

## TRANSCRIPT OF RISK MANAGEMENT PANEL DISCUSSION

WEDNESDAY 20 AUGUST 2008, MORNING SESSION

**CHAIR:** Now I would like to alter what I said before and since it's almost twelve o'clock, we will proceed with the panel. It's a panel discussion on risk management. Excellencies, distinguished delegates, ladies and gentlemen, I would now open this morning's panel discussion. Once again, as you can see, we have on the podium a group of experts. Today's panel will help us get to grips with risk management. It is a pleasure that the panellists were able to make their time available to us and I would like to start off this morning by offering our panellists thanks from both myself and from all the BWC States Parties. In my efforts to prepare for this meeting, I look back at what BWC has done on biosafety and biosecurity. I also attended a number of relevant meetings and discussed these issues with various experts and organizations. Throughout my efforts, I heard time and again the importance of adopting risk management approach. What we are trying to do here is to find a way to minimize the risks posed by biology. It seems to be common sense that we should tailor our preparedness and response efforts to best fit the reality of those risks. Through my efforts to prepare for this meeting it became clear that risk management might well allow us to do this. I was intrigued to find out more about how risk management works in practice. The more I found out, the clearer it became that this would be a useful issue for us to cover in our meeting. Before I hand over the floor to our panellists, I would like you to think about what risks we are talking about today. The BWC deals with deliberately caused diseases, outbreaks and poisoning, but these are not the only types of incidents to involve biological agents; there are also accidental and natural outbreaks. It is unlikely that should any of these events occur we would immediately be able to tell them apart. As a result, our work here fits into a broader context, one of biological risk. These biological risks are connected by their common cause. I believe that just as the risks are connected, so should our response be. To some extent, this already happens. For example, the World Health Organization's response to biological risk, irrespective of whether they have a natural, accidental or deliberate origin. Part of what we are doing here this morning is looking for sets of tools, commonplace in other settings that can be adopted to meet our needs under the BWC. We should however bear in mind that the efforts pursued under the BWC also tie into other issues and especially this spectrum of biological risk. What we should aim to do is create a mutually benefiting environment where better coordinating leads to work one part of the spectrum, benefiting for all of it, where wheels are not reinvented and limited resources are used to their best ability. I'm sure we will be hearing more about the spectrum of biological risk throughout this panel. We are privileged to have with us today experts on variety of aspects on risk management. All of the organizations represented in this panel will all probably be familiar to you; some of the individuals might not.

It is a real pleasure to be able to introduce to you Dr. May Chu. Dr. Chu is a microbiologist with a specialty and laboratory systems. Her background includes diagnosis and detection of plague and tularaemia and anthrax incident response. At the WHO, Dr. Chu is the coordinator for Laboratory Core Capacity activities in compliance with the International Health Regulations.

Dr. Iain Gillespie, you know from yesterday, is the Head of the Organization for Economic Cooperation and Development's Biotechnology Division. He has worked in academia, UK and Middle East, in the biotechnology industry and for his government. Dr. Gillespie is well versed in the issues we are dealing with at this meeting. He has a PhD in Microbiology and a Master of Arts in International Relations and European Politics and an MBA.

Dr. Keith Hamilton. Dr. Hamilton worked as a veterinarian in the UK and overseas for several years before studying human infectious disease control at the London School of Hygiene and Tropical Medicine. Following this he joined the Veterinary Exotic Disease Team in the UK government department for Environment, Food and Rural Affairs. In July 2007, Keith joined the OIE Scientific and Technical Department where he coordinates the joint OIE/FAO network of expertise on avian influenza, the OFFLU, and the OIE laboratory twinning programme which aims to extend the OIE network of animal health laboratory expertise to areas where there is a need and that are currently under represented, with an emphasis on developing countries.

Dr. Paul Huntley is the principle consultant with the DNV, Det Norske Veritas, specializing in risk assessment associated with biological systems, and in particular, studies relating to laboratory biosafety, biosecurity, biorisk measures. Paul has provided consultancy advice on biorisk and conducted biorisk audit and assessment for a variety of organizations, including the World Health Organization, China CDC, Aquin Institute of Indonesia, Institute of Animal Health, UK, the Swedish National Institute for Infectious Disease, The Canadian Centre for Human and Animal Disease, and GSK Biological, Belgium. Microbiologist by training, Paul has specialized in management system approach for managing risk in scientific environments and was closely involved in the concept and development of the recently released laboratory biorisk management standard. Paul is currently project manager for biorisk within Det Norske Veritas, and although based in Singapore, works extensively through Asia and the rest of the world.

Dr. Brook Rogers. Dr. Rogers is a research fellow in the King's Centre for Risk Management, where her current work focuses on risk management communication. She is a professional psychologist by training. In addition to her academic success, Dr. Rogers consults on risk management issues for her government as well as for regional and international organizations.

Dr. Cathy Roth. Dr. Roth is the Coordinator of the Biorisk Reduction for Dangerous Pathogens Team in the Department of Epidemic and Pandemic Alert and Response, Health Security and Environment Cluster, at the World Health Organization, Geneva. She is a physician and a medical virologist by background, and came to WHO from the UK Central Virus Reference Laboratory, London, where she focused on imported infections and vaccine-preventable diseases. She leads a team responsible for readiness and response to severe emerging diseases, including Viral Haemorrhagic Fevers, SARS, Nipah, and Monkeypox, and the associated areas of infection control, biosafety, biosecurity, and preparedness for accidental and deliberately-caused outbreaks. Her

group coordinates WHO's work with many high-containment level reference laboratories working on emerging pathogens, and oversees the WHO programme on smallpox research. She has participated in, and led, field responses to outbreaks of emerging diseases, like, Ebola, Marburg, Monkeypox, SARS CoV, and avian Influenza.

I will now invite our panellists to make their opening remarks. Therefore, Dr. Gillespie, perhaps you will go first.

