not to read it out if you don't want to modify it …

Canada

819. All right. I understand Dr Andow has a copy of our questions.

Chairman

820. Yes, he does.

Canada

821. So should I just read out the question as opposed to …

Chairman

822. No. Only if you want to reformulate it.

Canada

823. OK. Well, if I could just ask Dr Andow to respond to questions 11, 12 and 13, please. Thank you.

Dr Andow

824. So question 11, I'd like to say that I will respond to the part associated with the environment but not to the part associated to adverse effects on human health. So if you would delete that from the question I would appreciate that …I had formulated an answer about half an hour ago and I'm now in the process of reconstructing that. I'm sorry to take your time. OK. So I would say in all three, the issues, if we leave the references to human health. And I answer them in association to the question of the monitoring system proposed. I'm understanding you're asking about my rationale for why I believed there is a scientific justification, and maybe I'll start with that …To summarize this issue, it's certainly true that the original competent authority, and the EFSA concluded that there were no identifiable risks to the environment. And I go into this in detail. My reading of Austria is that they suggested that there was a concern that they did not feel was addressed. OK. Italy raised a concern as well. I conditioned my answer to Italy on whether or not this actually had been covered some place

else, and I couldn't find whether it had been covered some place else, so I simply said that I expected that it would then be covered some place else, but without knowing that I was unable to eliminate that for sure. The UK. The general perspective here, the UK is asking that monitoring can be used to verify the conclusions of a risk assessment, in this case that there are no environmental risks. And this is a position that the NRC Panel in 2002 also pointed out, that monitoring can be very helpful because by doing that – and I don't elaborate on this in my answer –one can confirm that the risk assessment process itself is doing a good job, and it gives greater confidence in the risk assessment process. So I understood that that was the overall function of the UK. I think I may be missing one … but those are basically the overall rationales for my conclusion, that there are scientific justifications for having a monitoring plan.

Canada

825. OK, thank you Dr Andow. Are you suggesting that that justifies having a monitoring plan? Or it justifies why the EFSA conclusion would not be something that you agreed with, that the proposed monitoring plan was sufficient?

Dr Andow

826. Again I apologize for the delay. I didn't see that aspect in the original questions, and so my conclusions on the sufficiency of the monitoring plan are related to the specific issues raised by those countries, and then what I did was I used the general criteria that I developed for, that I proposed for what is a sufficient monitoring plan. I can't remember to which question that answer was in, but it's in my response to one of these questions. I applied those criteria to that monitoring plan and that's detailed here, and I point out that there are certain points that the proposed monitoring plan do not meet the needs expressed by those countries.

Canada

827. Thank you, Dr Andow.

Dr Andow

828. Thank you.

Canada

829. We have a question for Dr Snow, if she would care to comment.

Dr Snow

830. Yes, I see your question. I don't think I answered this in my responses, did I?

831. You don't have a reply from me in writing?

832. But is this another case of importing for processing only, and in that case my answer would be similar to my other answers having to do with import and processing where I didn't understand the need for environmental impact studies if seed spillage is going to be very, very limited and there is going to be plans for minimizing seed spillage. But I'd rather wait until we get to those questions, since I didn't reply specifically to this one.

Canada

833. Thank you.

Chairman

834. Any other complainant on GT73? This is not the case. The EC on GT73 please.

European Communities

835. Yes, thanks. I will leave the floor to Dr Sweet.

Dr Sweet

836. Thank you, Mr Chairman. I'd like to move on to our question no. 12, since this is also on the subject of post-marketing monitoring. I'd like, just slightly, to rephrase that question, but still direct to Dr Squire and perhaps Dr Snow would like to comment. But following on from Canada's questions to Dr Andow, on the post-marketing monitoring, referring to the comments yesterday on feral oilseed rape derived from seed spillage that Dr Squire made, and considering especially that we're talking here about glyphosate tolerance and glyphosate is widely used on farmland in Europe and also along roads and railways, would you consider it reasonable for a competent authority to request a post-marketing monitoring plan in this instance?

Canada

837. Is that not our question with respect to regulation?

European Communities

838. The question is about whether it was not unreasonable to request a monitoring plan, and I think that's a scientific question. Canada has been asking so many questions about regulatory policy that I find it rather strange they should be raising an objection on this question, which is a scientific question.

European Communities

839. And also, Mr Chairman, it's following on directly from Canada's questions on monitoring plans to Dr Andow. Dr Squire, would you like me to repeat the question? It's no. 12 on the EC list. I had slightly rephrased it because we'd already entered a discussion on post-marketing monitoring, but bearing in mind your comments yesterday on spillage, and the fact that we are particularly looking here at a glyphosate tolerant oilseed rape, and glyphosate is widely used on farmland and roads and railways in the EC, is it not unreasonable to expect the competent authority to request a monitoring plan in this instance?

Chairman

840. Dr Squire will you reply to the scientific part of the question?

Dr Squire

841. Yes. There's no question in the way that glyphosate is applied. The frequency and extent over which it is now applied. And that GM plants of this type would become part of feral populations, so it would seem reasonable to me to request a plan to assess that post-marketing, yes.

Chairman

842. Canada …

Canada

843. Thank you, Dr Squire. Would your answer be any different if the application related simply to importing processing where the seeds were being moved into a port and then from a port to a nearby facility, as opposed to cultivation?

Dr Squire

844. It would depend upon the layout and the infrastructure involved and the quality of the vehicles that transported the material- their leakiness in particular. There would be issues of distance, tortuosity of road network, and so on. Clearly, if it could be ascertained that there was absolutely minimum spillage because the vehicles were entirely contained – sorry, that the seed inside them was entirely contained – and that transport was simply from port to plant, along well defined roads – then I would say that there was much less need or call for that. The importance or the need for doing this would depend upon this range of factors and I think that they are uncertain at the present time. The need is not great as it would be if the product was for growing and harvest in the country.

Canada

845. I'm not sure if Dr Squire could read a passage from the EFSA opinion, where it discusses these issues, that might allow him to provide a more complete answer. Is it possible to do that?

Chairman

846. Dr Squire, you're aware of that opinion?

Dr Squire

847. I'm happy to re-read the passage. I don't have it with me.

Chairman

848. We'll take a break on this one, and we'll stay within the GT 73 case and move back to the EC.

European Communities

849. Yes, just a follow-up to that question directly to Dr Squire. I was wondering if Dr Snow would also like to comment, bearing in mind we're talking about glyphosate tolerant oilseed rape.

Dr Snow

850. I have the same general opinion as Dr Squire, that it all depends on how effectively spillage can be controlled, and that glyphosate is the type of herbicide that is used so widely that that gene, if it does escape into small populations, might spread. So there may be some concerns about the spread of glyphosate resistance that I didn't address in any of my comments. But it's hard to answer the question because we don't really know much about how these seeds are transported. When I read these questions, my thought was, if they're just going straight to processing, the amount of spillage would be very, very small, but I don't know enough about how that works.

European Communities

851. Thank you, Dr Snow.

Chairman

852. Dr Squire, have you had the chance to look at this opinion?

Dr Squire

853. Sorry. I haven't got the paper with me.

Chairman

854. OK. It will be given to you right now. In the meantime I have a layman's question to, actually any of the experts. Is every herbicide also a pesticide?

855. Dr Snow.

Dr Snow

856. I think so, in general usage, yes.

Chairman

857. That's quite enough, thank you. Maybe Dr Squire needs more time, but then we have still open the floor on GT73. From the EC perhaps another question. Not to Dr Squire.

European Communities

858. We can move on to Dr Nutti, then. And as you saw in our comments to your replies, we actually identified in the applicants own experiments a number of reported abnormalities in the animals fed with GT73, and they admitted a shortcoming in the design of these experiments. So we were wondering whether, given these shortcomings, and these facts, you would consider it unreasonable for a competent authority to request additional data or to repeat these feeding studies?

Dr Nutti

859. You see, when I checked these studies, I checked the feeding studies with rainbow trout, quail, broilers and lamb, and I could not find differences. If I could see the case, I could answer, because of course if there are differences …???

860. … It was also the conclusion that the SCP has arrived at. So if we could see what are these abnormalities because I didn't find them when I checked it. So if maybe at lunchtime I could see these studies. Then I could answer, because as you can see my answer shows the SCP they didn't find the difference. If I could see the things I would be happy to check it.

European Communities

861. Sure. They are contained in our attachment too, so we will print it out for you and we will show it to you, and I refer to the rat studies, rat feeding studies.

Chairman

862. EC. More questions on GT73 to other experts?

European Communities

863. No more questions on GT73, thanks.

Chairman

864. Dr Squire, have you had the chance to look at the opinion?

Dr Squire

865. Yes. This describes the methods that are likely to be used to transport imported … rapeseed, to crushing plants, and the fact that the people doing that work, operators, are trained to avoid or minimize spillage. It comes down to the leakiness of the vehicle and the distance over which things travel. It's common knowledge in a number of European countries that oilseed rape likes dockland areas and ports. They occur there as a result of spillage during unloading and storage. Now clearly if the distance between the point of dockland (?) storage and the plant is short, if the vehicles concerned are leak-proof, and if people are very careful, then this risk is minimal. I accept that. Those would have to be conditions for the risk to be absolutely minimal. If the distance was long and the vehicles were leaky then feral populations of the imported seed would generate and persist along roadsides. Under the terms of this paragraph it would seem … If these conditions, as applied here, were applied very rigorously, then I would say that the risk was minimal. There may well be no need for a post-marketing plan, but I do not know personally whether the vehicles used in these instances would be leak-free, regarding seed. And that is something which is outside my knowledge at this stage.

Chairman

866. Any other expert on this question? No. Is Canada satisfied with the answer? Thank you. The United States on this point. You raised your flag.

United States

867. As soon as you've done with this point …

Chairman

868. We are done with this particular point. We're still in GT73 for follow-up questions by the Parties. Any party I take this opportunity to give you an advance warning, after this point we'll move to case 94.

869. Follow-up questions on GT73, the United States you have the floor.

United States

870. I just wanted clarification. The EC was going to provide a document with an attachment and I just want to make sure that we all know where to find it. I presume it's been submitted before I just want clarification as to where it is so we can also look at it over lunch. If the EC wouldn't mind...

Chairman

871. EC, which attachment is it?

European Communities

872. We are talking about CD-ROM No. 1, exhibit EC 70, attachment 02, in Adobe PDF file.

United States

873. A little slower please, sorry.

European Communities

874. It was on our CD-ROM 1, it concerns exhibit EC 70, it is its attachment 02, and it's an Adobe PDF file of 77,691 Kb.

Chairman

875. European Communities, do you have a follow-up question on GT73? This is not the case. So with the open mandate for Dr Nutti's lunch break, we will close GT73. I see no objections from the floor. So, as a test to your flexibility we now go to case 94. The reason being that this is the only open question to Dr Snape. The only one on record, that is. And we'll take the whole case in one, so as to finish it before the lunch break. On 94 we have questions – recorded questions – from the EC and from the Panel, to Drs Andow, Nutti and Snape. We'll start with the complainants to ask them if they have any additional unrecorded questions on Monsanto 8-10. This does not seem to be the case for the time being. I'll give the floor to the EC on this particular case. EC, you have the floor.

European Communities

876. Thank you, Chairman. So our first question would go to Dr Nutti, and this is about compositional analysis of hybrid GM. In your reply to question 44, you referred to different approaches that can be used to perform comparisons, based on the compositional analysis on a hybrid GM. All we would like to know from you is whether the approach chosen by the competent authority is one of these different approaches that you are referring to?

Dr Nutti

877. Can I check my answers here and answer you back?

Chairman

878. EC, try someone else?

European Communities

879. Sure. Do you want me to ask another question, in the meantime?

Chairman

880. Yes, please.

European Communities

881. Right, Dr Andow, can we ask you what you mean by alternative techniques, that the competent authority would have to address concerns about additional DNA fragments? Thank you.

