HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

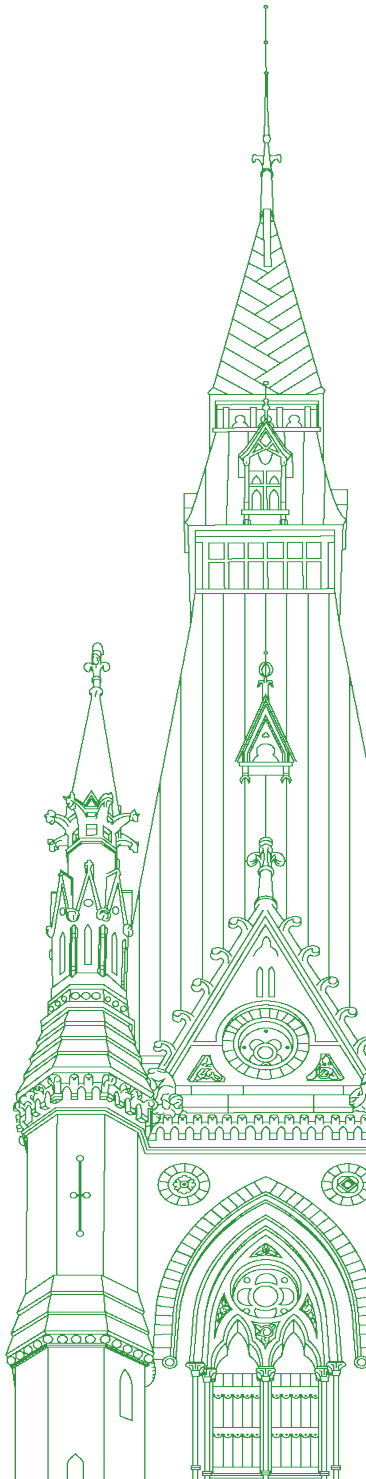
44th PARLIAMENT, 1st SESSION

Standing Committee on International Trade

EVIDENCE

NUMBER 078

Tuesday, October 31, 2023



Chair: The Honourable Judy A. Sgro

Standing Committee on International Trade

Tuesday, October 31, 2023

● (1100)

[*English*]

The Chair (Hon. Judy A. Sgro (Humber River—Black Creek, Lib.)): I call the meeting to order.

This is meeting number 78 of the Standing Committee on International Trade.

Today's meeting is taking place in a hybrid format, pursuant to the Standing Orders. Members are attending in person in the room and remotely by using the Zoom application.

I need to make a few comments for the benefit of witnesses and members.

Please wait until I recognize you by name before speaking. When speaking, please speak slowly and clearly. For those online, please mute yourself when you are not speaking. I remind us that all comments should be addressed through the chair. For members in the room, if you wish to speak, please raise your hand. For members online, please use the "raise hand" function.

For interpretation online, you have the choice at the bottom of your screen of either floor, English, or French. Those in the room can use the earpiece and select the desired channel. If interpretation is lost, please inform me immediately, and we will ensure that interpretation is properly restored before resuming the proceedings.

I ask all participants to be careful when handling the earpieces in order to prevent feedback, which can be harmful to our interpreters and cause serious injuries. I invite participants to speak into the same microphone that their earpiece is plugged into, and to place earpieces away from the microphones when they are not in use. We should just have that on a video, and play it at every meeting.

Before we deal with Monsieur Savard-Tremblay's motion, I need approval of the budget request. I believe you all have it in front of you. It's for approximately $8,000 for this study. Is everyone okay with that?

(Motion agreed to)

The Chair: Thank you very much.

We have witnesses before us today. Thank you very much for making time to come before our great committee. I think you will find that we're a super group of people who have many questions. We look forward to some answers.

From the Department of Foreign Affairs, Trade and Development, we have Callie Stewart, executive director, technical barriers and regulations.

From the Department of Health, we have David Lee, chief regulatory officer, health products and food branch; Celia Lourenco, associate assistant deputy minister, health products and food branch; and Lisa Duncan, acting director general and chief registrar officer, registration directorate.

Welcome to you all.

We will begin with opening remarks from Ms. Lourenco.

Dr. Celia Lourenco (Associate Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Hello. Thank you for the opportunity to appear before you today.

My name is Celia Lourenco. I am the associate assistant deputy minister of the health products and food branch at Health Canada. I am joined by David Lee, chief regulatory officer of the health products and food branch, as well as colleagues from Health Canada's Pest Management Regulatory Agency and Global Affairs Canada.

In Canada, biocides are products that sanitize or disinfect nonliving and non-liquid surfaces to prevent disease in humans or animals. Examples of biocides include wipes or sprays applied to sanitize or disinfect surfaces such as countertops, floors or objects.

Depending on their use or purpose, biocides are currently regulated under two separate legal frameworks: either the Food and Drugs Act or the Pest Control Products Act. As the federal regulating authority, Health Canada oversees the market authorization and safety of these products to help ensure that Canadians have access to a wide range of biocides that meet safety, efficacy and quality standards.

As members of this committee are aware, Health Canada is proposing to create new regulations for biocides under the Food and Drugs Act that would consolidate the regulation of these products under a single framework. The current system of multiple frameworks results in inconsistent oversight, confusion for some stakeholders and delays to market access. Stakeholders have been asking for change for a number of years.

In addition, the COVID-19 pandemic increased the demand for biocides, leading to shortages. Also, the department experienced an influx of biocide applications that led to delays, underscoring the challenges with the current system. Interim measures were put in place during the pandemic to expedite access and reinforced the need for a more agile way of regulating these products.

The new regulations aim to build on the lessons learned from the pandemic and to create a more modern approach, with risk-based requirements that will reduce market disruption. They will provide more clarity and predictability for industry and Health Canada and bring innovative biocides to the market sooner, while also continuing to protect the health and safety of Canadians.

One of the innovative approaches in the proposed regulations is that Health Canada would allow applicants to leverage the authorization of a trusted foreign regulatory authority to expedite the review and authorization of the same product in Canada. This review pathway recognizes that scientific and regulatory standards used in the development and regulation of these products are aligned internationally and would create efficiencies in the regulatory approval process in Canada without compromising our standards.

While Health Canada's regulatory review would be streamlined, the same level of scientific evidence as for any other biocide would still be required prior to approving a product. Additionally, once these biocides are on the Canadian market, a greater level of safety oversight would be applied to these products, as compared to other biocides.

● (1105)

[*Translation*]

As is standard for all regulatory proposals, this proposal has undergone extensive consultation to date. We have gone through the rigorous Canada Gazette process that included a 70-day public consultation period beginning on May 7th, 2022. In addition, Health Canada has met regularly with stakeholders, starting in July 2019, to inform the development of the proposed regulations.

We have heard from many stakeholders who welcome these measures to simplify the regulations and encourage market access of innovative biocides. However, some stakeholders representing Canadian companies have expressed concerns about competition from foreign products entering the market. As mentioned, regardless of the review pathway, all biocides must meet the Canadian scientific and regulatory requirements before they can be approved.

In closing, Madame Chair, the proposed Biocides Regulations are an innovative set of measures that will simplify the regulatory process and bring about a more agile framework without compromising safety, efficacy, and quality.

We are committed to continuing to work with stakeholders and evaluating their feedback as we move to final publication.

Thank you once again for inviting us and I look forward to answering any questions that the committee may have.

[*English*]

The Chair: Thank you very much. We will now open the floor for questions.

Mr. Seeback, you have six minutes, please.

Mr. Kyle Seeback (Dufferin—Caledon, CPC): I want to briefly ask a question of Ms. Stewart.

Have there been any trade issues raised with respect to this matter from any of our trading partners on this new proposed framework?

● (1110)

Ms. Callie Stewart (Executive Director, Technical Barriers and Regulations, Department of Foreign Affairs, Trade and Development): No, not to my knowledge.

Mr. Kyle Seeback: This is not like the digital services tax, on which we get letters from the ways and means committee, or with respect to Bill C-282. We've heard from many trading partners of their unhappiness with that bill. There are no trade implications, it would appear, with respect to this piece of legislation. Is that correct?

Ms. Callie Stewart: To the best of my knowledge, that is correct. In fact, I had to look this up before coming to this committee. Concerns really have not crossed our desk from the perspective of either trading partners or stakeholders.

Mr. Kyle Seeback: That's my understanding as well.

To the other members who are here today, was there broad consultation on this new framework with industry stakeholders?

Dr. Celia Lourenco: Yes, absolutely. We consulted quite broadly on it. We started our consultations in 2019, and, in the last few years leading up to Canada Gazette, part I—CGI—we continued to consult. We launched our CGI consultation last year, with ongoing engagement following CGI as we worked towards CGII to revise the proposal.

Mr. Kyle Seeback: Would you say that there is broad support for this framework?

Dr. Celia Lourenco: There is broad support in some areas. There is mixed support in others. There is a bit of concern on one of the aspects of the proposal that has to do—

Mr. Kyle Seeback: Is that the use of foreign decision?

Dr. Celia Lourenco: It's the use of foreign decision.

Mr. Kyle Seeback: Is that where the concern would lie with some of the stakeholders?

Dr. Celia Lourenco: Yes, that's where the concern lies.

Mr. Kyle Seeback: Before, different disinfectants or sanitizers went under different reviews. Now it's going to be under one review. I would call that cutting red tape, streamlining and more efficiency. Would you agree with that assessment?

