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Chair

Mrs. Joy Smith

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● (1530)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good afternoon, everybody.

I would like to welcome our guests to our committee. It's indeed a pleasure to have you.

Today we have our witnesses from the University of Toronto, Dr. Ghalami, senior biosafety officer for environmental health and safety. Welcome. We have Wayne Conlan, principal research officer, as well.

From the Public Health Agency of Canada, at the second round, we have Dr. Butler-Jones and Dr. Tam.

This round is going to go from 3:30 to 4:30, so we're right on time. I would ask that each organization give a ten-minute presentation. We're looking forward to your presentations.

Dr. Ghalami, would you like to start first?

Mr. Ayoob Ghalami (Senior Biosafety Officer, Environmental Health and Safety, University of Toronto): Honourable members, first of all I would like to mention I do not have a PhD; I am not a doctor.

My name is Ayoob Ghalami. I am the senior biosafety officer for the University of Toronto, speaking as an individual today. Thank you for the opportunity to come and talk on Bill C-11. I think it is a fantastic bill. I fully support it, for reasons I will explain.

As a biosafety officer, my job is on a small scale of what the Public Health Agency of Canada does. I look after 250 labs and three campuses at the University of Toronto. I look after animal facilities that deal with biologicals and I also deal with clinical settings that are set within our university-controlled premises.

I think I would be terrified if I were in public health and got supervision of a lab where I don't know what they have, what they deal with, and where they have it. The burden will be on my shoulders to go and deal with it tomorrow if anything goes wrong. How do I do resource management? How do I do proactive means to make sure individuals are trained? And how do I deal with emergencies?

It's really hard to do proper risk management and risk assessment when you do not know the calibre of the stuff you have to deal with. On the other hand, as we all know, we are in a society of licences and permits. You can't drive if you don't have a valid driver's licence. You can't get married if you don't have a valid licence. You can't open a restaurant if you don't have the proper permits to open a restaurant. However, it seems we are all fine if someone doesn't have a valid licence or permit to deal with biologicals that have and could have the possibility of having an enormous impact on our community. That terrifies me.

On one hand, as an institution what we have decided to do is.... I think this bill would level the playing field for everyone. Currently if I have a principal investigator who imported the biological agent, they're under binding contract with the Public Health Agency of Canada to follow their guidelines. But if another lab gets the same bug from a hospital they have no obligation to do anything. As an institution we don't see that visible practical, so we treat everyone the same. Another reason for that is the memorandum of understanding, which as a public institution we have signed by tri-council government granting agencies, provides the university with the financial means to do research. So that is how we practise that.

I would also like to mention to honourable members that I am a father of two. I have an eight-year-old and a seven-year-old. I really think I have to build a legacy for us to do the right thing so our kids have a safer and a better work environment than we had. I think that's the least we can give our kids.

So far I am 100% for the bill and I see it hands-on in the field. I run the biosafety program for the biggest university in the country and I think we have an established program. Having said that, we in the university try to do our best. We have established a biosafety committee that has 14 faculty members. We have a virologist, a prion specialist, a microbiologist, we have a vice-dean of medicine who sits on that panel, 14 faculty members. We have an occupational health doctor, two veterinarians, me, and three other senior administrators on this panel to decide on everything. We have mandatory training. Whoever works with biological has to be fully trained. Even if they're faculty members, they have to write a test so we understand they know their obligations. We have mandatory medical surveillance. What that means is if you work with human blood, you will possibly be exposed to hepatitis C and you have to be immunized before you do that. And we also have planned post-exposure prophylaxis for you so if you splash your ocular membrane with blood you can go to the hospital and get treated, because if you've got HIV in your system you have to be treated very quickly; time is of the essence. These are what we have achieved as an institution. But if there are no guidelines, these aren't following the guidelines.

● (1535)

For that reason, I really feel and hope members see it that I as an individual, a citizen, feel how important it is for us to have it. When you send your young kid to a university, hospital, or workplace, you really want to make sure all those proactive actions have been taken, so they're in safe hands.

These were the positive things I had to say about the bill. Now I'll come to the other side.

Biological agents are extremely fluid. To put it simply, we have researchers who work with HIV, which is an anti-virus; they use it as a viral vector, so they use it for gene therapy. The anti-virus can infect dividing and non-dividing cells, but it has a narrow host range. What they do is they take HIV, change the membrane to make sure the host range is broader. So now the target cells it can infect are not just one cell; it can infect anything. On top of that, sometimes they put an oncogene, a cancer-causing gene, inside it to infect. How do you do a risk assessment on that? How do you put it in a schedule? This is not fluid. Schedules are there, fixed, done. This changes all the time.

We want to make sure the bill meets the needs of industry. We change all the time. To put in a solid schedule without input or without routine change is not going to help us. I think there has to be a provision on that.

We, as the University of Toronto, have met with the Public Health Agency of Canada in Toronto and we have mentioned it, and they have agreed there will be some changes, or at least there will be input from experts in the field when they change the category.

The second thing we have confirmation on and that will be cited is the security clearance. I think it's extremely important that we have a secure country. I am not a sportsman. I don't think I needed to say that—my physical looks show it—but the reality is that if you're not a good soccer player you'll run after every single ball and you'll exhaust yourself. When it comes to the time you're going to go score, you don't have the energy and means.

As an institution they decided, and I as a biosafety officer feel that —and I think public health has agreed—risk group two should be exempt from security clearance and all the other stuff. At the same time, public health should have full authority to go to check the institutions for risk group two. Listeria is risk group two. E. coli is risk group two. Varicella is risk group two. It's extremely important that they do have supervision, and there is a model existent out there already.

The Canadian Nuclear Safety Commissioner gives the institution as a whole a permit, so you have a permit to function and they know what you have. At any given time they have the right to come and audit your operation to see what you're in compliance with and what you're not in compliance with. At the same time, you don't have to get a permit to buy anything that you want to buy at any given time. If we get that model for risk group two and have as much control as Bill C-11 says for risk group three, most institutions would be able to function and we would leave a good legacy for our kids, because they would be in better hands than we are.

I thank you for your time, and I welcome questions when my turn comes.

● (1540)

The Chair: Thank you so much.

Now we'll hear from Mr. Wayne Conlan.

Dr. Wayne Conlan (Principal Research Officer, National Research Council, As an Individual): My name is Wayne Conlan. I'm a research scientist with the National Research Council, but I am appearing today as an individual. I'm a microbiologist with 27 years' experience working in level two and level three containment labs in the United Kingdom, the United States, and Canada.

I was a member of the committee that compiled the current Health Canada laboratory biosafety guidelines. Currently, I run a small-animal level three biocontainment facility at the NRC with a focus on highly virulent biodefence pathogens that cause life-threatening infections when inhaled.

I've been the responsible official for the design and implementation of all the biocontainment, biosafety, and biosecurity policies associated with this facility and for training staff in all these areas. And the requisite paperwork occupies more of my file space than all my other activities combined.

Annually, for the past ten years, my facility has been certified for its purpose by the Public Health Agency of Canada and the Canadian Food Inspection Agency. I receive significant funding for this work from the U.S. National Institutes of Health, and therefore my lab must also comply with the U.S. select agent rule, on which Bill C-11 appears to be partially modelled. Consequently, our level three containment facility has been inspected by representatives from the U.S. Centers for Disease Control and Prevention, most recently in October 2008, to ensure that it is operating in conditions equivalent to those required by the select agent rule.

In complying with the select agent rule, our laboratory is already fully operating within the limits being proposed by Bill C-11. For instance, all of our staff with access to our level three biocontainment facility have secret level clearance. Likewise, we already quantitatively update our pathogen inventories every three months. So I don't anticipate that compliance with Bill C-11 will impose any undue additional hardship on the operations of current level three containment facilities in Canada.

It needs to be remembered, in this regard, that many thousands of U.S. researchers are having to comply with the select agent rule, since their federal funding depends on it.

Interestingly, the revelation that the anthrax attack conducted by the U.S. Postal Service was an inside job now calls for even greater restrictions on the U.S. research community, including recommendations that staff with access to select agents undergo mandatory psychological screening. But given the innate eccentricity of many scientists, this could lead to the complete dismantling of the entire U. S. research enterprise in this area. So I hope we choose not to go down this road in Canada.

For the Canadian research community, it's the proposed oversight of level two labs that seems to be the most contentious issue. To date, this has been exclusively managed by the host institutions themselves. However, all such labs ought to be complying with the current biosafety guidelines and should therefore be readily able to comply with the provisions of Bill C-11.

In this regard, prior to the anthrax attack, the worst deliberate case of bioterrorism in the U.S. involved a religious cult contaminating several restaurant salad bars with a level two salmonella species, causing over 700 cases of food poisoning. Indeed, under normal circumstances, level two pathogens kill far more Canadians than level three pathogens. So there is a realistic argument to be made for more formal regulation of these organisms. I guess, on the other hand, it could be argued that level two pathogens are so ubiquitous in our everyday lives that they deserve no special consideration simply because they're being used in research. An analogy with this can be drawn between laboratory rodents, the use of which in research is highly regulated, and wild rodents, which anybody is allowed to kill by any means.