Dr Andow

882. Yes. This is elaborated in 44.10-some, but I guess the main point here is that if you have a transformation and there is a possibility that there are many insertions going on, they could be on any of the number of chromosomes and anywhere on a particular chromosome. You really only want to retain one of them. So one way to try to deal with that is you try to find them all molecularly, and characterize them all, which is the approach that has been proposed in the package here. But a different way to do it is to try to eliminate them. With an inbreeding plant such as soybean it's hard to eliminate them, because when it inbreeds, all of the genes are retained any time there's inbreeding. So it's like a brother/sister mating, you get that going on … But with an out breeding plant like maize it's very easy to get rid of a lot of other genes, because you use a technique called recurrent back-crossing. So you have your plant that has all the various, the hypothetical transgenes all in it, and you have your variety that you'd like to get the transgene of interest in, you cross them, and then you evaluate the progeny and you only take the ones that have the transgene of interest. You keep doing that, and if you do that for several generations you're going to get rid of all the other transgenes that are on all the other chromosomes. So then you just have to deal with one chromosome. And maize chromosomes are long enough, that most of that is going to get crossed out through recombination during that process. So depending on how many generations you do this, you can limit the area you have to be concerned about to a relatively small part of the chromosome, and then you can test in that one area rather than having to do the whole thing. You can be even more efficient if you used molecular markers to help you to screen the plants that you want.

Chairman

883. I'm sure that was very clear to Mrs Fries. Dr Nutti are you ready to answer question 16?

Dr Nutti

884. Yes, OK.

European Communities

885. Excuse me, Dr Nutti, could we have a second to make sure we've fully understood what Dr Andow just said? Thank you. Chairman, may I attempt to ask hopefully a simple follow-up question? Yes, to Dr Andow. This is just to make sure that the method you're proposing would deal with the problem of multiple insertions. And only with that problem. So am I correct in saying that it would not deal with the other possible unintended defects? And only molecular characterization would? Thank you.

Dr Andow

886. As I've indicated, unanticipated – I call them unanticipated effects – would come about from a number of different sources, some of which can be dealt with molecular characterization, some of which can't be. So in general the point … the breeding scheme that I suggested is not going to deal with all of them. It will certainly deal with any of the multiple insertions that could be possible, but there is still the one insertion that you're interested in, and that would need to be characterized.

European Communities

887. Thank you, that would be enough. Dr Nutti, can I now turn to you?

Dr Nutti

888. In my answer, when I stated that my understanding is that there are different approaches, I could say there are two different approaches that I underline that can be used when GM traits have been combined by traditional breeding (stacked). And I would like first, before answering you, to point out that when we were in the Codex- discussing the guidelines-, we didn't address this issue because there was not an agreement if a stacked is a GM or not. There were different views and different opinions because it is obtained by a traditional breeding of two GM. So when I am talking about two different approaches, this is not in the guidelines because some countries have one approach and some other countries have another way of viewing it. It's not written in the guidelines. So one is that the comparison of the new hybrid should be done with the GM parental lines, and this GM parental lines should have been compared with the conventional counterpart. Another is that the new hybrid should be compared with this non-transgenic parental lines. My understanding is that the request from Europe was according to the second approach. But I would like to point out that this is not in any guideline that you should go in this way or in another way. I mean, you have to analyse what are the possibilities. Thank you.

European Communities

889. Thank you. Just to make sure, that means that the approach chosen by the competent authority is a valid one. It's not in a guideline, I understood that much, but it's a scientifically legitimate one.

Dr Nutti

890. There is not … Yes, because both ones can be done … also the competent authority could have analysed the other one because there is no document saying that you should go in this way or other way. So if there was not in that way it could have analysed the first option. For instance, in Brazil when we have to do that, we try to analyse the information that is available and then try to

discuss if it's possible or not possible. I am not saying that this is wrong. I am saying that there are different ways to analyse and they submitted it in one way. That can be analysed in that way.

European Communities

891. Thank you. Chairman, our last question would go to Dr Snape. So within the process of stacking two independent GMOs, DNA sequences may be partially lost, rearranged, etc., This may, for instance, alter the gene copy number or gene expression profiles in the stack as compared to the parental lines. In turn this may explain the difference observed in protein content. Do you agree with the Dutch authority that detailed molecular characterization and DNA sequence analysis of the stack are therefore elements needed to carry out an adequate risk assessment?

Dr Snape

892. Thank you. I have not read the information/dossier on this particular product so I cannot comment on the quality and quantity of the molecular information supplied. My understanding is that I presume that when you mean two independent GMOs, you mean two independent transgenes, you don't stack genetically modified organisms, you stack transgenes into one genetically modified organism. My understanding would be that there are different ways of stacking transgenes. You can, first of all, take them from individual products and backcross them into a single individual where they would be in the homozygous stable inherited state. The other is, if you were creating a maize hybrid, is to put a different transgene into each, or the same transgene into each half of the hybrid into two separate inbreds, and then you would put those together in the heterozygous state within a single hybrid, which I presume is what's happened with the product we're talking about.

893. Yes. Thank you. My opinion would be that, if the individual inbred lines that the molecular characterization had been carried out to show that the transgenes were stable and stably inherited, then I don't see any reason why they should be instabilities introduced just because they're in the heterozygous state. So I'm not sure what information these phrases, that DNA sequences may be partially lost or rearranged, is based on, unless the transgenes are the same, in which case there are opportunities for them to recombine or that, if there are homologous sequences between the transgenes then there may be opportunities for them to recombine.

894. If the transgenes are separate and there is no homology between them, I see no reason why they should recombine or why there should be any problems of stability, or why it would be necessary to resequence. If they do recombine because they have homologous sequences, or there is the opportunity for homologous sequences, then this could lead to a situation in which there would be a rearrangement in the transgene structure. Therefore it might be a necessity to reanalyse the molecular characterization of the recombined transgenes.

European Communities

895. Thank you, Dr Snape.

Chairman

896. Does that conclude the EC's interest in MON 810 for that state? It does …The Panel has two questions on this case. They are questions 31 and 32. And they go to both Dr Andow and Dr Nutti. Whoever wishes to take the floor first, is invited to do so … Dr Andow.

Dr Andow

897. I'll go ahead. I'm not sure I'm going to answer your questions directly. I'm going to say simply why I can to my view, and then put the burden on my colleague Dr Nutti to explain the difference …So first of all my response is not given in the context of Dr Nutti's responses are given, of food safety in terms of the codex issue. I'm looking at it from an experimental design perspective. And there is a certain uncertainty, for me, what are the main questions that are being addressed? So you have a non-transformed plant maize, you have the transformed maize, and then you have the transformed maize with glyphosate applied. And so if you want to know what the effect of the transformation is, on the food content, you'd probably want to compare the non-transformed one with the transformed one, without the herbicide. In the event that the herbicide could have an effect. The experiment that they conducted was essentially the non-transformed variety and the transformed variety with the herbicide. So, I concluded that they couldn't really determine that the differences were associated with the transformation. Now the thing about that, is that you could argue that any difference that occurs between those two are going to be the sum with the interaction between the herbicide and the transformation. So if you don't see any difference between them, then maybe there's no difference in either. But it's also possible that they cancel each other. That's why we wouldn't consider it an effective experimental design for isolating one factor. Now whether or not that was essential to isolate that factor, I couldn't determine from the information. But if the question was that you want to determine that the transgene had no effect on food, then I felt that the experiment didn't really conclusively address that question.

Dr Nutti

898. In my answer, I was looking at the food composition and usually the main thing is to compare the GM with the non-GM, because usually you have the information about the herbicide being done before, when the herbicide is approved. So when we try to look at this, you have to have the comparison with the GM or the non-GM. There are cases that further information has been requested, as was in this case, and then you can check that there was no difference. Because if the herbicide was being used according to the level that was established, it would be no different, so this is why I answer in this way.

Chairman

899. Thank you. 32?

Dr Andow

900. I have to say I can't find the notifiers response in exhibit 90, in the case 94.

Chairman

901. We're having a look. In the meantime I will ask the EC to take the floor.

European Communities

902. Chairman, we would like to ask a follow-up question on your question 31 to Dr Nutti.

903. Thank you, Mr Chairman. Dr Nutti, the Codex Alimentarius guidelines, mention among others things with regard to the design of field studies for compositional analysis that herbicide

treatment should be taken into account. Do you agree with the Codex Alimentarius paragraph on this issue?

Dr Nutti

904. Can I point out what is the paragraph we are citing? If it's in the GM or in the pesticide analysis?

European Communities

905. In the guidelines on foods derived from GM crops.

Dr Nutti

906. Can I just check it?

European Communities

907. Yes, it's in paragraph 44, in the fourth and fifth line, where it says "in some cases a further comparison with the recommended DNA plant grown under its expected agronomic conditions may need to be considered, for example, application of an herbicide".

Dr Nutti

908. Yes, but I think this is why we are using the word "may", so you have to check if it's considered or not. So we can check the opportunity to see. So maybe consider …

European Communities

909. Thank you very much for your answer.

Chairman

910. It looks like on 32 we need some more time. The United States has asked for the floor.

United States

911. It's a follow-up to Dr Nutti, unless she's working on 32. OK. This goes to …We were talking about the different approaches for crosses and the EC asked you a question about it, and you spoke about the different approaches in the discussion on Codex. In your answer you wrote "in conclusion, my understanding, is that the information submitted by the applicant was sufficient to ensure the validity of the safety assessment". That was your conclusion. Does your discussion with the EC about the different approaches change that conclusion?

Dr Nutti

912. No. My discussion didn't change that conclusion. I just agreed that they can go in another way to try to check but the conclusion, I think, will be the same, because the information is the same.

Chairman

913. The floor is still open on 94.

914. The EC has the floor.

European Communities

915. Chairman if I may comment on this. May I? I can put it in the form of a question.

Chairman

916. You must!

European Communities

917. My understanding of what Dr Nutti said is that there are two different approaches, and my assumption is – and maybe Dr Nutti wants to confirm – that these two different approaches are based on differing views as to what is necessary and how you want to go about doing it. And my understanding is that you're saying that the approach chosen by the competent authority is valid because that's from their point of view what is necessary. We're not contesting that from the point of view from the applicant who has chosen the other approach, it would be equally valid from their point of view, but we're talking about two different approaches here which are equally valid, right?

Dr Nutti

918. I will try to make myself clear again. There is no guideline saying that you go in this way or that way. So in my personal opinion you can go in either way. The applicant has chosen one way. And in my view the way the applicant chose has proven that the product is OK. But if you choose the other way, you can, because there is no guideline saying that you have to go in this way or the other way. But in this case the applicant will be able to show to you that his information is also valid and the way that he has chosen can prove that the product is safe. So this is what I'm trying to say. I don't think that you were not …

European Communities

919. Can I still follow-up? Could it be possible that if, on top of the first approach chosen and the data submitted in line with the first approach, you request the second approach, there could be a different outcome?

Dr Nutti

920. I don't think so.

European Communities

921. You don't think so?

Dr Nutti

922. Yes. But I didn't see the other way, so this is …

923. I'd like to make it clear that we don't have any guidelines saying you should go in this way. So you can try to go in one way and reach one conclusion.

European Communities

924. Thank you. I think that's all.

Chairman

925. Dr Nutti, can I clarify this review?

926. Does it mean the applicant was not given the information on which way to choose, no instructions, no … he was not?

Dr Nutti

927. As far as I know, there is not an information saying when you have a stack, you have to go on this way … You try to go on the way that you can or that when you believe that you are going to prove … When you have a stack, you have a cross, a conventional cross of 2 GM, so how are you going to compare? Are you going to compare these two with the one that they are derived from, which are GMs? But in this case you say, oh, but you need to compare also with the non-GM, that was before. This is one way. And the other way is to prove that the first alteration was done and then the second was done. So there are two ways but nor the Codex or anybody has said you have to go in this way or the other way. This is what I was trying to say in my answer.

Chairman

928. And both ways are likely but not necessarily leading to the same result. That's what you were saying in answer to the questions from the EC.

Dr Nutti

929. Yes. The way that I analyse it, the results confirm that they are safe. My personal opinion is that the other way would lead to the same conclusion, but they didn't have this information, so … And nowadays we don't have these established because for a lot of countries involved, they don't believe that staked should be treated exactly as a GM because it was a conventional breeding. So this is why we never reach an agreement.

Chairman

930. Thank you. Dr Andow would you be ready to reply to question 32, or Dr Nutti for that matter? OK,we have to wait a little more. Thank you, Dr Andow.

Dr Andow

931. The answer to the question, according to the chronology the notifier did not provide a response until February 2002. In terms of whether the additional information would require 19 months to gather and provide, part of that depends on how the notifier decided to respond. They provided considerable information in their response. My response was concerned primarily with the glyphosate treatment. And in reading their response, the response to that part of the question would

not have required 19 months to gather. However, I do note that there is extensive experimental results on a broiler study and I would have to defer to Dr Nutti for an opinion on that.

