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Chair

Ms. Bonnie Brown

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● (1110)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good morning, ladies and gentlemen.

It's my pleasure to welcome you to the 32nd meeting of the Standing Committee on Health. We are reviewing Bill C-28, an act to amend the Food and Drugs Act.

Before we begin the actual formal part of our meeting, I believe there is a motion from Mr. Merrifield that I don't think should require any debate. It seems to me it's the conclusion of our discussions on the last bill we passed.

Mr. Merrifield, would you please just introduce it?

Mr. Rob Merrifield (Yellowhead, CPC): This is just asking us to report to the House the motion we passed here. I would ask for support from around the table.

[*Translation*]

Mr. Réal Ménard (Hochelaga, BQ): We're against the motion.

Madam Chair, we're against it but we're not going to ask for a vote. We can refer the report to the House with dissent, but we do not support the motion requesting the federal government to put a... In light of all the arguments made the last time, we don't have to engage in the same debate again.

We were against the motion the last time and therefore we will not support Mr. Merrifield's motion. On the other hand, we don't have to vote. It can be passed on division.

[*English*]

The Chair: Is that agreeable? Thank you.

(Motion agreed to on division)

The Chair: Now we'll go back to our business of the day, which is Bill C-28.

It's my pleasure to welcome representatives of the Canadian Animal Health Coalition, Mr. Matt Taylor, the executive director, and Mr. Gordon Dittberner, a director.

Mr. Taylor.

Mr. Matt Taylor (Executive Director, Canadian Animal Health Coalition): Thank you very much, Madam Chair.

Ladies and gentlemen of the committee, we thank you for the opportunity to meet with you and speak with you today.

Our purpose in speaking with you is both general and specific. In general, we wish to indicate that, to the best of our knowledge, the food animal industry has supported the measures set out in Bill C-28 insofar as it relates to veterinary drugs and administrative maximum residue levels, which I'll refer to as MRLs. Specifically, we would suggest that if the committee has any remaining concerns regarding our industry's support for this important bill, they may wish to extend their consultation to consult directly with those groups whose names we'd be happy to provide afterwards.

In our comments today we'll describe our organization and our mandate, briefly highlight the industry we represent, comment directly to the bill, and make our conclusions.

Our organization, the Canadian Animal Health Coalition, was initiated in 2000, and was legally constituted in 2002 with a broad membership comprising most of the animal health stakeholders, from producers, processors, exporters, etc., through to the scientific expertise of the veterinary profession and the veterinary colleges. Our members include national associations representing the producers of beef, dairy, pork, poultry, sheep, and equine and other related commodity groups.

Our mandate is to assist industry in meeting domestic and international market needs by promoting a collaborative approach to animal health. Our activities in this regard include working towards strategy with the Public Health Agency of Canada, as well as Agriculture Canada and the CFIA; emergency management; identification and traceability; program development; animal care; and monitoring development of international guidelines, etc., as they relate to animal health.

Here are some brief highlights of Canada's food animal industry: we were recently recognized as part of Canada's national critical infrastructure by the Government of Canada; we are the world's fourth-largest exporter of meat and livestock-related products; we are the country's ninth-largest export sector; and we are a major employer, with estimates of the number of people indirectly employed being as high as one in three. We provided other information in the brief, which you have in the material we provided earlier.

Now I'd like to introduce Dr. Gordon Dittberner, who is one of our directors. He will speak directly to the bill.

Dr. Gordon Dittberner (Director, Canadian Animal Health Coalition): Thank you, Madam Chair.

Our purpose today is to briefly describe for you the rationale behind our support for Bill C-28 as it relates to veterinary drugs.

Veterinary medications are used in food and in non-food-producing animals to keep them healthy and productive. These products are used by veterinarians and animal owners to treat, prevent, control, and enhance the health and well-being of these animals, as well as to prevent the spread of diseases from animals to people.