Overall, given the level of compliance being sought by Bill C-11 with respect to level two pathogens, it is difficult to argue against their inclusion in the act. However, level two labs are far more numerous than level three and four labs, and the system for regulating these could be overwhelmed if all these facilities try to register at once to comply with the act. It is incumbent on the Public Health Agency of Canada to ensure that the process of online registration of level two labs is an essentially painless experience that does not delay research progress. Allowing organizations to register all their level two labs in a single application should help in this regard.

There are a few issues obviously addressed by the act on which clarification would be helpful for assessing likely impacts of the act on the research community. For example, many labs use crippled strains of risk group two and three pathogens that are completely harmless, but it's not clear that these will be exempted from the act.

● (1545)

Additionally, many labs not involved in pathogen research use certain toxins in small quantities. A lot of immunologists use cholera toxin or enterotoxin in their immunology research as vaccine adjuvants, for example. Will these labs need to register? My own belief is that they should be allowed to possess a threshold limit of such toxins before being expected to register their facilities.

I thank you for your time. I am willing to answer any questions you might have.

The Chair: Thank you, Dr. Conlan, for your presentation. It was very insightful.

Before we go into the first round of questions at seven minutes per person, I just want to check that it is the will of the committee, as we have some important business that has to be done. I have a motion and a request before us, and I'm going to have to suspend the committee at 5:15. We have bells at 5:30. Is this okay with the committee to proceed in this manner?

We will now be open for questions. Please go ahead, Dr. Duncan.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Good afternoon. Thank you so much for coming and for your comments.

We've been having hearings for the last few days. I think people appreciate the spirit of the bill, and we all want good biosafety and biosecurity, but a number of concerns have come to light.

An example is consultation. Was there consultation? With level two labs, which you both mentioned, will this be very expensive? Will it be onerous? Duplication was a concern, particularly in Ontario and B.C. Privacy was also a concern. There were suggestions that perhaps this should go back to consultation and then be brought back to committee with the regulations.

I'd like to begin by asking whether your organization was consulted in this process. How were they consulted?

Dr. Wayne Conlan: I personally was consulted through direct contact through the Public Health Agency of Canada. They just walked me through the whole process.

Ms. Kirsty Duncan: What concerns, if any, did you bring forward at that time?

Dr. Wayne Conlan: I had a lot of concerns that have probably been raised over the past few days about the level of regulation and how overburdening it might be for the people concerned. The questions I had at that time were largely answered, and the answers largely assuaged my fears.

The spirit of this act isn't that onerous for level two labs. I suppose to somebody who has to deal with all the oversight required for level three, it doesn't seem that particularly hard. Of course I'm not in the situation of the U of T, which may have 250 such facilities to oversee and register.

Ms. Kirsty Duncan: Thank you.

Mr. Ayoob Ghalami: We have been consulted. I think it was in late 2007 that they initially came. Unfortunately, I haven't prepared time schedules and I don't remember. We were also consulted last year and they also came this year. We had three sessions. There was a public session that U of T hosted and a closed-door session with only U of T, at which we had two VPs, a few lawyers, and lots of faculty members. We also hosted one that was for U of T and all other Ontario universities and teaching hospitals. That was closed-door.

They were happy with what was explained. The competency of the individuals who deal with the scientific side of it was not a concern at all. Public health has an extremely good relation with research institutions in regard to the competency of their staff.

The only concern, as I mentioned, was the security clearance for risk group two. If you look around the university, you will see that more than 60% of our staff are from outside. I personally have an Iranian background. I've been in this country for 20 years, but if we go with the George W. Bush definition, I belong to the axis of evil. That puts you in a position to see how much impact it could have on your individual institution. We have people from China and the Middle East, so it enormously impacts risk group two.

● (1550)

Ms. Kirsty Duncan: Okay. I understand.

Mr. Ayoob Ghalami: At the same time, I think it's extremely important that you put it for risk group three, because doing nothing is not a choice.

Ms. Kirsty Duncan: Agreed. Thank you.

Are you satisfied that the government has chosen the most appropriate way to level the playing field?

Mr. Ayoob Ghalami: Absolutely, because now we have two standards. I have a level three lab that is certified. I won't mention the university, but there was a university that wanted some of my HIV samples, but they didn't have a certified lab. And they're more than welcome to run an uncertified lab, because it's not regulated. We refused to give it to them, but I'm sure they'll be able to find it from any hospital. All it takes is to get a blood sample infected with HIV, bring it in, and propagate it.

Nowadays, technology has advanced so much that you really don't need to do anything if you don't want to import anything. There are always alternatives. I think that will be a playing field for everyone.

Ms. Kirsty Duncan: Dr. Conlan, do you think it would be useful for the government to establish an advisory group for this, or a blue ribbon panel?

Dr. Wayne Conlan: I don't want to add to the bureaucracy surrounding this. But I can see for contentious issues, so long as the panel was made up of bona fide experts that the rest of the community had faith in, then why not? I can't imagine there are too many contentious issues that are going to arise as a consequence of this bill.

Ms. Kirsty Duncan: There is duplication. For example, you're at the University of Toronto, you're in Ontario. How will it be to work with duplicate legislation? Do you think it will be changed?

Mr. Ayoob Ghalami: It's totally different. I'll give you other examples.

Any restaurant gets inspected by the Ministry of Labour because it's a workplace. At the same time, you get health inspectors checking on food quality. I think the Public Health Agency is the ultimate authority, but nowadays technology has changed so much that a regular Ministry of Labour inspector won't be able to comprehend the scope of the research. I'm not offending them by any means—they're really good at what they do—but technology has changed. You need a specialist to understand this stuff. I think this is the second complementary step. I understand, yes, paperwork is not good, but the consequence of not acting is not good either.

If you check the research, you'll see that American public health had statistical data from 1951 to 1996, and they had to study 4,000 cases. Out of those 4,000 cases, 61% were research institutions that got lab-acquired infection. You're the worst offenders, because you get used to your bug all the time, it becomes part of the family. There is no administrative control, there is no engineering control, you're in a research setting. The only thing we have is a second set of eyes to come and look, because you get used to your wrong practices. You need someone to come and correct you so you don't do that, and it's safe again.

Ms. Kirsty Duncan: Thank you.

Dr. Conlan, I'll ask you the same question.

Dr. Wayne Conlan: I guess it's a political matter. We're not governed by provincial rules and regulations, only by federal regulations.

Ms. Kirsty Duncan: But you all know other scientists in the field. How do you think that will impact—

The Chair: I'm sorry, we're out of time.

We're going to have to go to Monsieur Dufour.

[*Translation*]

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

Thank you for coming here today.

I have some questions, Mr. Ghalami. You stated that Bill C-11 was a very sound initiative. All of the witnesses who have testified so far have said that while the spirit of this bill is laudable, some of the details are problematic. For example, many scientists have voiced their concerns over the inclusion of risk group 2 pathogens in the bill. They also maintain that some of the concepts are too restrictive and that implementing some of the bill's measures could prove too costly for the laboratories.

You maintain that everything is fine for now, that your laboratories are safe and that you are doing everything you can to avoid any problems. My understanding of that statement is that the existing guidelines are adequate.

● (1555)

[*English*]

Mr. Ayoob Ghalami: Yes. What I can say is that the University of Toronto is a public institution. We have signed a memorandum of understanding with the tri-council that gives us funding. All the funds are conditional on the fact that we have to abide by the third edition of the guideline that the Public Health Agency of Canada has in place. So, institution-wide, we do that.

If this bill were to pass tomorrow and there is no security clearance requirement, as we have been promised by the Public Health Agency of Canada, we wouldn't need to do anything differently as an institution. It may not be the case with other private sectors because they don't have to abide by the rules. But for us, we have to meet that in order to get government funding.

So as a biosafety officer, I don't need to do anything differently from what I do currently if the security requirement is left out. And we strongly urge that this get lifted for risk group two, because that will have an enormous financial impact on us.

The Chair: Do you have another question, Monsieur Dufour?

[*Translation*]

Mr. Nicolas Dufour: Yes.

Why would the other universities be concerned about the bill?

[*English*]

Mr. Ayoob Ghalami: I can't speak on behalf of other people. I wouldn't know what their concerns are.

I have talked; I get calls from other institutions asking why and when we started our post-exposure prophylaxis in our medical surveillance program. I can guarantee you that half of our institutions don't have it. But we have worked hard, we do have it at the University of Toronto, and it's the right thing to do. If someone has not done it, and they don't want to do it, I can't talk on their behalf.

[*Translation*]

Mr. Nicolas Dufour: By providing for overly restrictive frameworks, particularly as regards the inclusion of risk group 2 pathogens, an area that poses a problem for the majority of scientists, are you not worried that research will be unbalanced? Some scientists told us that labs in the United States had shut down because of overly restrictive regulatory frameworks. Could the other universities or research centres be penalized if overly restrictive regulatory frameworks are brought in?