Dr Nutti

932. Usually the broiler study is 48 days, but here they have carried also other studies because they have carried the 90 days study and other studies. They have a 13 week feeding with rats. Sometimes you need to grow the grain, to prepare in order to feed exactly with the experiment. So, if they need to have the grain that they need to multiply, it would take more time, so this might be possible that it would take the time necessary.

Chairman

933. Thank you Dr Nutti. Now I believe this takes us to the end of 94 and also in that case to the end of the morning session. We will here say goodbye to Dr Snape, with our sincere thanks for his contribution, they were very valuable, and we will resume at 3 'o' clock sharp. Thank you. [Pause]

934. Before we start on Case 74 I would like to ask Dr Nutti if her lunch break has been successful. You are still looking at it. Would the EC care to come back on 64? There is no more point in 64. So that case is also closed, thank you. So, with an open point in 70, I now turn to Case 74 which is BT Corn and I have questions from the EC and from the Panel, but I will again ask first the Complainants on 74 whether they have any questions which have not been notified to the Secretariat. No for Canada, no for US, no for Argentina. EC has the floor on 74 please.

European Communities

935. Thank you Mr Chairman. We have a question for Dr Healy. We would like to know, Dr Healy whether, in light of your reply yesterday to Question 21 and recalling the submission of 2000, you would agree that it would have been feasible for the notifier to provide sequence-based information about the transformed and integrated sequence as part of the molecular characterization, rather than only the southern blot information as it was submitted.

Dr Healy

936. I'll preface my comments by saying that this is not one of the dossiers that I have reviewed, so I can only answer in a general way. Looking at Question 21 from yesterday, it was about whether the complete sequencing of the transformed and inserted sequences could have been done with the application of standard molecular techniques in 1995. You have just asked, would it have been feasible for the notifier to provide sequence-based information? I would expect that it would have been feasible for that information to have been provided.

European Communities

Thank you very much.

Chairman

937. No more questions from the EC? That is catching me by surprise. I have, from the Panel, one question to Dr Nutti and one to Dr Andow. Dr Nutti could you answer Question 24 please.

Dr Nutti

938. I was unable to reply to Question 32, because it was related to molecular characterization. I was unable to answer Question 33, since, as I explain in my answer, the information was very difficult to handle. The request for the information was not provided in a straightforward way, so it could not be analysed completely. I did not find the relevant data. This is why I could not give the information.

Chairman

939. Dr Nutti, do you refer to the documentation provided by the notifier?

Dr Nutti

940. By the notifier. The notifier did not give the straight information unlike the other files that I worked with. This is why I stated – it was not the Panel's fault, it was the notifier's.

Chairman

941. Thank you, that is clear.

Dr Nutti

942. Thank you.

Chairman

943. Dr Andow.

Dr Andow

944. Thank you Chair. Because of the nature of the product, I would have to assume that the information was somehow related either to a food or a feed issue, which is not my strength. That is why in my answer, I indicated that I could imagine some reasons, but I couldn't really be sure that any of them were valid. The only things that I could even start to imagine had to do with establishing substantial equivalence. What is puzzling here, is that in the other cases there weren't requests for specific geographic locations in terms of establishing substantial equivalence. I was not entirely sure about what the purpose of these requests could be, except to ensure representation in the sample.

Chairman

945. Thank you. This concludes the Panel's questions. Are there any follow-up questions to the experts, or perhaps a clarification from some party on behalf of the notifier? The EC has asked for the floor.

European Communities

946. I have some difficulties with these studies. I would like to understand better, because we tried to highlight in our comments what we thought was the reasoning. I'll go back to page 74. What we think is relevant here, is that this application for maize was for import and processing. Therefore the compositional analysis had to be done with regard to the geographical location of the growing of the plant. The problem here is that the notifier submitted field trials that were done either in France, or in

Italy, which being EU countries, would not be relevant because the plant would not be grown there, or Chile, which was not usually an exporter of maize into Europe. Could Dr Andow please explain what the problem is with asking for this kind of additional studies, in a situation where the analysis has to be done with regard to the imported product, plant, and the compositional analysis relates to where the plant is actually grown. The soil composition, the environment, or the habitat for pests.

Dr Andow

947. As I detail my answer, it is surprising that the notifier said that they were going to submit information from France and Italy about maize that was going to be imported into the European Communities. And so I agree on that point. I guess what I couldn't find when I was going through the files is a clear statement as to why the request was made. That is what led to my last comment in my answer, and probably stimulated the question from the Panel. My response to that was essentially similar to what I think you just said. But again, I have to say that it is not my area of expertise.

European Communities

948. Thank you very much

Chairman

949. Dr Nutti.

Dr Nutti

950. There was a lot of attachments in that file which had the title but did not include the annexes. So, for instance, in my case I tried, and was unable to see attachment 36. I didn't have the information that was in the annex. It can't be known what the purpose of the studies that they are referring to is.

Chairman

951. Thank you, Dr Nutti. Can I ask you, in terms of risks for feed use or food safety, what is the potential impact on safety from the place where it is grown?

Dr Nutti

952. When we design an experiment, for instance in Brazil, we try to grow the crops in three or four different places in order to have different habitat stresses and submit the product to variation. In these cases, it is important to have the information not only for one place, but for different regions with different stresses. That is why in the Codex we say that relevant differences should be taken into account. For instance, when we design a project with beans, we develop a few trials in five different regions of Brazil in order to have different information from different soil and different stresses. We cannot rely on only one or two, or only one that is the places where we will be growing. You have to have variation.

Chairman

953. I understand that this could affect environmental impact, but how then does this bean from different regions in Brazil have different effects on feed safety?

Dr Nutti

954. Sometimes it is not only the environmental impact. The soil can have an effect on the mineral composition.

Chairman

955. And that has different impact on the feed or food safety – not quality, but safety?

Dr Nutti

956. More on the quality. For the substantial equivalence we need to see if there will be any difference, so this is the first step. If there is a difference you have to pay more attention. This is why you have to grow the plants in different places.

Chairman

957. And it could be that one of those five regions in Brazil produces a bean which is unsafe?

Dr Nutti

958. You cannot give an answer about safety, based only on one issue. For safety evaluations you have to conduct many studies and compare all the results. You cannot give an answer about the safety of the product, based only on one result.

Chairman

959. Right, but it could be that the safety is differently affected in different regions?

Dr Nutti

960. It could be that you have a different result, and then you have to conduct other studies. And then you have to compare the results. I cannot affirm that, for instance, if the iron amount varies from one place to the other that this will have an impact on the safety of the product. But attention has to be paid, because there is a variation. Maybe the rat fed on a plant grown in one area will not gain the same weight as a rat fed on the same plant grown in a different area. I have to pay attention to this type of indicator.

Chairman

961. Thank you. Canada, on this point.

Canada

962. This isn't really our product, but I do have a question, because I am a little confused by the answer. This seems to suggest that food, no matter how it is produced, if it comes from different parts of the world, would have to be tested at least the first time that it is imported, given that there are changes in composition. Is that really the case, is that what the EU or other countries do? It doesn't sound to me like it's a GM issue *per se*, it's simply an issue of food importation.

Chairman

963. Dr Nutti, perhaps you can clarify? Dr Nutti?

Dr Nutti

964. Just to clarify Canada, I think the question for this is that, when you prepare a trial to submit for comparison that you need initially to have different growing locations. But in my opinion you don't need that the second or third time you submit a trial. You need to grow the plant in different places to have different stresses, in order to have a variation.

Canada

965. Thank you. I was simply asking is this a GM issue or is it a food issue? Thank you.

Dr Nutti

966. No, we are supposed to do this when we have a GM product, because it is a food issue. But you have to have information for both the non-GM and the GM products. Because, with regard to the information on the non-GM, you also have to have data from different places, to capture the a natural variation.

Canada

967. I'm sorry, just to be clear. There is a natural variation whether the food is produced through transgenesis or otherwise?

Dr Nutti

968. Or otherwise, of course.

Canada

969. Thank you.

Chairman

970. Does that conclude questions on 74? United States.

United States

971. We'll have to consult. Please put one of your special holds on this and go on. Thank you.

Chairman

972. 74 on hold. We move to 75, Bt corn again. And there are two questions from the Panel. One question to two experts. That is Question 26. Could one of you respond, or both.

Dr Nutti

973. My answer on 36 was with regard to the protein. On my understanding the protein used on the toxicological and allergenicity tests was obtained in a heterologous system and not from other maize. hen I read the question it seemed to me that the person who was asking had understood that the protein was obtained in another maize variety. Then the notifier explained that the evaluation had indicated it was not the bacteria that provided the protein. Maybe the reason for the misunderstanding resides in the fact that the same protein is expressed in two maizes, and they had these two numbers. his was very difficult to analyse. It is a lot of information. The important thing was that the studies were carried out with protein derived from recombinant micro-organisms that were proven to be the same.

Dr Andow

974. I would say that I agree entirely with that analysis. But the reason I concluded that the question was necessary was because the CA at that time was under the understanding that it was something different. They had to ask the question in order to clarify that it was or was not. Once they got their clarification, that was the information necessary to proceed.

Chairman

975. Thank you. Any follow-up questions on 75? From the Complainants? The EC?

European Communities

976. Chairman, I would like to ask Dr Nutti whether you saw our comments. We are under the impression that actually the misunderstanding is of a different nature, in the sense that you base your reply on information provided by the applicant *ex post* actually, following the request from the competent authority. Do you want to take a look at this? It is in 444. We are claiming that you are basing yourself on attachment No.1 EC-75 and that the data contained in this attachment is actually data that was provided in 2002. (This may be our mistake.) The request made by the competent authority dates from 2001. We can clarify this: probably attachment 1 is an updated SNIF or something. That misunderstanding might have come about this way.

Dr Nutti

977. I did not check exactly the date, I was checking the technical information. The information that was there, maybe it was 2002, proved that it was the protein that was necessary. So I can go back and check this.

European Communities

978. Well, Chairman, if you want, I have the attachment 1 in front of me, and indeed the top date given in this letter is 14 February 2002.

Chairman

979. Any more flags on 75? This is not the case, so we move to 76 and Case 603. Round-up Ready Corn and Cotton. Here we have questions from the EC, from Argentina and from the Panel. o I would suggest we start with Argentina, that's NK603 Maize to Dr Squire. Argentina, you have the floor.

Argentina

980. Thank you Mr Chairman, just allow me to make a clarification. The nature of the questions of the debate which took place yesterday and this morning, in our perspective, satisfy our related questions. We prefer to reserve our right to make a follow-up questions if necessary after the exchanges of questions that you or the Community may put, thank you.

Chairman

981. Other Complainants' questions? Not the case. The EC please.

European Communities

982. Chairman, we are on EC 76, right? I don't think we have a question on this one, thank you.

Chairman

983. I was given to understand that you did have question to Dr Nutti on food use of NK603. EC96.

European Communities

984. On food use – that is EC96. So we would come back to that later.

Chairman

985. 96 is not on my list, and it concerns the same product, right?

European Communities

986. But it concerns food use, so it's under a different regulation.

Chairman

987. Yes, I'd rather have it now, so that it won't be forgotten.

European Communities

988. In our document that we submitted this morning, this is in paragraph 20, it is a question to Dr Nutti on Question 53 of the Panel. Yesterday you replied to our question on Question 111 of the Panel that food studies and molecular characterization are complementary. Would you agree, therefore, that whole food studies can provide assurance regarding the safety of the second protein that was identified in the further molecular characterization.

Dr Nutti

989. If in this case there was a second protein, I would agree. When I was looking, I was not aware of a second protein. But if there is a second protein in the molecular characterization, I would agree with the test.

European Communities

990. Thank you, perfect. There was a second protein.

Chairman

991. Ok, so here we go with the Panel's question. Question 27 to Dr Andow, please.

Dr Andow

992. It does look like I am reversing my opinion between 37 and 38. But my opinion 37 is based on what I read by the lead CA. The questions that the lead CA posed in 2001 were all prefaced by the remark that I put in here - "although this is for notification, it is not for cultivation". We know that cultivation is going to come up soon, and so we are going to ask these questions in that eventuality. It seems to me that it is a not necessary for a notifier to answer questions, any questions related to a future event. I point out that it is true that these questions will need to be answered in the future. Then the CA makes a point specifically about accidental dissemination and germination. I could not see exactly how these points had been covered by the notifier previously. I felt that it wouldn't be difficult to cover them, but since they had not been covered, it would be necessary to have that information.