Under the food and drug regulations, drugs must undergo a thorough assessment by the veterinary drugs directorate scientists to verify the quality, safety, and efficacy of these products prior to their being marketed in Canada. For those drugs intended for use in food-producing animals—i.e., where the food is going to be consumed by humans—maximum residue levels, or MRLs, are established, as well as withdrawal periods to ensure that any remaining residues will not exceed the maximum residue level. The maximum residue level is defined as being considered to be at a level that possesses no adverse health effects if ingested daily by humans over a lifetime.

Marketing authorization for a new animal medication is therefore only given after Health Canada has completed the stringent scientific evaluation of the veterinary drug. The process is long and costly. On average, the time required to progress from the discovery of a food animal medication product to marketing authorization is around 15 years, with the cost of research and development amounting to about $250 million.

To the best of our knowledge, interim marketing authorities, IMAs, have not been applied in the case of a veterinary drug. Comparisons have been made between the interim marketing authorities and the administrative maximum residue levels used in veterinary drugs. An administrative maximum residue level is used when an MRL is established for a drug but has not yet been promulgated into the regulations.

Previously, a number of approved veterinary drugs did not have established MRLs. With newer technology able to discern minute traces of some residues—we're talking in parts per trillion these days, which is equivalent to one second in 320 centuries—new MRLs were established based on the latest scientific knowledge. Once set, the new MRLs may require 18 to 24 months to be promulgated into the regulations. Consequently, an administrative MRL is employed until such time as the MRL is published in the government gazette. This has proved to be essential in maintaining an orderly marketing system for meat, milk, eggs, fish, and honey.

Pesticides applied to crops to be consumed by livestock may result in residues being detected in their tissues, as may occur with anti-parasitic pesticides applied to food-producing animals. Therefore, we support the defining of MRLs for these products, as in the case of AMRLs for veterinary drugs. We support Bill C-28's providing authority to establish an IMA until the MRL is promulgated and published.

I'd like to emphasize that veterinary practitioners and livestock producers are keenly aware of the importance of food safety and are extremely sensitive to ensuring that appropriate withdrawal periods are respected when treating food-producing animals, in order to prevent hazardous substances from entering into the food chain. We disagree categorically with those who claim that your food is totally contaminated with antibiotics.

The bill, therefore, is important to food animal producers who are using such newly authorized products as modern animal health management tools but want to do so knowing the official MRL. It also means that Canadian food producers can operate in a regulatory system similar to that of other developed countries.

For example, the U.S. Food and Drug Administration publishes an approval notice for a new medication and the associated MRL in tandem, in the federal registry notice.

Thank you.

● (1115)

Mr. Matt Taylor: To conclude, Madam Chairman and members of the committee, we believe it is important that you know where the food animal industry stands on this bill.

We note that the committee may recently have heard conflicting positions relative to this bill. These are positions the food animal industry had not anticipated would be forthcoming at this point. So to conclude again, to the best of our knowledge, Canada's food animal industry has supported the development of measures such as are set out in Bill C-28, primarily insofar as they relate to veterinary drugs and the application to livestock through the use of administrative MRLs and IMAs.

The fact that our remarks are confined primarily to the bill's application to veterinary drugs and pesticides should not be construed as being negative with respect to other aspects of the bill. We're simply confining our comments to those areas about which we have experience and knowledge.

To close our comments today, and as well to suggest a path forward if the committee remains uncertain as to support for this important bill, you may wish to invite direct representation from the stakeholder organizations within Canada's food animal industry.

I'd like to thank you very much for the opportunity to be here today and to participate in your deliberations.

The Chair: Thank you very much.

We now welcome representatives from CropLife Canada. We have Mr. Peter MacLeod, executive director, and Mr. Chris Warfield, director, regulatory affairs for Bayer CropScience.

Please go ahead, Mr. MacLeod.

● (1120)

Mr. Peter MacLeod (Executive Director, CropLife Canada): Thank you, Madam Chair and honourable members.