Dr. Celia Lourenco: From our perspective, yes. For that reason, there is broad support. Because of the streamlining under one single framework, that aspect of the proposal is broadly supported.

Mr. Kyle Seeback: Removing the gatekeepers is wonderful.

I am going to share the rest of my time with Monsieur Martel.

[*Translation*]

Mr. Richard Martel (Chicoutimi—Le Fjord, CPC): Thanks to the witnesses for being with us today.

Ms. Lourenco, you say that the purpose of the new measures provided for in the new regulations is to ensure “a consistent and flexible approach to the regulation of biocides”.

What, more specifically, are the aspects of the process that you propose to improve?

[*English*]

Dr. Celia Lourenco: First of all, what we're aiming to improve is bringing the regulation of these products under a single framework under the Food and Drugs Act. Currently there are different categories of these products that are regulated under different acts that have different requirements and different timelines for the review. We'd like to consolidate that under one act.

The other change is that we're creating a new set of regulations that are a lot more appropriate for these types of products versus the regulations that we have currently. They will have requirements that are more risk-based and will also have different mechanisms for these products to be reviewed and enter the market. It would facilitate access to broader ranges of products.

One of the examples is the use of a foreign decision pathway. That would allow for products to come in through a process that's simpler, more streamlined and less costly for industry.

[*Translation*]

Mr. Richard Martel: Every country has its own particular standards for the regulation of chemicals?

Do you think it would be possible for Canada to recognize foreign approval without having to make any major compromises on safety standards?

[*English*]

Dr. Celia Lourenco: Absolutely. That is absolutely our aim, because in the regulations of these products there is a tremendous amount of international engagement and collaboration. The standards that we apply in Canada for these products are international standards that many other countries also use, and for that reason, if we rely on an international review of these products, it would not jeopardize our standards.

Also, when we conduct our review, we will continue to make sure that the products that are coming through that use a foreign decision pathway meet other additional requirements that we have in Canada, such as the requirements related to labelling, having labelling in both official languages and the requirements around packaging.

● (1115)

[*Translation*]

Mr. Richard Martel: All right.

How will you determine what a trusted foreign regulatory authority is? What are the selection criteria?

[*English*]

Dr. Celia Lourenco: To start off with, we have identified the United States Environmental Protection Agency as the first key competent international regulator that we will use to recognize their reviews, and the way that we've identified that is we did a very detailed crosswalk of their regulatory requirements against our requirements, including our scientific requirements, to make sure that they aligned very closely.

[*Translation*]

Mr. Richard Martel: Thank you.

[*English*]

The Chair: Thank you very much.

Go ahead, Mr. Miao, for six minutes, please.

Mr. Wilson Miao (Richmond Centre, Lib.): Thank you, Madam Chair, and thank you to the officials for being here today.

Could you provide an overview of the pathway that these proposed regulations have taken since 2019, including the engagement and consultation with industry and stakeholders in Canada?

Dr. Celia Lourenco: Madam Chair, I'm happy to provide details of that.

We have consulted very closely with industry stakeholders on the development of this pathway, starting out with engagements in 2019, as I've mentioned. Our idea was to make sure that our approach to the regulatory design would be met with good support from the different stakeholders, so leading up to the publication of the regulations in 2021, we consulted with stakeholders in July of 2019 and then through several months up to 2021, when the regulations were published.

We also considered a number of responses to surveys that we conducted on the cost-benefit analysis leading up to that publication, which occurred in May 2022.

Mr. Wilson Miao: Thank you.

I understand that currently biocides are regulated under two different legal frameworks. What impact does this have on oversight? You mentioned during your remarks that this can result in delays to market. What other factors are there?

Dr. Celia Lourenco: The new regulations will definitely provide additional ways for products to enter the market, but without sacrificing oversight of these products. We'll continue to ensure that the required scientific and regulatory standards are met, and then on the post-market side we'll continue as well to make sure that we monitor the safety of these products. If there are any incidents, we'll be able to follow up with compliance on these products, including revocation or suspension of an authorization if needed.

Mr. Wilson Miao: How will the proposed regulation increase our alignment with our neighbour, the United States, and internationally over a period of time?

Dr. Celia Lourenco: Can you repeat the question, please?

Mr. Wilson Miao: How will the current proposed regulation increase our alignment with our counterpart in the United States, and also with our international partners across the world?

Dr. Celia Lourenco: Thank you for the question.

One of the ways that will definitely increase the alignment is bringing it all under one regulatory framework. This will make sure that it's well aligned with how these products are regulated in other countries. They're all regulated similarly under a similar framework.

The other way that it will also align is in terms of the requirements that we're putting into the regulations. We're making sure that they're very much aligned with what the other requirements are internationally.

Mr. Wilson Miao: In your remarks, you also mentioned learning from the pandemic we just experienced.

How did this pandemic highlight or expose the challenges that can arise in getting biocides to the market and the impact of the cumbersome regulations that was experienced?

● (1120)

Dr. Celia Lourenco: Thank you for the question.

During the pandemic, we definitely experienced some challenges with availability of the products in the Canadian market.

First we experienced a significant number of shortages, and then we needed to react to make sure that we provided access to new products. We put in place an interim measure to allow for products to come in from other international jurisdictions, and the majority of them came in from the United States. We wanted to make sure that we had these kinds of products on the market to address the COVID-19 pandemic.

Mr. Wilson Miao: Do you see a rise in manufacturing of those biocide products here in Canada after this proposed regulation is sent forward?

Dr. Celia Lourenco: It's difficult to predict whether we would have an increase in the manufacturing of these products, but certainly there would be an ability for more products to enter the market and for more innovative products to enter the market from the United States, as an example.

In the future, we are looking to expand beyond the United States as a country of reference, but once those innovative products enter the market, there is the ability for companies in Canada to go under a licence agreement, as an example, to be able to also market the same product in Canada.

The pathways that we're putting in place will allow for that. They will allow for Canadian companies to be able to collaborate with international companies and market those international products in Canada through licensing agreements.

Mr. Wilson Miao: Thank you very much.

The Chair: Thank you very much.

We'll move on to Monsieur Savard-Tremblay, please.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay (Saint-Hyacinthe—Bagot, BQ): Thank you, Madam Chair.

Thanks to the witnesses for being with us.

Why do the proposed regulations not apply to certain products, such as certain disinfectants and surface sanitizers?

[*English*]

Dr. Celia Lourenco: Thank you for the question.

This regulation applies only to a product that has a claim that it will prevent disease by preventing the growth of bacteria or viruses or by being able to kill microbes so that it prevents disease in humans. These are the types of products that we're targeting. They are products that are applied to non-living surfaces, whether hard surfaces or soft surfaces.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: As we know, there are currently two quite different markets. We are considering a proposed harmonization.

In Canada and Quebec, many small and medium-size businesses are developing in this field. In the United States, we mainly see multinationals, whose headquarters are mostly established outside Canada, and mainly in the United States.

How can we ensure that harmonization is bilateral? The United States is the only foreign country whose name is published in Part 1 of the Canada Gazette. How can we be sure that the United States offers reciprocal treatment for Canadian products that they import?

[*English*]

Mr. David Lee (Chief Regulatory Officer, Health Products and Food Branch, Department of Health): Madam Chair, the question is an important one about knowing that we have the right safety.

Essentially, we analyzed that the United States does the same testing as we do here to show that it works and that it's safe. That's very exact. The laws are intended to be harmonized, so there's not a difference.

In terms of other regulators, we do interact with other regulators in other markets, so the conversations with the European Union will be an important discussion. We're having those now, and as we get more confident, we will add jurisdictions to the list.

This is a beginning. Again, they're very well known. We work with the EPA quite often and we know their science. This gave us the confidence to put it on the list, but certainly there are others that will populate the list in the future.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: Is it very likely that other foreign regulatory organizations, other than those in the United States, will be added to the list? I would ask you to answer with a yes or no.

● (1125)

[*English*]

Mr. David Lee: We're in research and conversations even now.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: However, some stakeholders have told us about their concerns. We know that the important factor in gaining market access for new products is speed.

You mentioned streamlining and more flexible regulations. Under the current proposal, the review of products from the United States would be streamlined, but, at the same time, Canadian businesses seeking to sell their products here in Canada would be put at a disadvantage. Their products won't be pre-approved in the United States, and it will take more time to process their files.

What are your observations on that subject?

[*English*]

Dr. Celia Lourenco: The use of the foreign decisions pathway will be more efficient. The products coming in through that pathway would take 90 days to review. Products that require a full assessment would take a bit longer to review—180 to 210 days, as an example.

However, we do have other abbreviated pathways that Canadian companies can use. Two of the pathways that would rely on a smaller set of evidence that Canadian companies can use would be a 45-day review or a 60-day review, based on standards that Health Canada sets in advance. As long as the Canadian company can follow those standards, then they can also use those pathways, which would be faster than the use of a foreign review decision pathway.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: You're referring to a Canadian business wishing to sell its products in Canada, aren't you?

[*English*]

Dr. Celia Lourenco: Yes, that is a Canadian company selling products in Canada, but those other faster pathways would also be available to other companies if they wish to use those pathways in Canada.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: However, the regulatory regime isn't formally harmonized yet.

You're telling us that you've seen similar procedures in the United States. Would you please give us more details on how that has been audited?

[*English*]

Dr. Celia Lourenco: We work very closely with the United States Environmental Protection Agency. We have a very close relationship. We've worked together on standards, so we have a lot of confidence in their approach to the way they review those products, just through the long-standing relationship we've built with them over the years.