Chairman

993. Thank you. Dr Squire on Point 28.

Dr Squire

994. Maize and soybean and thousands of subtropical and tropical plants exist in Europe. Often they exist around points of entry, where foodstuffs are imported, around plants for the processing of those foodstuffs and sometimes around restaurants and other places where the food might be put into refuse. Maize is one of those plants. It exists widely, but not in any great density in these locations. Where it is cold - this is a generalization - towards the north of Europe, it doesn't really last beyond the season it emerges in. Now, it is less cold towards the south, and there is the possibility that this kind of seed, the seed resulting from spillage or from refuse might persist for more than one season. The level of problem here is much less than that of crops that shed their seed in fields and persist over many years. It is a minor problem, but it seemed to me that because it was fairly widespread in the case of maize that the CA was making a reasonable request about this issue.

Chairman

995. Any follow-up questions on Dossier 76? Argentina you have the floor.

Argentina

996. Thank you Mr Chairman. Argentina would like to go back to Question 53 on the so-called second protein in NK603. Argentina would like to point out that the second protein was the same protein, CP4EPSPS which was introduced purposely, as two copies. The second copy was mutated in one single nucleotide, so this second protein was actually the same protein with one permutation. This so-called second protein was analysed by protein structure activity, toxicity, allergenicity, using bioinformatics approaches, invitro digestion procedures and studies on experimental animals and animal field trials. These analyses indicated that this NK603 so-called second protein is absolutely

similar. It has the same biological effects that the non-mutated NK603 CP4EPSPS protein. There is no second protein. It is the same protein, but the second one has a permutation which didn't alter any of the products. Did Dr Nutti examined or analyse the statement in our 25 page 2, fourth paragraph and if, so what does she think about that?

Chairman

997. Can you give the text to Dr Nutti? Thank you. Argentina you want to quote the text so everybody can have a look at it? Just give us the number of the Exhibit.

Argentina

998. It's Exhibit EC76, Attachment 70, which we submitted as Argentina 25. It's the same exhibit that we provided to Dr Nutti just now.

Chairman

999. Does that allow everybody to look up the text? United States?

United States

1000. I apologize, the EC Exhibit number we are working on now is which?

Chairman

1001. I understand we are talking of EC-76 Attachment 70, also submitted as Argentina 25. So now Argentina must repeat the question, not the statement, thank you. And which particular question are you referring to. Which product, Sir?

Argentina

1002. The question for Dr Nutti is, if in view of what the Exhibit shows, she is of the opinion that the second protein, being substantially equivalent to the first protein, can be dealt with as the same protein for food purposes. Page 2, paragraph 4.

Dr Nutti

1003. I read page 2 and paragraph 4. I would like to go back to the question that the EC asked me, because you are referring to the same point. I don't know the number of the question. Could you please inform me what the product was and what was the question? They were asking for additional feeding studies. If I don't see the question I don't know which additional feeding studies.

Chairman

1004. Help from the EC?

European Communities

1005. We are talking about Question 53 of the Panel. I put a question to you just ten minutes ago about its NK603 food use, and I was referring to our paragraph 444 in our submission. It is in our

paragraph 20 and this was going back to what you said yesterday in the context of Question 111 of the Panel.

Dr Nutti

1006. When I answered this question, I said that the applicant has provided in the dossier all the information usually requested for food safety assessment, for toxicological assessment, he presented the studies for CP4EPSPS protein digestion in animal gastric and intestinal systems, acute gastric studies in mice, homology to known toxins, and allergens, and exposure to human diet. It was also confirmed that the GM maize was equivalent in composition and nutrition to the conventional counterpart. Therefore in my opinion there was no need for requesting a semi-chronic toxicity study.

1007. Yesterday you asked me if I had a doubt in the molecular characterization and if I agreed with another feeding study. I said yes, I agree, because if the molecular characterization raises any doubt, it should be taken into account. Today when you asked me about a second protein, I thought if in fact there is a second protein, for me this raises a doubt. But when you look here in the analysis of the scientific panel of the European Union in this paragraph, there is no doubt. The analysis shows that the protein is equivalent. This is not a second protein, it's almost the same. As a result of the genetic modification the product contains two slightly different proteins expressed from two copies, CP4EPSPS. The proteins differ from each other in one amino acid, and analysis of this change indicated no apparent changes in CP4EPSPS protein activity, toxicity or allergenicity. In this case a second study is not necessary. There is one point that we need to pay attention to, that is a case by case evaluation is needed. I cannot answer these questions generally. I would like to go back to the product and to the question, because it is fair to analyse it this way.

European Communities

1008. Thank you Dr Nutti. I realise that it is difficult if people start throwing documents at you in the middle of the meeting and expect you to provide expert reply on the spot. I would just like to point out that the document referred to by Argentina is the EFSA opinion of the year 2003. We are talking about a request for additional information for the year 2001. That is all I would like to say, thank you.

Chairman

1009. Thank you. Does this clarification take us to the end of dossier 76? That seems to be the case. I then move to 85 and read that this is Monsanto Upgraded Corn again. Here I have a question. United States, is this on 76 or 75?

United States

1010. We think it is on 76 but are not exactly sure where we are.

Chairman

1011. I'll put you on hold then. Does anybody from the Complainants have a question to the experts on 85? No, then I give the floor to the EC for your question to Dr Nutti.

European Communities

1012. Thank you Chairman, this should be a straightforward one. We are talking about EC85, that is the Monsanto Roundup Ready Corn GA21. That was the Question 40 of the Panel to which you replied. The question is simply whether you agree that animal feed might differ from foods from the same crop. I think we talked about this today already, as well as that the animals consuming the crops can differ widely in physiology, intake digestion etc. We would like to know whether you think that such differences exist, and whether that affects the risk assessment.

Dr Nutti

1013. There are differences that exist and usually we start the risk assessment with a 90-day study with rats. Then you also go to 48-day study with boiler chicken study because this gives you a better answer with less time. Then, depending on these first two, and also the acute toxicity study, you analyse whether you should continue with different studies. The person who is conducting the safety assessment should take into account the first results and then look for the need to go to the next ones.

European Communities

1014. May I follow up on this? Could additional studies include studies on target animals, because my understanding is that boiler chicken is not necessarily the target animal of the feed used, but ruminants.

Dr Nutti

1015. There were some cases which asked for more tests on target animals. If you go back to the Codex, you see that the Codex is very clear that if none of these tests show any difference, going to the target animals will not always be necessary. You have already an indication that there will be no differences. The Codex is very clear that additional animal testing is not necessary when the composition is comparable. Only if you see differences for instance in the fatty acids and the profiles, then you should go for additional testing. But if you don't see differences, it is questionable if you need to go further.

European Communities

1016. Thank you. We all agree that Codex is on food, and we are talking about feed safety here.

Chairman

1017. Ok, here is a question from Mr Kumar

Mr Kumar

1018. I wanted to address a simple question to Dr Nutti. If something is safe for human beings can it ever be unsafe for animals?

Dr Nutti

1019. I don't believe so.

Dr Kumar

1020. So there is no practical evidence of anything which has been declared safe for human beings being possibly or potentially unsafe for animals?

Dr Nutti

1021. I cannot remember, because I have to think about specific papers. In general, as far as my knowledge goes and based on everything I have been dealing with, I don't see any practical evidence. This answer is limited in the scope of this product, and not in the scope of different products.

Chairman

1022. I have ticked off 85. EC you have the floor.

European Communities

1023. What Mr Kumar asked is interesting. There is a lot of brainstorming going on around this table because we all would know of immediate examples of things humans can eat, and animals can't eat and the other way round. As far as I understand, there are parts of a plant which a human would never eat, and animals eat, so there are certain tests which simply do not provide the data you would need on animal safety. Second it seems that there are certain things we eat, that you could not feed to an animal without killing the animals, such as sugar in excessive amounts to cows. Everyone around the table can eat excessive amounts of sugars, but apparently that is not very good for ruminants, right Dr Nutti?

Dr Nutti

1024. When I gave my answer I tried to state very clearly that it was in the scope of this product. The question was if this maize grain is good for a humans, whether it is going to be bad for an animal. That was the question, and my answer was in the scope of this product.

Chairman

1025. We have a follow-up question to Dr Kumar's question. Would you say Dr Nutti, that this is both the case with regard to potential adverse effects on animal health and with potential adverse effects to humans from consuming the meat of those animals? You said that this product is basically safe, if it is safe for humans, it is also safe for animals. Would that apply both with regard to potential adverse effects on animal health like you said, but also with potential adverse effects to humans who consume the meat of those animals?

Dr Nutti

1026. I have addressed this issue in one of my answers, when you asked about the potential effects of the GM products in milk, meat or products thereof. In my answer I even cited a bibliography of the studies that have been done with these products. Up to now with the products that are not different in composition there is no difference in the meat, in the eggs, or in the milk. Maybe in the future when we have products that will be different in the fatty acid composition, we will have differences on the composition of the product, but with these products that are on the market now we don't have differences in the composition of the meat. For instance if a cow was GM fed with one of these products that were not different in the composition, the studies that have been published up to now

show no difference in the composition of the milk or the meat. EC in its comments to my question and my answer, gave the example of the high-oleic soybean. I don't believe that anyone will feed a cat or a pig or a chicken with a high-oleic soybean because it has been used for capsules. It has a different concentration in the fatty acids than the products that are being used for feeding the animals. Thank you.

Chairman

1027. Thank you. The EC.

European Communities

1028. One last point on the issue of GA21 maize and how animals and humans eat that product. Assuming that, this is indeed only about kernels and I am told that humans eat only some grams of maize kernels per day if at all, whereas cows can eat between 5 and 10 kilos of maize kernels. The intake might be substantially different which might have an effect on how it affects the being eating it.

Dr Nutti

1029. The question that was before me was from the Panel. I don't think I need to answer it.

Chairman

1030. Thank you.

European Communities

1031. What was before you and what was put to you from Mr Kumar was to know whether the food safety assessment on this product could be transferred without any hesitation to the issue of feed safety. The point I am trying to make is that it cannot be transferred without any hesitation because the intake is different and that might make a difference in how it affects safety.

Dr Nutti

1032. I pointed out several times that the composition matters. This is a key issue. If the composition is the same, we can go further. While you are talking about kernels or the grains, I was talking about the grain and the composition of the grain. The way we are going back and forth with the different products is misleading.

Chairman

1033. Here is a contribution from the Chair. When we wanted to supply raw milk cheese from Switzerland to Australia, the health authorities took a long time to assess the risks to humans, and when they finally got through, the veterinary authorities wanted to have a check on their own, because possibly our Gruyère could contaminate Australian cows. That case was eventually also solved. Anyhow there seemed to be differences in at least, in some parts of the world, on intake by humans and by animals of the same product.

Dr Healy

1034. I think that this is an interesting example, but that comes to different pathogens that would be associated with the product. Some pathogens may affect animal health and some pathogens may affect human health.

Chairman

1035. We have no more questions on 85 now. We go to 87. The Panel has one question on this case. It goes to Dr Nutti and Dr Squire.

Dr Squire

1036. I'm not certain that I can comment competently on the food safety risk in this case, and would defer to Dr Nutti. I think my interest in this question was on the plants that might survive. I would say that I am not competent to respond to this one.

Dr Nutti

1037. As far as I can remember, this was a case in which the lead CA asked for at least two seasons, because usually when you make the comparison, you need to have information from more than one growing season for a particular product. If you need two seasons the applicants has to grow each two times, extract and then analyze both seasons. He could not have done that with only one season. I do not remember if they had presented two seasons at one time. When I answered this, what I was looking at in the papers was the notification that the additional information regarding the data of the composition of high-oleic soybeans lectin content and composition data was from at least two seasons.

Chairman

1038. The question is whether this could have been all asked at the same time. If you see that the request came in December 1998, in January 1999 and in October 1999.

Dr Nutti

1039. Yes, it could be done at the same time. If you look at the information and you see only one season you ask for the other ones. It is not necessary to do it in different times.

Chairman

1040. Dr Squire is of the same opinion?

Dr Squire

1041. From what I have just heard, I would agree with you.

Chairman

1042. Thank you. Any follow-up questions from the floor on Dossier 87? EC.

European Communities

1043. A hold on this one please, Chairman.

Chairman

1044. Meanwhile we move to 88. Monsanto Sugar Beet. The EC has a question to Dr Nutti.

European Communities

1045. This is a question on EC-88, that's Monsanto Syngenta Round up Ready Sugar Beet. It is a question on allergenicity. I would like to know whether you agree that small amounts of allergenic proteins might be enough to cause an allergic reaction?

