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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1530)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Welcome to our committee once again. We're so delighted to have you here.

Ladies and gentlemen, we have before us Dr. Peter Singer from the McLaughlin-Rotman Centre for Global Health. Welcome.

From Laval University, we have Dr. Marc Ouellette.

From McGill University, we have Dr. Greg Matlashewski. Welcome.

What we're going to do is ask each of you to give us your 10-minute presentation, and then we'll go into round one of the questions from the committee.

We'll start with Dr. Singer, please.

Dr. Peter Singer (Director and Professor of Medicine, University Health Network and University of Toronto, McLaughlin-Rotman Centre for Global Health): Thank you very much, and good afternoon. My name is Peter Singer. I'm a professor of medicine at the McLaughlin-Rotman Centre for Global Health at the University Health Network and University of Toronto. I'm speaking as an individual.

I became involved in biosecurity in 2003 when I joined the committee of the U.S. National Academy of Sciences, which released a report on globalization biosecurity and the future of the life sciences. I've been a member of the biological threat reduction project of the Center for Strategic and International Security in Washington. I'm currently an advisor to the UN Secretary General's office on the Secretary General's biotechnology initiative.

In January 2009 I wrote an editorial in *The Globe and Mail* entitled “Is Canada ready for bioterrorism?” In short, my answer was that I'm not sure. In contrast to at least five independent committees that studied that question in the U.S., there's been no comprehensive independent assessment of that question in Canada to my knowledge.

Bill C-11, the Human Pathogens and Toxins Act, does make us more secure, which is why I support this legislation. In these remarks I wish to make two points related to the act, leading to specific recommendations.

First, the act will succeed in making us more secure only if it's implemented in close partnership with the scientists whom it regulates. I want to pick up from some of your discussions on Tuesday, when you delved into this area.

Secondly, the act is only a part of the web of protection needed to make Canada more secure and prepared for bioterrorism, especially when it comes to next-generation threats.

In making these points I think it's very helpful to emphasize how different biosecurity is from nuclear security. Nuclear security has a single choke point, namely the control of highly enriched uranium and plutonium. Nuclear security is achieved by keeping secret the means of producing these weapons-grade materials. The technologies are capital intensive, require state support, and if you control the highly enriched uranium and plutonium, you get nuclear security.

Not so with biosecurity. Pathogens are ubiquitous, knowledge is freely disseminated, technology is not capital intensive. Non-state actors, therefore, are a key issue. In short, the cooperation of scientists and a web of protection is needed to gain true biosecurity.

I want to elaborate on those points.

The first point has to do with implementation in close partnership with scientists. The act must be implemented in close partnership with scientists. As you discussed previously, the social well-being and economic prosperity of Canada will depend on scientific discovery. Imagine if a regulatory regime got in the way of Banting and Best's discovery of insulin, or the commercial production of insulin in bacteria, the insulin that's used by all of Canada's patients with diabetes.

I think the proposed act does strike a reasonable balance between scientific openness and the mitigation of risk, but this calculus will play out initially in the regulations, and it will need constant attention and rebalancing that can be done only through ongoing dialogue with the scientific community.

Because biosecurity does not equal pathogen security, what this act does do is really raise the barriers to those who would seek to misuse pathogens. It lowers the background noise of what's happening in laboratories so the signal of aberrant activity can stand out better. But we also need the help of the thousands of scientists in those laboratories, very few of whom, if any, intend to misuse human pathogens, to make sure that 99.99% constitute a network of vigilance to bring that signal to the attention of authorities. Because biosecurity is achieved by winning the scientists' hearts and minds, not through legislative compulsion but by fostering a scientific culture of awareness and responsibility, it's extremely important to have them on side.

I've reached out to a university, a provincial health prevention agency, and an industry association to ascertain whether they feel they've been consulted in the process of developing this legislation. I was pleased to hear a generally favourable response, but the important question, which was raised in your committee on Tuesday, is how to ensure that dialogue continues. This leads me to my first recommendation, which is that the committee recommend the creation of an external advisory group to the minister consisting of representatives of universities, provincial public health agencies, private industry, and others—possibly CIHR—to ensure that the regulations and the subsequent implementation of the act beyond that two years of regulation work proceed with the input and the support of the scientists they regulate.

● (1535)

I think I emphasized in these comments why that's needed even more with respect to an act around pathogen security than it would be with respect to many other acts in terms of implementation.

The second area and the second point I want to make is about the web of protection and next-generation threats. Biosecurity has several moving parts, which all need to work well, and they need to work together. There are the military aspects of biodefence, regulated by the biological weapons convention, and in the non-military area, there's law enforcement intelligence and national security, where there probably is a need for better interaction between those communities and non-governmental communities than there currently is. There's the public health response, which is really the final common pathway of defence. Unfortunately, we had a dress rehearsal with SARS, but for that reason, I think it's likely we're reasonably well prepared in the public health domain. There are the pathogen security and laboratory biosecurity and biosafety issues, the focus of this bill. We need that; that's why I support it. See remarks about implementation above.

But the one piece that hasn't really been attended to, and the one I'd like to focus on, is the idea of next-generation threats. This is about how life sciences can create new and far more serious threats, and I'd like to discuss it and suggest a way to deal with that.

Tomorrow's threats are not going to be the pathogens and toxins in the schedules of this act. A key recommendation of the report of the U.S. National Academy, which I was on, was to adopt a broader perspective of the threat spectrum. We highlighted how terrorists could use techniques like DNA shuffling or synthetic biology to design bacteria resistant to antibiotics. A procedure called RNA interference could be used to switch off genes that protect us from cancer. Systems biology could identify ways to disrupt the body's immune system, making us vulnerable to infection or to wipe out memory. Nanotechnology could figure out better ways to deliver bioweapons, which is actually the Holy Grail of bioterrorism. There's a whole spectrum of next-generation threats, not necessarily only pathogen-related, that need a focus.

At the same time, our committee recommended we maintain, to the maximum extent possible, free exchange of information in the life sciences, because the bioterrorists win without launching a single attack if we choke off these future advancements. Open science is also important to the development of countermeasures. This balance means making sure universities and companies promote a common culture of awareness, a shared sense of responsibility to prevent misuse within the community of their scientists—another recommendation of our National Academy committee. This is done using codes of ethics, teaching role modelling—also not a particular focus of the biosecurity agenda in Canada yet.

An earlier National Academy committee issued a 2004 report entitled *Biotechnology Research in an Age of Terrorism*, identifying, for instance, experiments of concern, like showing how to render vaccines ineffective, or turning non-pathogens—which aren't anywhere on your schedules—into pathogens. We need to make sure medical journals and granting agencies are sensitive to these matters and have processes for dealing with them.

Also, these threats change extremely quickly with the progress of science, so that our National Academy committee recommended creating by statute an independent science and technology advisory group to the intelligence community. To my knowledge, there is no group in Canada attending to these next-generation threats in a comprehensive, systematic way, the way I've seen in the communities in the United States, or attending to how the working parts that I mentioned form a web of protection together and how those various communities work together. If there's one thing I've learned, how those pieces work together is at least as important as the individual pieces, not just the coordination within government, which you talked about on Tuesday, which is also important, but the relationship between the government communities and the non-government communities in the universities, the private sector, etc.

In my *Globe and Mail* piece, I proposed that the federal government request an assessment of the question of whether Canada is ready for bioterrorism from the Council of Canadian Academies, working with the Canadian Academy of Health Sciences and the Canadian Academy of Engineering—the top academics in the country. These national academies of scientists were created, and in the case of the Council of Canadian Academies, funded to conduct just such an assessment. The mandate of such a study, which could complement the pathogen security focus in this act, would be to evaluate whether Canada is prepared for bioterrorism, with an emphasis on next-generation threats and the overall web of protection about how these pieces move together.

I won't go through in detail the specific questions that such a mandate might include, but I could do that in the discussion period.

● (1540)

To take a couple of examples, what is the nature of the threat, including the next-generation threats? How well do the pieces work together to form a web of protection? Do we have the capacity in Canada, outside of the government, to engage in these biosecurity issues? Is the public adequately involved in biosecurity issues? It's questions like those.

In closing, I would like to propose my second recommendation, which is that the committee recommend to the minister that PHAC request from the Council of Canadian Academies, working with the Canadian Academy of Health Sciences and the Canadian Academy of Engineering, a study to evaluate whether Canada is prepared for bioterrorism, with special emphasis on these next-generation threats and the web of protection—how the various pieces and communities work together. That is really what leads to biosecurity, not just the control of the pathogens.

It's a good act, but we don't want to have a false sense of security around the act. We want to look at biosecurity, generally.

I want to thank you very much for your attention. It's been my honour to address you, and I look forward to your comments and questions.

The Chair: Thank you, Dr. Singer, for a very interesting presentation.

Dr. Ouellette, would you present to the committee as well now?

[*Translation*]

Prof. Marc Ouellette (Professor, Laval University): Very good; thank you.

My name is Marc Ouellette and I work at the Infectious Diseases Research Centre at Laval University. I hold a Canada Research Chair in resistance to anti-microbial agents, which my colleague has just talked about. We can treat micro-organisms, whether they be viruses, parasites or bacteria, but they are all becoming resistant to anti-microbial agents, and that is one of my specialities.