[*English*]

Mr. Ayoob Ghalami: You mention a great point. When George Bush came into power and they didn't want stem cell research, we got lots of scientists. It was their loss, our gain. We got lots of scientists from the States who couldn't do research there and they came to Canada, exactly. If we have such a restrictive rule, we will lose scientists to elsewhere.

But the reality is, if I go back to my initial statement, that if the security requirement, as promised, gets lifted off risk group two, and if, as we have discussed with the Public Health Agency of Canada, they adopt what the Canadian Nuclear Safety Commission does—namely, you get certified as an institution so that you can deal with anything under risk group three—it will not have any paperwork burden or administrative burden on us.

There are two "ifs" that I put: one, if they give us an institutional licence, which they've agreed to because it will be good for them as well, since they won't have to do 250 labs individually; and two, if they elevate the security requirement for risk group two. My clearance on the bill is that if these two, as promised, go out, then we won't have to do anything differently than we do. If other institutions are not doing it, they owe it to their staff and students to do it, because that is the right thing to do. I can't talk on their behalf.

[*Translation*]

Mr. Nicolas Dufour: Have your scientists made any recommendations concerning Bill C-11? Have they shared their concerns or views with you?

[*English*]

Mr. Ayoob Ghalami: Absolutely. Change is always hard. One major concern that scientists especially have is the jail term, that if you do something wrong you go to a jail, with a car thief. But I guess this is the only way that bill could be introduced. There are concerns, and the reality is that the consequence of not acting properly is something I personally disagree with, having a scientist go to jail. If we can introduce a bill that has a different kind of consequence, as with the Canadian Nuclear Safety Commission, I would personally prefer that. But that does not eliminate the fact that we need Bill C-11 yesterday.

We need a federal baseline that tells every single individual who works with virus bacteria, with the potential to make individuals sick, that they have the same rules to play with. Listeria, as I mentioned, is risk group two; E. coli pathogen is risk group two; salmonella is risk group two; varicella is risk group two; HIV in blood is risk group two. These are serious pathogens. We need to regulate them.

● (1600)

The Chair: Thank you very much, Mr. Ghalami.

We're now going to go to Ms. Hughes.

Mrs. Carol Hughes (Algoma—Manitoulin—Kapuskasing, NDP): Thank you.

This certainly is a bit different from what we've been hearing across the board with regard to the other witnesses, so you can sense the little bit of apprehension that we have now. We're trying to figure out what's going on.

I'm curious, Mr. Ghalami, how long have you had the responsibility at U of T?

Mr. Ayoob Ghalami: This is my third year.

Mrs. Carol Hughes: How have you been coping up to now with regard to the way things are in terms of your restrictions and all that? I'm just trying to get some sense of it, because you've indicated that there is a mandatory training, but you've used words like "terrifying" and "underlining your concerns". I'm just trying to get some sense of whether you've raised these concerns in the past.

Mr. Ayoob Ghalami: I said I would be terrified if I were the Public Health Agency of Canada and having the authority without knowing what I am responsible for. It was nothing to do with or relevant to my work. If the University of Toronto had hired me as a biosafety officer without telling me what we have, where we have it, and who does what, I would never have signed up for that job.

The Chair: Go ahead, Ms. Hughes.

Mrs. Carol Hughes: We've had some concerns with regard to what's in the bill.

First of all, they talked about broad powers for the minister. Now, you didn't talk about the broad powers, but other people did. This bill actually would give broad powers to the minister and there is some concern with regard to that.

You talked about E. coli. What we heard over and over again is that E. coli actually would probably be even more prominent in a grocery store when you're handling chicken and all of that, so if you put in those types of restrictions—

Mr. Ayoob Ghalami: There's a category four for that.

Mrs. Carol Hughes: —it becomes problematic.

Mr. Ayoob Ghalami: There is a key point that needs to be addressed. That comes with the concentration. When you go to the grocery store and you deal with chicken, with the cold temperature you will not have as much as E. coli as you will when you have a culture in which you cultivate that E. coli and you produce large numbers.

When we deal with biologicals and we put them in risk groups, we look at the infectious dose: how much of it do you need to get sick? These are other factors. One E. coli is totally different from one million E. coli. E. coli is a bad example to use because we have a lot of non-pathogenic E. coli. There are more than 300 different strains, but there is a pathogenic one that cost a lot of people their lives in Walkerton.

Mrs. Carol Hughes: But at the same time, this bill actually covers all E. coli. It doesn't actually restrict some of them. Let's be clear on that.

Mr. Ayoob Ghalami: If you go back to my comments, I did mention specifically that I do not like the schedules. I think the schedules should be supervised. This is an extremely fluid industry. Biosafety changes all the time. When I worked in research, the promoter was 25 base pairs. They changed it to ten. Now I don't even know what it is. Having a rigid schedule is not going to really help that much. There has to be a panel that decides what goes in and what stays out.

Mrs. Carol Hughes: Now, this question is addressed to both of you. Really, how do you determine this? Don't you think it may be problematic with regard to getting students to work on this, especially when you're looking at international students, or even with the cleaning staff in regard to getting clearance for them to go to these labs and clean them? These are some of the concerns that were raised.

This one is actually from Dr. Hynes: "Does this mean that undergraduate students or visiting scientists pursuing activities in such facilities on a short-term, temporary basis will not be permitted to do so unless they apply to the minister for security clearance"—and we all know how long that takes—"and that security clearance is awarded? And what about the custodial staff?"

I'm just wondering about your concerns and your feedback on that.

● (1605)

Mr. Ayoob Ghalami: Honourable member, again, I go back to the comment I made. I said that I will live with this bill if the security clearance has been lifted for risk group two organisms. I addressed that concern earlier.

Dr. Wayne Conlan: Bill C-54 didn't have that provision for level two pathogens in its original form. That security clearance was only for level three and four pathogens in Bill C-54. All Bill C-54 was asking for was a list of what pathogens an organization held and where they held them. It wasn't that onerous a thing to produce, I don't think. You know, there's a safety issue: if I'm a firefighter and I go into a burning lab, I think I'm entitled to know what I'm going into.

Mr. Ayoob Ghalami: Actually, there is an example, if I could come in here. There was a teaching hospital that had a fire. The lab had a biohazard sign on it. The firefighter didn't enter. Four million dollars later, when they got the PI, they entered the lab. There is a consequence of putting a level two sign on your door.

They have asked us, saying that they're going to do it like CNSC does. You give a blanket list saying that these are the bugs you have and these are the locations you have, and we don't have to go through them every time we get a risk group two organism. The only restriction that is going to apply for security clearance and others is the select agents. Not even risk group three, like HIV, can be used as bioterrorism means, so it's going to be select agents, the agents that could be misused in the wrong hands. Those are the guys that have to go through security clearance and others. That was the understanding we had when we met with the public health people at the University of Toronto.

Dr. Wayne Conlan: It would take CSIS decades to go through the number of security clearances required, if everybody had to get a security clearance to work in a level two lab. It's not practical.

Mrs. Carol Hughes: Are you worried about the red tape at all? I know that we've talked about the security thing here, and there are some concerns about that, but what about the delays in being able to get people to work in these labs, just the duplication in the paperwork that needs to get done and the delays in maybe being able to find a cure using these—especially when you find yourself in a crisis situation like SARS?

Mr. Ayoob Ghalami: That would deal with the clinical side. Unfortunately, my side of the clinical area is only dentistry, and I don't deal with the other side, so I can't make any comment on it. I do not have the expertise.

Mrs. Carol Hughes: Do the others have any comments?

Dr. Wayne Conlan: Is it going to have some impact on research? Sure, but if you work with animals, the red tape surrounding the use of laboratory animals is far more onerous than the red tape proposed for level two pathogens by Bill C-11. The red tape surrounding the use of radioisotopes in laboratories is more onerous than the red tape for level two pathogens proposed by Bill C-11. We have to have inventories of all the chemicals in the laboratory; why shouldn't we have an inventory of all the pathogens in the laboratory too?

The Public Health Agency of Canada, over the years, has produced MSDS sheets for just about all of these pathogens, with really good, detailed instructions about how to handle them. So there's really no excuse not to go this one extra step and just have a list of who's got what. I would hope that the Government of Canada would like to know who's got what—and where they've got it, as well. That's the whole essence of Bill C-11, knowing where pathogens are kept.

The Chair: Thank you, Mr. Conlan.

We'll now go to Dr. Carrie.

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

I want to thank the witnesses for being here today, because we have heard some other things from different witnesses.

Mr. Ghalami, you brought up something that I found to be quite an interesting way of putting things. You said "you get used to your bugs all the time". I remember years ago working on a construction site, where there were guys who were explosive experts, who got used to working with their dynamite. You'd see these guys and you'd think they're handling the dynamite quite clumsily, but they get used to it. But it's still dynamite, and it's still explosive.