Dr Nutti

1046. Yes I agree.

European Communities

1047. Thank you. So your statement in your reply that allergens do occur at higher levels than one per cent, does not preclude the risk of allergic reactions to small amounts of proteins - smaller than one per cent?

Dr Nutti

1048. This is different. The protein that can cause the problem is in a very small amount. What I was saying here was that food allergens are generally abundant in food, usually greater than one per cent of the protein. This is a statement that everybody who deals with allergenicity knows. I am not saying that you need one per cent to cause an allergy, I am saying that the food allergens usually have more than one per cent of the protein.

European Communities

1049. May we follow up on this. Dr Nutti, Given your answer to the previous question, would you agree that if a cross-reactive protein were present in a plant at low levels, this could, in theory, illicit an allergic reaction?

Dr Nutti

1050. Under allergenicity, we need to follow all the steps that are recommended for allergenicity, in the Codex guidelines. You cannot just pick one example, you need to go with the entire analysis and then see if it will probably cause a reaction or not. We cannot rely only on one data point. You have a step by step procedure in the Annex that you follow one step at a time. If there is a doubt at a certain step, then you go to the next step, and to the next step. I would not answer based only on one set because we need to analyse all the points.

European Communities

1051. Just for clarification, calling a protein cross-reactive implied that other parameters had also been confirmed, but thank you for your answer.

Chairman

1052. Thank you. Any more questions on 88? Otherwise Dr Nutti can close her microphone, and give her a break for some moments. We are going on to 89 and here the Panel has a question to Dr Healy. Question 30.

Dr Healy

1053. There are a number of documents in the dossier that relate to this question, but the dossier does not appear to be complete. As far as I can work out the history associated with the development of this detection methodology, the company involved had been developing a detection method. Then there was either a need or a requirement - and I am not sure which - to undertake some sort of validation process. It seemed to be in conjunction with the joint research laboratories. In undertaking that joint work, using the method that had been developed by the company, some technical difficulties were identified. The joint laboratories then proposed to the company that they could further develop a method, which the joint laboratories themselves had been developing under a research project. It was that method that was ultimately developed. A lot of that history is available in the dossier through email correspondence.

1054. There are two substantive documents that talk about the technical difficulties. The first set of difficulties seemed to relate to the amount and the quality of the DNA that the company had developed, that would form the basis of the method. Certainly one of the documents shows that the different laboratories were detecting different amounts of DNA which seems to be a bit odd, but nonetheless that's what seemed to be happening. The quality of the DNA seemed to be an issue as well. In the Dossier there is a technical report that comes from the joint laboratory where they have tried to use the DNA provided by the company to do what has been called a pre-validation test. It is to see whether the method is sufficiently robust to move forward into a validation test. The document in the Dossier that comes from the joint European laboratory - who undertook this pre-validation test - and the document identifies or states that the reproducibility and the repeatability of the method was not sufficiently good to move to the validation stage. This is particularly so at low concentrations. Now this is quite possible because we are talking about very small amounts of DNA. Starting DNA usually is used in very small volumes. The quality of the DNA needs to be very good and it can be very difficult to establish the right parameters to make the method work very well.

1055. I am unable to go the last step in the Panel's question and make a judgement myself about whether those problems that were identified in the document are really sufficient to explain the delay. I think you need to be very specialised in method development and the optimization parameters that are described in the document to really make that judgement call. I certainly don't think that I am. A range of problems were identified. If indeed someone who was competent to make the judgement calls said that the DNA fell outside the parameters, then they would be of sufficient magnitude to slow down the development of the method.

Chairman

1056. Thank you Dr Healy. Do the parties have views, questions on this particular Dossier follow-up? This does not seem to be the case. 94 we have dealt with this morning. We come to Dossier 101. There we have questions from the EC and from the Panel to Doctors Andow and Squire. Would the Complainants like to start with something we have not announced before. This is not the case. The EC has the floor.

European Communities

1057. Thank you Chairman, I am just trying to make sure that we dealt with Bayer Liberty Link soybean, that would be EC-93. We would have a question on that, it relates to Question 50 of the Panel. It's in our paragraph 19 of our document.

Chairman

1058. So why don't you start with 93.

European Communities

1059. This relates to Bayer Liberty Link soybean. Some herbicides such as glufosinate and glyphosate inhibit enzymes that are important in plant metabolism. Do you agree, Dr Nutti, that the effect of herbicide treatment on the composition of herbicide-resistant GM crops should be tested?

Dr Nutti

1060. Yes, I agree, but I don't want this to be confused with my statement, that for the GM we need to compare the GM and the non-GM. Usually the herbicide has its own evaluation. I would like to make this very clear in order to put two answers together.

European Communities

1061. Can I follow up on this? This may be a regulatory question. Still, I think it should be on record. Do you think, Dr Nutti, that when you assess the herbicide you assess the composition of the GM crop that the herbicide is used on? You are making a distinction here between the assessment of the herbicide treatment and the assessment of the GMO as such. My question to you is when you assess the herbicide treatment, and I understand you to be assuming that this takes place elsewhere in the safety assessment of the herbicide, do you think in that in the safety assessment one looks at the composition of the GMO in question that is going to be treated with the herbicide?

Dr Nutti

1062. I didn't get your question. In my understanding, when you are going to access the GM, even if this GM is going to be treated with the herbicide, you compare the GM with the non-GM. Further treatment with the herbicide can be discussed and can be looked on a case by case basis. For instance, this was the approach in the files that I examined. You can have one herbicide that has already been approved by the Codex, the limit has been established, and if the doses that have been recommended are inside this limit, sometimes you don't need to have this further evaluation. There are cases in which the third trial and a third experiment are done. Then you compare with the treated GM. Of course you cannot have the control with the treatment because the control will die. There are cases where you do that and there are cases where you don't do that. This morning when we talked about this, the term used in Codex was 'may' – you may evaluate. You have to look on a case-by-case basis. I was trying to explain that the herbicide has been assessed in a different way. The first thing you do when you are looking for the comparison is to compare the GM and the non-GM. Then if you still have doubts, then you go with further studies.

European Communities

1063. Thank you Mr Chairman. I think there is some misunderstanding here. What the EC's question is trying to point at, is whether the herbicide applied to the GM plant might have an impact on the compositional analysis of compounds expressed by the plant or the plant compounds and the nutritional quality of the plant. How would you assess that, if you don't test the plant sprayed with the herbicide?

Chairman

1064. Before you reply, Dr Nutti, the United States has a point of order.

United States

1065. Is it possible that we are discussing Question 49 of the Panel, because I am a little lost.

European Communities

1066. I was under the impression that we are discussing Question 50, so this would be the request for additional information regarding nutritional composition by Belgium. That should be EC93 attachment 23.

United States

1067. I just didn't see anything in 50 related to what we are talking about here. Maybe my questions are numbered differently.

Chairman

1068. Dr Nutti. You have the floor to reply to the EC's question.

Dr Nutti

1069. I am just pointing out that she thought that it was related to Question 50 of the Panel, and it is not. We are discussing another thing. Because question 50 is about nutritional composition.

European Communities

1070. Can I clarify this is on Question 19 of the European Communities?

Chairman

1071. Let me try to phrase that question. Here is the question. Is the only concern with the herbicide a question of potential effects of residues or can the herbicide use affect the composition of the GM plant itself?

Dr Nutti

1072. If I expect the herbicide to change the GM plant, I would expect the herbicide to change the non-GM plant also. This is what I was trying to say. If this herbicide has been approved, and you have to look at the residues, I am not expecting the herbicide to have differences in the GM plant.

Chairman

1073. Thank you. EC.

European Communities

1074. Can I first clarify where this request -for additional experiments on GM treated with herbicide -is, for the benefit of the US. Also to correct the mistake we must have made, because indeed it is not Question 50. We are referring to Question 49, and we are talking about the Italian request. We are all agreed, and I apologize.

European Communities (Dr Hilbeck)

1075. Yes there might be effects of the herbicide on the GM plant that changes the compositional nutritional quality of that plant, and it is clear that if you apply the herbicide to the control plant, the control plant dies. In order to see whether there are changes in a compositional analysis and nutritional quality of the plant, you have to use the control unsprayed and you have to use a sprayed GM plant. That gives you the valid comparisons. We were asking whether you agree with that.

Dr Nutti

1076. Can you give an example that this difference had occurred?

European Communities

1077. No, not offhand. But I know it exists.

Chairman

1078. EC.

European Communities

1079. Chairman. We are not asking about whether in retrospect the effect occurred or not, but whether the effect is conceivable and is it therefore valid to ask the question. Perhaps this is the question to Dr Nutti. It is theoretically possible in our view that the herbicide changes the composition of the plant and the fact that you cannot compare it with the non-herbicide tolerant plant, because non-herbicide tolerant plant can never exist after the herbicide has been applied to it. My question to Dr Nutti: is it conceivable that the application of these herbicides to herbicide-tolerant plants would change their composition?

Dr Nutti

1080. The fact that Codex kept the word 'may', was exactly related to this discussion, because there were opinions on both sides. The word 'may' in the guideline is exactly to give space for discussion and to see if it can be done or not. I will not say that it will never be done. I think that it should be studied so to see whether it should be done or not. That is why, as I said this morning, in the guideline the word 'may' is used and not 'shall'.

European Communities

1081. Thank you.

Chairman

1082. Any follow-up on 93? Otherwise I will ask the EC to move onto 101. EC you have the floor.

Dr Nutti

1083. I still need to answer 70. EC-70.

European Communities

1084. I am afraid we are not through yet with the issue of herbicide treatment. This time the question is in the context of a hybrid. I personally, don't know whether that makes the discussion any different. I don't think so. Our question goes to Dr Andow to give Dr Nutti a break. You were saying Dr Andow, regarding the fact that you were referring that there is a legitimate scientific debate as to whether all three sets of data from non-treated, control and GM crops as well as herbicide-treated GM crops are necessary for a conclusion on safety. That's what we have been discussing for the last 20 minutes. Would you agree that the Codex guideline paragraph 44 supports the view in that scientific debate that calls for all three treatments?

Dr Andow

1085. First I would like to preface my remark by thanking Dr Nutti for clarifying the answer to my question. I don't know what Codex guideline paragraph 44 says. But as Dr Nutti explained, there is a debate that is embodied within the Codex guideline about the three treatments. I agree that there is a debate. Because of that there are several perspectives a scientist could take on this. Therefore depending on which perspective you take, you could justify different approaches towards what you need.

European Communities

1086. Thank you.

Chairman

1087. EC is finished with 101. The Panel has its last question on 101, and would like to ask Dr Squire our Question 33. You have the floor sir.

Dr Squire

1088. The Panel is quite correct in drawing attention to this temporal anomaly in my answer. Of course the Codex guideline which I take to be – CAC/GL45-2003 - did not have any relevance to the answer in 2001. What I was drawing attention to, and this seemed to me to be the case throughout a number of the requests, was that the kind of requests put by the EC were quite compatible with what turned out to be within the guidelines in 2003. Where the other countries appeared to claim that the requests were too rigorous or too stringent, two years later guidelines appeared that were very stringent indeed. I accept that there is a temporal anomaly in my response.

Chairman

1089. Thank you Dr Squire. I would like to call for. EC, another question on 101?

European Communities

1090. We would like to ask Dr Nutti to explain how these Codex guidelines came about, especially when the process started because, as Dr Squire points out, this is a debate that has been going on for over a few years. The Codex guidelines reflect the ultimate result of that debate. Perhaps Dr Nutti could briefly tell the story of these guidelines and when discussions started on the Codex.

Dr Nutti

1091. It was over four years. We discussed the guidelines in 2000, 2001 2002, and 2003. By 2003 everything was approved. I just don't remember if the first meeting was 1999 or 2000. The Commission asked us to start working on them in 1998.

European Communities

1092. I'd just like to point out that it was under discussion in the Codex at the time the request was made.

Chairman

1093. Other questions on 101? This does not seem to be the case. This brings us to the end of the questions in order. I will now return to the mental marks put on questions on dossier 74 by the US, 76 by the US and 87 by the EC. I will start with Dr Nutti who had a chance now to look at dossier 70 and give us an answer.

Dr Nutti

1094. I looked at the dossier and didn't change my answer. In my answer I had pointed out that there were studies on different types of animals including, rat, trout, quail and lamb. The EC emphasized that the abnormality was found in the rat studies. There were three rat studies. The first and the second ones raised some doubts. In the third rat feeding study they concluded that the body weight gained, food consumption, and liver and kidney weights were not different. I do not change my statement.