One of the reasons why I am pleased to be here today—my thanks to the committee—is that I was the academic representative who contributed to the drafting of guidelines for biosafety. This is the archetype document that researchers in Canadian universities must abide by when they import or export human pathogens. I know the topic quite well. We were consulted extensively when the document was being drawn up.

Each university in Canada has a biosafety committee. Having the approval of those biosafety committees is an indispensable condition for obtaining research funds. I am on the Université Laval's committee. I will come back to that later. But I am going to speak today as an individual and especially as a frequent importer and exporter of Risk Group 2 pathogens.

I am on page 2 of the document you have before you.

● (1545)

[*English*]

I would like to acknowledge the people who invited me here. It has actually been quite enlightening to read Bill C-11, and even more enlightening to read the transcript of the debate that the MPs had about Bill C-11. I was quite amazed. The quality of the interventions was wonderful. There was a very good understanding of what was going on, and that was very useful for me.

We were informed by PHAC but we were never consulted by PHAC, whereas when this was written we were consulted and then the writing happened. Bill C-11 arrived from almost nowhere, and we were fairly surprised. The research community, as a whole, was actually very surprised by the predecessor, Bill C-54. We were caught by Bill C-54, but now I am quite happy to see that there is consultation. Now I am here at the Standing Committee on Health in the House of Commons to discuss biosecurity and I thank you.

The first message I want to convey is that biosecurity matters, at least within all of the universities in Canada. I'll give you a few examples. First of all, there are three national agencies that fund research. There is CIHR, NSERC, and SSHRC, which is for social sciences and doesn't work that much with micro-organisms—the only one is probably a virus they have in their computers, but the bill is not directed at that.

When we write a proposal for NSERC and CIHR, we have to pick a box about the biocontainment of the organism we have. We say yes, it's level 2, level 3, or level 4. Level 1 is actually the usual, and I'll come back to that, but level 2, let's say, is frequent. By good luck we get the grant. It is a 20% success rate, so we're not always a winner, but when we get it, we now have to get the institutional okay. Every university has its own committee looking at the grant and saying if it is level 2 or level 3, and only then, when you have the okay of the committee, can you get the funds. There is already a structure in place to look at that.

Now you have the money. Now you can start doing some work. So you want to import pathogens that you don't have in your lab. The first thing you have to do is work on a permit from the Public Health Agency, PHAC. This is what we have to fill out to get the okay from the Public Health Agency of Canada. I can provide this to the committee in both languages. Almost every human pathogen is also a pathogen of animals, and CFIA is also interested in that, so we also have to file for a permit from CFIA. This is the permit, and this is the extra paper we have to write. This is the real paper because French and English are on the same form.

Once we have that, it's often a dialogue. They will say, we are missing that piece of information, we are missing this protocol. What I'm saying is you cannot just get a pathogen like this. You have to go through paperwork to be able to do that, and once you have it, then you get your organisms. But now the people who work with this organism need training. The students, the personnel, have to be trained to be able to work with this, and it is the institution that is also responsible for that.

The message I want to convey is that the importation and manipulation of human pathogens is already under competent administrative scrutiny. Now, of course, we're all in favour of increasing the strategy to increase public health, for sure—nobody can be against that—but it is to find the best strategy to be able to have a dialogue, and with that I totally agree, between the legislators, the civil servants, the national agencies, and the people who are doing that on a day-to-day basis.

On the third page there are some comments.

[*Translation*]

One of the problems with this document, Bill C-11, which, incidentally, is very well done, is that Level 1 micro-organisms are not even mentioned. Level 1 are those that pose no threat to humans, except in huge quantities, but the quantity of micro-organisms is another factor. E. coli, for example, is one of those Level 1 micro-organisms. Everyone has heard of Escherichia coli. In the list, it appears as a Level 2 pathogen, but the biology laboratories in Canada that work with E. coli, who take pieces of a gene and put them somewhere else, are all working with non-pathogenic E. coli.

So, we must be very careful because, with E. coli, or any of the micro-organisms shown here, there are kinds that are pathogens and kinds that are not. It would complicate research enormously if there were no distinction between pathogenic forms of E. coli and the other forms.

Believe me, I sit on a number of committees, and everyone in Canada is worried and wondering if the things we have done for years and years are going to become a problem eventually.

One of the unique features of the bill is that there are Level 2, Level 3 and Level 4 pathogens. The bill makes no distinction between them, but the risks for the community from Level 2 are virtually nil. Level 2 organisms must not be considered in the same way as Levels 3 and 4. So, as to security clearance, I feel that those working with Level 2 pathogens should not be required to have a security check.

All university laboratories are Level 2. Professors' offices are laboratories. So how would students wanting to see their professors go about it if they had to have a security check first? These are things we have to think seriously about.

Six pages of this document deal with the role of the inspector, a position that does not presently exist. This individual (or more than one) will have a lot of power. We will need to see how we can limit that power to prevent an abuse of power, to prevent the person going on a power trip and end up hurting...

● (1550)

[*English*]

The Chair: Dr. Ouellette, I don't want to interrupt you, but I just want to remind you that you only have one minute left.

Prof. Marc Ouellette: Very good. Thank you so much.

I'll go to page 4 now, the end of the document. The schedules can be fairly confusing in terms of level 2, level 3. As I said, E. coli often has to be a level 1 pathogen, not a level 2. We often manipulate these bugs. Once we have different bugs, will we have to report them as new pathogens or not? If we put a plasmid in them, is that a new parasite, a new bacteria?

In the bill, the clinical microbiology is not discussed that much. How will clinical microbiology deal with these rules, with these regulations, or with this law?

In conclusion, because now I only have 30 seconds, first, thank you for the bill. I think it's very timely and it's nice to have discussions, but please listen to the users, because we are the ones who will either benefit from it or suffer from it.

[*Translation*]

Thank you so much for your attention.

[*English*]

The Chair: Thank you very much for that, Doctor.

Now we will go to Dr. Matlashewski. Did I do better this time on the pronunciation?

Thank you.

Prof. Greg Matlashewski (Professor, Department of Microbiology and Immunology, McGill University): Yes, that's fine.

First of all, I'd like to thank the committee for allowing me this opportunity to give some feedback on the bill. What I'm really going to be talking about is what's written in the bill here and my interpretation of it.

Just to give you a bit of background, I'm the chairman of the department of microbiology at McGill University. I teach microbiology and immunology, but more important for this committee, I also do research, and I practise microbiology and immunology. My research has contributed to over 90 publications. I also sit on advisory committees for the Canadian Institutes of Health Research; the National Institutes of Health, in the United States; the FDA, the Food and Drug Administration, in the United States; the World Health Organization, in Geneva; the United Nations; and Médecins Sans Frontières.

I have sat on these committees to deal with infectious diseases and microbiology over the years, and I continue to sit. So I feel competent in addressing the people here concerning this bill.

Like the Public Health Agency of Canada and the people on this committee, my concern is for health and the protection of people from infectious diseases. Because of that, I am largely in agreement with this bill, but there are some modifications that have to be made before it is passed. So I am only going to focus on that aspect and give you my reasons for that. I'm not being overly negative. I just want to focus on what needs to be changed.

The best thing to do to change this bill is to remove level 2 pathogens from this bill. They should not be linked. This is the same point Marc just made. Level 2 pathogens should not be linked with level 3 and level 4 pathogens.

Let me explain. Level 2 pathogens generally pose a low risk to public health. They are unlikely to cause serious disease, and the risk of spread is low. Completely different are level 3 and level 4 pathogens, which pose a high risk and are likely to cause serious disease. The risk of spread for level 4 pathogens is high. Therefore, the way you work with these pathogens is very different.

With level 2 pathogens, you work one way. You work with a biological safety cabinet, in which air can't get in or out, and you work with your hands like this. With level 3 and level 4 pathogens, you need a completely different infrastructure, which is a multi-million-dollar infrastructure, with a completely different negative pressure room and so forth.

So to work with these pathogens, you have to work under very different conditions. Therefore, the administrative and security levels also have to be different. This bill links them together. The administrative and security issues link level 2 and level 3 and level 4 together. That cannot work. You have to separate them just the way you separate working with these pathogens. You can't have them linked together. If you link them together, the consequences are enormous for this country.

For example, from a scientific point of view, a lot of research on level 3 and level 4 pathogens, the most dangerous pathogens, is actually performed using level 2 pathogens as a model system. For example, mycobacterium tuberculosis, which is passed through aerosol, is a pathogen that gets into the lungs, survives in the lungs, and causes tuberculosis. It's a fatal infection. Mycobacterium smegmatis is a very similar organism. It looks the same under the microscope. It has the same genes, or virtually the same. It has the same biochemical pathway. But it has evolved slightly differently to survive only in the soil, and there's very low risk of it infecting people. It is a level 2 pathogen because of its low risk of infecting people.

Drugs that kill mycobacterium smegmatis will also kill mycobacterium tuberculosis, so working with a level 2 pathogen reduces the risk and, as important, reduces the cost as well. So if this bill is passed the way it's written, it will link level 2 and level 3 together in an administrative way, and you'll lose that advantage. Working with the level 2 and level 3 pathogens will become equally administratively difficult and you will lose that ability, that advantage, of working on a level 2 pathogen.