We've had other witnesses who say this level two stuff isn't that bad, but could you let us know what can happen with some of these level two pathogens? You mentioned that HIV is a level two pathogen, and you said that salmonella and different strains of E. coli were too. What can happen to the public if these things aren't controlled?

Mr. Ayoob Ghalami: A part of my job that I like is the fact that "it depends". That's one typical answer I give to individuals. The strain of E. coli is one factor; the health status of the individual is another factor; the dose the individual gets is another factor. So there are lots of combinations of those factors.

You could check at CDC. I don't think we have a statistic on this in Canada, but I do go to the CDC for data. I do teach a course on biosafety at U of T, and I show different examples of lab-acquired infections to the attendees. As I mentioned, there are lots of them all the time.

The consequence would be different. If someone is immune-compromised, or let's say someone is pregnant and walks through a room and is exposed to listeria varicella, they would most likely no longer be pregnant after that. So that is a consequence. Is it a big consequence, or a small consequence? You be the judge. It's really hard for me to say, but that is one example.

● (1610)

Mr. Colin Carrie: I've noticed from different witnesses that they almost say that if there weren't a requirement for biosecurity.... As you mentioned regarding labs that are just level two, you wouldn't even have a problem implementing this right away—

Mr. Ayoob Ghalami: Yes.

Mr. Colin Carrie: —that it would be something you could put right through. So that's maybe something we should think about.

Dr. Conlan, you mentioned that you have experience with level two and level three pathogens in the same labs, or that your lab runs level two—

Dr. Wayne Conlan: We run both level two and level three labs.

Mr. Colin Carrie: Is it a concern that labs who don't import can just pass these things around, lab to lab?

Dr. Wayne Conlan: For sure. It used to be common practice for researchers to share their pathogens.

As far as level two pathogens are concerned, the most risk is to the researcher, unless there's malicious intent. If there's malicious intent, you could do a lot of damage with a level two pathogen, if you decided, as they did in the U.S., to take some listeria and go to several Pizza Huts locally and spike the salad bars with listeria or salmonella or shigella. So there's potential to do harm, but what's the likelihood that people would do so?

But in day-to-day research, the people who are primarily at risk are the researchers. So it's more a workplace hazard than anything else. Level two pathogens don't tend to be that contagious, so the primary risk is to the individual who's working with them.

Mr. Colin Carrie: You mentioned a little bit about research, because we did have some researchers here. Do you think there would be a serious effect on research with the bill written as it is right now with the people who do mostly level two?

Dr. Wayne Conlan: If there's a requirement for a formal security clearance by a federal agency, yes.

Mr. Colin Carrie: We keep hearing that it's the security issue, and you did mention that in Bill C-54 you don't remember that being—

Dr. Wayne Conlan: In Bill C-54 the intent was that people engaged in levels three and four work would require security clearance.

Mr. Colin Carrie: Okay.

Dr. Wayne Conlan: All government employees undergo an enhanced security clearance, so I guess it's a matter of what level of clearance and how fast it can be done. That fact is that the federal government is a big agency, and most of its employees have some level of enhanced security screening before they're employed. So clearly at one level it's possible to screen large numbers of people at a very superficial level.

Mr. Colin Carrie: If we clarify the fact that level two wouldn't have the same security necessities as the ones that have levels three and four, do you think that would be a very good solution to put forward?

Mr. Ayoob Ghalami: If security is lifted, and if the operation of licensing would be adopted like the Canadian Nuclear Safety Commission does, I can confidently say that we don't have to do anything different at the University of Toronto. Everything should run that way, and it should have been that way, because we have signed a memorandum of understanding with the tri-council to abide by the guidelines, third edition, that the Public Health Agency has put out there.

Regardless of that, it is a good practice to do, because we're making sure—just going back to the previous question you asked—risk group two are considered moderate individual, low community. So if something could be aerosolized like TB, it will never be risk group two; it will be risk group three. Risk group two is always the individuals, as my colleague mentioned, the individual who is performing the research.

But do we want our researchers to get sick? No. Again, it comes to the fact that you want to make sure the mandatory training is there. You want to make sure you have a reporting system, and if you get lots of people who are exposed to the agent, they work. Maybe the institution needs to revisit how they practice to train their individuals, or what means they have. So it goes back to that route.

As I said, you don't have to do anything at my institution because we have everything in place as the guidelines mandate.

● (1615)

Mr. Colin Carrie: You mentioned that this is bringing the levels up to a level playing field. How do we fit and how do we match up internationally? Are you aware of the regulations in the United States, and do you work with them a lot, being an importer yourself? Are we going to come up to that same level internationally?

Dr. Wayne Conlan: As I receive a lot of my funding from the U. S., I have to abide by the equivalent of Bill C-11 with the select agent rule. That's a little different because pathogens are considered select agents not based on their risk group. So you can be a risk group two pathogen and still be a select agent, and then you are governed by the select agent rule, whereas in Canada you would be a risk group two pathogen, and some risk group two pathogens would certainly be treated even under Bill C-11 with less concern than they would be if they were being handled in the U.S.

The Chair: Thank you, Mr. Conlan.

We're now going to go into our second round of questioning, which is five minutes per person, and we'll start with Ms. Murray.

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

I find a little confusing, Mr. Ghalami, your huge enthusiasm for this project, and then, on the other hand, your acknowledging it would make absolutely no difference to your operations or your lab whatsoever. I guess you're responsible for security, and not responsible, I presume, for the quality and productivity of research that comes out of your lab, the hiring and training of researchers, and the meeting of deliverables in terms of research grants and so on.

Mr. Ayoob Ghalami: It's completely to the contrary. I'm not the security officer. My background is molecular biology, so I relate to the science part more than anything else. If you are the only scientist, you've got to talk the talk and walk the walk, so—

Ms. Joyce Murray: So you are responsible for the production of research?

Mr. Ayoob Ghalami: I'm not responsible for production, but my background is science, and I look at it as that I have to understand the science part and I have to understand the regulation part and enforcement. I'm not the research for that, so I don't do bench work myself, no.

Ms. Joyce Murray: Okay.

You made a comment, Mr. Conlan, that if there was malicious intent, schedule 2 pathogens could be a problem. I've got a letter from the provincial minister of health in British Columbia, essentially describing many of the pathogens in schedule 2 as things that are ordinarily found on the body, in the ground, on animals. So my question is this. If there were malicious intent, would this new regulatory regime protect anyone, or prevent that malicious intent from taking place?

Dr. Wayne Conlan: Not as far as risk group two pathogens are concerned. My understanding is that it boils down to whether the federal government wishes to know what risk group two pathogens exist in laboratories in Canada and whereabouts in Canada those laboratories are based. It's that simple. For risk group two, that's all the information...if you do away with the security clearance, the only information you will gain from Bill C-11 is that you will know all of these labs and they will also come now under the microscope. All these labs are off the radar right now. Unless you import these organisms, you don't need to interact with the Public Health Agency of Canada or CFIA at all.

Ms. Joyce Murray: But perhaps with the provincial regulatory bodies. That's one of the key concerns the provinces have: that this is an additional layer of regulatory burden. Presumably, Mr. Ghalami, you have that regulatory burden already and that's why you're saying this wouldn't make any change. But the provinces are concerned that there's now another regime.

When I read the act, I must admit that with respect to the comment that other than security clearances there wouldn't be any impact on the schedule 2, I see disclosure of information, licensing, registering, security clearances, inspection, enforcement, and so on. All looks to me in the bill to be covering the schedule 2 as well, even though the verbal description of what may be intended is different than that. It's woven throughout this bill. I think that's a concern as well.

Do you experience registering and requirements through the provincial regime for your labs, or perhaps that's not the case in Ontario, and just in British Columbia?

● (1620)

Mr. Ayoob Ghalami: I will go back to my initial comment, and I said I 100% respect the bill and like the bill if two provisions aren't made. One is security. One is licensing. So those two are handled.

We do not report to provincial legislators or provincial enforcers, namely the minister of labour, in regard to our biologicals. It's the workplace. They do have the right to come and inspect at any given time they decide to, but they do not deal specifically with biologicals. They look at it as a workplace. So they need to make sure we abide by the Occupational Health and Safety Act.

But the Public Health Agency, their whole focus is biologicals. They don't care if a floor is this and that. They want to make sure you know what bug you're working with and you understand the consequence of using the wrong one or understand using the wrong biological safety cabinet. I challenge committee members to get scientists and ask them. There are four different types of biological safety cabinet. Ask the scientists which one you need to use when you have radioisotopes mixed with your biologicals. Half your scientists wouldn't know. Scientists are like kids in a candy store; they're focused on their work and their work only. The other stuff is not of that much interest to them, so we need someone to come and just enforce that part.

The Chair: Thank you so much, Mr. Ghalami.

We'll now go to Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Madam Chair, and thanks very much to both our presenters.