**Dr. GILLESPIE:** Happy to, Chairman. (I have some slides. I don't know if ... shall I move seats, is that the simplest thing? It should be BWC Gillespie 2. Don't worry. There's not a Gillespie 3. That's it). Thank you very much. Well, thank you very much Mr. Chairman and thank you for the opportunity to make some comments again. There are only three slides so don't be too concerned. What I want to do is just say a few words about risk assessment and risk management as a process, or indeed, a series of processes. You will recognize this slide from the comments that I made yesterday and I think the very key point to look at here is the first word of the title: framework. And, what we are focused on in the OECD, I think most of what we will hear from my fellow panellists today will be around developing frameworks for risk governance and most certainly not recipes. (Perhaps I can have the second slide, please). In terms of risk assessment and risk management, here's another schematic which tries to do two things: first of all, it tries to lay out some of the different elements of risk assessment and risk management. So at the top of the screen, "identification of risk hazards." Having identified that hazard, what is the likelihood of that hazard being manifested and what is the consequence of such a hazard being manifested? Thus, do a risk determination. How can you manage that risk and have you then reduced that risk by a management step? These are all very familiar elements of risk management and risk assessment that I'm sure most colleagues in the room will be at least as familiar with as I am. But I think the point of showing you this diagram here and that this is a process and is an ongoing process and much of what we see in thinking about risk management and risk assessment is focused on equality process, which continues throughout the work that has been carried out by individuals in entities. Now I have not mentioned risk communication yet. Now I have not mentioned risk communication because, in my view, risk communication is something that you have to do throughout the process. It's not just, well, we've done the risk assessment, we have management in place, now let's communicate the answer. No. It's part and parcel of the entirety of this process. Hence, I've put it in the middle of this diagram. (And could I have the last slide, please?). And, some introductory points in thinking about risk assessment and risk management. Risk management is about exactly that. It's about managing risk. It's about reducing risk. If you want zero risk, then there's a simple answer: don't do it. But if you are looking at reducing, managing risk, then there maybe some low level risk left over. Some people talk about effectively zero, some people apply the precautionary principle, but these are details that I'm sure my colleagues will pick up on. The second key point: be proportionate. In your response, in your management, be proportionate to the risk. Be proportionate to the consequences and the likelihoods. Don't over-engineer for the sake of engineering. Thirdly, build in the human factor. We're all people. We feel, we think, we have views, we make errors, we make innovations. So the human factor built into risk assessment and management can

be an asset. There's this communication element throughout. Fourthly, standards and best practices, not recipes. I'm sure others will pick up on this theme. What we look at generally in the field of risk assessment and management is developing standards that can be applied, best practices that can be used, but there are many ways to apply a standard harmonization, not rigidity. We've heard people talk over the past couple of days about harmonized approaches. Harmonized means bringing together, it does not mean that there is one approach that must be taken by all. Finally, the role of certification and accreditation. I wondered through the last debate this morning in particular whether there is some confusion about what certification is, what accreditation is, and what licensing is. Typically certification and accreditation are about demonstrating your ability to do something. They make you marketable, they can be seen as an asset. Certification means you have certain procedures in place, loosely, accreditation means and you've shown your competence to apply these procedures. They are not the same as licensing. A State based licensing system allows you to enter the field. Certification and accreditation prove that you have a certain ability to work within certain standards. Thank you very much, Chairman.

**CHAIR:** Thank you, Dr. Gillespie for the brief introduction. Next, perhaps Dr. Hamilton, will you make your remarks?

**Dr. HAMILTON:** Thank you, Mr. Chairman. On behalf on OIE, I am very honoured to have been invited to sit on this panel with my esteemed colleagues. As Dr. Brookner mentioned in the presentation on Monday, OIE is the world organization for animal health. We deal with animal pathogens. As my introduction, I'd just like to mention some relevant examples where OIE is involved in risk management and it should also help to illustrate some of the applications of risk assessments. As Dr. Brookner described in his presentation, many animal diseases are a threat both to human and animal health. So OIE works closely with FAO, the Food and Agricultural Organization, and the World Health Organization to share a common approach to risk management in biosafety and biosecurity. The OIE sets the standards on biosafety and biosecurity for veterinary microbiology laboratories and animal facilities. These standards are described in one of the OIE texts that's called the OIE manual of Diagnostic Tests and Vaccines, and it manual also describes other things. It describes procedures for carrying out diagnostic laboratory tests for all OIE listed diseases, through internationally agreed upon standards. And it also talks about how to safely manufacture effective animal vaccines. Now, OIE has a network of reference laboratories and these reference laboratories uphold these standards and help other national laboratories to meet these standards. And just to give you a feel for the type of guidance that we give on risk management in regards to biosafety and biosecurity, I'm briefly going to run you through some of the things that the diagnostic manual have mentioned on biosafety and biosecurity. In the chapter on biosafety and biosecurity, the guide describes how to assign animal pathogens to one of four groups, and these groups are based on their risk to human and animal health. Group one is the lowest risk and group four is the highest risk. And to put these pathogens into group 1 to 4, to decide with group they should go into involves a simple, qualitative risk assessment. The chapter then describes how to determine the appropriate containment level that will avoid risk to laboratory workers working with these pathogens or animals

and people outside the laboratory. Essentially the containment level guidance is ensuring that the pathogen remains safely where it should. Based on the groups 1 to 4, 1 being the lowest risk and 4 being the highest risk, the containment levels are categorized from biosafety level 2 to biosafety level 4, where 4 is the highest and that is reserved for the most dangerous infectious organisms. Examples would be Hendra virus or Nipah virus, the threat to human health as well. Now, I mentioned that simple risk assessments allow you to categorize these pathogens into these groups and then to decide what containment level they should be assigned to and the chapter provides guidance on risk assessment methodology and what factors need to be considered in the risk assessment to give a comprehensive answer. Of course, this is done in such a way to allow flexibility and it must account for the varying resources and levels of epidemiological expertise in the countries that will be carrying out these risk assessments. There are currently 172 members of the OIE, and more than 70% of these are developing countries, so the methodology should be appropriate so that all the countries from developed to developing are able to conduct a risk assessment and safely assign pathogens to these groups. Now, another very important role of the OIE is to set standards for the control of transboundary animal diseases, these are diseases that don't respect borders or barriers as such. And these are measures that countries use to reduce the risk of introduction of disease through importing animals or animal products, and they're also published in OIE publications, the Terrestrial Animal Health Code and the Terrestrial Aquatic Code, covering both aquatic and terrestrial animals. Now these standards support the World Trade Organization's Sanitary and Phytosanitary agreement that states that all health measures must be based on scientific principles and not maintained without scientific evidence. In certain circumstances a country may decide not to use the codes in the manuals, but to base import restrictions on a risk assessment. And OIE provides guidance on how to do this in two other publications, one that gives guidance on qualitative and one that gives guidance on quantitative risk assessments. Therefore, OIE uses risk assessments when developing standards to facilitate safe trade in animals and animal products and to set standards for safe laboratory diagnosis and handling of animal pathogens. It also provides guidance on the methodology for carrying out risk assessments to allow flexibility so all countries are able to conduct a risk assessment. Thank you.