That's a very important point to take away. Marc gave a very good overview of the administrative point of view, so I won't go into that. I'll just give one example. If I had a sample of mycobacterium smegmatis—a very safe organism to work with in a laboratory—and I gave it to my colleague next door, I couldn't do that with this bill. I would have to get a permit from Ottawa first, which would take an enormous amount of time.

I'm not sure if I understood correctly, but according to this bill, if I did do it, I would be criminally responsible and could be fined $250,000 and put in jail for three months. And that has really scared my colleagues across the country. My colleagues across the country have been calling me and asking me to clarify whether in fact this is what is true within the bill.

● (1555)

Another point is that Canada has to be able to compete globally on a scientific level. Something very good that's occurring in Montreal is that Merck Pharmaceuticals, which is one of the major pharmaceutical companies in the world, has recently developed a very good vaccine against the human papilloma virus.

They're relocating their research in infectious disease from the United States to the facility in Montreal. This will be a multi-million-dollar research facility. They will have to be supported by Canadian science in microbiology and immunology. We will have to be able to train students and graduate students to be able to support a facility like this. I've spoken to them already, and they want to be able to work with McGill University, the University of Laval, and the University of Montreal, because they want that academic interaction.

The way Bill C-11 is written it will slow our ability to conduct this research and our ability to interact with companies like Merck. If Merck can't survive in Montreal because of the effect this bill could have on research in Canada, other companies may not come in. I think it will really hurt us economically as well as scientifically if our ability to interact scientifically is impaired.

Marc brought up the important point that we have to be able to teach our students. We have 350 undergraduate students in microbiology and immunology at McGill. We teach them how to use level 2 pathogens. The way this bill is written we couldn't teach them any longer. We would no longer be able to train the students because they wouldn't have the proper security clearance. That has to be changed within the bill.

Another point is that in Canada, most professors' offices are in the laboratory. If I give a lecture in the morning, a student could not come to ask me a question in my office because the office is in the laboratory and the student wouldn't have the proper clearance. That's a problem with the bill.

We have visiting scientists coming into McGill University every week, and we like to talk science with them. They would not be allowed in my laboratory. We couldn't actually get into the lab and discuss results there the way the bill is now.

I'd like to finish by saying something that I think is quite important that I'm quite passionate about. Doing research in Canada has been wonderful. The Canadian Institutes of Health is as good an institution as there is anywhere in the world. They funded my research on Leishmania for over 15 or 20 years.

Leishmania is a level 2 pathogen. It's transmitted by sand flies, so it can't cause disease in Canada, but it does cause disease in the developing world, particularly in Peru, where it causes a severe form of leprosy. With the support of the Canadian Institutes of Health Research we've developed new treatments for this infection. We've taken it from the laboratory and we're now doing clinical trials in Peru. We're able to actually treat people before they get that form of leprosy. This is supported by the World Health Organization and Médecins Sans Frontières. It's because of the wonderful research environment we've had in this country that we can actually do this kind of research.

I can honestly say that if Bill C-11 had been passed the way it's written here to include pathogen level 2 organisms, we would not have been able to make that progress. We would not have been able to make those contributions and compete on an international level.

I think there are many positive things about this bill, but the thing that worries the Canadian scientific group is that linking level 2 pathogens with level 3 and level 4 pathogens is a mistake. It can be easily rectified by just removing level 2 pathogens and focusing on level 3 and level 4 pathogens. This should focus only on level 3 and level 4 pathogens. That's the message I'd like to put across today.

Thank you very much for your patience in listening to me.

● (1600)

The Chair: I have to thank you for your presentations today. They've been very thoughtful and insightful. We're quite looking forward to having the opportunity to ask questions.

Ms. Duncan, can you start?

Ms. Kirsty Duncan (Etobicoke North, Lib.): Thank you, gentlemen.

You gave very interesting presentations. I appreciate the biosafety level 2 to level 4 perspective, and that the legislation is there to protect both Canadians and those working in the lab.

I have a number of questions. How does this legislation compare to WHO recommendations, and how does it compares to the U.S. and the U.K. in terms of the different classifications? Are we separating level 2 from level 3?

Prof. Greg Matlashewski: I could give my perspective on that.

The way Bill C-11 addresses level 2 pathogens in this bill in Canada is not what happens in the United States. They do not have those kinds of restrictions in the United States on level 2 pathogens. They do on levels 3 and 4. This bill is right on level 3 and 4, but it's not right on level 2.

In the United States there is a much freer exchange of reagents without having to get a federal permit first. There is not the security. I can walk into any laboratory in the United States and speak with a scientist there. They cannot do that to me. If a scientist comes from the United States to my lab, they can't come into my lab. So there is a difference. And it's the same thing in the U.K. and it's the same thing in Europe as well.

● (1605)

Ms. Kirsty Duncan: That's what I wanted to know. Thank you.

What changes would you like to see? You've mentioned the level 2 separation. We work with students. What's the training...not just the laboratory work but the ethics around training students to work with level 2, if we're going to separate them, which they are currently?

Prof. Marc Ouellette: Every graduate student and every undergraduate student also—I don't know about all universities, but at least I know what's going on at our university—has to follow ethics courses on the conduct of research, not specifically on the pathogens, but this is included in the larger framework of compulsory courses on ethics of research. When they come into the lab, they have to pass training on biosecurity. It's not 10 years of training, but they do have to have all the know-how and how to deal with micro-organisms. They have to be trained to be able to work in the lab when they are there and have a contract and will stay there for a number of weeks.

And the second part of your question was?

Ms. Kirsty Duncan: No, that's okay.

Dr. Singer.

Dr. Peter Singer: On the ethics, in my former life I used to run a bioethics centre, and one National Academy committee's recommendation had to do with this culture of responsibility. Let me just tell you a story.

A guy called George Church is one of the world's pre-eminent producers of bits of DNA, and some next-generation threats are associated with some of those life sciences procedures. He's an excellent role model for his students. He talks about the ethical issues of biosecurity. He actually keeps track of all his students and what happens afterwards. So a lot of work can be done, I think more in the informal curriculum and role modelling, even more so than in the formal curriculum. That work, yes, around pathogens, but also around life sciences, folds very much into next-generation threats.

Ms. Kirsty Duncan: That's where I was going with that.

Dr. Peter Singer: You won't be able to deal with it in this bill. That's why my second recommendation about the broader look on life sciences, next-generation threats, and the whole pieces of the puzzle, including the ethical aspects, which don't do well through legislation, or even regulation.... That's an unaddressed piece in Canada that would make us more biosecure.

Ms. Kirsty Duncan: It's the additional web, that's true.

Is there anything from the toxins list that you think might be missing, or are there any changes you would like to see in this schedule? Be very specific.

Prof. Greg Matlashewski: I think everybody will see things they would like to change, but one of them is mycobacterium bovis. BCG is a level 3 pathogen. In fact, one-third of the world has been injected with this as a vaccine against tuberculosis, TB, so I'm not sure it should be a level 3 pathogen if it's already being injected into people as a potential vaccine.

Ms. Kirsty Duncan: Are there any others? For example, ricin doesn't seem to....

Prof. Marc Ouellette: E. coli. There has to be a way of putting escherichia coli.... There are some level 2 pathogens, but several strains of E. coli are also level 1, and this is what is going on. Every lab in Canada and every lab in industry works with E. coli that is non-pathogenic to humans. So this is a big worry in the community.

Ms. Kirsty Duncan: And what about toxins?

Prof. Marc Ouellette: Toxins are less special. But are there guidelines for toxins? My biosecurity officer at my university commented that there no real guidelines for the use of toxins.

Ms. Kirsty Duncan: That's what I was going to ask Dr. Singer.

Dr. Peter Singer: I was going to say that those lists, especially the level 3 and level 4 lists.... Again I'm not a microbiologist, but they look pretty reasonable to me; they look comparable to the select agent rule. But the one thing I want to emphasize is that a good molecular biologist can turn a level zero pathogen or non-pathogen into—I'm only exaggerating a little here—a level 3 or level 4 pathogen in a little bit of time, or certainly can increase pathogenicity. That's the nature of the threat that you can't address in a piece of legislation like this. It's a crucial element of biosecurity.

I've made a recommendation about how we can really move forward on that through the Council of Canadian Academies studying it and making recommendations, which may actually be outside a legislative framework.

● (1610)

Ms. Kirsty Duncan: Would you be willing to draft an amendment?

Dr. Peter Singer: Along the lines I just mentioned, sure.

Ms. Kirsty Duncan: All of you? The recommendation?

Dr. Peter Singer: Yes.

The Chair: Thank you very much, Dr. Singer.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you, Madam Chair.

Thanks to all the scientists for being here this afternoon to give us a perspective that is a little different from what we have already heard.

Dr. Ouellette, from what you say, the research community was not really consulted. There was just an information session.

Dr. Matlashewski, you tell us that, in the scientific community, there are still a huge number of questions and a huge fear that laboratory activities will be reduced or compromised.