It's been said here this afternoon that we've been hearing a totally different story. I'm not so sure we have. I think we heard concerns raised by other presenters who have been here, but I think when we pare down those concerns and we look at them methodically, I think the concerns have been over the inclusion of the level twos and they have been over the security factor that's in this bill, and I think that's exactly the same thing you're saying, Mr. Ghalami.

Mr. Ayoob Ghalami: I strongly believe, personally and as an institution, and even agree that as an institution we told Public Health Agency of Canada that they're more than welcome to give us a blanket licence for risk group two. We will tell you what we have, where we have it, and what we do with it, just don't regulate every individual lab, because that would be onerous for scientists and this is not fair. We don't want to overkill our scientists with paperwork. And they have agreed, and they also have agreed with the security clearance. And as I mentioned in the first statement I made, if these two are lifted you don't have to do anything different, because that is the right practice that is required by the memorandum of understanding and that's what we do at work.

What the others say, unfortunately I can't talk on their behalf. I don't know their reasoning.

Mrs. Patricia Davidson: No, and those were the two main things others have been expressing concern about and the things we've been trying to understand.

Hon. Carolyn Bennett (St. Paul's, Lib.): On a point of order, for clarification, when you say "they have agreed", does that mean that will be government amendments? What does "they have agreed" mean?

Mr. Ayoob Ghalami: We were hoping that it will be in the bill when the next readings will come, in black and white, that these exclusions or these modifications have been changed. That was the understanding I was on, that it will come.

Mrs. Patricia Davidson: The understanding is with Health Canada?

Mr. Ayoob Ghalami: With Health Canada, yes.

Hon. Carolyn Bennett: The future tense: it will come.

A voice: Yes.

The Chair: Just one moment.

Dr. Butler-Jones, you wanted to mention something. Could you come to the table, please?

Dr. David Butler-Jones (Chief Public Health Officer, Public Health Agency of Canada): Just very briefly on that point, members, the intent of this legislation is broad. It is in the regulatory and program framework that all of those issues will be dealt with. I think the committee has seen the draft regulatory framework that actually identifies these issues as we move forward. You'll have an opportunity with me later, so I'll leave it at that.

The Chair: Thank you, Dr. Butler-Jones.

Ms. Davidson, please go ahead.

Mrs. Patricia Davidson: Thank you.

I'm glad Dr. Butler-Jones has intervened here and made that statement, because another one of the concerns was the fact that other people did not feel that the regulations were developed to a stage where they had any firm idea as to which direction they were going. They felt they were left too open-ended at this point to be in agreement with them.

There was also concern raised about the fact that some people didn't feel they had been consulted. They felt they had been, perhaps, to an information session but not to a consultation. Yet both of you today have used the word "consultation". Do you feel that you were consulted and listened to?

● (1625)

Dr. Wayne Conlan: I do, yes. This was for Bill C-54, not for Bill C-11, but I was certainly apprised very fully of its content and was given the opportunity to comment on it by the Public Health Agency of Canada.

Mr. Ayoob Ghalami: For me, I will still wait to see what comes in the regulations on what comments we have made. Obviously if it's not in the bill, it comes in the regulations. I can't say yea or nay because we have not seen the regulations, so I can't make any comment on that.

The Chair: Thank you, Ms. Davidson.

Mr. Malo.

[*Translation*]

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

I may leave some time before 4:30 p.m. for my other colleagues, if they have any questions.

I'd just like to come back to a comment that Mr. Ghalami made a little earlier. You stated that because universities that conduct research rely on grant money, they must follow certain safety rules.

Are you prepared to say that the explicit exclusion from the bill of all university research would not pose any kind of problem because universities are already subject to a number of stringent safety rules? If so, that would deflect some of the criticism and alleviate some of the concerns that have been expressed in the past few days.

[*English*]

Mr. Ayoob Ghalami: Thank you, honourable member. That's a great question.

Obviously now I am the inspector. I have a biosafety officer who goes and inspects labs. If she has any problems, I go to inspect the lab. No one comes to check my work to see if I have done it right or wrong.

From a personal perspective, if the Public Health Agency of Canada doesn't come, my call goes. If the Public Health Agency of Canada comes, then you have another unbiased, second set of eyes that check your functions. We do get audited by the tri-council, but all they care about is making sure we have a system in place. They don't go and inspect labs. They're chartered accountants. They want to make sure you have all your paperwork in order and you have a system in place. So they check the entirety of your system, but they do not check the lab work at a hands-on level. As a biosafety officer, I would be more comfortable seeing someone qualified check my lab.

There was another comment we made as an institution, saying that we hope and request that the inspectors who are going to come to the labs have the same credentials or qualifications as we biosafety officers so that we do not deal with an individual who does not understand the scope of the stuff.

So far the Public Health Agency, I can confidently say, is one of the best regulators. They understand the scientific side as well, and I say it with pride. But the reality is that we don't know if it's going to be the inspectors or not. We hope that will be the case, and that they keep the legacy that when they send the inspectors, the inspectors would represent what they do currently.

[*Translation*]

Mr. Luc Malo: Thank you.

Thank you, Madam Chair.

[*English*]

The Chair: I want to thank you. I want to thank our guests for coming.

I will ask the Public Health Agency of Canada to step up now, and we'll begin our questioning of them.

Mr. Conlan and Mr. Ghalami, you've done a fantastic presentation today, as have all our witnesses we've heard in this last of couple of days. Thank you.

Mr. Ayoob Ghalami: Thank you, honourable members.

I always watch Dr. Bennett. It is an honour to see you.

The Chair: We'll now begin our second round.

I understand that Dr. Butler-Jones, who is the Chief Public Health Officer, will be speaking first. I want to welcome back Dr. Tam, the director general for the Centre for Emergency Preparedness and Response, infectious diseases and emergency preparedness branch. You have a very long title. I think it's wonderful that you're back again. Thank you. Welcome also to Jane Allain, from legal services.

Dr. Butler-Jones, please.

● (1630)

[*Translation*]

Dr. David Butler-Jones: Thank you very much.

[*English*]

I want to begin by thanking the committee members. I'm going to be very brief in my comments and leave lots of time for questions.

I really want to thank you for the time and the work being put into reviewing the legislation. We take all of it very seriously. It is interesting to reflect that part of my pleasure is that five or six years ago, before SARS and before the agency, it was difficult to get anybody to pay attention to these issues. Now people are paying attention. That is only a good thing.

I think we can agree that the proposed Human Pathogens and Toxins Act is an important tool—

Ms. Judy Wasylycia-Leis: Be careful what you wish for.

Dr. Butler-Jones: No, I prefer this, I must say, for protecting the health and safety of Canadians.

[*Translation*]

Accordingly, we've taken its development very seriously.

[*English*]

The legislation has already benefited from a series of meetings with over 400 stakeholders since it was tabled, including some of the witnesses you've already heard from. Through these discussions several common themes have emerged. These themes will provide the basis for continued stakeholder dialogue on elements of the proposed regulations moving forward. Our objective in working with stakeholders is to make sure that the program and the regulatory framework strike a balance between the needs of biosafety and biosecurity and the interests of ongoing science and research.

We have heard this committee.

[*Translation*]

We at the Public Health Agency of Canada will do whatever is necessary to provide this committee with the assurances needed.

[*English*]

We will follow through with our stated intentions regarding the program and regulatory framework, and I think you've seen the regulatory framework. In light of recent dialogue around this bill we will redouble our efforts to engage the stakeholders and to listen and respond to their concerns in keeping with the commitments we have made before this committee and across the country. We have made available this program and regulatory framework document earlier this week. I think you'll find it a good discussion point to start from with respect to a number of concerns that people have raised.

Let me thank you again for your time and thought. We are here to try to address all the questions you might raise.

Madam.

The Chair: Thank you very much Dr. Butler-Jones.

We're going to go directly into the questions, and we'll be back to the first round, seven minutes per person.

We will begin with Dr. Bennett.

Hon. Carolyn Bennett: Dr. Butler-Jones, in terms of the statement: "We will follow through with our stated intentions regarding the program and the regulatory framework", does that mean that in spite of the testimony to date, you are going to be recommending amendments to the minister?

Dr. David Butler-Jones: Well, at this point the committee is reviewing it. Under our original intent, the legislation itself was high-level, but often legislation is. At the point where the rubber hits the road, many of the concerns will be difficult to address in legislation, because it's a bit of a blunt instrument. For example, is it all level two pathogens that we are concerned about? No. Is it even all level three pathogens that we're concerned about? No. But it will require an extensive consultation with those who are experts in all of these fields to know which ones we're worried about and which we aren't. Questions about whether something is E. coli 157 or the E. coli that everybody has in their gut, et cetera, will require extensive consultation to make sure we have the right ones in the right categories from a regulatory standpoint.

It's the same with the issue of security clearance. We have no desire for or interest in security clearance for level two alone. That is an unnecessary burden and will not assist us. The whole intent of it, through the regulatory process and the program framework, is to have the least intrusive, most effective regime, with the fewest side effects—just as we have therapeutically. That will require a lot more detailed conversation and consultation than we can get by means of the development of the act itself. But the act will set the framework from which we can move. It will take us some time to get to the regulatory...but that's what I mean by our intent: to continue through with it.