The Chair: Thank you very much.

We will move on to Mr. Cannings, please.

Mr. Richard Cannings (South Okanagan—West Kootenay, NDP): Thank you.

This is a learning experience for everyone around this table.

I'd like to back up and learn a bit more about biocides in general. It's clear that they are sanitizer types of things that you would use to clean surfaces or skin or whatever. You mentioned the impact of COVID on that supply, and why we needed more sanitizers.

I have a lot of distilleries in my riding. They are small distilleries that switched over to, or added, the production of hand sanitizer in their business model. Are those various types of alcohols included in these regulations?

Ms. Lisa Duncan (Acting Director General and Chief Registrar Officer, Registration Directorate, Department of Health): Thank you for the question.

The disinfectants and sanitizers are used for hard surfaces and/or soft surfaces. Those microbial elimination products do include alcohols. However, hand sanitizers are not included in the biocides regulations. These biocides are used on hard, non-porous surfaces or on textiles such as soft surfaces or carpets.

There are two different pathways to authorization in Canada. The regulations here apply to the biocides, whereas there is a slightly different pathway for the hand sanitizers.

Mr. Richard Cannings: That doesn't include things that you put on your skin. When I get a vaccination and they scrub my shoulder, that substance is not included in this.

Ms. Lisa Duncan: No, this is really for non-living hard surfaces or soft surfaces.

● (1130)

Mr. Richard Cannings: Okay.

With other trade issues, we've heard of non-tariff barriers around meat carcasses here that are washed with certain chemicals to help preserve them. That causes problems when we try to sell that product in Europe, for instance.

Is that not part of this process?

Ms. Lisa Duncan: In your example, biocides that are used to sanitize a beef carcass are regulated under the Food and Drugs Act and are captured as part of this work on the biocides regulations.

Mr. Richard Cannings: Would there be any benefit to these changes in regulations to help bring Europe onside with that issue? Of all the trade issues about how biocides interfere with trade, this is the one that sprang to my mind.

Mr. David Lee: That question, again, goes to our analysis. Certainly this platforms the science so that we can organize the area and our supervision of it. However, assessing how much it will be like Europe is something that we will continue to do for those particular products.

Mr. Richard Cannings: If you're in talks with the European Union about making these regulations more similar, might that be a benefit down the road?

Mr. David Lee: It is certainly a point we can raise, Madam Chair.

Mr. Richard Cannings: Please do.

You say there are new, innovative products here. I'm trying to get at what spurred this need for change and what the problem was.

What kinds of innovative products are out there that somehow we can't produce in Canada, such that you wanted to speed up the process or make it more efficient? Can you give us some ideas there?

Dr. Celia Lourenco: Definitely. Thank you for the question.

The COVID-19 pandemic really demonstrated the challenges with the current framework and the need to be more agile and have the ability to bring in products more quickly when there are challenges in access to products in Canada. That was a key driver for the change. These regulations are integrating the lessons learned from the COVID-19 pandemic into this new framework that provides different pathways to market.

In terms of different kinds of innovations in biocides that we're seeing, I'll turn to my colleague Lisa to answer.

Ms. Lisa Duncan: Thank you for your question.

We've certainly seen a larger demand since the COVID-19 pandemic for a variety of innovative products, some of which are part of the biocides regulations, such as laundry additives. We've seen a higher demand for products that will sanitize textiles and clothing, as well as surfaces.

There's another subset of products that have a greater interest in entering the Canadian market, which will remain under the Pest Control Products Act. These are certain linked devices such as UV radiation-emitting devices and ozone-generating devices, for example.

We still have a different pathway to market for those types of products, given that they have a higher exposure scenario, which merits a different type of rigorous review, whereas the oversight of similar types of biocide products will be streamlined and consistent with our counterparts in the U.S.

The Chair: Thank you very much.

You have 32 seconds.

Mr. Richard Cannings: That's okay.

The Chair: Thank you very much.

We'll go to Mr. Baldinelli for five minutes, please.

Mr. Tony Baldinelli (Niagara Falls, CPC): Thank you, Madam Chair.

I'd like to thank the witnesses for being with us today. Thank you for the educational opportunity you've provided us in giving some more examples of what biocides are and the need for the regulations.

Based on what my colleague has indicated, there seems to be a universal acceptance that the regulations need to be updated into one system, as opposed to regulations under two different acts: the Food and Drugs Act and the Pest Control Products Act. That's been universally accepted, I think.

You've indicated that from the stakeholders, the one area of concern is the foreign decision pathway.

With regard to the concerns that are being raised by those Canadian firms, is it simply that their concern stems from the fact that it would probably be easier for some of the larger multinationals that exist in Canada to bring in their products from the United States? Is it that instead of Canadian manufacturers developing and manufacturing these type of products in Canada, they could simply be brought in from the United States?

● (1135)

Mr. David Lee: Thank you for the question, Madam Chair.

On the pathway for use of foreign decisions, a couple of things are important to lay out.

First of all, the companies in the United States would not be required to do any less science. They would still do the same testing. If you started the clock at “I'm going to develop a new product”, they would have to do all the normal tests that they would do here in Canada. All of those would be required in the regulatory text here. Frankly, it's that basis that brings the equity, at least in terms of filing under that pathway, because you'd have to get approved by the EPA and then come to us.

Again, you'd start the clock at the test and you'd still spend the time getting your primary approval, and then you'd come to Canada. The only thing we're not looking at is that primary scientific data to show effectiveness and safety. We trust that, because we work with the EPA and we know their tests are the same tests.

They have to keep the information on hand, so if we need to look at it, we can get it very quickly.

Mr. Tony Baldinelli: If they've already had their EPA approvals in the United States, how long does it take them to get those approvals in Canada, then? Is it under the pathways of 45 days or 60 days? I imagine they wouldn't need the 200-day approval method. Is that correct?

Dr. Celia Lourenco: For that pathway, it's a 90-day review, simply because our scientists would not need to spend as much time on the review process. They would take the review conducted by the American scientists into consideration and would be able to expedite the process.

Mr. Tony Baldinelli: You indicated that you're in discussions with other countries as well to expand the pathways. Do you believe you will be able to reach agreements before the final regulations are posted, or will that still take some time?

Dr. Celia Lourenco: We don't anticipate that the agreements will be reached before the regulations are posted. That is something that would unfold afterwards. We're starting first with the United States as a reference country and we'll initiate the review of other regulators afterwards.

Mr. Tony Baldinelli: Those will be based on that.

One year from the date of posting is when the regulations come into effect. Is that enough time for Canadian manufacturers to meet the regulations?

Dr. Celia Lourenco: One year after posting, they would come into effect, but then there would be a transition period. We are looking at a transition period of four years for existing disinfectants and surface sanitizers and a bit more time—six years—for products that are used in food establishments.

Mr. Tony Baldinelli: Finally, have the consultations ceased? Have you finished all of your consultations, or are they continuing?

Dr. Celia Lourenco: We carried out the CG I consultation process. We continued to have consultations up until very recently, and we continue to be open to receiving additional feedback as we work towards the CG II publication.

Mr. Tony Baldinelli: Thank you.

The Chair: Thank you, Mr. Baldinelli.

We go now to Mr. Arya. Go ahead, please.

Mr. Chandra Arya (Nepean, Lib.): Thank you, Madam Chair.

Several times you mentioned that you trust and work closely with the United States Environmental Protection Agency. How much trust did you have with the EPA under the four years of President Trump?

Mr. David Lee: I'm actually not aware of that. I know that as regulators, we talk about the scientific standards—

Mr. Chandra Arya: I understand that. Let me come to that.

Based on the study research done by Harvard Law School and Columbia Law School, the New York Times did a thorough analysis and came out with a list of 100 environmental rules that were revised, removed or reversed. Specifically, let me say the Trump administration repealed a clean water rule and rewrote EPA's pollution control policies. When we have a foreign government agency that has done that over a period of four years, I'm a bit concerned that you 100% trust the same agency.

● (1140)

Mr. David Lee: To our knowledge, there was no effect on the disinfectant and sanitizer side. We detected no change in the standard. They still had the same standards and performed the same science we would be relying on.

It's worth saying that when COVID came along, we had to work very closely together, and it's probably a very good thing for product safety regulators to be that co-operative. It really did bring together a lot of scientific evidence.

Mr. Chandra Arya: Thank you.

You did the consultation. How many people participated in the consultation process?

Dr. Celia Lourenco: I'm looking through my notes to see if I have the data. I'll have to come back to that. I'll have to check my notes.

Mr. Chandra Arya: What would it be approximately—300, 500 or 1,000?

Dr. Celia Lourenco: Well, several associations provided comments. We received comments from definitely a number of different associations. It was quite robust.

Mr. Chandra Arya: Was it 100 or 200?

Dr. Celia Lourenco: I don't have the—

Mr. Chandra Arya: That's okay.

What percentage of those responses were from domestic manufacturers?

Dr. Celia Lourenco: We had a lot of input from domestic manufacturers from different provinces in the country. We definitely had robust input from different manufacturers.

Mr. Chandra Arya: But you don't have the percentage of the responses that were from domestic manufacturers.

Dr. Celia Lourenco: In terms of the responses, I don't have the percentage from domestic manufacturers.

Mr. Chandra Arya: That's interesting. For me, the regulations you have are generating reasons to do that. It appears that more has been done to ease imports into Canada rather than to promote domestic manufacturing.

Is that so?