Assuming that what the Public Health Agency of Canada tells us is true, that the regulatory framework is going to be constructed after extensive consultation and that all stakeholders are going to be met with and reassured, and considering what we know about these consultations and what has been done in the past, I wonder whether you would not consider that only real solution is to completely remove all mention of Level 2 pathogens from the bill. The regulations could then be prepared quicker and more precisely. You explained that Level 2 human pathogens are in no way comparable to Level 3 and 4 pathogens.

Mr. Marc Ouellette: That is certainly the case as regards the risk for the community. If a person is sick with a Level 2 or Level 3 pathogen, he can still die. But it is not the same thing.

I was not consulted about Bill C-54, nor were any of the colleagues I know. But we were informed. The member of Parliament for our constituency, the former member, that is—Luc Harvey, from the Conservative Party—was also very active. He arranged for us to visit the offices of the Public Health Agency of Canada. He came to the Université Laval to discuss the matter. He was surprised that we were shocked.

This is great now! We are being consulted on Bill C-11. I understand that the consultation is going to continue. Everyone is in favour of making the public safer. Some practices already exist and have proved their worth. If we can improve them, can have a framework, so much the better. Do we feel reassured that Health Canada tells us that there is now going to be a regulatory framework that is going to weaken the law, change it, or express it differently? We are people of good will. If we are asked for our opinions and our efforts so that the law is as proactive as possible, we will participate.

Mr. Luc Malo: So do you agree with Dr. Singer's proposal that the regulatory framework should be established not only by bureaucrats but also by the scientific community, by stakeholders in the area? An independent committee with a proper mandate?

● (1615)

Mr. Marc Ouellette: Absolutely.

Mr. Greg Matlashewski: Mr. Malo, I agree for group 2. Group 2 should not be included in this bill. It would cause too many problems.

[*English*]

It would be easiest and I think would solve a lot of the problems if we didn't impose group 2 on this bill.

I would say that over 90% of the research done in Canada in microbiology and immunology involves working specifically with level 2, not level 3. Removing level 2 would not put Canadians at any greater risk than they face now. Canadians are well protected with what is already present. Keeping level 2 in this bill will certainly slow research in this country and slow our ability to compete internationally and our ability to attract biotechnology and major industries like Merck pharmaceuticals.

Merck is coming to Montreal because of the expertise we have in Montreal, not because they think it's a good place to live. We have the University of Montreal, we have McGill University, we have Laval University, and we have some of the best microbiologists in the world. Merck is going to come to join us because we are that. I am convinced that keeping group 2 will slow down our economic development and ability to work in this area.

[*Translation*]

Mr. Luc Malo: As a researcher at McGill, were you consulted about Bill C-54? Were you able to express these very legitimate fears about the content of the bill?

[*English*]

Prof. Greg Matlashewski: We weren't really...or at least I'm not aware of consultation with McGill University before the bill was written. I think we were shown the bill after it was written, but I think if we were approached before it was written, we would have had input at that point, certainly.

[*Translation*]

Mr. Luc Malo: Were the fears that you expressed today, very legitimate fears, I repeat, made known to the Public Health Agency of Canada before today? They have representatives in the room at the moment.

Mr. Marc Ouellette: Absolutely. In fact, when Bill C-54 was introduced, one of the first things we did—as a research community—was to start a letter-writing and e-mail campaign. Representatives of the agency were very proactive. They came to see us and explained the bill. We presented our concerns about the bill and then it died on the Order Paper. The present bill C-11 is a reincarnation of Bill C-54. In broad terms, I feel it is the same, except with regard to a pathogen that was Level 3 and is now Level 2. We lobbied hard on that because it was plainly a mistake. Yes, we let our concerns be known.

We all arrived here today at the same time and we talked for almost half an hour. Everything they said made a lot of sense.

[*English*]

The Chair: Thank you, Dr. Ouellette.

We'll now go to Mrs. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson.

Given the dialogue we're having, I think it would be wonderful if somehow we could get the department reps at the table with you and could have an exchange on what they think about what you said and could go back and forth. I'm a little—

The Chair: Ms. Wasylycia-Leis, they will be at the table in about 10 minutes, so let's continue with this group.

Ms. Judy Wasylycia-Leis: It would be good to have Dr. Plummer and Dr. Tam right here now, and we could do some back-and-forth.

Let me ask this, first of all. According to the minister's documents, consultations were held in September 2007 about this area. Were you consulted in September 2007?

They went on to suggest that there was no opposition expressed, although some issues were raised around implementation.

You can't remember any consultations?

Prof. Marc Ouellette: No, I don't remember.

Prof. Greg Matlashewski: I wasn't consulted in September 2007.

Ms. Judy Wasylycia-Leis: I guess you're raising the whole question of what the right balance is in this legislation. While I hear what you're saying in terms of not wanting to impede research, I think we're struggling as members of Parliament, and the public is struggling with the need for health protection.

These days we're dealing with a lot of level 1 or level 2 issues that are causing death. Listeriosis is a good example of this: that's on the list of level 1, I believe. E. coli has caused numerous deaths and illnesses. I think the department is probably listening to a bit of that and struggling with how to provide that kind of balance.

I think the first priority has to be the protection of health and well-being. Secondly, do not impede research. I can imagine you're going to get an earful from the drug companies; they want as few restrictions as possible. We, and you as academics, have to be very vigilant about that balance, and give us your best advice.

In her presentation the other day, Dr. Tam said that the program and regulatory framework around this legislation tends to be less stringent for those individuals who are handling less dangerous human pathogens and toxins and more stringent of those handling the most dangerous. She gives the example of security screening not required for people working with risk group 2 human pathogens.

Are you saying that's not true or that there are other restrictions that cause a problem? How would you in fact balance health protection versus innovative research?

● (1620)

Prof. Marc Ouellette: As I said, just as you've been saying, we've heard the same message from the Public Health Agency, and we were quite pleased by what we heard. We were asked to give our opinion about what was written, and what is written is not what you're saying.

Can I just come back to listeriosis, Walkerton, SARS, clostridium difficile?

Ms. Judy Wasylycia-Leis: Salmonella, E.coli, everything....

Prof. Marc Ouellette: Yes, all these things are infectious diseases that will happen all the time, despite the tightest regulation that one can have. This is how we handled the pathogens. Listeriosis had nothing to do with handling the pathogen. It had to do with not carefully cleaning the meat plants. SARS was an infectious disease from Asia that was not spotted maybe as rapidly as possible in Toronto. This is an infectious disease; this is public health. It has nothing to do with the manipulation by itself of the pathogen. How the manipulation of a pathogen will help is if we can do research about this, where we may have improved diagnostics, improved treatment for those diseases.

Ms. Judy Wasylycia-Leis: I appreciate your explanation. I'm going to look forward to the response from some of the Public Health Agency folks in the department.

Mr. Singer, you might want to comment on this as well, as I'm really interested in your comments around bioterrorism. A concern I've raised in the past is what would appear to me as a lack of coordination within the federal government. With all the people who should be ready in case of a bioterrorist attack, how do we get that coordination and that preparedness?

Dr. Peter Singer: Let me deal briefly with the coordination question, and then come back to the level 2 issue.

On coordination, I heard the question that I think you asked, and I heard Frank Plummer's response from Tuesday. It sounded to me like Frank Plummer presented a pretty good case for a lot of table-top exercises and coordination within the government.

My point is that coordination within the government is necessary, but it's not sufficient to achieve biosecurity. The governmental communities, the life science communities in the universities, and the private sector communities all need to be working together and on the same page.

When I was on this National Academy committee—and I'm not proposing this for Canada—it started with people talking about their conflicts of interest. These were all scientists like these guys, from Stanford, etc., and every single person went around and said, “I'm on the XYZ committee of the Defense Intelligence Agency.” There was real outside-of-government input into government. That's the sort of coordination or interaction I don't see in Canada. Maybe the Americans have taken that too far, but maybe there's a middle road.

So that's what I mean by how the pieces are working together, the web of protection. I think you need a detailed look at that, and I'm suggesting the Council of Canadian Academies can do that.

With respect to the issue of level 2, very briefly, I think what you're facing is this—and I don't want to do their job for them; they're doing such a great job themselves, the PHAC people, in their comments. But I'm sure they'll come and say, “Look, we've guaranteed to you that in our regulations, level 2 will be different. Most of the scenarios that Greg raised we'll deal with through regulations. They won't be a problem. We won't require security clearances for level 2.” And so on.

So I think the choices for this committee are.... On the one hand, do you say it's enough to leave it to regulations, the distinction between level 2 on the one hand and levels 3 and 4 on the other? At the other extreme is what these guys are saying, which is to take level 2 completely out of the bill. And I think you'll want to ask them what the harm of that would be.

In the middle, should you decide not to take either extreme, is exactly why I've proposed the advisory committee mechanism. Because that's a user committee that provides ongoing input at the level of the minister into implementation issues even beyond the regulatory period, where there are other mechanisms for input.

● (1625)

The Chair: Thank you, Dr. Singer.

Dr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Madam Chair.

I want to thank the witnesses today, because you've certainly been thought provoking for the committee members, I can tell.

I do want to get you to elaborate a little bit more and also ask if you will be staying afterward, because we're having the officials come forward. As Dr. Singer mentioned, there may be some really good responses to the questions you brought up, and I'm looking forward to that.