We all want this to be right; we all want it to be a minimum burden; we all want to be effective. We have already had situations.... For example, some members of the committee will remember when we identified H2N2, being distributed all around the world.

H2N2 was the last pandemic virus, from the 1960s. No one born since then has any immunity. It was sent as a lab proficiency test labelled as pathogen level two to 8,000 labs, including doctors' offices, around the world. That could have been the next pandemic. It's only because we had the regulatory framework in place for imported pathogens that we were able not only to identify where it came from, but also to deal with all the facilities in Canada that had imported it, so that very quickly they could destroy it. That's just one instance.

● (1635)

Hon. Carolyn Bennett: In terms of what you're saying, a lot of the testimony has been that "high-level" is too broad and takes in too much stuff, particularly in the schedules. Will you be helping the minister with some amendments to this?

You know what our problem is. People were invited to an information session—today's testimony was a bit different—that they now perceive was a one-way communication. Every concern they then expressed they expressed again here at committee. They do not feel that their concerns were reflected in the new bill. Continuing to consult on the regs when people have serious concerns with the bill isn't going to do the trick for those of us who heard the witnesses and are worried that what may be "high-level" is too broad or has unintended consequences around security clearances and duplication.

Both B.C. and Ontario are upset. They're also upset with being treated like a stakeholder instead of a partner. Somehow the prework to bring a bill to the Parliament of Canada doesn't seem to have been done, in terms of the two-way communication needed to get a better bill.

Concerning my comments last week that the minister was let down, I believe that in any kind of stakeholder engagement people need to feel that they were heard. If you're not able to do what they said, then it is our requirement to go back to them to say: "you said this; we're not going to be able to do it because of Y"; or, "you said this, but harmonizing with the world means we have to do this". The concern we had, that two big universities in the States have stopped dealing with certain pathogens because of this too-restrictive regime, is very worrying to us, as a deterrent to getting a safe Canada; certain people just think it's too expensive or complicated to do the research that is required.

I want to ask again. On quality assurance around citizen engagement, you heard a lot of stuff that a lot of witnesses say is not reflected in the new bill. Could you, even at your own agency, go back to find out what you heard and table for us what you heard and tell us why you can't do it? Why is it not reflected in the bill?

The Chair: We just have a minute left, but you can have more than that if you can answer some—

Dr. David Butler-Jones: I'll be very brief.

With both the previous bill and the current bill we have engaged with a whole range of people—partners and others—in the last while. We'll be quite happy to table it once we have it translated. This is basically on who was there, what they said, and what we heard. We will continue to do that.

The issue, which is partly a parliamentary and government decision, is what do you put in the act versus what do you put in the regulations. It's not that we won't address it, but what is absolutely necessary in the act versus the specificity you need in the regulations? So it is partly for the legislatures to pursue that conversation.

What we have heard through the discussions and what we have heard now resonates with us and our intent. If you look at our draft regulatory framework you see that most of what they're talking about is actually accommodated in our plan as we move forward. But we will need to consult quite extensively throughout this whole process over the next while in the development of the program architecture and the regulatory framework to make sure we have it right.

At the end of the day, to be a little bit realistic, until things are actually in force and they see how it's applied, people will be putting down markers: please don't do this, or we're worried about that. Until it's actually lived with.... I don't really know these guys, so it's interesting to hear them talk about their experience—because they're already regulated by us due to their importation—and their comfort level with the way we've been doing it. A lot of the others don't have that kind of requirement, so they're nervous about what might be, and just us saying it until they see it is difficult.

● (1640)

Hon. Carolyn Bennett: So you think the bill is perfect the way it is right now.

The Chair: Thank you, Dr. Butler-Jones.

I have to go on to Mr. Malo. We're over time.

[*Translation*]

Mr. Luc Malo: Thank you, Madam Chair.

Thank you for joining us once again.

I'd like to start with a general comment. We have heard today from two individuals who genuinely feel that they have been consulted and who are both supportive of the bill. Earlier, we heard from other witnesses have truly believe they were not consulted and who are opposed to the bill, with some qualifications. While they agree with the substance of the bill, they object to some of its provisions. That should be a lesson to us. When consultations are held, there is a greater likelihood of garnering widespread support. That is what has been lacking thus far. Feel free to comment if you like.

Now then, I'd like to discuss a letter that we received from the Privacy Commissioner. I felt it was important to seek out her opinion because certain aspects of the bill pertain directly to the disclosure of information. Here is the Commissioner's response:

> We had hoped to see a privacy impact assessment (PIA) to understand how any privacy risks in this Bill had been mitigated, but we have not yet received one. [...] Our Office should be seeing PIAs well before the decisions have been implemented so we can provide feedback early in the process.

Why have you not provided these PIAs to the Commissioner? Have they been done?

Dr. David Butler-Jones: We welcome suggestions from most partners in Canada, but it is impossible to retain every single one. Occasionally, we do have discussions with them and subsequently, the problems are resolved. However, a week or two later, another problematic issue may arise.

We have promised to consult and to verify that the regulations are appropriate. As for the situation in the private sector, I will let Jane answer that question. As a rule the assessment is done within the framework of the program. We still do not have a program, but we will have one later. The three provisions in the bill are identical to the ones contained in the other piece of legislation.

Ms. Jane Allain (General Counsel, Legal Services, Public Health Agency of Canada): The privacy impact assessment will be carried out as part of the process of developing the program and the regulations. The department is required to conduct this assessment.

The Privacy Act and the Charter will continue to apply when authority is exercised pursuant to the new act. We always do a PIA when we tackle such issues.

We have read the Commissioner's letter. Certain principles will continue to apply, particularly the ones having to do with the application of section 4 of the Privacy Act. Two principles are entrenched in the act. When the government is authorized to collect and disclose personal information, it must comply with certain regulations. We refer to this as

● (1645)

[*English*]

the minimum collection rule and the minimal disclosure principle.

[*Translation*]

These two principles will continue to apply in the case of all powers exercised pursuant to the new act.

I know the Commissioner has commented on similar provisions that appear in different acts, whether it be the Quarantine Act or the Food and Drug Act. These two acts contain similar restrictions. We strongly believe that our assessment has enabled us to draft these provisions properly and mitigate their limitations. We will continue to apply these principles.

Mr. Luc Malo: Thank you.

Earlier, Mr. Ghalami testified that the application of Bill C-11 could result in a brain drain. Can you give us any solid numbers as to the potential impact of the bill, given that witnesses have told us about lab closures in the United States? Mr. Ghalami even said that Canada had benefited from an influx of eminent researchers. Have you truly weighed the impact of the bill, to avoid having to contend with a similar situation here?

Dr. David Butler-Jones: Mr. Ghalami was speaking in connection with a risk group 2 security clearance. However, most labs that analyze viruses and other risk group 3 and 4 substances have certain expectations. They have told us that because of import laws, we really don't need to regulate risk group 2 pathogens for safety reasons.

Mr. Luc Malo: Do you agree with some of our witnesses who contend that certain E.coli strains are pathogenic while others are not?

[*English*]

Dr. David Butler-Jones: Absolutely.

[*Translation*]

Mr. Luc Malo: A "human pathogen " is defined in clause 3(1) to mean:

> A micro-organism, nucleic acid or protein that:
>
> a. is listed in any of Schedules 2 to 4 or in Part 2 of Schedule 5; or

Someone argued that this definition does not specify whether certain strains are pathogenic or not.

Are you mindful that some provisions of the bill need to be amended?

Dr. David Butler-Jones: I will answer that question in English, for clarity's sake.

[*English*]

It gets back to this question, which is a legislator's question: what amount of detail do you need in the act versus follow-through in the regulations?

We felt that the general provisions in the act, and we would deal with all of these...and specificity in terms of what bugs are in or out. Even at level three, not all level threes are we as concerned about. Tuberculosis we're not as concerned about as we are with some other level threes.

So that will be the process of the development of the regulations. As the witnesses said earlier about the need to be flexible in what's in and what's out, I can—

[*Translation*]

Mr. Luc Malo: Can you understand that—

[*English*]

The Chair: Mr. Malo, you're out of time.

Ms. Wasylycia-Leis....

Order, Mr. Malo, order.

[*Translation*]

Mr. Luc Malo: —the student career that hold so dear is at issue here. The bill must be very clear on this score because they still have some concerns. In their view, the solution is not to give people carte blanche.

[*English*]

The Chair: Mr. Malo, I'm calling you to order. I will not address you if you're going to be that rude. Please don't do that again.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Do you want to answer that question first?

Dr. David Butler-Jones: It relates to human disease.

Theresa or Jane, do you want to pick that up?

[*Translation*]

Ms. Jane Allain: In reviewing the bill, it is important to check the definition provided of risk groups as well as the schedules containing the list of substances. It is clear that the bill refers to pathogens, that is things—I'm not a scientist, so I don't know what they are called—that can cause disease in a human.