**CHAIR:** Thank you, doctor. Dr. Huntley, would you like to say a few words of introduction?

**Dr. HUNTLEY:** Yes, by way of introduction I come to risk assessment from two different angles, really. I have to do risk assessments and help people conduct risk assessments, but also whenever we do audits and assessments we also review many risk assessments. So I have experience of trying to do them, which is not always terribly enjoyable, and I have the experience of reviewing other people's, which tends to be a little more enjoyable. And I just want to share with you some of my thoughts and experiences. These are not directed towards any particular organization but just some of the issues that we come across when we do these exercises in practice. (I'll have the next slide please). What is risk assessment? I think that if you look at any of the guidance documents, you'll find that it basically underpins every one of them, everything that is done is supposed to be done on the basis of risk. A number of different times when we

might do a risk assessment, it might be that you have to work with a new organism, it might be that you have a new facility, it may be that you are going to use some new equipment, change your operating practices, but there are also times when you would do risk assessments which may be higher level. So sometimes when people start a new project, they should do a risk assessment on the new project. Biological risk assessments are not just about the organism and how it's going to be used in the laboratory. Why do a risk assessment? Often it's a regulating requirement and the manner of the risk assessment is dictated by the regulator. Often they're done to assure stakeholders that things are being done properly. But the main reason in my view for doing a risk assessment is to really understand the hazards with the work you are going to do and understand the nature of the risk associated with those hazards and then to really implement adequate controls and would emphasize the word "implement" because the worst risk assessment in the world is one where you identify hazards and risks and then don't implement the controls in order to make sure that those are managed effectively. I'm happy to give people these slides if anybody would like them, so you don't need to note this down. Risk assessment is not a single activity. It's a wide range of different techniques and you can buy many, many books with many, many papers on different ways to do risk assessments. They range from very simple structured brainstorming, through task risk assessments, different techniques that we use that are based around scenarios, some are semi-quantitative, some are quantitative, but basically just to make the point, there is no such thing in my view as a risk assessment. There is a number of different techniques and approaches that are applied to a particular situation and you need to take care in order to apply the correct approach. But risk is very simple. Risk is the probability or the likelihood of an event multiplied by the consequence. So very often when people talk about risk, they talk about consequence without considering the likelihood and in this field it's quite difficult because often we lack data on what the likelihood is and to determine what the consequence might be can also be a challenge. But to look at risk without taking both of these factors into consideration means you are not looking at risk. Again, this diagram just indicates the process. The first thing that you must do is identify and analyze your hazards. If you do not identify your hazards, you will never manage the risk. So you look at what are the hazards, what are the things with potential to go wrong. You then do some kind of assessment using likelihood and consequence in order to arrive at the risk level and then you do your risk management, which often results in trying to reduce the perceived or actual risk from the activities that you are going to conduct. And then just a few words on likelihood and consequence, because again, if you don't understand your likelihood and consequence, you won't understand your risk. So we work with people to try to identify what are reasonable descriptions in this field for things like likelihood. So this is important particularly when there are a number of different people involved in the assessment, because you want to have consistency within the group. So if something is unlikely or rare, what we try to do is write that down in words people are familiar with, so that they can readily use it in the assessment. And then similarly with consequence, and the difference normally between likelihood and consequence is you can have multiple consequence categories. And very often when we do an assessment we don't just look at a single consequence. So we wouldn't only be looking at security. People are also interested in, "is there a risk to the performance of my facility? Could it affect my image? Could it affect general health and

safety? Could it effect the environment?" And often through discussing these multiple consequences you find that there are actually issues with some of the other areas, including security. But again, it's necessary to write these down and define them so everyone has a common reference point. And then similarly with likelihood, you have to say what is a significant risk in terms of security, performance, etc, so that when you have the discussion everybody can use a common frame of reference. And then finally you arrive at often a risk matrix where you have red risks, which are normally considered to be high or unacceptable, then you have medium risks where you would normally look to see if you could have controls in place to reduce, and then you have the broadly acceptable risks but these still needs to be monitored. So even although it's in the green it can migrate back up through the matrix to be something that is less acceptable, so you cannot forget about them. And different people, different groups, will have different ideas as to what is acceptable. So, one group may think there should only be one red box in the top right hand corner and other people will have a different perception and you need to agree that before the assessment. Some observations on how we see risk assessments being done. The traditional way to do biological risk assessment where it is really focusing on the organism and its properties, we see that often being largely part of hazard characterization. So you are not always getting to actual risk assessment through looking at the organism and how infectious it is and whether or not there's a vaccine. There's more to it than that. We would say probably that we do not see enough risk assessments. So very often people do not have the number or the structure there that we would expect, although they are the basis for the guidance documents. Often the systematic process orientated approach is missing. People have great difficulty getting information on likelihood and consequence which is something that maybe I think the Biological Safety Associations could help with. Confusion over approaches – often the risk from biological hazards is not adequately addressed. So people being concerned about slips and falls and electric shocks when the real problem for them are the biologicals, and the need to address the risk holistically, so the hazards could be the people, the procedures, or external factors. And then finally, what we feel are the needs: more information and guidance relevant to this sector, so not necessarily telling people how to do risk assessments because I think the principles are fairly simple, but when you do them what is the information that you actually need; consideration for what is acceptable, particularly where there are multiple stakeholders with different views on acceptability; better support and training for the people who actually have to do them; ownership for those conducting the work, I get very concerned when I hear a risk assessment is done by a third party, particularly if the third party is the regulator. It might in my view be done by the people who are going to conduct the work activity. And I think we would also like to see more rigor in implementing risk assessment and actually using it as a tool with real benefits.

**CHAIR:** Thank you, Dr. Huntley. It was quite an introduction. Next I will give the floor now to Dr. Rogers to make the introductory comments.