But again, I want to look at the level 2 pathogens, how you suggested that perhaps we need to take them out entirely. I do see a little bit of a conflict here.

You were saying, Dr. Singer, that a good microbiologist, even with regular research, may be manipulating a pathogen that might start off as a level 2, but may become a level 3 or level 4, even. The lab that would be working on that may not be prepared to handle that type of scenario, and there are biosecurity issues.

I had a recent conversation with the nuclear people, and they were talking about the heavy water incident. With nuclear waste you can make dirty bombs, which are not as bad as a nuclear bomb, but there are different regulations for that.

Would you be able to comment on the balance part of it? I'll ask each of you to elaborate a little bit more, because this is a challenge we're facing here on committee.

Dr. Singer, could we start with you?

Dr. Peter Singer: It's really important for committee members not to be trapped in metaphors, which is why I said what I said about nuclear. Nuclear security—real nuclear bombs, not dirty bombs, which are a little easier—are at one end of the spectrum. You can get nuclear security by controlling highly enriched uranium and plutonium. At the other end of the spectrum is cyber-crime. Some 12-year-old in your basement can do a lot of damage with a virus—it's so disseminated.

Close to cyber-crime, but a little bit closer to nuclear, you have chemical, and just to the left of chemical is about where biological sits. What I was really saying is, don't get trapped into the nuclear metaphor and think that just because you have pathogen security you have biosecurity. It's necessary, but not sufficient.

I thought that was really important for the committee to understand, because then you're not going to go to the nth degree on every last little thing in pathogen security. It won't get you to where you need to be anyway. You need the support of the scientists, because of the “needle in the haystack” problem, and you need to deal with the other issues, such as the life sciences outside of this bill.

So that's the spectrum.

In fact, the first recommendation from our National Academy committee was a broader perspective on the threat spectrum. Scientists who had lived in the United States with the select agent rules—the analog of these rules—for five years said stop being so pathogen-centric; don't only think of pathogens.

You must think of pathogens, but the extreme version of those guys wouldn't have any select agent rules at all. I disagree with that, especially when it comes to level 3 or level 4. But very clearly what they're saying is, don't be pathogen-centric alone; think about these other things. I was exaggerating a little, but not too much, about going from level 0 to level 3.

I wanted to give you that context, so that you're looking at that balance: you realize you're getting some stuff, but you're not solving the problem; hence the parallel process and the need to engage scientists.

Does that help as an elaboration?

Mr. Colin Carrie: It does, indeed. But I would like the other doctors to—

The Chair: Thank you, Dr. Singer. I'm sorry, but right now we've reached 4:30 and are going to ask the Public Health Agency members, Dr. Tam, Dr. Plummer, Mr. Gilbert, and Ms. Allain, to come forward. We would invite you folks to sit in the audience and listen and have dialogue.

I'm not going to suspend the meeting. I would like the exchange of witnesses to be as quick as possible, and then we can get right into it.

We've had some very interesting questions and dialogue today. I want to thank you so much, Dr. Ouellette, Dr. Matlashewski, and Dr. Singer.

● (1630)

Prof. Marc Ouellette: Thanks also to you.

The Chair: Could the Public Health Agency please move forward? You can sit in the seats that were formally occupied by the Global Health agency. Thank you.

We're going to start straightaway with a new round. You made your presentations yesterday, so we'll go straight into the questioning.

Ms. Murray, you're up first.

Ms. Joyce Murray (Vancouver Quadra, Lib.): Thank you.

Ms. Tam, have you seen the letter to Dr. Butler-Jones from Craig Knight, the assistant deputy minister of the B.C. Ministry of Health Services?

Ms. Theresa Tam (Director General, Centre for Emergency Preparedness and Response, Infectious Disease and Emergency Preparedness Branch, Public Health Agency of Canada): Yes, we have received that.

Ms. Joyce Murray: It's pretty strongly worded there that outstanding questions about this bill have not been satisfactorily addressed by previous information sessions. There are some very strong concerns, I would say, not just about the duplication that I brought up last time, but really about the process of consultation or the lack of consultation. We just heard that from some of the very eminent heads of labs at the universities, who essentially weren't consulted on this either.

The question I have is, what's the rush? Why do the process this way? Why not take the time to adequately bring in the provinces, especially when there is concern about stepping into provincial jurisdiction and when your bill may well be subject to a court challenge as to whether it's even constitutional, for this kind of jurisdictional overlap? Why not take the time to get this right? What's the cost of waiting? Has there been a major incidence of problems that you're rushing to address, or what's the reason?

Mr. James Gilbert (Director General, Strategic Policy Directorate, Public Health Agency of Canada): First of all, it is viewed as an important security and safety issue. It's a gap in the country, and we recommend that Parliament address that.

On the consultations, there's been dialogue and there were information sessions before the bill was introduced. But I would agree with the witnesses about the kind of in-depth consultations on the bill itself. At the Public Health Agency of Canada, we have discussed the issue. We went out before the bill was introduced with a paper on what a framework would look like, but it was a quick information session.

On the role of the department in this, we've provided good policy advice to the government of the day on the legislation to bring forward. The tradition is that the legislation is seen when first introduced by the government in Parliament. So it's not the usual case that you consult on the legislation itself before it's introduced in Parliament. But we do need to have the stakeholder input, and this is what we heard from the witnesses. As soon as the bill was tabled we were out there across the country to talk about what it meant. We talked about the difference in risk levels between level 3, level 4, and level 2, with our specific interest being the safety and security on the level 3 side, and using the level 2 in a mostly voluntary regime to be able to get good biosafety messages out there.

Once the bill was a public document, we knew right away that we had to get out there, and we were free to talk to researchers across the country on that. We've looked at the letter from B.C. and we want to continue that. That's where true consultation can start on the regulatory side of things.

As far as what's there, concerns were put forward about whether we were going to get the regulations right. You have a clear view from a province of what they're going to be saying to us in the regulation, and I think that's the start of a very good dialogue.

● (1635)

Ms. Joyce Murray: Thank you.

I would contend that's not the only way to do it. Having brought forward a number of bills myself in a past life, I know you can consult fully before you draft the bill so it actually reflects the input of the very important jurisdictions this will be affecting.

I'm not sure who this question goes to, but clearly the regulatory burden goes up with this bill. I know that years ago in British Columbia we did a count of every regulation and regulatory—

The Chair: You only have 30 seconds left, Ms. Murray.

Ms. Joyce Murray: Is there any assessment of exactly what regulatory burden this will apply on the labs and the client sites?

Ms. Theresa Tam: I think that is in the development of the regulations where we really need to consult. Our intent is to get that balance between science and innovation and biosafety and biosecurity, which means that the burden is going to be much less in terms of level 2 than for select 3s and 4s.

We think the level 3 and 4 laboratories already comply—almost all of the 150 laboratories—with the current human pathogens importation regulations. So for them this is essentially already in place.

I think what we're hearing today, and what we have heard in the information sessions and in a letter that British Columbia has crafted, are some of the details, and the devil really is in the detail of implementation. How would you structure your program so that cost is minimized? How would you structure a program for people who are working with the less dangerous pathogens, the risk group 2s? We're suggesting a less stringent requirement. So if you have no requirement for security clearance, if the inventories are very basic and you don't have risk groups 3 and 4, we're promoting a basic level of a national standard on laboratory biosafety.

I think the risk group 2 discussions are interesting, because we already require that people who import risk group 2 pathogens follow the laboratory biosafety guidelines under the human pathogen importation regulations. What we're suggesting is that for the 3,500 labs that we know are already doing this—including risk group 2 for importation purposes—we level the playing field in terms of all the other ones also requiring reasonable laboratory safety guidelines. If you remove risk group 2, you're going somewhat backwards on the human pathogen importation regulations and saying we're going to have a lower level than what we currently have for the 3,500 laboratories.

I think we will discuss all of the issues in terms of security clearance, costs, and not duplicating efforts already being made in the provinces in terms of how they're already looking, for example, at inspections of laboratories. We'll see where we can harmonize processes and increase efficiency in the development of the programmatic framework and the regulations development.

The Chair: Thank you, Dr. Tam.

Ms. McLeod.

Mrs. Cathy McLeod (Kamloops—Thompson—Cariboo, CPC): Thank you, Madam Chair.

It's actually been very timely, at least to my thinking, that we had our previous panel and now we have an opportunity to discuss with you also. It really gives a much more robust understanding of the issue.

I'm sort of puzzling over one piece a little bit. We certainly heard very clearly from our university researchers that level 2.... They had a discomfort that the regulations would take care of that piece of the problem. But I also understand that we have laboratories across the country with level 2 that are not university laboratories. Are you suggesting that this is going to up their standard in terms of care? Can we just talk a little more about that piece?

Ms. Theresa Tam: Yes, it speaks a little bit about the different schemes currently existing in provinces as well. Provincial schemes and provincial guidelines and requirements tend to address certain laboratories—for example, the medical diagnostic labs, or there may be requirements for research grants for the research labs. There is not a single national standard that addresses all laboratories, and they may include people handling water treatment testing laboratories, environmental labs, as well as research, and Canadian academic and diagnostic communities. We believe it's very important for them all to have a national foundational piece of laboratory safety level. So we absolutely want to level the playing field.