In drawing up the lists of substances, the minister must refer to the schedules mentioned in clauses 1 and 7. If the schedule lists E. coli, then this is a reference only to substances that can cause disease in a human. Your interpretation could be off if you read only one clause. However, when you look at all of the clauses together, it's clear that the reference is solely to pathogens that can cause disease in a human.

● (1650)

[*English*]

Ms. Judy Wasylycia-Leis: The problem we're having is that this legislation is a pretty tough regulatory approach. What we're hearing from most of our witnesses is that some of the provisions may be good and necessary, and some are not. Almost all of the witnesses up to today have actually suggested that we find a way to ensure this act does not apply to the level two risk group. I'm wondering if you have a problem with an amendment that would actually add on page 5, in clause 7, after line 22 as part of the exemption clause "any activity involving a microorganism, nucleic acid, or protein that is listed in schedule 2".

Dr. David Butler-Jones: Let me step back in answering that question and explain the reason for having level two in there. There are a number of reasons for that.

I mentioned earlier H2N2. Currently the import regulations include level two. Transportation includes level two. So we already regulate level two at the import, export, and transportation levels. The issue is that we don't regulate it at either end. In other words, does this lab have the capacity to receive this organism? As I'm saying, the intent of the regulations is that we would regulate level two labs differently from level three and level four labs. So the regulation regime, the expectations, the security clearance, and all of those things would be different for level two from what they are for level three and level four, because they're risk-based.

Ms. Judy Wasylycia-Leis: The trouble for us and for the witnesses who have been before us is that we have to take your word. I may trust you, Dr. Butler-Jones, and believe you have integrity on the job, but you might not be there forever. The regulations are something that cabinet approves. We don't know how they may be changed by the political powers that may be.

So we're interested in making sure that as much as possible the concerns of these folks are reflected in this legislation. They say that the way it now sits, they're going to lose research and they're going to experience some of what happened in the States with the Patriot Act. Some of the witnesses remarked that MIT had lost researchers because of the restrictions. I think the last thing we want to do is lose the little bit of leeway we have in this country around innovative research. Wouldn't it be better to actually follow the U.K. model of having a registry, as opposed to taking this tougher regulatory licensing approach?

Dr. David Butler-Jones: I have two points. One I have spoken to and would speak more to is the issue we face, sometimes, with level two labs. It's not the universities I'm worried about. It's not the provincial laboratories I'm worried about. There are a large number of labs out there that don't have that same kind of discipline, scrutiny, oversight, and so on. For example, with respect to the recent H5 incident in Europe, the Europeans are asking us what means we have to ensure that we can find out what is where and what's been sent where so we can actually trace this stuff. Currently we have no authority to do that.

Where provincial acts exist, they tend to be about occupational health and safety and about quality, not about biosecurity or biosafety. So it is filling a gap. It will require extensive consultation, as I said before, to address these issues. It will also require close cooperation with the provinces and territories to make sure that we're complementary. We're even talking with them about joint kinds of regimes in terms of how we minimize the burden on facilities and minimize paperwork and ensure that we actually address these things effectively.

On the question of how much you'd like to be clear about the intent in the legislation, how you proceed with that is a decision of the committee. As I said earlier, people may trust me. They may trust the agency. They want to know where we're going. But there are provisions. We're required by the whole legislative process to ensure that we consult extensively throughout the regulatory development process, which is what we will do. We are committed to that. You see in the regulatory framework, in the statements today, what our intent is and what our plan is, which is on the record.

● (1655)

Ms. Judy Wasylycia-Leis: Would you have difficulty if we amended the bill to require the regulations to come back to this committee and Parliament for final approval?

Dr. David Butler-Jones: Quite honestly, I don't have an issue with what the government and the committee do to facilitate this process. This is important legislation. We want to see it happen, and we want to get, as quickly as possible, something that is effective and useful for everybody.

Ms. Judy Wasylycia-Leis: You seemed to reject my proposed amendment to delete level two from the effects of this act. Do you have other amendments you have in mind to address some of the concerns raised by some of the other medical scientists and researchers who came before our committee?

Dr. David Butler-Jones: There are ways—and this is something, again, for the committee to look at—to clearly signal the intent. I've said it, and not only in terms of the draft regulatory framework. If there is a willingness on the part of the committee and the government to look at wording that will make the intent clearer than it is now, personally, I have no issue with that. All the statements and concerns we have heard we understand. For the vast majority, I would agree with ensuring that we address them through the regulations. We had set out to do it through regulations. The question now is a legislative one: What fits in the act versus what fits in the regulations?

The Chair: Thank you, Dr. Butler-Jones.

We'll now go to Mr. Carrie.

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

Just to follow up on Judy's line of questioning, some of the people said we should get rid of level two, but I think they based their objections on a belief that the security was going to be a problem for them. Even Mr. Ghalami said today that if we could get rid of that security requirement....

You mentioned that there is no intent to do what these previous witnesses thought you were going to do, so I see that there has been a misunderstanding among the witnesses we had before.

I want to talk to you a little bit about how the stakeholders have been engaged. My understanding was that you had sessions in Saskatoon, Quebec City, Montreal, Ottawa, Winnipeg, Halifax, Toronto, Vancouver, Guelph, and Calgary. Over 2,700 e-mails were sent out. You held up something, Dr. Butler-Jones, about your list. How many pages is that? What do you have?

Dr. David Butler-Jones: It is 62 pages.

Mr. Colin Carrie: You have 62 pages, and there is more than one person on each page. When they say that they weren't consulted, is it possible that maybe they missed stuff in e-mails? Can you give us an idea? They are saying that they weren't. Obviously, you have given evidence that you did a pretty good job of getting it out. So how do you account for the disconnect?

Dr. David Butler-Jones: I'll let Theresa speak to the sessions.

The only thing I want to say is that I really appreciate all the input. At the bottom line, we want to get this right, in any legislation, in anything we do. To be effective, we have to be transparent. We have to be collaborative as an agency. Public health respects no borders. So at whatever point it comes into the process, when we're told, “Oh, you haven't thought about this,” I'm quite happy to hear that.

That said, we've also had all these discussions, etc., over time, and some of it is placing down markers. In other words, as in Judy's question, let's make sure it is clear what we're saying here and what we plan to do. As to whether you do it in the act, in the regulations, in the consultations, or in the related documents, that's a bit of a judgment call, from my perspective, as long as we get there.

I'm quite happy to hear all of this, even if some of the people we've already had conversations with have left the conversation saying “I'm fine with that”, and then come back. They have a second thought, as we often do, or they hear from someone else and then rumours start. So we address that input then.

I'm quite happy to have it come forward at any time, because it's better to address it. We're taking account of all this, including the deliberations of this committee, and we will make sure that we address that in the best way possible.

Theresa can speak to it, if you wish.

Mr. Colin Carrie: I just have one more thing to throw in there.

Dr. Bennett had a legitimate concern. She said that B.C. and Ontario were upset. Obviously you did consult the provinces. When did you first find out there was upset in Ontario?

● (1700)

Dr. David Butler-Jones: The questions are ones that were raised and we were paying attention to and planning to do through regulation. I was a bit surprised to see it then reflected as if we'd never had the conversations or had never dealt with the issues they've raised or planned to deal with them. But that happens.

I've spoken with both the deputy minister in Ontario and the deputy minister in B.C. They're quite comfortable with the way forward. But all of them will say, "We want to see the regulations. We want to be engaged in the development of the regulations." And I say yes.

Because they know me by reputation and personally in terms of how we've worked during the past, they're comfortable with that. But again, not everybody is in that position.

Mr. Colin Carrie: We heard earlier from Dr. Conlan. He's a gentleman who engages U.S. labs. We heard a concern that because of the new regulations in the States, labs actually got shut down. He said this bill is not as onerous as the American one.

Do you foresee that there will be a problem on this side of the border with job losses or something along those lines, careers being lost, if we implement it as it is?

Dr. David Butler-Jones: For me, it's hard to imagine that it would.

We have the only level four lab in the country. Everybody has to have a security clearance, everybody who is working with level four pathogens.

In terms of level three pathogens, again it depends on what the community decides are important enough to include as regulated pathogens. If they are important enough to require a security clearance, there are many other bugs that people can work on in the meantime without a security clearance. So I don't anticipate that kind of issue.

Theresa, do you want to add to that?

Ms. Theresa Tam (Director General, Centre for Emergency Preparedness and Response, Infectious Disease and Emergency Preparedness Branch, Public Health Agency of Canada): I think it was always intended to treat risk group two differently than risk groups three and four.

I just want to address that. We did listen to stakeholders, and we did adjust the bill in light of stakeholder input.

On the security clearance, it's actually quite an interesting piece. Originally we had, in clause 33, concerning security clearances, all risk group three and risk group four. The language was adjusted so that it was for select pathogens and toxins, because we wanted to have the flexibility for risk group three so that we might not have to include all of them. But now it is being read as, "Well, are you including risk group two?"