Chairman

1095. These were laboratory studies?

Dr Nutti

Yes.

Chairman

1096. US on this one? Or anybody else? So 70 is closed, 74 ...

European Communities

1097. Dr Nutti have you realized though that I gave you several attachments? The issue is chronologically in the first attachment, you only had a summary of these studies. Attachment two was the request for additional information from July 1998. The requests of the lead CA, the Netherlands in this case, attachment eight and thirteen are dated November 98 and August 99 respectively. The document which you looked at which gives the full analysis - which the lead CA hadn't seen then- is attachment 90 of our chronology and is only dated 5 of August 2003. The question is: based only on that first summary and given the flaws in the first two studies, wasn't the lead CA entitled to ask to have the full report to look into them?

Dr Nutti

1098. No, if it was only the summary it was OK. Because looking at the full report the information is here.

European Communities

1099. Thanks a lot. So your answer is positive.

Chairman

1100. United States.

United States

1101. This question is for Dr Nutti. We are returning to the issue of comparisons of compositional data from multiple locations. Is the purpose of conducting multiple trials in different locations to determine whether the range of nutrients found in the new product falls within the natural variation of those nutrients for the crop?

Dr Nutti

1102. Yes, absolutely. Because we need to look to see if there is a variation if this is due to the stress of the place that the product was being grown. We need to see if the variation falls within in the natural variation.

United States

1103. Would comparisons of compositional data from corn grown in three countries with a range of climatic conditions provide the kind of comparative stress data that you described?

Dr Nutti

1104. Yes, and I think I pointed this out in my answer when I answered it in writing.

United States

1105. Are you aware of any evidence in which Bt corn or any other corn has had a change in composition that could affect food or food safety based on the location of where it was grown?

Dr Nutti

1106. Not on food safety. I don't know publications. There might be a difference in the mineral composition of these things. So, maybe it could have to do with the quality.

Chairman

1107. Anybody else on 74? The EC.

European Communities

1108. Dr Nutti, my understanding is the requirement is for trials at a number of locations. Is it your understanding that the reason for this is to look at the stability of expression of the gene over a range of different environments and seasons?

Dr Nutti

1109. The expression of the genes has to be confirmed before you go for a food trial. You cannot go to a food trial with a product for which the expression of the gene is not confirmed. You go for two seasons, at least two seasons, to confirm your results. For instance in the group that I am conducting studies with we only go to the food trials after the fifth year. You first have to confirm the expression of the gene. The food trial is for the expression of the gene.

European Communities

1110. My question was on the uniformity and the consistency of the expression of the gene under a range of different environments and the different seasons. Surely this is the reason why we ask for data from a number of years and a number of locations, to ensure that stability of expression of the gene under those conditions.

Dr Nutti

1111. Usually when you design an experiment you look for different places and at least two seasons. You cannot have only one information

European Communities

1112. We also have a follow-up on 87.

Chairman

1113. That concludes the discussions on 74 I believe. The US wanted to raise a question on the next dossier which is 76.

United States

1114. This question is for Dr Andow and Dr Snow. Could you tell us whether you are aware of any evidence to suggest that hybrid corn can establish itself as a weed?

Dr Snow

1115. I haven't really studied hybrid corn or volunteer hybrid corn so I don't know. I think Dr Squire was mentioning in Southern Europe there is the potential for volunteer. I don't know if you would call it a weed. I doubt it.

Dr Andow

1116. As you know the definition of a weed is a plant that a person doesn't want to have and a lot of farmers believe that the volunteer corn plants are weeds. But I don't think that is really what you are trying to get at. You would like to know whether it can actually escape and become weedy and afterwards establish feral populations. I think that outside of Central America I haven't heard those kinds of reports related to weediness. My points were not necessarily aimed at weediness however.

Chairman

1117. Anybody else on 76? This is not the case. So, the final open dossier is 87, with the possibility for the EC to come back.

European Communities

1118. Chairman, I would like to come back to Dr Squire and Dr Nutti. Your question was whether the competent authority could have asked all these requests for additional information at the same time and Dr Squire and Dr Nutti replied yes. I would like to know from both of them what they base themselves on because my understanding is the following: The first request was made in December, 7 December I think. It is a lengthy document, seven pages, explaining what it is that was missing. Then there is an e- mail exchange between the applicant and the competent authority. The competent authority explained in more detail what the options for the applicant were related to providing that additional data. Then there is a second letter, in January, barely a month afterwards, in which the competent authority does nothing but confirm that they have put this request for additional information to the applicant. There is nothing new in that letter. It is repeating the essential points of the first letter. Then, there is the second request of October 1999 which is indeed a new request for additional information but which is based on the information that has been provided in the meantime. So, I would like to know why you say that the competent authority could have asked all of this in the first letter. Thank you.

Chairman

1119. Dr Squire?

Dr Nutti

1120. Do you know how many dossiers we read for you since October?

Dr Squire

1121. I'd like two hours to reread that dossier before I answer this question if that's possible. I'm prepared to do it this evening, but you better get up very early tomorrow to get my answer.

Dr Nutti

1122. My point is that you need at least two seasons. If the person that was looking at the document and saw that there was only one study this would be one of the first things to say. "There is only one we need at least two for comparison." We had to read all the dossiers in less than two months.

European Communities

1123. I realize that this was a lot of documents to read. I also realize that the point you just made is what you said in your reply. It is not what the question the Panel asked you about in its question of today which has a potential negative consequence for us, which is whether the competent authority could have asked all of this earlier. My point was to put on record that there is a reason as to why the sequence of letters was such. I note here that both experts actually cannot confirm that the requests for information could have been made in a different sequence. If this is subject to verification this might make perfect sense.

Chairman

1124. Before you answer Dr Nutti, I would like to clarify that the applicant provided the answers to the first one or two questions in July 1999 and the further request were handed back three months later. Would you like to respond Dr Nutti to the EC's question?

Dr Nutti

1125. I really don't know what you are asking.

Chairman

1126. I think the answer has been given

European Communities

1127. This is a comment more to the Panel than to you Dr Nutti. We are talking about a delay of three months until a request was made in October, instead of what looks like a large amount of time for a competent authority to send out letters one after the other asking whatever questions came to their minds. This is simply not the situation. I don't think Dr Nutti needs to follow up on that. It is clear by now that they have not looked at this particular question you have in mind.

Chairman

1128. We take note. I believe this takes us to the end of the questions on product-specific questions, issue one. On our agenda is still the possibility for all of the parties to come back with any questions referring to the subjects we discussed yesterday. That is both open general questions and both issues two and three. And the Panel, will on its own have two additional questions to the experts as well. Before we do so I suggest we take a break, especially for the mental health of our experts, and resume in fifteen minutes. That is ten past five. [Pause]

1129. We have forty-five minutes of the paid presence of our experts and the unpaid presence of the Panel. I would now suggest the parties start with their questions arising from the discussions yesterday or possibly such questions which could not be put forward because of the time allocation

which was very strict yesterday. I do repeat that we do not wish to hear comments, but scientific questions only. So this being said I'll turn to the complainants in any order. Canada.

Canada

1130. Thank you Mr Chairman, my first question is for all of the experts and it relates to an exhibit that Canada filed on Thursday in response to the Panel's instructions. It is exhibit CDA-195. I provided you a copy of the front page as well as a copy of page 64. I appreciate that there's a considerable amount of information that you've had to absorb over the last number of months. I would certainly appreciate the fact that you may not have had an opportunity between last Thursday and now to review the additional information that was submitted by Canada. I would like you to look at the graph on page 2. First, if I could ask if any of the experts are aware or have been involved in the safety of genetically engineered foods approaches to assessing unintended health effects by the Institute of Medicine and the National Research Council. And if they then would feel comfortable commenting on this. If you are not aware of this study and do not feel comfortable in answering this question I certainly understand.

1131. The graph here shows the relative likelihood of unintended genetic effects associated with various methods of plant genetic modification. According to the description, it says the grey tails indicate the committee's conclusions about the relative degree of the range of possible unintended changes. The dark bars indicate the relative degree of genetic disruption for each method. As you can see on the left hand y axis, there is a ranking of all of the various forms of genetic modification -if you will- and along the x axis, the horizontal axis there's a scale from less likely to more likely. This graph illustrates or attempts to estimate the varying degree of unintended effects associated with various forms of genetic modification. I am using that in a generic sense. My question to the experts is whether or not you think this represents a generally accurate view as to the likelihood of unintended consequences or unintended genetic changes of these various forms of genetic modification.

Dr Andow

1132. First, as you probably know, I'm a member of the NRC Committee on Agricultural Biotechnology Health and the Environment. That standing committee essentially developed the parameters of the study, so I am familiar with the fact of how the study was commissioned and what the overall scope of the project was supposed to be. I have to admit though, that I am not entirely familiar with all of the contents of the study. I would like to clarify first, what exactly the y axis is. You were using a number of different words, you settled on one. I noticed that it must be either in the text or someplace else exactly what they used and it does make a difference as to how to interpret this figure.

Canada

1133. You are referring to the x axis? If we look at it this way there is a horizontal axis and a vertical axis. It says "Figure 3.1 the relative likelihood of unintended genetic effects associated with various methods of plant genetic modification". The grey tails indicate the committee's conclusions about the relative degree of the range of potential unintended changes. The dark bars indicate the relative degree of genetic disruption for each method. I'll read the whole description. It is unlikely that all methods of genetic engineering, genetic modification or conventional breeding will have equal probability of resulting in unintended changes. Therefore it is the final product of a given modification rather than the modification method or process that is more likely to result in unintended adverse effect. My apologies for not providing a copy of the entire section.

Dr Andow

1134. Thank you. So the x axis then - if you hold the book sideways- is relative likelihood of unintended genetic effects. And for the benefit of the Panel the bars that are refer to transgenic plants would be the -if we hold the book like this- the second bar from the right, the third bar from the right and the fourth bar from the right and the fourth bar from the left. Those are the transgenic bars. The bar that Canada has been talking about quite a bit is the bar furthest to the right.

Chairman

1135. Is that clear to everybody? It is.

Dr Squire

1136. I'd like to request a point of clarification on this late, incomplete and confusing submission. I'd like to ask Canada to define what a genetic effect is in this context. Is it a change in the genome, a change in the phenotype or a change in the impact of that plant on other things? Is it a change in the impact of the plant on ecology? It is very difficult to interpret this, as I say, incomplete and late submission unless you know what the definition of the axis is. Otherwise I think we are wasting our time.

Canada

1137. The changes are translocations, breakages, delusions, cross-linkages, insertions any kind of unintended effect that arises from the process of plant breeding or genetic modification. There are series of unintended effects that are possible. This graph attempts to illustrate a lot of the technical evidence and comments that we have been hearing and to put it down in a synthesized form, putting biotechnology in the context of other plant breeding mechanisms.

Dr Andow

1138. So let me try to clarify once more then, that what we are talking about is changes to the genome. We are not talking about changes to the phenotype or any other thing like that. We are talking about changes to the genome. I'd also like to elaborate, that for those who may not be aware, the NRC process in putting together these reports is usually comprised of a panel of about ten to fifteen independent scientists. The vast majority of these scientists are from the United States although a few Canadians serve on these panels. I don't know about this one. And the product is considered to be a consensus product of all those scientists. The scientists are usually selected from a broad range of backgrounds, in order to get good representation of opinions and to make the conclusions as broad as possible. Saying that, I do not believe I am in a position to argue against this graph without considerable analysis of it.

Canada

1139. Would any of the other experts like to comment?

Dr Snow

1140. I did look at this when the book came out. The picture is a representation of a consensus viewpoint. If you hold it so the writing is right side up, most effects come from mutation breeding. This argues the point that Dr Healy made yesterday: that maybe that type of breeding should be

looked at more carefully for unintended health effects and maybe even environmental effects. The next four categories all involve common methods used in genetic engineering. I don't really see it as a strong argument for why this is so safe -if that is what you are trying to say.

Canada

1141. No. We are not trying to say that it is safe at all. I am just asking whether or not you think it is an accurate reflection of the range and likelihood of unintended effects or changes as a result of modern plant breeding techniques.

Dr Snow

1142. I'm not really qualified to evaluate the accuracy of it.

Dr Andow

1143. For the benefit of the Panel though, the clarification that it's about changes to the genome is quite important, because in many plants there is a lot of DNA that is not functional. A lot of these changes would occur in non-functional parts. That compresses everything down proportionally. I'm still not willing to dispute the shape of the graph but it is important to realize the translation from unintended genetic changes to adverse effects is quite substantial.