We know that the research labs are probably the really good ones; the ones that the witnesses are from are already following laboratory biosafety guidelines. We do not believe the implementation of the bill, when you're already doing what we're expecting you to do, will result in a lot of extra effort in terms of duplication.

In terms of the processes and reducing administrative burden, we will do what we can in terms of program design to try to harmonize some of the different pieces. But you're correct, we're trying to level the playing field. There are lots of other labs out there that are not your absolutely brilliant research laboratories that are already following the guidelines.

● (1640)

Mrs. Cathy McLeod: That would add two quick things.

One, we saw a very extensive document for importing pathogens. I would presume this would be something that could be harmonized, so that it's not duplicated harmony.

Ms. Theresa Tam: Exactly.

The idea is that under the licensing scheme, for example, for a university or whatever, we will take into account the importation fees as well as addressing the licence to transfer pathogens of a particular risk group across Canada between institutions, etc. The requirements for permits and licence can actually simplify and harmonize some of those areas. We will not be requiring separate import permits and separate other licences for the domestic fees. That will be harmonized.

Mrs. Cathy McLeod: Thank you.

The Chair: You have another minute if you would like to use it, Mrs. McLeod, or if you'd like to share your time with one of your colleagues.

Mrs. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Madam Chair.

I think Dr. Singer said pathogen security does not equal biosecurity. He had a concern that this bill couldn't cover everything, but that was a concern he raised.

Could somebody please comment further on that?

Ms. Theresa Tam: I think we welcome Dr. Singer's ideas. The two of us certainly have other dialogues. There is a much bigger piece to the whole picture, for sure. However, this bill and the ensuing regulations will address one step of the way. It is not the whole answer to biosecurity. He suggested other ideas, and I'm sure other researchers or other experts will have other ideas as well.

I think the witnesses preceding us also gave us some ideas as to what might be in an expert advisory committee to advise us on the development of the regulations and, over time, on what should be in the different risk groups, etc. We are envisaging the development of a committee. This is already under the Public Health Agency of Canada Act whereby the minister can strike expert committees to address the needs of the development of the regulations.

The Chair: Sorry, Mrs. Davidson, your time is up.

Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you very much.

Mr. Ouellette's presentation and Mr. Matlashewski's were very interesting. The scientists said that they had not perhaps been consulted on the now-defunct Bill C-54. Instead, they had information sessions.

You heard them. They agree with the idea behind Bill C-11, but they have some concerns with very specific points. I would like you to tell me how you could amend Bill C-11, now that you have heard Mr. Ouellette and Mr. Matlashewski give their side.

● (1645)

[*English*]

Ms. Theresa Tam: Thank you for the question.

Again, the experts are supporting our concept that we must have really robust consultations on the development of the regulations. We know it would take another two years or so before we can develop the regulations. That's not only because the regulatory process in Canada is very robust. We need them to input into how we're going to design and implement the programs. Without their input we can't draft the regulations. That's very clear to us. This is the beginning of a very meaningful dialogue we hope we're going to have with them.

Mr. James Gilbert: If I could add to that in terms of specific questions, when we got out there with the legislation there were a lot of questions. The act itself is the shell, and the real details that are of concern to researchers and administrators of the universities are in the regulations and the program design. In terms of the bill itself, only certain elements are going to come into force right away, like the prohibition on smallpox. We think that makes sense. We want to have that prohibited. The rest of it is only going to take force through the regulatory consultations we're going to go ahead with. We're learning a lot by discussions. How we would set up a program around a large university like the University of Toronto with very sophisticated biosafety committees and governance around that is going to be a lot different from how we deal with an individual lab doing some testing in food safety, for instance. There's a cabinet directive that we need to consult on regulations, and of course we'll do that, but to get good programs, to get good regulations, we'd need to because of the complexity of the work.

With the bill itself, after dialogue with stakeholders, we think we've got the right balance in the bill between innovation and safety and security. It's really going to be the regulations that need to take quite a while. The Public Health Agency of Canada is committed to do this robust back and forth dialogue with stakeholders.

[*Translation*]

Mr. Nicolas Dufour: There was another fear, mostly expressed by Mr. Ouellette, that the inspectors would perhaps have too much power under Bill C-11 and that this could slow their work down. I would like to hear your response to that.

[*English*]

Ms. Theresa Tam: I believe there was a change between Bill C-54 and Bill C-11 so that the inspectors must have a reasonable belief that whatever is happening in a laboratory pertains to the application of the act or the ensuing regulations.

We have also thought about how to harmonize what might be already in existence in provinces. One of the ideas was to delegate authority, and the bill does allow that. If we trained provincial inspectors already inspecting labs to also have the delegated authority to inspect under the Human Pathogens and Toxins Act, we would be able to leverage each other's capabilities and resources and not duplicate the impact on the laboratories.

The Chair: Thank you very much, Dr. Tam.

I will now go to Mr. Uppal. I understand you're sharing your time with Mr. Brown

Mr. Tim Uppal (Edmonton—Sherwood Park, CPC): That's right.

The Chair: Thank you.

Mr. Tim Uppal: Thank you, Madam Chair.

Thank you for coming back.

My question comes from our guests previous to you. They were talking about security screening and how it's going to be bothersome in some ways, especially for students and others visiting. Can you explain why it's needed and why it was put into the bill?

Ms. Theresa Tam: The bill does deal with biosecurity, and post-9/11 many of our allies moved forward with legislation that dealt with biosecurity. We do not currently have any scheme in Canada that focuses on the need to keep inventories or track who has access to the most dangerous pathogens.

We are proposing in the regulatory framework that the security clearance be commensurate with the risk group of the pathogens. For risk group 2 we are not thinking of requiring security clearance, and that applies to the vast majority of laboratories. There are only about 150 of them left that deal with risk groups 3 and 4.

We are thinking of looking at select risk group 3 agents. For example, working with HIV or TB is not the same as working with anthrax, which is also in risk group 3, or the SARS virus, which has disappeared from our human population but is a risk group 3. Through the development of the regulations, that will also be consulted upon with the stakeholders.

In terms of risk group 4, Dr. Plummer and his next-door neighbour have the only level 4 laboratory in the country, and they already do security screening.

● (1650)

Mr. Tim Uppal: Thank you.

The Chair: Thank you, Mr. Uppal.

Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you.

It has been mentioned that there haven't really been any serious incidents of bioterrorism in Canada involving human pathogens or toxins. Are there examples you could point to outside of Canada that would highlight the need for this regulatory framework?

Ms. Theresa Tam: Yes, and I think Canadians remember most the SARS virus, which has now been eliminated from the human population through a global effort.

In Beijing, China, the SARS virus came from infected laboratory workers who infected their family members. So if that type of situation isn't contained, the SARS virus could re-emerge in our population, and nobody wants to repeat that scenario.

That is something that luckily has not happened in Canada. But let me stress that after the elimination of SARS circulation in Canada, there are probably a number of laboratories that host the SARS virus. We would like to know which laboratories these are, but there's no formal, systematic mechanism to find that out. You can do surveys and things, but we have no authority to ask who possesses the SARS virus.

On another example, salmonella is a risk group 2 pathogen, but in Oregon it has been used to spike salad bars. Someone put salmonella in the salad bar, and that is an act of bioterrorism. Another example is the anthrax letters in the United States. But in the former Soviet Union there was a release of anthrax that not only affected lab workers but was distributed in a plume because of the winds, and it infected people outside the laboratory in the community itself.

So many of these agents are in the risk groups 3 and 4. They are the ones we worry about the most, but people can use salmonella, E. coli, or other viruses.

Another thing that people may know about is the polio virus. The polio virus is undergoing eradication. It has been eliminated from the Americas. As part of our responsibility to the World Health Organization—and we signed on to this—we should know where polio viruses are in Canada. Save trying to do some surveys, we have no authority or ability to actually figure this out. So we were not able to complete our reporting to the WHO to the extent we would have liked. We did the best we could, but this bill will allow us to really track who has the polio virus, the SARS virus, etc.

The Chair: Thank you, Dr. Tam.

We're certainly learning very valuable information today.

Ms. Duncan.

Ms. Kirsty Duncan: Thank you.

I'm struggling with the fact that we do not know what labs contain levels 3 and 4 viruses today. It is very positive that we will know that.

What about emerging threats or acts of bioterrorism? Are we going far enough with this legislation?

Ms. Theresa Tam: It again speaks to the more comprehensive, overarching approach we need. A bill or regulation can only go so far in ensuring biosecurity. Security screening provides you with one level of reassurance, if you like, that those who have access to levels 3 and 4 pathogens have at least undergone security screening. Beyond that, there will always be some individuals who do something you never really anticipate.

● (1655)

Ms. Kirsty Duncan: What are the possibilities, after the rights have been created, to bring this back to committee?

Ms. Jane Allain (General Counsel, Legal Services, Public Health Agency of Canada): The regulation-making process, as Dr. Tam alluded to, is a very onerous process with very transparent and meaningful consultations. On the process itself, they go out and consult on their intentions in the regulations, and then they pre-publish the regulations they draft. That is in the *Canada Gazette*, part I, and there's a consultation period following that.