It was really because we heard that even putting risk groups three and four didn't give the flexibility, so through consultation in the regulations it would allow some flexibility to only determine select risk group three.

We also heard from them about the issue of students and others needing security clearance, and we actually included in clause 33 allowance for a complement of individuals who do not have security clearance in the labs. The intent is not to have security clearance for risk group two. The intent of that sentence was actually to give more flexibility to be more specific on specific pathogens. Whilst doing that, then, obviously some people found that the intent for risk group two isn't evident. But that was the intent.

If there are issues with the wording, we have actually made some changes because of it.

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

I'll now go to Ms. Murray.

Ms. Joyce Murray: Thank you.

Dr. Butler-Jones, are you in possession of the letter from the Minister of Healthy Living and Sport of British Columbia that went to Minister Aglukkaq?

Dr. David Butler-Jones: I have a letter from both the deputy minister in British Columbia and the deputy minister in Ontario. I have responded to them. I have spoken to them personally about it. They're comfortable with our way forward.

Ms. Joyce Murray: Well, I'll make sure you receive a copy of this.

I don't want to get into a "he said, she said", but I can tell you that the chief medical officer's office was very clear that they were not consulted during the course of Bill C-54, and—

Dr. David Butler-Jones: Sorry; the chief medical officer's office from where?

Ms. Joyce Murray: From British Columbia.

Dr. David Butler-Jones: Well, they're part of the Council of Chief Medical Officers in Canada. They were part of those consultations, specifically with all chief medical officers across the country, and our engagement in discussions and stuff. They will be part of the ongoing process.

● (1705)

Ms. Joyce Murray: Their record is that the consultation came out to Vancouver the day before this bill was tabled, in February of this year. Their experience was very clearly to not have been consulted, but to have been invited to an information session very recently.

I noted that you said you agreed with many of the comments you heard. Yet here we have a comment from the minister in British Columbia, as follows:

> We agree that some regulation...is justified. However, the overly broad reach of this bill is such that we feel it should be either withdrawn or substantially amended by reducing the scope to address our concerns. It is not clear that regulation of this wide range of toxins and organisms will have public health protection benefits. ...our strong preference is that a new bill be considered which is collaboratively developed through consultations with the provinces and territories.

Clearly there's not an experience of consultation to date.

The minister goes on: "It's the province's view that the current bill carries a grave risk of, paradoxically, harming the public health management of pathogens." Then she goes on to list some very specific concerns.

Hon. Carolyn Bennett: And if it's not withdrawn, she gives very specific amendments to the bill.

Ms. Joyce Murray: Yes.

So there is a set of amendments here. I would like to have a response from your office to these specific amendments that have been proposed.

Dr. David Butler-Jones: Obviously we'll do that. But I'm sorry, I'm at a loss here; I don't actually have that letter. I'd have seen, in the letter from the deputy minister and others in terms of issues—

Ms. Joyce Murray: This letter says, "My officials and experts at the B.C. Centre for Disease Control have reviewed this bill, and the following comments are based on that review." I am sure I don't need to remind you or any of your officials that the B.C. Centre for Disease Control was at the lead of dealing with the SARS problem, is widely respected across the country, and is credited with how few mortalities we had in British Columbia compared with elsewhere. When that respected an organization gives this strong feedback, I believe it's incumbent on your organization to consult properly and include the views of the Province of British Columbia.

Dr. David Butler-Jones: We will certainly follow up with them.

As I said, I've just had a conversation with the deputy minister of health, who was responsible for all of that. He's quite comfortable with where we're going, but wants to see—as does the deputy in Ontario, as do all the deputies, as do I—what it translates into in regulations.

Hon. Carolyn Bennett: But you have amendments to the bill in the letter.

Dr. David Butler-Jones: No, no, I hear you. As I said, that is a legislative decision as to how much in the regulation versus how much in the bill. I'm comfortable with however we wish to proceed with that.

We have been engaging; we have the Public Health Network in Canada, which includes the most senior public health officials from across the country, including expert groups, etc. This has been before those groups, has been before advisory groups in conversation and discussion, in the previous form of the act—

Ms. Joyce Murray: That's why I'm saying, with due respect, it's not productive for me to—

Dr. David Butler-Jones: —and in the current act.

It's interesting that it needs to come at this point, but we will address them all.

The Chair: Thank you, Dr. Butler.

I just want to let everybody know that the letter will be distributed to the whole committee once it's translated. That way everyone will be aware of that particular letter.

Thank you very much for your answers—

Dr. David Butler-Jones: I'm sorry, may I ask a question for clarification? Who was the letter addressed to?

Hon. Carolyn Bennett: Minister Aglukkaq.

The Chair: Yes, to the health minister.

Ms. Davidson.

Mrs. Patricia Davidson: Thank you very much.

I just have a quick question, and perhaps it's my naïveté that leads me to ask this question. It seems to me that a lot of the concerns we've been hearing are the fact that we're beyond the trust-me mentality in these days, and people are not so much concerned about what the bill is doing or what we hope the bill will do, because I think everybody believes in biosecurity, safety, and so on. What they're concerned about is what's going to be in the regulations.

When I look at the document, the "Potential Program and Regulatory Framework", dated February 2, I look at things that say "could involve", "also likely", "it is likely", "could be a phase-in", "no intention", "could be". Why can you not change some of the things in this document to be more definitive and address some of the questions and concerns people have? Would that not allay some of the fears?

● (1710)

Ms. Theresa Tam: Yes, the language was used because it's proposed the stakeholders can give input into that document. There are certainly areas where, for sure, we're not going to require security clearance for risk group twos. That can definitely can be put in there, and I think that's reasonable and can be clarified.

The other areas were intentionally done so they give the stakeholders a chance, through our next two years of consultation, to mould it into something they can work with and is feasible. I think our intention was good in that we were wanting to not put this in concrete and black and white terms, so they are allowed to give input into it.

We're certainly happy to further clarify. We'll further reassure our intentions if some language changes are required. It is proposed only because we feel that document and its ensuing regulations and programs require a lot of input from stakeholders.

Mrs. Patricia Davidson: Thank you.

I'll give the rest of my time to Mr. Uppal, if I have some.

The Chair: Thank you.

Mr. Uppal.

Mr. Tim Uppal (Edmonton—Sherwood Park, CPC): Thank you, Madam Chair.

Could we just talk about the cost of implementation for a minute, what this bill is going to cost laboratories, what their costs are going to be because of this bill?

Ms. Theresa Tam: For the laboratories already complying with the human pathogens importation regulations, I would say we think almost all the group threes and of course the risk group four lab already do that. The clear messages to us are concerns around risk group two.

For risk group two, we have laid out a proposed regulatory and program framework that says we do not intend to require security clearance. We intend for people to keep inventories simple, so they can be produced if we need them to. Inspections are not going to be every year; they're going to be as needed and spot checks as required. All those program designs and the regulatory intent was there to minimize the impact.

We have a level two lab within the Public Health Agency. Some of the ways we were trying to look at impact were in fact to ask them directly. So we asked, "Upon royal assent, what would be the impact on your lab?", and they said, "Very minimal. All we need to do is make sure we provide a contact person, a name, and whether we have any prohibited organisms." Then, really, it's in the program design. Regarding the cost, we've done some ballparking, but that cannot be done in detail—and we have accountants trying to work this through—until the program design is done in detail, and that requires the stakeholder input.

We're in a circulatory design mode right now whereby we want to reduce impact; we don't want to lay it down in stone. At the same time, then, you can't have the exact cost, but I could safely say for risk group two we are trying to minimize the impact.

Mr. Tim Uppal: You had mentioned ongoing stakeholder consultations. I know you've done extensive consultations previous to this, but can you tell us a little bit about the future consultations?

Ms. Theresa Tam: I think one of the proposals we have going forward is that not only will we design a consultation plan, but we will let the stakeholders have a look at it and say, "Is there anything you want to change? Can you provide input into the consultation design?" Of course, we are looking quite extensively at different methods and different groups, and of course the stakeholders include the laboratories we know.

Upon royal assent, we will actually require all labs to contact us and give us a name. When we have that name and know the other 4,000 contacts, we would also be able to consult with those laboratories we don't already know about.

We will definitely be consulting with the provinces and territories very extensively at different levels.

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

It's 5:15 right now, and we have a motion and some other things we have to deal with before the bells ring and we vote.

I want to thank you so very much for your contribution today. It's been very insightful.

● (1715)

Dr. David Butler-Jones: Thank you.

Thank you, committee. It's always a pleasure. Hopefully it's been helpful to you. I'm happy to address any issues, and look forward to the next time. If there are any questions we can follow up on we'll be happy to do so.

The Chair: Thank you so much.

We are going in camera. We have some business that has to be attended to before the bells ring at 5:30. I'd be so appreciative if you could exit the room as quickly as possible and take any conversations you might have outside.

Thank you.

[*Proceedings continue in camera*]

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