Mr. David Lee: The use of the foreign decisions pathway is one pathway. Really, the whole regime is meant to be tailored to these products. For many years, they've been regulated as drugs, which was not suitable, so there are efficiencies—

Mr. Chandra Arya: I apologize. I have limited time. I have one minute left.

What is the size of the biocides market in Canada? How much of it is bought from Canadian domestic manufacturers, and how much through importation?

The Chair: Perhaps the witness could possibly get that information to the committee following today's meeting.

Dr. Celia Lourenco: I can answer the question, Madam Chair.

The Chair: Okay, please go ahead.

Dr. Celia Lourenco: In terms of the size of the markets, it's estimated to be worth about $200 million annually in terms of the biocides sector. In terms of companies, we have a split: About 69% of the companies are Canadian-based, and about 31% are international.

Mr. Chandra Arya: No, it's the size, because 69% may be tiny manufacturers. From the $200-million market, what percentage is from domestic manufacturers and how much is through importation?

Dr. Celia Lourenco: Out of the $200 million, we would need to get that. Regarding the percentage of the Canadian market, we would have to get that data for you.

The Chair: Thank you. If you could have that sent to the clerk, it would be appreciated.

Next we have Mr. Savard-Tremblay for two and a half minutes, please.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: Thank you, Madam Chair.

We're told that this isn't a new product category and that there won't be a variable-geometry process for Canadian and Quebec companies, on the one hand, and American companies, on the other.

What will these new proposed regulations make easier for our businesses, which are small and medium businesses, SMEs, and have to face competition from extremely powerful American multinationals?

How does that contribute to the domestic market supply chain?

[*English*]

Dr. Celia Lourenco: We know that about 25% of the companies that market these products in Canada are small businesses. A good majority of them, about 75%, operate through licence agreements in Canada. The use of the foreign decisions pathway and additional products entering the market could create new opportunities for Canadian small businesses to enter into licence agreements.

● (1145)

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: Yes, how many of those businesses, which represent a 75% majority, are in fact a profit centre in the United States?

[*English*]

Dr. Celia Lourenco: We know that about a third of the companies that market these products in Canada are international. The vast majority, over 90%, are American companies. The other 66% or so are Canadian companies, and out of those, 25% are small businesses.

A good majority of those small businesses do those licensing agreements, as I explained. They can do licensing agreements with Canadian companies, American companies, or with companies from elsewhere that may not be interested in Canada as a smaller market. They may want to leverage an agreement with a Canadian-based company to sell their product in Canada and not have to worry about bringing the product in themselves.

The Chair: You have 15 seconds.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: I won't have enough time to ask any more questions. Let's go to the next round.

[*English*]

The Chair: Thank you very much.

Mr. Cannings, you have two and a half minutes.

Mr. Richard Cannings: I want to find out more about the genesis of all this and what drove the decision to change these regulations.

It seems that the use of these foreign decision pathways mainly benefits companies that have already gone through the EPA process. Was it pressure from some of those importers into Canada that were exporting from the United States, or was it that your departments were facing an increase in applications and that this would make it more streamlined? I'm trying to get an idea of why you decided to make these changes and what was driving your department internally to do that.

Dr. Celia Lourenco: These changes have been a long time coming. We've been hearing from industry stakeholders for quite a long time about the concern of having different products with similar risks, similar applications, similar uses and similar claims regulated under different frameworks. We've been hearing from industry for a long time about the desire to have this fixed so that depending on the product they have, they could just go to one single place to get their application. That's one of the key drivers that's been in play for a long time.

The COVID-19 pandemic highlighted that even further. Some of our earlier pathways would take longer for products to enter the market. The COVID-19 pandemic highlighted the need for more flexibility in our different pathways for these products. That was another key driver.

The third one is that the regulations that are in place now, before the biocides regulations come, in have standards that are not quite risk-based. They don't quite fit the need for these products. There was, really, a need to create a new set of regulations that would be able to address all of these concerns.

Certainly during the pandemic, we saw a very high influx of products. Usually we get about 200 to 300 applications for these products per year. During the pandemic, 900 applications came in per year. It really highlighted the need for more efficiency as well.

The Chair: Thank you very much.

Mr. Richard Cannings: I had one more question.

The Chair: I'm sorry, Mr. Cannings. We now have Mr. Jeneroux for five minutes.

Mr. Stéphane Lévesque: Thanks, Madam Chair. I'll just put my timer on quickly.

Thank you for being here and joining us today. It has been fascinating to learn about this from all sides of the table.

Just so I'm clear on how this works, if a company wants to do business in Canada or vice versa, do they come to Health Canada? Does Health Canada go to them? Is this through the Department of Trade? Can you walk through an example of this?

● (1150)

Dr. Celia Lourenco: Sure. If a company wants to market one of these products in Canada, they file an application with Health Canada. They can also come and meet with us in advance to talk about their application and what their plans are. We are happy to provide guidance on that.

We also have guidance that's published on our website for companies to be able to follow the process in terms of applying to Canada.

Mr. Matt Jeneroux: That's the first part. Then, after that, if they're approved already in the U.S., for now they then say that they have this approval under everything that's done in the U.S. Then, at that point, do we go through the process of the approval, or is that essentially what the application is from the start?

Dr. Celia Lourenco: The companies are the ones who initiate the process in terms of getting a product reviewed and authorized in Canada. There are different ways that they can have their product approved, depending on whether it's a new product, a product that's copying another one that's already available on the market, or a product that is already marketed in the U.S. Depending on the product, they have different application types that they can follow.

They'll come to talk to Health Canada about what kind of application they want to file and what their product is about. Then we provide guidance on that application. Once we receive it, we review it and then issue an authorization. Then they can market their product in Canada.

Mr. Matt Jeneroux: The review started in July 2019, as you said. Prior to 2020 it was very rigid, then, throughout COVID, there was a lot of flexibility put into the process. It's now returning to the rigidity a bit, so it is not quite as flexible as it was during COVID. Would you agree with that assessment?

Dr. Celia Lourenco: I'll turn to David to talk abut the exceptional application.

Mr. David Lee: The mechanism we put in through an emergency measure only addressed imports, so it wasn't the full regulation of products. There was a driving need to have supply come in. We wanted to make sure it was a safe supply, though, so we said that it had to be approved by a list of countries, again predominantly the United States.

There were also labelling requirements, but it really wasn't meant to pull out a full scheme for appraising products.

This is tailored, I would say. It's different from the current drug regime, but it's tailored for these products. That's the advance.... It's not less, but it's focused on the types of products.

Mr. Matt Jeneroux: The review started in 2019, and then COVID happened. It paused the review, I assume, and provided a ton of flexibility, and now we're going back. Is this where we're at now? Are we through the review process?

What would be the holdup, then, of approving a country like the U.K., for example? Is that more on the trade side of things, or is Health Canada the hurdle here? What is slowing things down?

Mr. David Lee: It's more of a regulatory rigour than a hurdle. We are required to make sure there is comity: Are their regulatory requirements and tests the same? We need to really make sure that we can trust that. It is a longer process. We get to know their scientific review teams.

It's worth saying, though, that the way we've made the proposal is that as soon as we are okay with the company, we can add it by an incorporation by reference. We don't have to make a regulatory change; we can just put it right on the list when we're ready.

Mr. Matt Jeneroux: Would this be part of trade agreements, then, with the U.K. free trade agreement hopefully in its final steps, and the CPTPP and the extension with that?

Ms. Callie Stewart: Not directly. When we negotiate trade agreements, we often have regulatory co-operation chapters that encourage regulators to work together. We look to encourage mutual recognition and this kind of streamlining because it helps to get Canadian products into other markets and needed products into the Canadian market.

However, because consumer safety is paramount, it is up to the regulators to tell us trade negotiators whether or not this is any good. We encourage co-operation, but we leave it to the regulators to ultimately make the decision on whether or not they will harmonize or recognize the standards.

● (1155)

The Chair: Thank you very much.

Ms. Fortier, you have five minutes.

[*Translation*]

Hon. Mona Fortier (Ottawa—Vanier, Lib.): Thank you, Madam Chair.

Good morning, everyone.

Thanks to the witnesses for being with us.

Ms. Lourenco, in my role as President of the Treasury Board for nearly two years now, I've had the privilege of learning about the regulatory processes involved. So I know that you and your colleagues work very hard. My questions will focus more on the process, not how you engage in it.

As I understand it, representatives of Canadian businesses participated in the consultations conducted before the proposed biocides regulations were published in Part 1 of the Canada Gazette.

Would you please tell us a little bit about the challenges and risks associated with the biocides market that industry representatives told you about during those consultations.

I'm trying to understand the pressures experienced by Canadian businesses, SMEs in particular, wishing to operate in this sector. What pressures do they experience?

[*English*]

Dr. Celia Lourenco: During consultations, we heard a significant amount of feedback from different sectors and stakeholders.

Definitely the areas of support were on the idea of combining the regulations under one framework, as we've already discussed, as well as providing support for that transition period that I talked about earlier.

Some areas of concern include wanting to bring in other products under this framework, perhaps sanitizers for air, water and other uses, other than hard- and soft-surface sanitizers. Some companies suggested that we should look at bringing in other products under the framework. Others wanted to see additional countries of reference listed, other than the United States. They wanted others to be considered, which we will do. Some of them raised the concern, as we've already discussed, of the use of a foreign decisions pathway.