Based on the feedback and the information they receive, the department goes back and looks at it again from a more critical view and does another full re-write of the regulations themselves before they publish them finally in the *Canada Gazette*. There's a requirement through that gazetting process to talk about your regulatory impact assessment and describe what you heard from the stakeholders and why you addressed them in a certain way. So all of that is public.

Ms. Kirsty Duncan: This is something we talked about on Tuesday. I think we acknowledged that a duplicate system has been created, for example, in Ontario. How will that be addressed?

Ms. Theresa Tam: To the extent that there are provincial-territorial guidelines, or some provinces and territories have requirements in place, they generally are regarding workplace health and safety or quality assurance related to diagnostic capabilities. They differ from jurisdiction to jurisdiction. Rather than just directing a specific population, such as laboratory workers, the bill is broader—the Canadian public.

There are no comprehensive provincial schemes that address every type of laboratory in a province, such as medical diagnostic versus water testing versus university, etc., and they certainly don't focus on requirements such as keeping inventories or tracking who has access to what.

Ms. Kirsty Duncan: Dr. Tam, I understand that, but the question is, how are we going to look at...? There is a system of duplication here, so what are we going to do to deal with it?

Ms. Theresa Tam: In the development of the program implementation and regulations, what we are looking at is areas where we can harmonize. So, for example, if there is an inspection scheme in a province—it may only be directed toward medical diagnostic labs, but if one exists—we would leverage and not duplicate the efforts. As I say, you can have the same inspector reporting, and we may have a more streamlined reporting mechanism so that the lab isn't required to have too many routes of reporting. We could harmonize some of those.

Ms. Kirsty Duncan: Is that in the legislation? There's some concern from the universities, for example, and the labs in this area. Could that information be in there and clarified?

Ms. Theresa Tam: The way we've approached this is really to do it through the regulatory development process. We had some very extensive discussions about this concept of equivalency at the bill's drafting stage; there was much discussion. The issue was the interpretation of equivalency and the objective of certain schemes, and it was very difficult to arrive at that benchmarking piece. Really, we feel that the key step, moving forward, is, as we've now publicly stated, that we would look at ways of harmonization through the program implementation process.

● (1700)

The Chair: Thank you, Dr. Tam.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you very much.

I'd like to hear a direct response to Professors Ouellette and Matlashewski. Maybe you, Dr. Plummer, as someone from the research/academic/scientific community, heard their concerns. They're very worried about the impact on their ability to encourage students and be able to teach them and provide opportunities for scientific innovation. Can you respond to their concerns?

Dr. Frank Plummer (Scientific Director General, National Microbiology Laboratory, Public Health Agency of Canada): Yes, I'd be happy to.

In my testimony on Tuesday before the committee I mentioned that when I initially looked at what was being proposed in the bill, I had many of the same concerns. I've been reassured and convinced by my colleagues in, I would say, rather vigorous discussions within the agency that this will be addressed through regulations, that there will not be onerous burdens placed on individuals working on level 2 agents, and that teaching and research will continue. There will be some burden, but I don't believe it's over-burdensome; it can be managed.

Many of the things that need to be put in place or would be required by the bill should be there anyway in a well-managed laboratory—inventories and those sorts of things. Although the risk to the public health of a laboratory-acquired infection by a level 2 agent is low overall, there is a risk. There's an influenza virus currently circulating, of H1N1 type, that probably originated from a laboratory accident or intentional release in Russia in the 1970s. It's been circulating ever since, causing a minor pandemic. So it's not zero-risk.

Ms. Judy Wasylycia-Leis: I hear what you're saying. I thank you for your assurances, but I'm a little concerned and wary about leaving everything to regulation. We've been down that path before. We lose control as parliamentarians. Unless we require and pass a motion that says all regulations must come before this committee, as we've done with reproductive technologies, and we're still waiting—I think about eight years after the fact—I'm not confident we have any assurances we're going to achieve the desired results. We're hearing some very significant concerns, and I think we need to be able to tell the academic community something more than to just wait for the regulations.

So I'd like to hear about that, and then of course the other suggestion around something more concrete than simply saying we deal with external advisory committees all the time, or it's part of the process...something. If it's not in the law and we're going to leave it to regulations, then we need something we have some relationship with, some way to hold accountability and transparency.

Mr. James Gilbert: For us there's always a choice in terms of recommending what would go into legislation and what would go into the regulation, but as I was saying the last time I was before the committee, it's very complex, and members and witnesses are rightly saying you need to work with stakeholders and get it figured out. A lot of this is working over a long period of time to make sure the governance systems mesh, to make sure the program is designed in a way that makes sense and the regulatory system fits the issues we're dealing with. To try to get that right in legislation, where it's locked in, is very difficult, and the regulation moving it in there allows us to have the consultative process we need at the Public Health Agency of Canada to be able to set up the best program.

Beyond that, though, we are here today saying, for instance, we're not going to have security clearance for level 2. We're in front of the House committee to say this is our intent in moving forward with that, that the inventories will be more simple, that the licensing for the regime for level 2 will be a web-based system where you'll put in your request to the Public Health Agency and analysts will have a look at it and make sure you've got an inventory, and there's your licence. So we're really trying to make this difference between the really deadly level 3 and level 4 pathogens and what that's going to look like and very clearly articulating that on level 2 the focus is going to be on good biosafety, just so we know who's got what and that what they actually have in their lab is a level 2 and not a level 3 or a level 4. So we need to find that out, and that's why we're going to the level 2 side.

But on the regulatory side, we want to get it right. We want the dialogue with stakeholders, and the regulatory process allows us to do that much better than the legislative process does.

● (1705)

The Chair: Thank you, Mr. Gilbert. I'm sorry. Our time is up.

Mrs. Davidson.

Mrs. Patricia Davidson: Thank you, Chair. I'll ask the question I didn't get enough time to ask the last time.

We were talking about pursuing biosecurity issues. Does the department have concrete plans to continue on biosecurity? Are there concrete plans to set up an advisory committee to continue with this further implementation? I think everybody has said this bill, although it gives pathogens security, hopefully, it does not give biosecurity. So are there further plans to go ahead with that?

Ms. Theresa Tam: I think we heard some good ideas today. Dr. Singer has already discussed with us the concept of having the Canadian academies look at a study, at least to start off with. So we are certainly going to be looking at some of those approaches.

In terms of counterterrorism or bioterrorism, there are many other aspects to the approach the Public Health Agency does take. For example, we have a smallpox plan and we have vaccines stockpiled. We have anthrax countermeasures, etc. So there are many other components, but I think what Dr. Singer has spoken to in terms of the emerging pieces are probably the areas...the "state of the art, what might be coming next" approach. We haven't really looked at it in any concerted detail. There may be other aspects of government, such as in defence research, that do look at some of these aspects, and we will certainly be collaborating with those departments as well.

Mrs. Patricia Davidson: Thank you. I'm sorry I wasn't here Tuesday to hear your presentations, but I have a letter I received from the Ontario Agency for Health Protection and Promotion, and I'm assuming you have received that letter as well. They had expressed some concerns about several specific areas where they thought further scrutiny was warranted, and they talked about consultation before making regulations, avoiding multiple inspection regimes, and that may be what Ms. Duncan was referring to. They also talk about the scope and application of a legislation, the licensing, clarity on occupational risk versus public risk, and disclosure of information to the minister.

Would you like to comment on some of those things as far as Ontario is concerned, and could you tell me if they are similar to the concerns raised by British Columbia?

Ms. Theresa Tam: I think they are quite similar. Some of the implementation issues are also similar to what we heard in the initial information sessions. We are going to be meeting with Dr. Vivek Goel next week to go over things in detail.

We've talked a little about security clearance. We're going to have a concerted look at trying to harmonize and not duplicate efforts in the program design and regulations.

I think there's also some anxiety about not having bottlenecks in security clearance, for example. On the one hand, having the federal government shoulder the cost of security clearance is a plus point, but there is anxiety around whether they can process them fast enough. We need to look at the security clearance program itself, with the stakeholders as well, to see what is acceptable, feasible, and reasonable.

Regarding the issue of the power of the Minister of Health, while it's essentially on par with the usual legal language in a bill, we wanted to reassure the provinces and territories that there are limits. The minister can have information disclosed or exercise the powers in the bill only if it pertains to the act itself. On the two other conditions, certain information can be disclosed if there is imminent danger or a public safety incident, or if there are international reporting requirements, such as the international health regulations. So there are some very specific boundaries pertaining to those powers.

I don't know if Jane has anything to add on that.

● (1710)

The Chair: Thank you, Dr. Tam.

We'll now go to Dr. Carrie.

Mr. Colin Carrie: Thank you very much, Madam Chair.

I want to bring forward a couple of things. With any type of regulation or legislation you want to make sure it is balanced. I think you've put in a significant effort and done a good job of getting that right, but I do have concerns. I think Dr. Ouellette was saying that sometimes in these labs they do genetic manipulations, and pathogens are modified. Will each of these things, in day-to-day work, be put under onerous regulations? I don't want to do anything to impede the research and development we do here in Canada.