Dr Nutti

1144. I would not comment on the graph. Yesterday I made the point that I would like to have the food safety evaluation for products of mutagenesis done in this same step by step way that we do for genetically modified.

Dr Healy

1145. I also noticed with interest when this came out and when it was circulated around again earlier this week. I've not looked at the literature in a systematic way that would allow me to comment on the accuracy. I certainly would concur with the earlier comments though, that there is lots of DNA in plants and other organisms that does not translate into functional products. Nonetheless this is a fairly interesting shape of the curve.

Chairman

1146. I suggest we take turns, starting with the United States, taking questions from each party in turn until we more or less finished with it. United States.

United States

1147. I don't have a follow-up question. I'd just like to reserve a couple of minutes at the end for each of the delegations to have a chance to thank the experts

Chairman

1148. Well thanks by all means. For comments, we have time on Monday. Argentina, questions for the experts.

Argentina

1149. We don't have follow-up questions Mr Chairman.

Chairman

1150. The EC? One question.

European Communities

1151. Chairman we are inclined to sympathize with Dr Squire that we risk wasting our time by asking lots of further questions. We could ask lots of questions. We could also read out to you the recommendation number four from the paper which is in front of you but we are not going to. We can do that later on and so we don't have any questions.

Canada

1152. Canada has no further questions.

Chairman

1153. The Panel will ask one question then. We have a follow-up question to our first questions from yesterday and it goes to Dr Snow and Dr Squire. With respect to the biogeochemical cycle, would any impact that the release of GM plants might have on this cycle be of concern because it affects the health of micro flora and or micro fauna in the soil, or because it effects the health of plants in the soil or above the ground? Is this impact one directional, in the sense that it would lead to a deterioration in the ecosystem, or would it simply result in a change in the ecosystem which might be beneficial in some respects and harmful in others?

Dr Snow

1154. Just to remind you about biogeochemical cycles -that's referring to decomposition of plants and other organisms that release nutrients and organic matter back into the soil. If the GM plant affected that it could have an effect on the micro flora micro fauna in the soil and that could affect the health of plants, or soil fertility and the soil health. The question is, could any of these products that we are considering be of concern and require more studies. None of us are specialists in this area but I know that a lot of questions have been raised and studied. I can't think of any that would be irreversible or of larger magnitude than the normal variation within agriculture. There could be many changes, they could be beneficial or negative as you pointed out. They could be neutral. People have detected the effects of DNA on soil micro organisms, but they have not detected major differences in function with the possible exception of slightly slower decomposition rates from Bt corn.

Dr Andow

1155. I'd like to clarify that there is not one biogeochemical cycle. They are called biogeochemical cycles because they typically are oriented around a particular chemical element. For any element that you can see on the periodic table almost all of them go through biotic systems. We consider the way that they move through the biosphere to be the biogeochemical cycle. Of course sometimes we consider water as a separate element even though it is not technically an element. These elements go through all different kinds of ecosystems. The carbon cycle is one that has been quite receiving a lot of attention because of its connection to global climate change for example. Decomposition of course

is part of the global carbon cycle. That is one of the reasons why some people have had concerns, not necessarily only about GM plants, but in terms of decomposition in agriculture more generally. (I did not see in the materials a direct link between the evaluation of GM plants regarding this issue. From the point of view of the ecologist that would be something to be thinking about.) Whether or not there is an important effect is another question. It is more than just the health of the micro flora and micro fauna and more than just the health of the plants and the soil itself.

1156. I would simply agree with Dr Snow that the effects on the biogeochemical cycles may either be positive or negative. If the decomposition rate is reduced, then that means more carbon is retained in the soil and less carbon is released in the atmosphere. The soil can become a sink for global carbon. In that sense the decomposition rates, if they are slowed down in GM crops could actually be a benefit to the eco-system. Of course if they are faster, it could possibly be a benefit. But it could also possibly have a negative effect on the environment. Of course the understanding of the soil micro flora and micro fauna in relation to soil health is much more complicated than I can go into here. I probably couldn't give you quite so simple an example without getting into many more technical details about the ecology of the soil.

Chairman

1157. Thank you. Dr Squire

Dr Squire

1158. To build on those two responses briefly, I agree it could go both ways with this. Agriculture affects or has affected the biogeochemical cycle, the carbon or the nitrogen cycle. It can affect it very easily by exposing soil to very high temperature through sunlight in the tropics or very heavy rain. You can erode the amount of carbon held in dead matter and in some GM bacteria very rapidly. You can get rid of it. You can prevent the cycle from occurring. This is most in evidence in areas where the encroachment of deserts takes place. Fortunately in much of Europe that is not happening yet. Let's use the carbon cycle as an example. There are large amounts of carbon in European soils generally, and this is added to every year and taken from every year in different ways. The shifts in carbon going into different parts of that cycle are of the order of about 1 per cent a year. You can bring about fairly small shifts in the timing of events in the carbon cycle and the amounts of things going into it. But they are very small. Because of the mass of carbon in there, it is difficult in Europe to shift it quickly. Repeated effects can accumulate but it will take time in a system like Europe, with generally not too hot temperatures and not too intense rainfall. But it can happen. I think that GM can take it either way depending on the nature of the GM. It will be a slow process in this part of the world. Ten years would probably give you a 1 per cent or less change in some of the main elements of that cycle within arable systems as an order of magnitude approximation.

Chairman

1159. Thank you. Dr Andow.

Dr Andow

1160. If the chair would allow me to tell an ecology story to illustrate the point. There has been concerns about earthworms and how earthworms are affected by GM plants for example. You asked would a change in earthworms in some ecosystems create benefits in some places and adverse effects in other places? Let's suppose the earthworms are killed by a GM plant. We can say that in the Northern deciduous forests of North America there are no earthworms. Because there are no

earthworms the understory soil is very soft and many of the herbaceous plants that live in the forest are growing in that soft duff layer. About halfway up Minnesota we have had an earthworm invasion. The earthworms come in and eat up all the duff. Then the duff shrinks down and most of the herbaceous layer is killed. We believe that the entire process of regeneration of those forests will be changed from now into the future because of the earthworms. So in this case it probably wouldn't be a bad thing if the earthworms were killed. However in many agricultural ecosystems the agricultural soils are so hard that the earthworms loosen up the soil. Unlike in a forest where you have a huge duff layer and very soft soils, in the agricultural soils you have very little or no duff and very hard soils. The earthworms are beneficial in that situation because they loosen that soil.

Chairman

1161. Thank you I think that is a sufficient answer to our question number 1. I will turn to Canada for our next question to the experts.

Canada

1162. Thank you Mr Chairman. This is a question for the food experts or the food safety experts. In your opinion or to your knowledge, in cases where no new risks have been identified during a pre-market food safety assessment how would post-market monitoring of human health effects be designed and conducted? Thank you.

Chairman

1163. Is this a scientific question Canada?

Canada

1164. I believe so Mr Chairman.

Chairman

1165. Would someone care to respond?

Dr Nutti

1166. From the food safety perspective, given that I didn't comment on any question about post-monitoring that was here. Even in the Codex consultations we thought this might happen in the future but nobody knew how to do it. In the Codex discussion there was an acknowledgement that it could happen but we never discussed how. So, I don't feel competent to say how to do the post-marketing as far as food safety is concerned. Furthermore, I understood that the questions were dealing with environmental issues and I did not cover these issues.

Chairman

1167. Thank you. Dr Andow

Dr Andow

1168. Although I am not a food scientist, I would like to respond from a more general perspective about monitoring for unintended effects. Because you don't have an end point, you can't be

monitoring for anything specifically. Instead it seems that the monitoring system has to be set up so that you can trace back information should something be detected later. For the environmental side, what has been recommended in one of the NRC reports is that you want to monitor how much of the crop is planted in different parts of the country so that then if an environmental effect is found, you can use epidemiological tools to try to associate the environmental effect with the previous distribution of the crop plant. I think a similar sort of approach could be used in any other kind of setting, where instead of thinking about an endpoint that you are monitoring you are trying to monitor in order to allow you to extract information from the monitoring system later.

Chairman

1169. Canada any more questions?

Canada

1170. No thanks that's all.

Chairman

1171. There is one more question from the Panel. It goes as a follow-up question to our question 14 of yesterday to Dr Nutti. If I understood your reply of yesterday correctly, you are essentially saying that it made sense for Codex and the EC SCF to distinguish between toxins and allergens. Because a toxin can be a protein a fat or a carbohydrate whereas an allergen could only be a protein. If that is so, does this mean that instead of referring to toxins on one hand and allergens on the other hand, Codex and the EC SCF could also have referred to allergens and other toxins. What I mean, is, scientifically speaking, are allergens a sub-category of toxins or are they in a completely separate category?

Dr Nutti

1172. I think that, in this case they are a sub-category because they are proteins. The allergens are always protein. But we still need to go with a complete evaluation of the allergens.

Chairman

1173. Any differing opinions from any of the other experts? This is not the case. Any follow-up questions. Dr Andow.

Dr Andow

1174. So then are you saying that a toxin is defined purely on its protein, fat or carbohydrate?

Dr Nutti

1175. No. Yesterday I said more. I talked about the new metabolites. The new substances can be conversion of components of the plant such as proteins, fats, carbohydrates, vitamins which are novel in the context of the recombinant DNA plant. New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the new introduced DNA. The Chair is wondering if allergens are toxins. Allergens are always proteins, so why should they be listed separately if in a general view you can put these proteins inside the big group of toxins?

Dr Andow

1176. I didn't mean to restrict it. Can we define allergens on the basis of their chemical class essentially or do we define them on other bases?

Dr Nutti

1177. As far as my knowledge goes, most of the allergens are proteins in the cases that we are looking at in this year.

Chairman

1178. Thank you Dr Nutti and Dr Andow, you appreciate that our questions are loaded. I'm sure the parties know what we are referring to. United States, you have the floor.

United States

1179. Thank you Chair for giving just this brief moment. We know that the experts have a terrifically hard job and we really thank you. We hope that you have enjoyed the time here with our coffee bars and numbered paragraphs and we've always enjoyed listening to you . You were always very clear and kept it interesting. We enjoyed being in your world for a couple of days.

Chairman

1180. Canada you have the floor.

Canada

1181. Canada wants to reiterate the US statement. I already thanked the experts for all their hard work and effort when we began this session. After these two days I would also like to express Canada's deep appreciation for their patience. So thank you very much.

Chairman

1182. Thank you. Argentina

Argentina

1183. Thank you Mr Chairman. I would like to thank the experts, particularly for their patience and the attention they gave to the questions that were put forward in the name of Argentina.

Chairman

1184. European Communities

European Communities

1185. Chairman if you would allow us we would just come back to the issue of allergens and make one clarification. Is that agreeable? Sorry it took us a time to figure it out. In the meantime everyone has already thanked the experts...

Chairman

1186. EC your very last chance on allergens.

European Communities

1187. We want to make sure Dr Nutti that you are referring to the issue of allergenicity in the context of food safety, because my understanding is that there can be broader allergenicity issues. In other words that you can have allergic reactions to compounds that are not proteins, such as nickel and certain metals for example.

Dr Nutti

1188. I was referring to GMOs. If you go to the Codex, when you go to the annex "Assessment of possible allergenicity", you see all newly expressed proteins produced by GMOs. As far as GMOs are concerned when you go to look for allergens you are looking for the proteins. This was my answer. I was not thinking of nickel or zinc or these other things. I think the question was in the context of this.

European Communities

1189. Thank you Dr Nutti

Chairman

1190. The EC has the floor again.

European Communities

1191. Chairman, we wanted to thank the experts, because we do appreciate they have done a monumental task and they have, at least for us, elucidated the facts. We would like to thank them very much for the seriousness with which they have approached their work. Thank you.

Chairman

1192. Now we have reached the end of our deliberations. I will give the floor first to the experts for their concluding remarks and then it will be the privilege of the Chair to conclude the meeting. I will start in the alphabetical order. Dr Andow

Dr Andow

1193. I would like to thank the Panel for providing me this opportunity to address you on these issues. I'd like to thank the various delegations for their interesting questions. I would like to say that I found the Canadian questions particularly interesting and many of them were quite useful in terms of clarifying important points that were left ambiguous in my answers.