[*Translation*]

Hon. Mona Fortier: Did they tell you which countries, in addition to the United States, should be on the countries of reference list, or was it more open to any country?

[*English*]

Dr. Celia Lourenco: Yes, there's an interest in European countries as a next step.

[*Translation*]

Hon. Mona Fortier: So that confirms the information. I don't have much time left, but I'd like to talk to you about foreign markets.

Are these new regulations a good opportunity for Canadian businesses to access new markets and prosper?

Do you see any trends taking shape in that regard?

Ms. Callie Stewart: We didn't take that into consideration in connection with these regulations.

I'll continue in English, if I may, because I'll be more comfortable speaking.

[*English*]

When we're talking about basing our regulations on international standards and encouraging our trading partners to base their regulations on international standards, we always think about whether, as they regulate, it will be better for our exporters as well as for Canadians receiving the imports.

In this particular case, I cannot say we did a study thinking about whether or not there would be greater access or growth opportunities for biocides. However, in general, this is very much in keeping with what we believe to be useful for increasing trade.

Hon. Mona Fortier: I don't know whether anybody knows this: Do we know how many jobs we're talking about in the biocides industry in Canada?

You said $200 million in scope, but is there an increase? Was the pandemic a driver of many opportunities for small businesses to decide to try that and innovate during COVID? Do you have that type of information on the market we're talking about?

● (1200)

Dr. Celia Lourenco: The estimates are that the current market employs about 10,000 in this space in Canada. We don't have the numbers, though, about how the market grew during COVID. We don't have those numbers, unless other colleagues do.

The Chair: Thank you very much. Time has lapsed.

I want to thank the witnesses for their valuable information today.

We will suspend briefly to bring in our upcoming witnesses.

Thank you.

● (1200)

_____(Pause)_____

● (1205)

The Chair: I bring the meeting back to order.

Welcome back.

For the second hour of today's meeting, we have by video conference, from Association pour le développement et l'innovation en chimie au Québec, Mr. André Côté, member of the board of directors. We also have Stéphane Lévesque, general manager at GPIM. From the Canadian Consumer Specialty Products Association, we have Ms. Shannon Coombs, president.

I welcome you all to this important study today.

I will ask you to make opening remarks.

I will turn it over to Mr. Côté and Mr. Lévesque for opening remarks of up to five minutes.

[*Translation*]

Mr. André Côté (Member, Board of Directors, Association pour le développement et l'innovation en chimie au Québec): Thank you, Madam Chair.

Good afternoon. My name is André Côté. I'm here as an expert and member of the board of the Association pour le développement et l'innovation en chimie au Québec, or ADICQ. I work in the field of product approval by Canadian authorities—

[*English*]

The Chair: Monsieur Côté, can you hold on for one minute, please? We have a translation issue.

There's an issue with the sound. I'm going to go to Ms. Coombs first. Then we will go back to you, and hopefully we will have been able to correct the challenges with the sound.

Ms. Coombs, would you like to start off, please?

Ms. Shannon Coombs (President, Canadian Consumer Specialty Products Association): Good day, Madam Chair and members of the committee. It is a pleasure to be here to provide our input on the committee's study of the biocides regulations.

My name is Shannon Coombs. I am the president of the CCSPA. For 25 years, I have proudly represented the many accomplishments of this proactive and responsible industry.

The last three years have been very challenging but rewarding for both industry and government, as we collectively worked together to address product shortages and supply chain barriers as a result of the pandemic.

In addition to supporting increased supply of disinfectants, CCSPA is a founding member of the Canadian hand sanitizer exchange, which supported companies in sourcing materials, ingredients and packaging to manufacture hand sanitizers during the pandemic. Along with our submission, I have provided the clerk with our one-pager, “Imagine Life without Us?”, which illustrates the types of products CCSPA represents.

Who is CCSPA? We are a national trade association. We represent 40 member companies: collectively, a $20-billion industry. We employ 12,000 people in over 82 facilities across the country. Our members are Canadian companies, including SMEs, Quebec manufacturers and global companies with Canadian facilities.

In my five minutes, I will outline why the regulation is important to Canada.

What are biocides and how are they regulated? Biocides include disinfectants, sanitizers and food-contact sanitizer products. They are used in our homes, hospitals, schools, workplaces, food establishments and long-term care facilities. They prevent disease in humans and animals.

Currently, the disinfectants and sanitizers are regulated under two federal acts: the Food and Drugs Act and the Pest Control Products Act. While disinfectants and sanitizers are similar, their regulation under the separate frameworks creates duplication of review and two separate sets of user fees.

Why are the regulations important?

To address these ongoing challenges over the past 20 years, and specifically as an outcome of the pandemic, CCSPA has advocated a single risk-based framework for disinfectants under the Food and Drugs Act.

The biocides regulations directly respond to this need by establishing a single framework for the review of these products at Health Canada. The framework includes tailored biocide regulatory requirements, a modern licensing model and new registration pathways, including an authorization pathway that recognizes decisions from comparable foreign jurisdictions.

The timing of these regulations could not be more crucial as we work to directly respond to the lasting economic challenges and Canadians' increased focus on infection prevention and control in a post COVID-19 environment.

While I could speak about the importance of all the components of the regulation, I did want to speak directly to the committee's study on the potential impacts of the use of a foreign decision pathway on Canadian manufacturing.

What is the use of foreign decision and what does it do? It is an additional Health Canada review stream that will allow a company to leverage a trusted foreign regulatory authority's decision to approve a product when applying for marketing a new product in Canada. The pathway will have a condensed review, and registration fees will be commensurate with the review time.

To be clear, manufacturers and importers have many other registration pathways available to authorize their innovative biocide products, some of which have similar timelines and fees. As such, the use of foreign decision, or UFD, does not compromise the ability of Canadian manufacturers to compete in the Canadian marketplace.

How does the UFD pathway enhance and benefit the framework? It facilitates an increased supply of disinfectants and sanitizers to Canadians. It supports international trade and advances regulatory co-operation. It supports a competitive business environment, reduces red tape and aligns with our emergency preparedness objectives by codifying those temporary measures discussed earlier by Health Canada that were put in place during the pandemic. I think this regulation is a prime example of applying lessons learned during COVID to support regulatory agility in the face of a future global crisis.

How do the framework and UFD benefit Canadian SMEs? The answer is twofold. The UFD pathway offers an important option for Canadian businesses to register more novel and specialized technologies by enabling companies to sublicense. This facilitates Canadian-owned and Canadian-operated businesses to bring to market products that would otherwise be cost-prohibitive.

Canadian businesses are also supported by complementary policy measures, including the use of efficacy data generated by the National Research Council at no cost to these companies and the use of a monograph, which is another registration pathway in this regulation with reduced review times and fee mitigation for smaller businesses.

In closing, I would like to say that the biocide regulations support good public policy. There will be increased product availability. There will be innovation and a promotion of the competitive marketplace. It advances our collective objectives of regulatory modernization and agility and complements the government's objectives around drug shortages, supply chain disruption and lessons learned from COVID.

We support this regulation and we thank you for your interest in this important topic today. We believe the study and its recommendations will support and further strengthen this proposed regulation.

Given the importance of these regulations to our industry, we believe they should proceed to Canada Gazette part II without delay, accompanied, of course, by the appropriate resources at Health Canada for implementation.

● (1210)

I look forward to any questions the members may have.

Thank you, Madam Chair.

The Chair: Thank you very much, Ms. Coombs.

It's on to Mr. Lévesque, please.

[*Translation*]

Mr. Stéphane Lévesque (General manager, Groupement provincial de l'industrie du médicament (GPIM), Association pour le développement et l'innovation en chimie au Québec): Good afternoon.

My name is Stéphane Lévesque, and I am the general manager of the Groupement provincial de l'industrie du médicament, which represents the SMEs working in Quebec in the production and commercialization of drugs and natural health products, including disinfectants and biocides.

I have scientific training and 29 years' experience in the pharmaceutical field. I am very familiar with the role of disinfectants, particularly in combating the C. difficile bacterium, which is a cause of infections in hospital facilities.

Health Canada's proposed regulations will not solve the problems detected and will even result in excess work for government officials in the coming years.

There are valid reasons to question the actual intent of this regulatory framework. Products approved in the United States will not be regulated as strictly as those manufactured in Canada, which will thus result in a double standard that will work to the detriment of Canadian SMEs. This framework will not improve the productivity of Health Canada's review team but rather will result in additional delays in the approval process for our manufacturers.

Health Canada's natural and non-prescription health products directorate has tried for years to meet its own approval standards for disinfectants. Only a portion of Canadian marketing licence applications would be approved on the first round, compared to those submitted for American disinfectants, which would be approved immediately.

There must be no increase in the size of the bureaucracy. Lastly, our opposition to these proposed regulations concludes with a call for a moratorium for the purpose of determining their impact on the Canadian industry.

If the proposed regulatory framework were adopted in its present form, Health Canada would favour American businesses over Canadian businesses, most of which are SMEs.

[*English*]

The Chair: Mr. Lévesque, could you just hold on for one second?

Mr. Côté, could you restart your computer?

He's restarting his computer. We're trying to figure out some sound problems for Mr. Côté.

Please continue, Mr. Lévesque, and we apologize for the interruption.

● (1215)

[*Translation*]

Mr. Stéphane Lévesque: In recent years, Health Canada's natural and non-prescription health products directorate has asked representatives of the chemical industry to take part in confidential discussions on a regulatory framework for biocides.