**Dr. ROGERS:** Thank you Chairman. And I'd just like to thank everyone for inviting me today. I'm going to try and tie together a few of the themes between risk analysis and risk management by addressing risk communication as a whole. Before I do that, I

thought I'd introduce myself and my institution and tell you a little bit about the applied research that is taking place. My name is Brooke Rogers, I'm a lecturer in risk and terror, at the King's Centre for Risk Management at King's college, London. We do take part in risk analysis and risk management, and to me that includes risk governance. And I seem to be responsible for quite a bit of the risk communication that ties these two areas together. As Dr. Gillespie identified, risk communication takes place throughout the process, so that's before, during and after risk analysis or risk assessment and risk management. We do quite a bit of work in a variety of areas, ranging from nuclear energy to food safety and risk governance. I've applied risk perception and risk communication. I am a psychologist, so I focus in on attitudes and beliefs and behaviour and I'm very interested in the public perception of risk and the public understanding of risk in the way in which we can shape behaviour through improved risk communication. At the moment I'm involved in a three year project which ends in February 2009, that's funded by the home office in the UK and we've looking at public psychological and behavioural reactions to CBRN terrorism. So that's chemical, biological, radiological and nuclear. We've been fortunate enough to have enough funding to run focus groups with members of the public and one of our focus groups focuses in on plague and the other one focuses in on a dirty bomb, of RDD. We're also working with emergency response organizations and as I'm listening to many of the presentations taking place this morning, it appears that a lot of the discussions around risk management and risk analysis are focused on the practitioner level, looking at ways of improving safety and improving practice at the practitioner and expert level. And we are interested in that, we do work with the emergency response units, but I'd like to broaden it out and actually talk about the group that is the reason that we're actually sitting in this room today talking about risk, and that's members of the public. At the end of the day we're trying to protect members of the public from biological weapons or ... I'm sorry, because I know it's a much broader issue than that, I'll try not to be too focused on terrorism, biological threats. And one of the key stumbling blocks to that is the fact that members of the public and experts actually have very, very, different understandings of risk. And when we start communicating about these risk issues, members of the public might hear our communication and receive our communication and behave in exactly the opposite way that they would have in the first place. So, why is effective communication important? We have a very, very, extensive literature around risk perception and risk communication and public behaviour and we know that the public's psychological and behavioural responses actually help determine the subsequent morbidity and mortality rates. There's a lot of work taking place in the USA, Canada and other countries, looking at the way in which local responses and public responses will impact the health system or the health response to CBRN terrorism. And what we're trying to do is take all of that literature and actually apply it in our own countries and see what the public response will be, because it's very different between countries that have different information needs. And we also have found that effective public communication can reduce morbidity and mortality by enhancing the likelihood that at risk populations will take precautions, so we can encourage appropriate protective actions. Most importantly, and this is going to be the majority of the population, we can reassure those who are not at risk and we can do that if we communicate about CBRN threats by reducing rumours and fears, facilitating relief efforts and overall, maintaining public trust and confidence in the agencies who are

responsible for ensuring the welfare of the public. And this is very, very, important because if we communicate with the public properly, then we can actually sit down and do our jobs and have a little bit more time to figure out what's going on. And overall I think that one of the most important messages that comes out is if we don't actually test our messages before an event takes place, and I'm quite a big supporter of what I call pre-event communication, then, on the day we're likely to get it wrong. The public won't understand what we're asking of them, we'll be overloaded and our systems won't be able to keep up. I think it's very important to differentiate between pre-event communication, which is communicating about very complex risks and in that I mean dread risk, so in that I mean no matter what we say about the risk, and this could be nuclear or radiation issues, no matter what type of information we provide, there's quite an emotional reaction and these types of risk take more communication attempts. So pre-event communication is very important. We need to communicate before an event takes place and create familiarity with the terminology, with our response procedures, but what I see a lot of governments focusing in on are what I would like to call pre-packaged communications, or pre-packaged crisis communications, so it's the Ikea approach; it's all built, it's all in the box, it's ready to be constructed when an event takes place. I would like to urge everyone to start thinking about pre-event communication. And I'll just finish this by saying that in terms of the public understanding of risk and the expert understanding of risk, when speaking about risk lay people and experts are often speaking different languages, solving different problems, disagree about what is feasible, and they see the facts differently. Thank you for your attention.

**CHAIR:** Thank you, Dr. Rogers. Dr. Roth, would you please make your introduction\_

**Dr. ROTH:** Good morning to everybody. I've been asked to provide a practical example of risk management in action. WHO on a daily basis does not deal with risk management for biosafety, biosecurity, but we do deal with risk in a process working around epidemic work and response. So since we do this everyday, and we're continually revising our approach, I thought I would use this as an example, as a model, from which we can extrapolate certain principles, many of which have already been described and maybe consider how this might be adapted to the biosafety and biosecurity context. So everyday in WHO we review epidemic intelligence which in comes in to us from a variety of sources, both from formal sources, such as a national IHR focal points, or from WHO country offices and regional offices, from ministries of health, from WHO collaborating centres. But we also receive a great deal of information from informal sources and in previous years probably most of the information we received was form formal sources. And these informal sources can include media, and we use a web crawler, the Global Public Health Information Network, which was developed in collaboration with Health Canada, to crawl the web for all mentions of anything, keywords that might indicate an important biological event or outbreak in the media and this information comes to us. But we also get information sent to us from NGOs, and even members of the public. So we have a large amount of information to look at everyday from this huge panoply of sources, and all of this information undergoes an initial screening and some triage. Again, here we bring in the initial risk assessment process; which of these bits of information requires a second look? Which might indicate a signal that there's something