CropLife Canada is a trade association representing the developers, manufacturers, and distributors of plant science innovation, pest control products, and plant biotechnology for use in agriculture, urban, and public health settings.

CropLife Canada's mission is to support innovative and sustainable agriculture in Canada, in cooperation with others, by building trust and appreciation for plant science innovations.

I will speak to our interest in Bill C-28.

In Canada, pesticides used on food commodities are regulated under two separate pieces of legislation. They're regulated as pest control products under the Pest Control Products Act and regulations, a ministerial responsibility, and as agricultural chemicals under the Food and Drugs Act and regulations, a regulation-setting process.

Therefore, once a pest control product is registered for use in Canada by the Pest Management Regulatory Agency, there remains an additional regulatory requirement—to establish maximum residue limits for pesticides under the food and drug regulations.

In specifying or establishing appropriate MRLs, the PMRA will take into account overall diet, particular concerns about children, older persons, and those with compromised immune systems. The science methodology used to set MRLs is well established and enjoys international consensus.

However, the system for promulgating those MRLs is hampered by delays as a result of the current process in place to make regulatory amendments. These processes, on average, take 40 weeks for consultation and final regulation-setting through parts I and II of the *Canada Gazette*. In some cases, when there is a new type of proposal—such as the use of crop groups—some of our member companies have been waiting two and a half years for the promulgation of maximum residue limits. Until these regulations are promulgated, the crops produced from the use of the registered pest control product are considered adulterated and cannot be sold.

Our interest in Bill C-28 is therefore to provide an avenue, through ministerial sign-off under the new Pest Control Products Act and regulations, for MRLs to be established at the same time as pest control products are registered, while maintaining high health and safety standards.

Why is change needed?

Canadian growers need pest control products available to them in a timely fashion, and at the same time as their international counterparts, to remain competitive. This concept is captured in the mission statement of the PMRA—"to protect human health and the environment by minimizing the risks associated with pest control products in an open and transparent manner, while enabling access to pest management tools, namely, these products and sustainable pest management strategies".

Even when the PMRA concludes its review of a new product in a time similar to that of a trading partner, growers are reluctant to use the product until they are sure the crop produced with the new product has a maximum residue limit in place and thus will be accepted for both domestic consumption and international trade.

It is essential that MRLs are established as close as possible to the product registration time, to ensure trade and domestic sale opportunities result at the end of the growing season. Yet the process to implement MRLs is slow, since it is dependent on both the evaluation and public consultation processes, under the PCP act and regulations, and on the full change in the food and drug regulation each and every time a new MRL needs to be established.

This process is simply out of date and presents unnecessary delay. Bill C-28 will not eliminate this need, but it provides for another way to establish MRLs that does not reduce the present high safety standards and public oversight.

Canada's agriculture trade depends on markets being open to receive our crops and for Canada to receive imported food commodities. MRLs help facilitate that trade, and therefore the regulatory system must be flexible and responsive.

The proposed changes to the Food and Drugs Act will allow Canada to address its obligations under the WTO and NAFTA trade agreements, while maintaining Canadian agricultural competitiveness.

The NAFTA Technical Working Group on Pesticides has been in place since the adoption of the NAFTA agreement to assist with removing trade barriers for pesticide-treated food commodities. Despite years of efforts to eliminate technical barriers to trade among the NAFTA signatories, there is no near-term solution in sight to deal with differences in MRLs and tolerances across NAFTA member countries. Again, Bill C-28 provides an accountable, more efficient avenue for domestic and imported MRLs to be regulated.

In addition, as we understand it, the changes proposed in Bill C-28 were prompted by the Standing Joint Committee on the Scrutiny of Regulations, whose chief concern was to ensure ministerial accountability for establishing both MRLs and interim marketing authorizations for food.

● (1125)

What is our ideal view of the world? Ideally CropLife Canada would like to see a system for pesticide registration that is North American and eventually globally focused. This is the most efficient way for governments to conduct science-based regulatory reviews for products in commerce, while making country-based decisions on the basis of well-established scientific risk assessments. Until that time, devices such as the one proposed in Bill C-28 will help ease some of the time pressures that currently hamper the MRL-setting process.