ADICQ is a non-profit organization, an NPO, that pursues the following objectives: to promote, develop and encourage the chemical industry in Quebec by paying particular attention to SMEs; to bring together businesses in the industrial chemical sector, manufacturers and formulators, in particular, in order to represent their common interests, promote foreign market development, trade and strategic and technological alliances; and, lastly, to ensure regulatory oversight and to inform members on all issues pertaining to their industrial activities.

Despite ADICQ's representations, Health Canada turns a deaf ear to our requests for political reasons and continues to threaten the Canadian chemical industry, especially its SMEs, and particularly in Quebec. In our view, the recognition of foreign approvals of disinfectants and biocides will harm Canadian manufacturers. Health Canada's proposed biocides regulations provide for the exclusive recognition of American approvals in Canada, which would amount to the equivalent of a form of American protectionism imposed on Canadian businesses by the Canadian government. The proposed regulations also provide for reduced fees and shorter approval timelines for foreign products, which would benefit American multinationals, and that could in turn preempt Canadian manufacturers.

Furthermore, by streamlining review during the approval process, Health Canada cannot ensure the public's protection or guarantee product quality. The proposed regulations provide for less content to be supplied in applications for American products. As a result, Canadian products would have to meet a greater burden in order to be approved as the proposed regulations do not set forth the same criteria as for American products. Health Canada has to date refused to define how public safety from foreign products will be assured.

The creation of a new category of regulated products will clog the file review process, particularly for food-contact surface sanitizers. In 2004, Health Canada began implementing the Natural Health Products Regulations, a process that took seven years. Implementation of the Safe Food for Canadians Regulations is still unfinished in 2023, five years after the process was announced in 2018. Experience therefore shows that the proposed regulations will generate red tape that will take up at least two years and involve costs estimated at some $20,000 per product for Canadian manufacturers.

In the meantime, foreign products could be recognized and approved without review, more quickly and at lower cost. Health Canada claims that the proposed regulations are part of an equity- and transparency-based process, but, contrary to Health Canada's allegations, there is no consensus in the Canadian industry.

Since 2018, ADICQ has attended all meetings and expressed its opposition to the proposed regulations on behalf of Quebec businesses. We have even sought a moratorium. The Canadian government must remind Health Canada that we can't rob Peter to pay Paul. SMEs in the Canadian industry, and the Quebec industry in particular, would be subject to a frontal attack that would benefit the American industry. There can be no double standards in an international free trade context.

ADICQ in no way disagrees with free trade policies, particularly with the United States. The same is true of the Canadian Federation of Independent Business, an associative partner of ADICQ. We remain receptive to any regulatory framework designed to protect the health of Canadians and the economic health of Canadian businesses.

Thank you.

● (1220)

[*English*]

The Chair: Thank you for filling in for Mr. Côté, Mr. Lévesque. It's much appreciated.

We go now to Mr. Martel for six minutes, please.

[*Translation*]

Mr. Richard Martel: Thank you, Madam Chair.

Thanks to the witnesses for being with us.

Mr. Lévesque, I believe you weren't that keen on the idea of this regulatory change. What aspect of these new regulations do you consider most harmful? What do you fear most for your businesses?

Mr. Stéphane Lévesque: We actually aren't opposed to improving the system. There has to be a new framework, but two major aspects need to be taken into consideration.

First, you need to review the decision to approve American products on a priority basis and the current recognition of approvals in other countries, including the United States.

Second, you need to consider the fact that Health Canada will be swimming in applications. The number of new applications for disinfectants and food-contact surface sanitizers has been estimated at more than 800. Consequently, Health Canada's system won't be able to meet the demand. As a result, approvals of Canadian products will be increasingly delayed because American products will be immediately recognized. It's as simple as that.

Mr. Richard Martel: From what I understand, there's a lot of red tape in Canada. So the approval process, which can be long and costly, may discourage some SMEs. That's why it's important to streamline it.

What do you think of these regulations? Will they create more barriers than the present system?

Mr. Stéphane Lévesque: That's definitely the case for American businesses.

You have to be careful not to mix things up, particularly with regard to Canadian companies headquartered in Canada and those whose decision-making centres are in the United States. In my opinion, those aren't Canadian companies, and they currently represent what I would call the industry Goliath. You must not hobble David to help Goliath.

Mr. Richard Martel: The bill will come into force one year after it is passed. Do you think that one-year period is enough for businesses to update their products so they can meet the new requirements?

Mr. Stéphane Lévesque: It's absolutely not enough.

It will actually take entrepreneurs at least two years to do so, and, based on my experience, it will take even more time.

Mr. André Côté: If I may, I'd like to add some information to my colleague's remarks.

I apologize for all these technical issues.

With respect to the two-year moratorium, it must be understood that an enormous number of products aren't approved because they don't exist and don't fall into any category of the present approval process in Canada. We've forwarded product lists to Health Canada in the past. They included approximately—

[*English*]

The Chair: Excuse me, Mr. Côté, but the sound is not allowing the translator to translate your comments.

Mr. Lévesque read your deputation. We thought maybe the sound problem was corrected, but it is still a problem for the translators.

● (1225)

Mr. André Côté: It's a shame that we cannot fix this kind of issue. I've been working for 25 minutes now....

The Chair: I'm so sorry, Mr. Côté, but once the translator says that the sound is not adequate—

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: We have access to the interpretation. Mr. Côté had started speaking in English, and I heard the interpretation French. It seemed to be working.

[*English*]

Mr. André Côté: If it's easier this way and we can get through the translation issues, I'll go ahead in English.

The Chair: I'm sorry, but I am not allowed to make that decision. Otherwise, I would be very supportive of your suggestion. The system is what it is.

[*Translation*]

The Clerk of the Committee (Ms. Sophia Nickel): Good afternoon, Mr. Côté.

You may answer the questions asked in the room in writing.

I'm really sorry.

Mr. Simon-Pierre Savard-Tremblay: Madam Chair, may I ask whether the technical tests were actually conducted before the meeting? We shouldn't be in this situation right now.

[*English*]

The Clerk: The tests were done and he does have an approved House of Commons headset. He's currently wearing it and selected....

The Chair: Mr. Côté has done everything right. He has the right headset on and the rest of it is correct. Somewhere the connection is not allowing the translators to be able to hear sufficiently to be able to interpret.

Mr. André Côté: Even if I speak English to the board, there's no way we can proceed?

The Chair: It seems to be your Internet connection that is not working, Mr. Côté.

[*Translation*]

Mr. Richard Martel: Madam Chair, I should have about a minute or a minute and a half left.

[*English*]

The Chair: Absolutely, you have your time back. I am making that decision. Go ahead.

[*Translation*]

Mr. Richard Martel: Ms. Coombs, are any members of your organization opposed to this regulatory change?

[*English*]

Ms. Shannon Coombs: No, we do not have any members with that position. We've been actively working with Health Canada on this file. I think Health Canada even mentioned before the pandemic about having discussions about this regulation.

I think we need to look at it from the perspective of how the use of a foreign decision pathway is going to enable all Canadian businesses, regardless of where that business is located.... It's really about the data package. If that data package isn't commercialized in the U.S., they can bring it here, and Canadian companies can use that data package. As well—as I mentioned in my comments—the National Research Council has created data packages for efficacy so that Canada companies can build on that information to be able to have Canadian registration.

I think the big picture is that this biocides framework, as mentioned by Health Canada, is tailored to those products and has various review streams for all of them to be reviewed and have Canadian approval. As well, it's to have the Canadian label that we need. It helps us with our pandemic preparedness as we go forward, Madam Chair.

The Chair: We'll go on to Mr. Sidhu, please.

Mr. Maninder Sidhu (Brampton East, Lib.): Thank you, Madam Chair. Thanks to the witnesses for taking the time to join us here today.

My question is for Ms. Shannon Coombs.

I'd like you to respond to the perspectives shared by other witnesses. Would you agree or disagree? I just want to hear your thoughts.

Ms. Shannon Coombs: Is that to anyone specifically?

● (1230)

Mr. Maninder Sidhu: I'll let you choose.

Ms. Shannon Coombs: We have had concerns, as we've gone along, with the regulation. I wanted to thank Health Canada for their continued collaboration with all of the industry and stakeholders to hear everyone's concerns about the regulation.

There have been some concerns around fee lines. One was around a novel technology, which is another pathway for review for a new technology brought into Canada. We actually went back and looked at the fees and tried to come up with a way that would address any SME concerns. We are waiting to hear back from Health Canada on that particular point.

I really have to say that this regulation is the gold standard for how a regulation should be developed. There's been extensive consultation. It is science-based. Scientists from the EPA and Health Canada were having discussions about what that regulatory package would look like. In the face of a pandemic, we were able to bring in products through the interim authorities. What was really great was that not only were those products available to Canadians, but also that our member companies were able to donate them to our communities. That's what I would consider a very rapid response in taking that emergency preparedness and actually putting it into the regulations. That's something we should all be very proud of.

Mr. Maninder Sidhu: Thank you for that insight.

We talk about updated regulations in terms of innovation. Do you believe that the updated regulations will result in more innovative products entering the Canadian marketplace? If yes, could you share some of the types of products?

Ms. Shannon Coombs: Absolutely. I think that's one of the things on which Health Canada has been very responsive. We've been able to address those concerns by bringing this data package to Canadian companies. We know that we have active ingredient suppliers who have no intention of bringing any end-use products into Canada and are going to be able to sublicense them to Canadian companies. It's to the benefit of all Canadian companies, regardless of where they're located.