going on that we need to do something about? From that triage, we select events; we again go back to our sources, to country offices, ministries of health, to verify the event. Is it real? Is it happening? And then we perform a risk assessment again, going back to our important counterparts in the countries. Is this event important? Does it require an international response, which can be anything from a team on the field on the ground to deal with something that might, for example, be an outbreak of Ebola? Or does it just require some information sharing, some guidance, perhaps some support for equipment, or methods or practices? At this stage we also have to consider information sharing with either the wider general public or again with our countries, our member states in a much more confidential way. (Next please). So I think one of the important elements in refining this process, was our thinking about how we improve our understanding of the quality of our information and how we can rely on this, how we can use it more effectively for our risk assessment process, how we can, in that sense, boost the strength of the signal and reduce the background noise and improve the positive predictive value of the incoming information, that is to say, our confidence that this information is going to be reliable, useful and valid. Now we need to consider all these sorts of information because (now just moving quickly to this) some bits of information may not be necessarily, terribly reliable, but they may be an early signal. So very, very, important to pursue, to verify, to see if the event is real, is it important, and then to consider how we should react. Others are more variable and some may have a very, very, high value for indicating that an event is real and must be reacted to immediately, such as information from the IHR national focal points for example, or other national responsible authorities. But this information may come in late, so one cannot sit back and wait. You do not want an outbreak to already become established, widespread for five continents before you start to react. So you have to use all this information but you have to weight it and balance it in your risk assessments and we do this as well on a daily basis with all of our partners, both formal and informal. (I'll just stay on this for one moment). And the kind of questions that drive our decision to share information, and to act, and to inform others, includes the same type of questions that one would be asking in the sphere of laboratory biosafety and biosecurity if applied slightly differently. What is it, where is it, has it already spread, can it be contained in this context, if so, what is required? If you transpose this kind of thought process to the laboratory, you'll have to ask yourself another set of questions, such as, is this a result of a random error or a systematic error, and what kind of remedial actions must be taken, both immediately and for the longer term to reduce not only immediate consequences but the risk that this same kind of error may happen tomorrow or next year. Does the affected state have the capacity to control the event and does it require assistance? Do other states need to know? And for WHO, are international control measures likely to be needed? So our alert and response operations group, cognate group to the group the would be operating in terms of laboratory biosafety and biosecurity, would draw together all current and contextual information, as well as expertise from multiple groups for these discussions and sources to make a coherent but also a composite analysis. This is the real world, it's extremely complex and our actions have to be proportionate and also, hopefully, effective. So just to put this in the context that we are working in a broader concept of risk management and risk reduction, which starts with and you can forget the word disease, because I think this is a more general concept, a process of risk identification and characterization, risk

reduction, specifically for an event leading to improved disease or risk specific preparedness and readiness, event detection, event investigation and risk assessment, event response where needed, either operational or under the international health regulations and my colleague May Chu is going to talk a bit more about the framework and criteria we use for decision making as soon as I've finished here. Evaluation and audit of response and audit to improve our process to manage future risk. And the biologists and sound engineers in the audience will recognize that this is a typical example of a feedback loop, with feedback coming in at various points in the cycle, all of them altering what is effectively an iterative process for risk management. And I'll hand over now to Dr. Chu.

**CHAIR:** Thank you, Dr. Roth for your introduction. Dr. Chu will you please make your opening remarks.

**Dr. CHU:** Well I am in the presence of some very impressive panellists. We have already spoken towards the process and I think you've heard many of the context and also some examples. I just wish to be short and to finish up for you in that we really do believe that you have to frame the context of the situation when you decide to start the risk assessment process and then you have to decide the criteria according to the situation of the risk that you want to handle. And following that, you have to develop a regime of how to manage it, and while managing that, you have to decide – I think Ian mentioned – about the consequence management, it's very important. And throughout this process I would endorse that he and others have spoken about risk communication to let people know what you're doing to be transparent. And quickly, an example that I will just allude to that Cathy kindly introduced is the criteria, how do you set it for the context, and I think that Keith also mentioned about the risk groups at they use at OIE. In the international health regulations, and I think upstairs there's some posters and there's some of these handouts, I'll just quickly go over it. It's a decision instrument in which you may decide what a public health emergency of international concern might be. And this dealing with an event that is of a concern. You have to ask the questions, for instance, for us, is the public health impact of the disease serious? And there's a series of questions you would go through that each of them will give you a particular consequence that you have to be ready to manage. Then following that, you ask the question, is the event unusual or unexpected? Because that brings in some of the possibility of an event for if you not have monitored carefully, then you would say that this is unusual, you may suspect that this could be an intentional, malicious use. Then the third criteria we would use is, is there significant risk of international spread? International health regulations is a code of conduct among nations to make sure that you are able to transfer and communicate this information as rapidly as possible. The last question you will ask that we felt was important was that, is there a significant risk of international restrictions? That is, if such an event happened, does it impact trade? Does it impact the communications between countries? Therefore, you must act quickly. And each of these have a category of different sub questions there. So I use this as an illustration to say you have to decide the framework and the context of the risk, you have to decide the criteria in which you are going to ask the questions and how you are going to manage this risk and the consequence of it, and you're going to have to, at the end of it, take a look at how

you're going to end up managing and go through the cycle of revising and looking at how your response was so that you're better prepared. I think I will just leave this now and then others can ask their questions.

**CHAIR:** Thank you, Dr. Chu. Now that we know more about our panel members, it is time to make things a little bit more interactive. Dr. Roth and Dr. Chu, the question is for both of you. Perhaps you can tell us about some practical application of the risk management approach.

**Dr. CHU:** I think we just mentioned one, which is for me. I was presenting the International Health Regulations, which is a framework adopted by 194 countries in the decision how to decide what constitutes a public health emergency of international concern. The risk assessment there is very much very process based but its clearly not a black and white system. It's clearly contextual, according to the various different criteria and the answers you get. So that we have to remain flexible, we have to use it. So, for instance, if something happens in a country, that could be a report of a smallpox case, and likely what we have done is you go through the criteria of the evaluation. It's very clear sometimes these reports come from a report that is picked up in a foreign journal and different language, and then when you get down to translating it, that is very clear that chickenpox and smallpox are all translated as smallpox in some languages. So then the risk assessment is at that point you decide that you can manage this, you can communicate to others that this is of no risk, that it is a common disease, and you can go back to your normal level of operations.

**CHAIR:** Thank you. Dr. Roth, anything to add?

**Dr. ROTH:** I think Dr. Chu has covered the main points and I think the example I gave earlier was also a practical example. But just to emphasize the importance of the context in your risk assessment and certainly in your management of the event. And context is very, very important, particularly for some of the higher consequence pathogens with which we are concerned. And so for an example, an outbreak of Crimean-Congo haemorrhagic fever in an endemic zone in South Africa where it occurs every year calls for the imposition, a medium position, of certain very well practiced and known measures but it is not a cause of international concern. There is no larger event to manage in that sense. An outbreak of Crimean-Congo haemorrhagic fever in the middle of Chicago would lead to a very, very different assessment of risk and response. So I think it's always very, very important to take into your assessment and your management the context.

**CHAIR:** Thank you. Anybody else wants to comment? Then, Dr. Hamilton, what are the comparative strengths and weaknesses of quantitative and qualitative approaches?