In conclusion, we support the bill as an important step in providing regulators with appropriate tools for regulating pesticide products. These tools will not compromise the present high safety standards established by Health Canada and the PMRA, and we applaud the government for taking this initiative in this difficult legal debate to find a mechanism to address both concerns of the government regulatory experts and the needs of the regulated community.

Thank you.

The Chair: Thank you very much.

We'll move on to the representative of the Infant Feeding Action Coalition—the national director, Ms. Elisabeth Sterken.

Ms. Sterken.

Ms. Elisabeth Sterken (National Director, Infant Feeding Action Coalition (INFACT Canada)): Thank you, Madam Chair.

INFACT Canada, the Infant Feeding Action Coalition, is a national non-profit membership organization consisting of health care providers and parents from across Canada. We work to support and protect optimal nutrition for mothers and children. Much of our work is centred on the protection of breastfeeding and the implementation of World Health Organization recommendations regarding infant and young child feeding. INFACT Canada is funded exclusively by its members.

Although as members of the Canadian public we are pleased to have the opportunity to address the Standing Committee on Health, nevertheless we do so with great concern. We wish to express our acute alarm regarding the fast-tracking of commercial food products and food commodities through the smart regulation proposal to issue interim market authorization for foods.

We are concerned that Bill C-28 is designed to fast-track food products with chemical additives, pesticides, biologically active drugs, and genetically altered constituents that are not normal to food, have not been adequately tested for safety, and are without the requirements to show efficacy.

We are particularly concerned that Bill C-28 is an approval mechanism that puts trade and commercial interests, especially those of transnational corporations, before the safety and health needs of Canadians. The Canadian public will be the unfortunate victims of this by not only paying the financial cost of this process but also the health cost both now and in the future, both personally and publicly.

INFACT Canada is opposed to Bill C-28 for a number of reasons. First, the act violates the mandate of the Minister of Health to protect the health of Canadians as required under the Food and Drugs Act. It is the responsibility of the minister to put in place legislation that reduces the risk of disease and not to increase it. The act puts every Canadian into a mass, uncontrolled feeding trial where the outcomes cannot be determined in the short-term or in a clear cause-and-effect manner.

Long-term sequelae such as increased cancers, increased allergies, autoimmune diseases, and other unknown health risks are being ignored or will be managed. To give some examples, about 1,300 new cases of childhood cancers will be diagnosed in Canada in 2005. An estimated 149,000 new cases of new cancer and 69,500 deaths from cancer will occur in 2005. On the basis of current incident rates, 38% of Canadian women and 44% of Canadian men will develop cancer during their lifetime. Given current mortality rates, 24% of women and 29% of men, or approximately one out of four Canadians, will die from cancer. This has just been released from the *Canadian Cancer Statistics 2005*. As well, the literature is abundant with reports on specific tumours in children that have been linked to pesticide exposure. These effects are cumulative and synergistic.

Thirdly, the act gives no consideration to the unique needs of vulnerable populations such as pregnant and nursing women, infants, and young children. Where is the evidence—the research—that a mother and a developing fetus will not be harmed by agricultural chemicals permitted under the Bill C-28 interim market authorization? How can the fundamental principles of safety and health protection be so easily waived?

It is unconscionable that an interim marketing authority can declare a food product to be unadulterated. We already have overwhelming evidence that pesticides and other chemicals found in foods and permitted under the existing legislation transfer across the placenta and cause developmental delays, cancers, autoimmune disease such as allergies, DNA damage, low birth weight, and congenital damage.

● (1130)

For example, in industrialized countries the rates of asthma, allergies, and atopic eczema have doubled over the past 20 years. This reflects increasing immunological system damage. Links have also been made in the scientific literature that antibiotic residues found in food increase the risk of developing asthma in children. The increased use of biologically active chemicals in food will contribute to these risks.