Mr. Maninder Sidhu: Thank you for that.

The Chair: Mr. Sidhu, you're frozen. It's most unfortunate.

I'm going to move on. We have three minutes.

[*Translation*]

Hon. Mona Fortier: I could take his time, Madam Chair.

[*English*]

The Chair: I have three minutes remaining for Mr. Sidhu. You can take it, Mr. Arya.

Mr. Chandra Arya: Thank you, Madam Chair.

Ms. Coombs, you said you represent the industry. How many members do you have, and how many of them are manufacturing companies?

Ms. Shannon Coombs: Our member companies have a wide range of products. Just in the biocide space, we represent 70% of the household use. Due to the complexities around institutional and hospital settings, we represent the industry leaders in that space.

Mr. Chandra Arya: My concern is that usually whenever industry bodies come here, they say they represent the industry. It's all good. Sometimes, depending on the size—the number of members and how big they are—the trading companies, the resellers who represent the foreign entities, have a dominant voice within the industry association.

When you represent this trade body, how much of your work is for domestic manufacturers rather than importers?

Ms. Shannon Coombs: Thank you for asking about how we do our policy inside our organization. It is very collaborative and consensus-based. We represent all of the companies that work in the space. We ultimately want to have good public policy at the end of the day that drives jobs in Canada and drives innovation in products—

Mr. Chandra Arya: That is the problem I have, Ms. Coombs—

Ms. Shannon Coombs: I know you look a bit suspicious, but it's true—

Mr. Chandra Arya: Ms. Coombs, that is a problem I have, because every word you said was perfect. It was about “the collaborative purpose” and “representing the voice of the industry”.

I have seen industry associations here whose membership was 100% made up of foreign companies. It may not be yours, but I've heard that. When they come and make a presentation, it may be good for the industry as they define it and it may be good for Canadian consumers, but at the end of the day, they don't represent the interests of Canadian manufacturers and what is good for Canadian medium to long-term growth.

I have a question to Mr. Lévesque. I understand you have some reservations. When you have reservations, are you speaking on behalf of the domestic manufacturing companies or are you talking on behalf of the sellers and resellers?

Mr. Stéphane Lévesque: It's domestic manufacturers.

[*Translation*]

I'm mainly speaking on behalf of Quebec manufacturers.

[*English*]

The Chair: Thank you very much.

Mr. Côté, I see you have your hand up. Did you want to try your sound again?

● (1235)

Mr. André Côté: I'm trying hard to get involved and participate. To answer the question involving Quebec, we do represent most of the small manufacturers of disinfectants in Quebec.

The Chair: Mr. Côté, I'm going to make a suggestion, because we're still having the sound problem with the comments coming back from translation.

Would it be possible for you to come back on Thursday and appear before the committee on Thursday?

Mr. André Côté: Yes, we can do that.

The Chair: That way you would have your full amount of time. I think that's fair, because I appreciate very much your waiting and trying to get this problem corrected. If that would be all right, we'll just leave anything that you have further to say to next Thursday, and you'll be a witness at next Thursday's committee meeting. Thank you very much.

Next we have Mr. Savard-Tremblay for six minutes.

[*Translation*]

Mr. Simon-Pierre Savard-Tremblay: Thank you, Madam Chair.

Gentlemen, since you prepared your testimony jointly, we could have put certain questions to both of you, but I'll keep a few for Mr. Côté's return on Thursday.

Mr. Lévesque, just before Mr. Côté spoke and the technical issues arose, you barely had time to discuss the fact that the coming into force of the bill did not allow enough time. You said that two years weren't enough. Would you please enlarge on that?

Mr. Stéphane Lévesque: Based on our experience with other proposed regulations in recent years, when we anticipate an enormous workload, we know that delays will be longer than anticipated. We've never been wrong. It's as simple as that.

In this case, the workload will be enormous because, as Mr. Côté said earlier, some products aren't currently approved by Health Canada. I'm thinking, for example, of food-contact surface sanitizers. They alone represent an enormous amount of extra work.

Mr. Simon-Pierre Savard-Tremblay: As I understand it, you aren't opposed to the idea of subjecting products to more audits. You don't think that's the problem at all. The problem is the lack of harmonization on both sides.

However, we could tell you that the United States applies a similar policy.

What do you say to that?

Mr. Stéphane Lévesque: As far as I know, the United States doesn't apply a similar policy. It's as simple as that. They'll never recognize our products. Reciprocity won't enter into it.

Mr. Simon-Pierre Savard-Tremblay: How does it currently work in the United States for a Quebec or Canadian business that wants to export its products? What steps do you have to take?

Mr. Stéphane Lévesque: In the United States, regulations are applied through the Environmental Protection Agency, the EPA, which isn't the equivalent of Health Canada, but more that of the Pest Management Regulatory Agency, the PMRA, here.

So these are two completely different entities that regulate our products. In Canada, our products fall within the pharmaceutical domain and are regulated by Health Canada and the natural and non-prescription health products directorate.

Mr. Simon-Pierre Savard-Tremblay: I see you enjoy sayings and comparisons. When you say “completely different”, it's as though we're comparing apples and oranges.

Would you please tell us more about that?

Mr. Stéphane Lévesque: We are the only G7 member country that regulates its products through Health Canada and the Food and Drugs Act.

Consequently, no harmonization as possible.

Mr. Simon-Pierre Savard-Tremblay: Until now, we've frequently evoked the COVID-19 pandemic in support of the proposed regulations.

Am I mistaken or did the United States say at some point that it would stop exporting sanitizing products and keep them for itself? I remember a time when there were empty shelves in the pharmacies.

So it was the SMEs from here that had no expertise in this area and that had to turn on a dime and develop sanitizing products.

In other words, Canadian and American businesses weren't fighting on an equal footing at all. Some multinationals based and operating in the United States since forever still aren't competing on an equal footing with SMEs that have been operating in the sector for two or three years.

Could regulations like those being proposed make the gap even wider?

Mr. Stéphane Lévesque: Yes, this could contribute to it.

We discussed innovation earlier. Quebec and Canadian SMEs can innovate too, and we shouldn't get in their way, make them pay more or saddle them with longer delays.

We also discussed product availability during the pandemic. We're still experiencing the same situation with regard to pharmaceutical products and generic drugs. The more we import, the more problems we'll have.

The day China and India want their marbles back, we won't have to go to war; Canada will be in a bad way.

● (1240)

Mr. Simon-Pierre Savard-Tremblay: Let's try using numbers to clarify the situation.

Let's say the proposed regulations come into force. If American businesses in general want to export their products to Canada, exactly how long will they have to wait to do so?

Mr. Stéphane Lévesque: That'll depend on the products to be exported and whether they enter the equation, but they won't have to wait as long as Canadian businesses as a result of the steps involved in the approval and recognition process.

Then American businesses won't have to bear the same burden of ensuring that their products are safe as Canadian businesses, which will be operating under a heavier burden.

Mr. Simon-Pierre Savard-Tremblay: What elements of American products are truly subject to audit now?

There's a lot of talk about reciprocity of standards virtually everywhere. We are a committee that focuses on trade, and the term often comes up in connection with free trade.

Earlier you mentioned a protectionist policy introduced by Canada for the benefit of Americans, and I liked the allusion.

Beyond the fact that we say we apply the principles of reciprocity theoretically, what are we really auditing?

Mr. Stéphane Lévesque: You should ask Health Canada that question.

We aren't saying that American products aren't good. We have to be clear on that point.

However, we must at least not harm Canadian and Quebec businesses, especially SMEs.

Mr. Simon-Pierre Savard-Tremblay: So you're calling for a moratorium.

Is that correct?

Mr. Stéphane Lévesque: That's correct.

Mr. Simon-Pierre Savard-Tremblay: How long should it last?

Mr. Stéphane Lévesque: It should last at least two years.

Mr. Simon-Pierre Savard-Tremblay: Why do you think that?

Mr. Stéphane Lévesque: We have to examine all the aspects and really improve the system. That's what we want. We don't want to block the proposed regulations; we just want to improve the system without interfering with Quebec businesses.

[*English*]

The Chair: Thank you very much, sir.

We'll go on to Mr. Cannings for six minutes, please.

Mr. Richard Cannings: Thanks to you both for being here today.

I'm going to start with Monsieur Lévesque.

You stated in your remarks that American companies would have lighter application requirements than Canadian companies, that it would take a shorter amount of time. Can you explain that?

I don't understand exactly how that works. Canadian companies have to go through Health Canada and American companies have to go through the EPA. What's the process? How is that different in terms of time, in terms of what they have to go through versus what Canadian companies go through?

[*Translation*]

Mr. Stéphane Lévesque: The proposed regulations will actually make it so that products approved in the United States will receive expedited review, at lower cost, by Health Canada.

In addition, then they won't be subject to the same monitoring requirements regarding safety and efficacy.

[*English*]

Mr. Richard Cannings: Okay, but you just said that products that have been approved in the United States.... A company there that is manufacturing a product that it wants to sell in the United States has to go through a process to get it approved in the United States. In Canada, the same thing applies for your industry. You have to get it approved in Canada. You seem to indicate that there was some difference in the time it takes to get it approved in the United States.

Mr. Stéphane Lévesque: No, it's here.

Mr. Richard Cannings: Okay, but you said that they were having an easier time of it when, the way I understand it, they've gone through perhaps a difficult process. I don't know. I was asking you what process they have to go through and how that compares with the Canadian process, because that's where the fairness comes in, I think.