**Dr. HAMILTON:** Okay, thank you Mr. Chairman. I'll be fairly general and vague in this answer. I just wanted to start by saying that both quantitative and qualitative approaches are valid approaches and acceptable approaches as well. When it comes to the areas OIE is involved in, both approaches, for measures for animals and animal

products, both are accepted by the World Trade Organization as acceptable measures. What is important is that the risk assessment methodology should be flexible and applicable to real life situations. And as I mentioned earlier, it's very important the methodology should account for varying level of expertise and access to resources so that all countries are able to sort of use the same methodology to conduct a risk assessment, even if they don't have access to complicated computer software or high level epidemiologists. The risk assessment should also take into account a wide range of valid and relevant information and expert opinion. Now, it's very important that they take into account valid information. The risk assessment is only going to be as good as the information that informs that risk assessment. And also, it must take a range of opinions, so you've got a range of ideas that are fed into the sort of black box. The risk assessment must be fully transparent so that the reader of the risk assessment is fully aware of how the answer was derived, how each step took place and what contributed to the thinking. And that transparency should also include a comment on the certainty that the risk assessment was correct. For an example, the risk assessment may say that there's a high risk of something happening but with a high degree of uncertainty, because sometimes we just don't know the full story, particularly with new and emerging diseases. The reason they're called new and emerging diseases is often we know little about them, so the information that's forming the risk assessments might be uncertain and lead to a level of uncertainty in the answer. Now, if you're not familiar with risk assessments, an easy way to tell the two types apart – quantitative and qualitative – is to look at the outcome. The outcome or answer to qualitative risk assessment is expressed as a qualitative categorical value, such as a high, a medium, a low or a negligible risk of something happening. Whereas the outcome of a quantitative risk assessment is expressed as a quantity, for example a percentage chance of something happening. (Now there's just some slides if you want to ... next actually. Next one as well). To just highlight some of the pros and cons of the two approaches, it's a very high level, and when I say high level, it's a basic level. Now, a qualitative risk assessment can be a very simple process. Many of us make them everyday without knowing; when we are crossing the road, we make a risk assessment to allow us to cross the road safely. And because they are qualitative, they can be easier to communicate. It's easier for a wide range of people to understand that some things are high risk or a medium risk or a low risk rather than getting into risk ratios or percentages or whatever. And because they're fairly simple, by the very nature of them you don't need complicated modelling skills, so you don't need such a high level of expertise in mathematics or using computer software. So that can sometimes make them more applicable to the field. It can also make them more applicable to situations where there is uncertainties or countries where there are less resources. And because they don't require calculations and complicated modelling skills, they can often be done more quickly than the quantitative approach. In the field you can do a quick and dirty quantitative risk assessment just to get an idea of what's going on. But the important thing is. If you are doing a qualitative risk assessment, the person that's doing it or the team that's doing it need a good understanding of the real world situation and all the factors that might affect the risk. They've got to take in everything in the available evidence that's there. Now again, the qualitative approach is useful when there is a lack of good quality quantitative data. If you're doing a quantitative risk assessment, you've got to be confident that the data you're dealing with is good quality. There's statistical

measures that you can use to minimize the risk of poor data, but it's an advantage of qualitative risk approaches that you can do them when the data is not so good. One of the things of the qualitative approach is sometimes to scientists they may appear to be less precise. And also because you're expressing it as a high, medium or low or negligible risk, they can sometimes appear less easy to compare with other risk assessments. Now quantitative risk assessment, you've got an answer that's a value, so it's easy to compare with other quantitative risk assessments. So, a risk assessment might have a 70% chance of something happening, another risk assessment might say 60%, and that might be over time. A year ago there might have been more chance of something happening and a year later there's less chance, or it could be between two different diseases or two different topics. So, you can compare them, which can be quite useful and that can be useful for policy makers when they want to try and prioritize things. Again when we talk about comparison, you can compare when you are using a quantitative approach, you can compare different interventions in terms of how an intervention might reduce the quantitative risk. So that's again very useful for policy makers when they're looking at different interventions. They might see that some interventions can sort of make a bigger difference than others and they might want to invest in those. Now quantitative risk assessments can be precise if good quality data is available and the interactions are well understood. But again with these models, they're as good as the data that you feed into them and also as good as the experts that are using them, and that's a caveat with quantitative risk approaches: you might be using a sufficient amount of good quality data. And as we mentioned with the qualitative risk assessments an advantage was that you don't require complicated modelling skills. With some quantitative risk approaches, you do need complicated modelling skills. Not with all of them, some models can be quite simple, but with others the more factors there are and the more interactions between these factors, you require a bigger model and you might require computer software to carry out the analysis. Again with the quantitative approach, it can be difficult to account for non-quantifiable data or for qualitative data such as behaviours and things. So that's just a general overview of the strengths and weaknesses of the two. And I guess I just wanted to finish by saying that no risk assessment, whether quantitative or qualitative should be the only decisive criteria for deciding on the final acceptable level of risk. And certainly as far as the OIE goes, in accepting the principles by the OIE guidelines for risk assessments that there is no situation of zero risk, sometimes there's an acceptable risk that has to be taken. And just on the last slide, I just want to show that OIE publishes two manuals, one on quantitative risk analysis and one on qualitative risk analysis, just providing a methodology for the risk assessments for the both types, import risk analysis to allow a consistent approach to be taken to these analyses, and they're devised in such a way, as I mentioned earlier, that they can be applicable to developing an developed countries because for the OIE that's very important because we have the wide range of members with varying capability and expertise.

**CHAIR:** Thank you Dr. Hamilton. If no one has anything to add, Dr. Huntley, perhaps you can tell us what lessons have been learnt from putting risk management theory into practice in a biological setting?