I wonder if you can think about what Dr. Matlashewski was saying and alleviate some of those concerns. We have this legislation in front of us. I've gone over it and it looks really good. Is there anything else you'd like to say that will help the research community know that you're going to be committed to consulting with them as things get phased in?

Ms. Theresa Tam: What is enlightening to me is that there is a gap in trying to increase awareness of what happens between the bill, which is all-encompassing, and regulations development. We need to do a better job of communicating that.

We're absolutely committed to consultation. On some of the current framework, we're thinking about a licence that will encompass the risk group as a whole. We're not asking for licences for individual pathogens. If you manipulate a pathogen, as long as you don't increase its impact on health or its pathogenicity, and it's within that scope, you're not required to have another licence just because you've manipulated an organism. If, however, the way you've manipulated the organism increases its pathogenicity and brings it to a level 3 or 4 risk, give us a call about any questions on that. We would like to discuss it, and this expert scientific committee can be brought to bear to discuss some of those situations.

In the licensing scheme itself we can certainly go a long way toward minimizing the actual burden on the research community.

Mr. Colin Carrie: Would anybody else like to comment? Did we learn something today, in listening to the researchers, on how to better set that out?

Dr. Frank Plummer: I think we were aware there would be concerns around some of those things. The scientists who work with me in the national microbiology lab have expressed those kinds of concerns. But if you have a very limited licence, as Theresa just described, I don't see that as being onerous. I'm going to have to implement this too, and I don't see this as being onerous at all.

Mr. Colin Carrie: I think my colleague Mr. Uppal wants to say something.

The Chair: Mr. Uppal, would you like to finish off the time? You have two minutes.

Mr. Tim Uppal: Thank you, Madam Chair.

Just to touch a little bit on what you mentioned about the committee of scientists who would be dealing with some of these issues, in a practical sense, how easy would it be to get hold of them, how often are they going to meet, and how quick would the turnaround be on a question a laboratory may have?

Ms. Theresa Tam: I think this is where, again, we have to develop the advisory committee. There is in existence a reference group already for the current scheme and for the consultations, potentially, on the development of the regulations.

What we will see is that when this bill and the regulations development come into force, as it were, we will hear from a lot of different people. There are many scientists and many experts, both in Canada and internationally, whom we can leverage.

Some of the concept includes that we will have an expert advisory committee, but we also have rosters of experts on very specific pathogens, people who are already on a roster and have agreed to provide us with expert advice as, if, and when needed, in a fairly nimble fashion.

We actually need rosters of experts not only for this particular bill or regulations; we will need them for a nimble response to emerging pathogens in any case. As you can imagine, we already have two Leishmania experts, and they will probably want to sign up to help us, because they'll be ready to provide input. So I think there are incentives on both sides to create a committee that is viable, up-to-date, and effective.

What we would like to do is, potentially, to draft a concept we can consult on—"What do you think of this concept of the structure of a committee?"—to see what the reactions are from our stakeholders.

● (1715)

The Chair: Thank you very much, Dr. Tam.

We have just a few more minutes. We have gone through our rounds. Is there anybody here who would like to ask some additional questions? We have a few more minutes, if you would like to do that.

I have Dr. Bennett, Monsieur Malo, and Ms. Wasylycia-Leis. We won't get through everybody.

Dr. Bennett, you were first.

Hon. Carolyn Bennett (St. Paul's, Lib.): I have two things. First, is there anything you want to answer respecting the previous panel's concerns? I'm sure you picked them up: the clearance piece, around colleagues sharing samples, and those kinds of things. Do you feel you would like to offer either a "what a great idea" or "yes, but" kind of answer to what the previous panel said?

My second question is this. We know that sometimes with advisory committees on science-based topics, governments are criticized on the grounds that as soon as the panel is announced, people know what the answer is going to be. Do you have any thoughts about how you'd put it in place and whether the Science Advisory Board of Health Canada could be involved in picking a panel of the best possible people to give advice on something as important as this?

The last question comes from Derek Lee. It seems that the back-end check on regulations is missing in this bill, in terms of their coming back to committee or back to Parliament. In all of these, on every single bill that has to do with regulations and science, we will be putting in an amendment from Derek Lee asking us to.... You can't take the front end and the back end out of parliamentary oversight.

Ms. Theresa Tam: There were a number of questions that some of the other panellists may be able to address better, but I want to pick up on a couple of other points that the previous witnesses mentioned.

The issue with risk group 2 is I think of greatest concern. What we have in the bill is a balance between a list that provides a level of clarity and some definitions, which will help us catch things that are not listed, for example. We've heard, from the E. coli issue, that you want to make sure we only talk about pathogenic types. We believe that the bill as a whole is only talking about human pathogens and does not address things that are non-pathogenic to humans.

But we are thinking of potentially putting in brackets—after "E. coli", for instance—the pathogenic strains, which is reasonable. It's clear to us, but it seems to have generated a lot of angst among the community. While we can clarify that as an overarching piece, there are fairly easy ways in which we can probably deal with the risk of group 2 pathogens. But we are only interested in the ones that are pathogenic, not in the non-pathogenic ones.

In terms of the advisory committee, we'll certainly welcome any ideas people may have. We want it to be open and transparent. It has to be science-based; I think that is the fundamental principle. It cannot—

Hon. Carolyn Bennett: The advisory committee must give transparent advice to the minister. The minister can do what she wants with it, but I think Canadians need to know what the scientists said. Then, if the minister has to make a political decision, that's different; that's fine. At least Canadians would know what the science says.

Ms. Theresa Tam: Yes, and I agree with that too.

The Chair: Thank you.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Thank you, Madam Chair.

Since the beginning of this study, since this bill was first introduced, the views we have heard most have been from people from the department. Today, we have heard from three researchers, three professors in the field. What we have learned today is quite new. We have learned that it is possible to preserve the spirit of the bill and what it tries to do while still removing everything to do with Level 2. I have not heard you make a sufficiently strong case that, if Level 2 is removed, problems will be caused and that the spirit and the goals of the bill will not be preserved. I would like to hear your response to that subject, amongst others.

Professor Matlashewski told us that it would slow down research, delay breakthroughs, and prevent our researchers and our industry from being on the cutting edge of technology and meeting the needs of an industry that wants to set itself up here. I would like to hear your response. It is a problem if keeping Level 2 in the bill prevents us from doing our job properly.

There is another problem. I am sure that you are going to tell us that everything can be settled in the regulations. I would like to know if you are aware that you are asking us, as parliamentarians and a community of scientists working in laboratories, to leave everything to you.

● (1720)

[*English*]

Ms. Theresa Tam: I'd like to answer that by saying that there's assurance that the program is based on the current human pathogens importation regulations. In fact, these labs are already doing this, and it has not stopped them from doing research or innovation. We're trying to level the playing field by having all the other labs that are not importing being brought up to the same standard as these labs that are already importing.

If you remove risk group 2, what you're dealing with is that we are going to probably have to keep the importation regulations—which have risk group 2 in them—as is, and then you're going to have an unlevel playing field, of those who are acquiring things domestically versus those who are acquiring pathogens from abroad. SARS is a domestic pathogen at this point, for example.

So really, it is built on a current regulation.

The other concerns are about security clearance. We're saying you don't need it for level 2, and you can have people accompany specific scientists working at level 3, if their security clearance has not already gone through. There are inventory issues that people want to discuss, and cost implications, and those are the specifics we cannot necessarily work through until the programmatic details are in place. That's why it's much easier to deal with those in regulations than to specify them in the bill itself.

[*Translation*]

Ms. Jane Allain: The only thing that I would add to Dr. Tam's remarks, is that, under clause 33(b) of the bill, if the person is accompanied and supervised by a person who holds a security clearance, work can go on. It is explicitly written into the bill. The other details of level of risk and who has to be subject to security will apply only to Levels 3 and 4. The concept of being accompanied is in the bill.

[*English*]

The Chair: Thank you, Ms. Allain.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you very much. I have one quick question.

I'm very worried about leaving so much to regulations. I'm worried on behalf of the academics who are here today and who have raised concerns. I hear you try to answer them, but I still think we need some other way to assure them that their concerns will be addressed.

But I'm also worried about the lack of control over regulations in the face of what some of big pharma might be looking to do under the rubric of this legislation. I don't think we've had any representation from big pharma come to our committee wanting to present. That makes me very nervous. They think the bill's great, and I think there's a concern. I'm not sure whether you've had consultations with them, but to leave things this wide open sure makes me uneasy.

Ms. Theresa Tam: Jane might be able to speak to why it's important to have the bill have the higher powers in terms of being nimble in circumstances where you really do have to act very fast in the interest of public safety or public health.

In terms of the pharmaceuticals, they were certainly involved in consultations. In Quebec, for instance, the GSK and others were at some of these sessions. It is true they have not voiced any concerns with this current bill. I think all of them already import pathogens, for example, already under current regulation, and they have not voiced specific concerns to us. But it would be interesting, for sure, to hear from some of these areas.

● (1725)

Ms. Judy Wasylycia-Leis: So we'll see.

The Chair: I want to thank you so very much, and a special thank you goes to our guests. You've come back twice, and I certainly appreciate your insightful comments. I think our committee has really benefited from your presence here. *Bon voyage* back to Winnipeg and other parts where you're going.

The committee is dismissed.

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