[*Translation*]

Mr. Stéphane Lévesque: What you're saying there is actually interesting.

We're setting a dangerous precedent, in that Health Canada is starting to withdraw from its main role by relying on third-country approvals. It's a dangerous precedent because it's the first step. Then it will be natural health products and, after that, generic and innovative products. What will be the purpose of Health Canada later on?

● (1245)

[*English*]

Mr. Richard Cannings: I understand that criticism. I understand that concern, but it's different from the concern around fairness in the time it takes a company to get a product approved.

It comes up with a new product it wants to sell. Whether it's in the United States or Canada, it has to go through fairly rigorous application processes before it would be available in Canada. Whether you agree with relying on the EPA or not....

[*Translation*]

Mr. Stéphane Lévesque: I don't deny it. Yes, the EPA does a very good job. There can be very good products when they're approved. However, we have an entity called Health Canada, and it shouldn't rely on foreign approvals to approve a product in Canada. Let me give you an example.

We're in Canada here, in the north. It's cold and the transport chain isn't the same. If we don't take that into account, products won't be the same once they get here. Some products are deactivated by cold, others by heat. If we don't audit that here, the product will be worthless.

[*English*]

Mr. Richard Cannings: You also implied that after the products are approved in Canada, Canadian companies have more stringent requirements that follow, whereas American companies would not. I'm still not clear on how that works.

[*Translation*]

Mr. Stéphane Lévesque: That's actually a good question for my colleague, Mr. Côté, because he's the expert in that area.

You can see the difference in clause 9 of the Biocides Regulations, which includes points that American companies won't have to comply with.

[*English*]

Mr. Richard Cannings: What points are they?

[*Translation*]

Mr. Stéphane Lévesque: I unfortunately can't name them for you. This isn't my specialization.

[*English*]

Mr. Richard Cannings: Okay.

The Chair: Maybe on Thursday Mr. Côté can speak directly to that.

I have Mr. Seeback for five minutes.

Go ahead, please.

Mr. Kyle Seeback: Ms. Coombs, I'm trying to understand what the concern from Mr. Lévesque seems to be. He was saying that it's unfair for American-manufactured products to come into Canada because they have an advantage.

My understanding is that he's actually comparing apples to oranges. He's talking about a new Canadian product having to go through all these longer approvals, whereas the American product has to have been approved in the U.S. first before it can be expedited.

Comparing a new Canadian product to one already approved in the United States is not a fair comparison. Would you agree with that?

Ms. Shannon Coombs: They're just different review processes within Health Canada. You can have a novel product and you can bring that into the Canadian marketplace. That's one pathway, or you can use the UFD as another pathway.

To address some of the concerns that were raised with respect to Mr. Cannings' point, Madam Chair, for the end-use product, the specifications between Canada and the U.S. are exactly the same. While I hear my colleague's concerns about this, we see this as being beneficial.

If you cast your mind back to the time during COVID when we didn't have any disinfectants and many of the members around this table were part of the special parliamentary committee on COVID, these shortages were in real time, and we were addressing them. We brought in 298 of those products through this interim provision, and I think it speaks to the leadership of this government to be able to address a concern in the pandemic and to also be able to reduce red tape and bring in the new regulation by embodying not only a UFD but also other pathways to the Canadian marketplace.

● (1250)

Mr. Kyle Seeback: I just want to say that with regard to a new product in the United States versus a new product in Canada, under these rules there's no huge advantage for the American product, as Mr. Lévesque seems to be saying. The American product goes through the American approval process through the EPA and then applies for the 90-day approval in Canada.

Ms. Shannon Coombs: The companies do, yes.

Mr. Kyle Seeback: The company does, and the Canadian company with the novel product just uses the Canadian process.

Ms. Shannon Coombs: We still get a DIN at the end of the day. We get a Health Canada approval and we have a bilingual label.

Mr. Kyle Seeback: That's correct.

The other concern seems to be that the EPA is not providing a similar review. That seems to be the other concern for Mr. Lévesque. He mentioned that it's cold in Canada. It's also cold in parts of the United States, in Montana and other places.

I assume the Government of Canada has decided that this process works only because these reviews are so similar that we needn't have any worries with respect to the approval of a product through the EPA versus an approval of the product by Health Canada. Would that be correct as well?

Ms. Shannon Coombs: Madam Chair, that would be our assertion, yes.

Mr. Kyle Seeback: Okay.

Mr. Arya talked about Canadian manufacturers that you represent. You certainly do represent Canadian manufacturers. I know that Clorox is in my riding in Orangeville. They produce a lot of these products, and in fact they produced a lot during the pandemic. They really helped out.

Ms. Shannon Coombs: This regulation speaks to the innovation that was able to be brought to the Canadian marketplace during COVID with electrostatic sprayers. I know this is a little inside baseball, but these are sprayers that were able to be used to deliver disinfectants to disinfect areas such airports, trains and planes, and that technology had never been in Canada before. This is the type of thing we're talking about with respect to innovation coming to the Canadian marketplace.

Mr. Kyle Seeback: The last concern I would see that we could have with this—because I don't think the other concerns about the different processes are real concerns—is this reciprocity with the United States. Do you know if there is any regulatory reciprocity now for Canada? If a Canadian manufacturer goes through Health Canada, is there going to be a similarly accelerated acceptance of this product in the United States? Does that already exist?

Ms. Shannon Coombs: That could be phase two of the regulation.

Mr. Kyle Seeback: Then it doesn't exist now—

Ms. Shannon Coombs: No, it does not.

Mr. Kyle Seeback: —but that's something that the committee could recommend.

Ms. Shannon Coombs: Yes.

Mr. Kyle Seeback: Okay, great.

That's it.

The Chair: We'll go now to Mr. Sheehan for five minutes, please.

Mr. Sheehan, I think you're on mute.

A voice: Oh, no—more technical difficulties.

Voices: Oh, oh!

The Chair: What's happening?

We're having.... Again, this is....

Okay, Mr. Sheehan, we cannot hear you. Can you unplug your headset and then plug it in again, please?

You see, Mr. Côté? It's happening even with other people, not just with you.

Try it again, please, Mr. Sheehan.

Mr. Terry Sheehan (Sault Ste. Marie, Lib.): Hello? Can you hear me now?

The Chair: Yes. Please go ahead.

Mr. Terry Sheehan: Thank you very much.

I'm sorry about that. I was thinking about all these excellent questions and answers because a lot of the questions I wanted to ask have already been answered.

However, this is a very interesting subject. Previous to this life, I used to work for the Economic Development Corporation in helping entrepreneurs start up and grow export and import.

My question is perhaps for Shannon.

During COVID-19 and the shortage that we had with sanitizers and the hoarding that was happening in the United States, people were publicly shamed, and they should have been. Obviously, both Americans and Canadians were trying to get their hands on literally anything, right? Today it seems, now that we're hearing some testimony from Canadian companies, that there seems to be some impediment to this.

What is it? When we deal with small and medium-sized companies versus large companies.... You know, I have trepidation, because a lot of times we'll see large companies trying to corner markets by developing patents, intellectual property, patents pending or copyrights on various pieces in the manufacturing process or in the end product. Are there any large companies in the United States, for that matter, that are doing that? I think about that, and the reason I asked that question is that I think of drug companies that try to patent the size and shape of a pill or the colour of a pill.

Shannon, are you aware of any kinds of movements of people trying to corner the market in this area?

● (1255)

Ms. Shannon Coombs: Madam Chair, as I mentioned in my opening comments, I've been with the industry for 25 years, and I have never seen that.

With respect to the disinfectants, I have never seen an industry work harder during a pandemic to be able to work with Health Canada to provide Canadians with the products they needed, whether in the hand sanitizer space or in disinfectants, due to the shortages we had. I see this as building on a really great collaboration that delivered for Canadians during a very difficult time, and the regulation really embodies that.

We're very pleased, and we're hopeful that we are able to move it forward and address some of the outstanding concerns that have been raised.

Mr. Terry Sheehan: Thank you for answering that. That first question leads to my second question, then.

If there's no real legal impediment to these products, what kind of dialogue is happening right now between Canadians and Americans about the importance of continuing that free flow of products that happened during COVID-19? We were sending stuff across the border. We were asking them to send stuff up to us. Where is that goodwill, and why isn't that goodwill being reciprocated these days to help our small and medium-sized enterprises?

Ms. Shannon Coombs: Madam Chair, I think that this regulation does exactly what you want it to do. The collaboration will continue, because our new hygiene reality is here to stay. The demand for the disinfectants is not waning. We're still seeing a 210% increase in submissions at Health Canada. There's still a need for these products because of the issues we have in and around infection control.

I don't see the goodwill diminishing. I'm hoping that with this regulation, Canada will move forward as a leader in how we regulate biocides and that other countries will want to emulate us.

Mr. Terry Sheehan: Yes, because I saw not just the private sector but also the public sector getting together in my community. The Canadian Institute of Forestry looked on its shelves and was able to put together a number of formulas to create barrels of hand sanitizers for our local community. I just want to see that happen expeditiously.

I understand the frustration of our local companies that want to get into the American market, obviously. The U.S. is 10 times our size. Just an eight-hour drive from Sault Ste. Marie are 40 million people, so—

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

I'm sorry; it's just that the time is up.

Thursday is another day for a similar discussion.

Thank you all very much.

Monsieur Côté, we will see you on Thursday. Thank you.

The meeting is adjourned.