**Dr. HUNTLEY:** I will be fairly brief because I think I covered most of these points in my opening comments. Part of what we have tried to do is to take tools and approaches used in other industries and apply them to the biological situation. And my view is by and large that is valid and it works but there are also some areas where you have to be very careful because the nature of the hazard in a biological environment is very different to most of the physical hazards. So sometimes when people get involved in these assessments they make assumptions which are just not valid given the nature of biological organisms and their ability to replicate, etcetera. Some advice given to me very early was, do not go for complicated methods when simple methods will do. I think quantitative methods in this field can be quite difficult and sometimes we do use them but we try to exhaust the less quantitative approaches first and then arrive at the point whereby we need to introduce numbers, etcetera, and that's partly because the numbers can be very difficult to gain in this particular field. In other industries there will be data on failure rates, etcetera, which is readily available and you can build it into the models. Sometimes in this area it's extremely difficult and you need to be very careful that the assumptions that you make are valid. Again, a point that I tried to make earlier is that if you do an assessment and you identify controls, you must implement those controls otherwise that's the worst form of risk assessment that you can do. I think there is growing interest in this area from a number of different parties. People like architects and engineers now are talking more and more about doing risk assessments to support the projects and really give them a firm basis. It would also be true that often when we do risk assessments that people who are going to go through the risk assessment are very reluctant and they don't feel that it is a useful exercise and position. I like to think at the end of the exercise in virtually every case they have actually realized that it was a very necessary thing to do and there were fundamental flaws with the project which were very easily identified through some fairly simple risk assessment approaches. So sometimes I think people are a little afraid, a little shy of it, think it's a lot of additional work, but in almost every occasion, there have been some major issues that we've helped them identify and to resolve. If it's done properly, it is a very useful tool because you lay out all the issues with whatever situation you have before you and then you can invite different people to comment. So if people are concerned about your activities or your projects, you can actually say, "we'll here is the risk assessment, here is the information, here's the data, if you disagree please help us by giving us more information or telling us why our assumptions are not sound", and that process alone often helps people a great deal in terms of justifying their activities. And just finally to say that I think of all the areas with get involved with, risk assessment is the area where we get the most questions. It's the area that people somehow, they haven't quite come to terms with and they're always looking for more information an easier and better ways to do things. And my hope is that risk assessment in the future will continue to be a central part of the work that we do and that we will see more and more people implement it more and more thoroughly.

**CHAIR:** Thank you Dr. Huntley. Dr. Gillespie, would you please tell us what can be done to improve the utility of a risk management approach?

**Dr. GILLESPIE:** Thank you, Mr. Chairman. I also would try to be brief. I've crudely split this into thinking about the process in four lumps. First of all, the inputs to the risk evaluation. One of the big challenges we face in this area is real information asymmetry. If one talks to practitioners, to the microbiologists doing work who largely will have to do risk assessments, they often don't know a lot of the information that probably you have to take account of in doing a first risk evaluation. So for example in the OECD context, there have little understanding of threats, they have little understanding of availability of counter measures, and they often have little understanding of things like the ability to weaponise a microorganism. So there's real information asymmetry which has to be somehow addressed. But it's a challenge there of course, because in addressing information asymmetry, that means that information by its nature becomes more public and more freely available than it already is. But it's a big challenge here for biosecurity. Around the process itself of doing risk assessment if you like, there's a lot that could be done to improve utility, to improve efficiency and effectiveness. We've heard about standards, we've heard about harmonisation, they're both very good approaches. But also there's very basic things like consensus documents, development of agreed data sets that people can draw upon to do risk assessments. Already some consensus documents exist. List based approaches for example, tend to use some basis of consensus. A good starting point, but they're often not very good end point. But sharing of methodologies, of best practices, whether it be through a standards approach, whether it be through a best practice approach, whether it be through some kind of forum approach, this is less important. But sharing of knowledge on how to do an assessment in the context of biosecurity is something where a lot more could be done. Then on outputs, if you like, the outputs of the risk assessment, what do you do about this? The implementation phase, as Paul put it. Well, people make different judgments. People make different judgments about what risk is acceptable and what risk is not acceptable. How can a microbiologist - I used to be a microbiologist myself - sitting in a laboratory, make the kind of judgment that needs to be made to ensure security of materials and information in this area. They need some guidance. They need some frameworks to work within and you need to be able to communicate with one another. So again, the notion of communication is perhaps at odds with the notion of security, but it's one that has to be addressed in getting to some commonality or some harmonisation of outputs, of judgments, of the level of risk management that may be appropriate, of actions that need to be taken, what simple shouldn't go forward. And finally, outcomes. And outcomes, from my organization's perspective on this set of issues, the outcome is that innovation continues and that economic growth continues and that some of the benefits of access to these organisms are delivered, whether it be health, whether it be environmental, what have you. So there again, there's much that can be done to improve the utility of the system to delivering better outcomes. In my view, certification schemes, accreditation schemes, schemes that assure a customer, help deliver outcomes. So too does the communication towards getting the public to understand and to buy into a process and an outcome. The public of course includes our political masters who at the end of the day, are the real litmus test, or should be, at least of public expression. And finally, chairman, underpinning all of that is good training, good communication. Thank you Chairman.

**CHAIR:** Thank you Dr. Gillespie. Dr. Rogers, perhaps you can tell us how should biological risks be communicated to the public and how do expert and public understandings of risk differ?

**Dr. ROGERS:** Thank you, Chairman. I'll do my best to address both of those as quickly as possible. I'll take the first one: How should biological risks be communicated to the public? And I'd like to say we are actually trying to find the answer to that right now and we are engaging with the public and running focus groups with the public, so, putting them through scenarios, trying to discover their baseline understanding and knowledge of terminologies and certain issues. We're finding a lot of confusion and quite a few misunderstandings in the area of CBRN terrorism. Sorry to couch it in terrorism so much but that's really what I know. We're testing the messages that we are coming out with, with members of the public as well, and we're also testing them with experts and they seem to want very different messages. So that type of research is taking place across a number of countries. I do think that it's interesting to note that members of the public are viewing governments as morally responsible for managing risks, especially biological risks, and there is also a lack of trust. So, the overall strong belief that the government will withhold information in order to prevent panic. I think that an interesting point was raised in terms of communication and transparency being at odds with security and when I address government panels especially, there's a lot of frustration, where we're saying, you must communicate, and they say, but if we communicate then the bad guys will know what we're doing. And we're not asking people to communicate our response capabilities and our response times, we're asking people to communicate and create a familiarity over terminologies and places that you might go and procedures that might take place if there is a biological threat. Health issues are at the core of public concerns and information needs, and the good news is that when it comes to communicating about biological threats versus radiological threats, the biological threat is the much easier job because members of the public think that medicine can cure it. They don't think that about radiation at all. So when we are communicating about biological risks, we must communicate and emphasize that the exposure can be avoided or reduced and that will be very important in helping with the worried well of people who aren't really in the area and aren't exposed. We should communicate that effects can be treated or managed, some effects can't be treated but they can be managed, and also that the agent can be survived if certain steps are taken. So we need to encourage people especially with some of the short time frames surrounding biological risks. I keep on saying that we need to communicate before an event. It's happening a little bit but it's not really being taken up very well. So, regardless of when we communicate or when we start communicating, we must issue the information repeatedly and we don't have to say that we have everything perfectly right, that we have the perfect solution. We just need to let members of the public know that we are responding. We also need to give continued updates on how the threat has changed and how it is likely to change. If we issue some advice and then change it, we need to tell them why we are changing it, how safety is improved by new procedures if the procedures are changing, how the government is actually working to ensure safety and what this actually means in their day to day lives. And I'll just go to the final question. I've got a lot more to say around that but I don't want to take up too much time. How do expert and public understandings of risk differ? And as I said, this