1194. I would just like to say a few words to the Panel though. Perhaps at risk of oversimplification I wanted to contrast the environment versus the food/feed issue. In general, the issues related to products derived from mutagenesis are not entirely clear. With the food/feed side there is generally a presumption that the presently consumed food is safe. The debates that we are hearing are more about how to do the comparison between the GM and currently considered safe food and while at the same time balancing the efficiency of the evaluation with the sensitivity. Whereas with the environment,

the presumption that the current production systems are safe to the environment is no longer granted. Indeed the current varieties produced by conventional methods are no longer all presumed to be safe. This is a point that was taken up in NRC 2002 Report, in particular. There has been an evolution of concerns associated with agricultural production, that stems over a period of about fifty years. To some extent GM crops are swept up in this broader movement of the evolution of concerns of new agricultural technologies that has been changing over a longer time period. Furthermore, because of their prominence they are getting a lot of attention on this point.

1195. What that means, then, is that a lot of the comparisons are *ceteris paribus* type comparisons (all other things being equal). The problem is with environmental issues often all other things are not equal and it is all these qualifications that then become important. Dr Squire says there is not a good comparator. One of the reasons is that environmental issues are not as cut and dried because all things aren't equal. It takes time to figure out what is a proper comparison. In addition, because of this change in approach to agricultural technologies that GM crops are swept up in, there is also a change in what is considered a good comparison. This is part of the issue that we are dealing with here, which makes it more complicated than the food/feed issue. I think you have realized that many of the responses to the food/feed issues could refer to the Codex guidelines and proceed from there. And those Codex guidelines are a way of comparing the GM crop with other foods. No parallel guidelines exist for environmental concerns.

1196. I'd like to turn to both the safeguard measures and product-specific issues. Since much of the discussion was on GMHT - genetically modified herbicide tolerant plants - I'd like to say that the scientific issue associated with these are made complicated by the regulatory issues. In particular, one of the issue that gets caught up in this is the resistance in the weeds, because technically and narrowly speaking the weeds become resistant because they've been exposed to the herbicide, not because they have been exposed to the GMHT plant. Some regulations make that distinction. However, it is also clear that the reason you use the GMHT plant is so that you can use the herbicide. It seems from a scientific perspective that the issues like the resistance in weeds are a scientific issue to be considered with respect to GMHT plants.

1197. There is also a question as to whether or not such risks or weeds are hypothetical. My answer to this is based on a view of how, biologists associated with pest control, have viewed the resistance problem over about the last 50 years. What we have seen is that resistance problems have emerged first in many species of insects. Then they emerged in many species of fungi and then they emerged in weeds resistant to the herbicides. Part of the reason is that the take off of the use of herbicides occurred later. There has been a delay in terms of when these issues have arisen within the three different pest control areas and what's happened on the insect side is that for each new insecticide product that came out, the entomologists thought that insects couldn't evolve resistance to "this one" (the new insecticide). By the 1980's the entomologists gave up on that argument, because every time they said it they were proved wrong. There has been a major change in entomology dating from some time in the 1980's. There is a similar change going on in the weed science community at this time with respect to concerns about resistance. One of the factors that seems to be driving it is the concern over glyphosate. Because, as I said earlier, glyphosate is one of the compounds that has lower environmental effects compared to many other herbicides, so there is a concern about losing it. At one point in the past one could have said that these are hypothetical concerns. But now no longer. There is a lag in the way that these disciplines have developed so that some disciplines recognize this more generally than other disciplines.

1198. Finally, I took note that all of the parties looked very carefully at my comments, and I must congratulate them. I'm glad that they discovered so many ambiguities in what I said. I'd also like to acknowledge that many of the points in those comments were not addressed here. I would like to tell

the Panel that I did look at them. Generally I don't agree with the re-interpretations. If there is a need to, I would be pleased to have the opportunity to clarify any of those issues that may come up in the future. Thank you

Dr Healy

1199. I talked a little bit in my opening comments about the approach I had taken to think about and answer the questions on the molecular characterization and the role of the molecular characterization in the safety assessment. There are several points that I would like to reiterate and a couple to add on the basis of the discussion that has happened over the last couple of days. The first is to perhaps re-emphasize the importance of a case-by-case approach involving the careful consideration of the available scientific information as well as the impact of any data or any information that is missing. In thinking about the scientific information, I gave consideration to both the quantity, as well as the quality, of that information and in particular to think about whether the available information gave any indicators of safety concerns and whether the missing information was likely to find an indicator of safety concerns. I was conscious to put it in the context of the other available information because I am of the view that there is not one scientific technique that will give you the definitive answer about the safety of the food. Generally we are talking about whole foods and we need to look at the properties of the foods from a number of perspectives. Looking at a whole food, is a very different situation from looking at a single chemical, such as a contaminant.

1200. I also wanted to pick up on the discussion on the scientific completeness of some of the dossiers compared to the information that might be necessary for a safety assessment. In reviewing the molecular characterization information in the dossier, I tried to make this distinction. From the perspective of a scientist this is not always easy because more data is always better from the scientific point of view. But, from that perspective of scientific completeness of the information it is certainly clear that not all the information that scientifically you'd want to see in the dossier was actually present. In fact in some places I was surprised that some information was either not supplied or not requested. That tended to be at the simpler end of the molecular biological tools that were available. But the questions that I was asked by the Panel to address related to the safety assessment. I tried to think about the relevance of the available, and of the missing, information in terms of the safety assessment. The information is only useful if it is going to help you with the safety assessment.

1201. One of the other points that's been discussed over the last couple of days is the extent of the change in the molecular biological technology over the past decade or so. The molecular biological tools that are available today are very different than those that were available ten to fifteen years ago. I guess this applies particularly to the ability to obtain information like the sequence information, the information about whether the genes are transcribed into messenger RNA, to analyse flanking sequences and so forth. Many of these techniques today are quite standard. However, again in the context of understanding the impact on safety, it is very important that one is able to relate the molecular information back to an impact on human health. When you are looking for differences between GM and non GM lines you really taking the first step, because differences are not necessarily bad. They may be neutral, even beneficial and they may have adverse consequences. The molecular information is only going to be useful for a safety assessment if you can, in some way, link that information back to biological impact and then ultimately a health impact.

1202. I want to reiterate the weight of evidence approach. I had been thinking about an analogy that I might be able to use to express this very simply. There is a saying in the English language, which I hope will translate appropriately: "If it looks like a duck, walks like a duck and quacks like a duck, it probably is a duck". It may be a goose it may be a pigeon, it is possible that it is something else. You can gather all sorts of other information to strengthen the probability that you are right in your

conclusion, but in the end it is probably still a duck. That statement summarizes this weight of evidence concept.

1203. The final point I want to make relates to the detection methods. The rapid changes in the molecular biological tools have also had a tremendous impact on the types of detection methods that are available today. We have very sophisticated DNA-based detection methods that were simply not available in say the mid-1990's. The rate of development of these techniques really accelerated in the late 1990's kind of around 1998 and 1999 and into the early 2000's. The tremendous advantage that these powerful techniques bring is the increased specificity, but it is also very important to recognize that such techniques are not useful in all situations, particularly in relation to complex foods or highly processed foods. We need to keep in mind the use to which the techniques are going to be put.

1204. I'd like to thank the Panel for asking me to be part of this process. I'd like to thank the Panel and the countries for a stimulating and thought provoking discussion over the last couple of days.

Chairman

1205. Thank you. Before I ask Dr Nutti, I must inform you that the interpreters are going to leave within a few minutes. They have accepted to do some overtime for us. So I would like to express my thanks to them. I'm sure you will agree that the vocabulary in this case had been extremely difficult - and sometimes even confusing- for normal WTO proceeding. My very special thanks on behalf of all of us and I am sure also on behalf of the Argentinean delegation for your services. Dr Nutti would you like to take the floor.

Dr Nutti

1206. First I would like to thank the Panel for the opportunity of being an expert in this Panel. I think it was a unique opportunity. Of course from the beginning when I knew that I would comment on the food safety issues, I knew that there was a lot of work to be done and that in for most cases I would have to go into the food safety. On the other hand, I was lucky because we have the Codex guidelines, the FAO/WHO consultations and also the OECD consensus documents. In this respect the analysis of food safety is a bit more organized than that for the environmental issues. That helped me a lot in my work. I would like to thank the parties for the questions. I particularly hope that these two days have given the parties the opportunity to consider how seriously I had taken my task as an expert to the Panel. I would also like to thank the other experts for being so supportive in all this time. Thank you very much.

Dr Snow

1207. I would like to echo all of my colleagues comments about how much we have learned from this process and how satisfying it is to be part of it. Coming from the United States and being more familiar with that system and learning about what is happening in Europe, it is almost like learning about another planet. I have tried in my answers to take the perspective of the EC in terms of what their goals are for the environment and what their values are in terms of preserving bio-diversity. These are not necessarily my views, but I was trying to get into the mindset of what their concerns are. I also was looking at the complexity of the regulations that were evolving as I examined these documents from 1998-2003, including the new directive and the demand for monitoring and labelling issues. That was very interesting and very challenging. I'm still unsure how to use the scientific information about gene flow in terms of coexistence issues and labelling. We've talked a little bit about how many surprises there have been in terms of genes getting out, moving around, and persisting, especially in oilseed rape. Even though I don't consider a transgene to be a contaminant in

any way some of the science could be relevant there. I'm really gratified that we have been through this whole process. I stand by my position in my answers, some of which have been clarified. I think on average people understood what I was saying and I appreciate having a voice in this. Thank you very much.

Dr Squire

1208. I've enjoyed the mental sparring. What struck me about the whole issue of having to think about these issues from the ecological view point, was how much has been learned through research over the past five or six years in particular: our knowledge - of detecting genes, of understanding their movement, of the pollination issue - has increased immeasurably in the last five or six years. This enables us to answer some of the questions that are being posed now. They were of course introduced several years ago. We couldn't have had this debate five or six years ago. It wouldn't have been possible to the level that we have now, not just in gene flow but in other areas as well. The same is not yet true about the ecological impacts and shifts that we have been discussing. Those of us in this area would appreciate something like a kind of Codex guidelines for soils and fields. They aren't there yet, but they are very urgently required. I hope international science funding will help generate those.

1209. We have been dealing with fairly small changes, compared to, for example, bioterrorism or nuclear winter or heat and cold or severe drought. The changes we are talking about are fairly small but they are small sequential changes which ultimately might have large effects, good or bad. They are not catastrophic changes in the ecosystem. There is one exception. This is where there is some regulatory threshold applied which prevents or allows a farmer to market a crop. In this case small changes can have a devastating effect on the farmer in question because he or she might have a crop that they intend to sell and they find that for no reason of their own that they can't sell it. The issue of co-existence is of a different order of magnitude than the ecological effects that we have been looking at as well

1210. While we had a difficult job, I've felt strongly that we have benefited from being here. I think all my colleagues here will agree that the three of you have a far harder job in the weeks and months to make decisions on these very complex issues. I am sure my colleagues wish you well in coming to those conclusions.

Chairman

1211. For your information the Panel does not intend to at this point in time to ask additional questions of the experts in writing. But in the light of the meetings next week we would reserve the right to do so. However, if we do so we would give you immediate advance notice so as to allow you to manage your time as best you can. There is a possibility that we may want to have your advice in writing one more time. But this is not yet decided.

1212. This brings me to the end of the meeting. I have first of all to place on record our thanks to the experts. I want to repeat my appreciation which I expressed yesterday morning. You have been working under three types of pressure, one of time, one from the amount and the quality of the material and one from the sensitive political character of this case. My appreciation since yesterday has increased even when I have been able to benefit from your contributions and performance, and this of course is very useful for us. Be sure that all the parties will make full use of your contributions, whether or not they did advocate recourse to experts and expert hearings and be also sure that the Panel will do its best to put all of this in the right perspective in our report to the Dispute Settlement Body. Incidentally, we have for the first time in WTO/GATT history a gender equality in

expert hearings. Ladies are even in a majority this afternoon. There is however a bias in language and this may not be without mere coincidence. I appreciate that Dr Nutti is, at least, trying to redress that balance in our favour.

1213. Next week's meeting will start as indicated on Monday, at 15.00 hours. It will be in Room E. The subjects we intend to raise have been given to you already, by a letter dated 7 February. I will repeat them here for your ease of reference. The Panel intends to give the parties an opportunity to offer comments on first of all the meeting with the experts

1214. This brings me to the end of my concluding remarks. Unless there are any other further questions from the floor I would like to adjourn this meeting. Thank you very much.