is the key stumbling block in taking all the very complex and important work that everybody's doing and turning it into useful information for members of the public, because we quite often find that we identify a risk, tell members of the public that they need to be aware of something or maybe worried about something and then there's radio silence. We don't really always carry on and tell them what they should do to protect themselves or to lower their chance of exposure. Some of the key issues around expert perception of risk and public perceptions of risk are the fact that experts use very qualitative understanding of risk, so, is there a cause and effect relationship? Is exposure an issue? Can we relate this to other risks in the environment that we are familiar with? Whereas members of the public use qualitative aspects of risk to make decisions. Is the risk voluntary or involuntary, has it been imposed on them? Is it familiar? Can we link it to other, let's say, smallpoxes, etcetera, around the world? Do they have control or do they believe that the government or the agencies responsible for responding have control? And again, dread versus no dread. It's a dread risk, especially with unfamiliar risks. So familiarity is really, really your strongest tool here.

**CHAIR:** Thank you Dr. Rogers. We have very little time left for this morning's session but I understand all these discussions and presentations have provoked the floor, so I see Poland has a question. Please take the floor, Poland and China will follow.

**POLAND:** Thank you mister Chairman. I have some reservations on the applicability of this everyday epidemiology experience on risk management to the setting of bioterrorism. I believe that the gap between theory and practice within bioterrorism is much bigger than concerning this everyday epidemiology we encounter in some accidental event. This is why we have example with Oregon case of Typhimurium. We remember how helpless were epidemiologists to deal with looking for the source of deliberate use of Salmonella Typhimurium in Oregon. The question is, you know with classic definition of the risk is a product of probability and the impact. A question is how much money we have to put into rationally management of risk if we don't know neither probability nor the impact of the event. Experience with body of knowledge concerning bioterrorism attacks with bacteria or viruses in contemporary epidemiology is next to nil. We don't have very many examples to build body of knowledge. So, applicability and I would like to hear from our renowned panellists how to, you know, make use of this big knowledge of epidemiology with accidental cases to situations which is absolutely unpredictable in cases of deliberate use. Thank you.

**CHAIR:** Thank you Poland. A brief answer please from the panellists. Dr. Rogers.

**Dr. ROGERS:** Okay, I'll say that we are trying to address your concerns and improve knowledge and inform the models because a lot of the health response models assume a rational public which isn't always the case. And I don't want to add fuel to the fire of the belief of a panic-prone public, let's say in the case of a deliberate release, but we can't always assume a rational public. They aren't robots, they won't do exactly as we say,

and that impacts our understanding of the spread and the impact of biological risks and diseases. So what we're trying to do is take quantitative information. Unfortunately, it's not, well, it is fortunately I guess, it's not always real time information, we have to ask people what they think they would do. We do have grants in line to go out immediately if there is an instance, ask them what they think they'll do which is very, very different when you actually sit people down and talk to them, take some qualitative information about what they think they will do. Because initially they say, "oh yes, we'll follow the rules", etcetera, etcetera, "we'll go inside, we won't have a lot of contact", but at the end of the day, they really want to go out and collect all of their children from school immediately, etcetera, etcetera. So we're trying to find the reality of assumed behaviour and real behaviour in the event of a real threat and that means that our health models cannot assume a rational public.

**CHAIR:** Thank you Dr. Rogers. Anybody else, very brief? I'll give the floor to China for the next question.

**CHINA:** Mr. Chairman, distinguished delegates, I would like to make a comment instead of raising a question. First of all, we agree with the panellist when they mentioned the issue of risk management. We believe this is an issue which concerns all part and parcel of this issue. Therefore we believe risk assessment is very important and in particular for preventive measures. In China in terms of risk assessment, China has done a lot of work. The Ministry of Health, Agriculture and other organs under the State Council organized experts to establish a national expert committee on biosafety in laboratories dealing with highly infectious pathogenic microorganisms. And also in the Center of Prevention and Control of Animal Diseases a division of laboratory biosafety management is established which is in charge of the accreditation of laboratories dealing with highly infectious animal pathogenic microorganisms and review of their technical work. The division is also responsible for biosafety oversight of such laboratories. Furthermore, we're of the view that in China in our risk assessment work we should do a better job in the following areas: first, we should formulate and improve guidelines concerning relevant laboratories; we should improve the preventive measures applicable to laboratories; we should prevent the accidental release of pathogenic microorganisms; exercise control of access to facilities and prevent unauthorized access to high risk facilities. Secondly, concerning the storage, weapon transport and transfer of pathogenic microorganisms, stringent management should be applied and security measures should be adopted. And thirdly, organizations and individuals engaged in biological research and development and activities which have high risks in biosecurity aspects, should be accredited according to the evaluation of their qualifications and capabilities. And fourthly, to carry out risk assessments under research of life sciences and reduce the risks of abusing the achievements in this field. Finally, we would like to get support from OIE in our future work. Thank you.

**CHAIR:** I want to thank the distinguished delegate of China for the comment. Excellencies, distinguished delegates, ladies and gentlemen, it seems that we have come

to the end of this panel discussion because time has already run out. I believe if there are any additional questions these can be raised in the afternoon session. I'm sure that you will all agree we had a productive session. Our experts on this panel have done a good job in demonstrating to us the power and the utility of risk management approach. We have heard a great deal of information and I know I will be considering it if and how it best fits to the BWC for some time to come. Before we turn our attention to our next session, I would like to finish this panel by thanking everyone that has been involved, especially our experts for taking the time to come and share their expertise with us. Thank you very much.