Health Canada reports that one out of eight school children suffers from asthma. This represents an increase of 40% in cases over the past 10 years and a three-fold increase in asthmatic deaths over the past 20 years. To give you an example just of the hospitalization cost for asthma, that is, the days of hospitalization across Canada—and this is from the report of the National Asthma Control Task Force's hospital stats—there are roughly 225,000 days per year, and that amounts to over $135 million per year in cost. This is just the hospitalization cost, and we're not talking about social or medical costs.

Fourthly, unregulated chemicals will increasingly appear in the breast milk of Canadian mothers. Can these contribute to untoward health effects for her and her baby? Breast milk is the only safe, nutritionally sound, and immunologically capable means of providing for the needs of newborn infants and young children. Any risk to the safety and efficacy of breast milk will seriously compromise population health. Breast milk must be protected from harm, as this is an essential and integral component of our reproductive system.

Chemicals currently permitted as food additives, such as trans fatty acids, for example, have been shown to be detrimental to both a mother's health and that of her infant. It should be noted that even though the negative health effects of these chemicals in foods have been known for decades, the legislation to remove trans fatty acids is still to this day not in full effect. It takes decades to remove things that have been permitted into the system. Pesticides are known to cross the placenta and into a mother's breast milk. The most vulnerable time of exposure is prenatally, and sudden neurological disturbances are now well-documented.

Long-term effects, especially on the development of ova of female children, caused by pesticide remains unknown. At present, breastfeeding is able to mitigate the postnatal risks of chemical exposure of newborns and infants. However, artificial feeding—that is, formula feeding—is unable to provide critical immunological protection from chemicals and in actual fact exacerbates the negative impacts of an infant's chemical exposure.

Then again, Madam Chair, early childhood exposure in addition to inter-uterine exposure to lead, methyl mercury, and PCBs has now been related to a number of neurological effects: learning disabilities, attention deficit hyperactivity disorder, developmental delays, autism, and behavioural disorders. As well, genetically modified foods, food ingredients, and chemicals, and foods developed as nutraceuticals have not been tested for safety in vulnerable populations. These ingredients now appear in nearly 75% of Canada's food products, including foods for infants such as infant formulas.

No testing is required to ensure that foods containing genetically modified ingredients are safe for infants, children, pregnant women, or nursing mothers. Yet these very foods are permitted to make health and nutrition claims as marketing tools, without concern for safety or efficacy. No health warnings about increased risk of autoimmune disease or allergies are required.

In summary, clearly an approach is needed that will ensure all Canadians that their government will act in their interest and has, as its primary priority, safety for our food system and the environment, so that our health and the health of our children and the health of our children yet to be born will be protected.

● (1135)

The special reproductive needs and vulnerabilities of pregnant women and lactating mothers, their infants, and children must be protected from harm. They are uniquely vulnerable to environmental toxins such as pesticides. Any amendments to the Food and Drugs Act should have the objective to reduce the body burden of chemicals and have a special child-protective, precautionary approach. Thus, INFACT Canada recommends that the precautionary principle be applied to the regulation of foods, their ingredients, pesticides, food additives, genetically modified foods, food ingredients, bioactive chemicals, and other additives and contaminants of the food system.

Secondly, we recommend that Bill C-28 be rejected in its entirety.

We also recommend that the Minister of Health actively work to reverse the growing risks and occurrences related to cancers, increased allergies, autoimmune diseases, increasing chemical burdens, and biologically altered ingredients found in Canada's food system.

We recommend that the Minister of Health work to protect the safety and accessibility of breast milk for Canada's infants and young children.

Lastly, we recommend that mother-child protective measures be put in place as regulation to ensure a safe and effective food supply for all. All Canadians have the right to safe and nutritious foods.

Thank you, Madam Chair.

The Chair: Thank you very much.

That's all we have for this hour. We'll move to the questions and answers, and we'll begin with Mr. Merrifield.

Mr. Rob Merrifield: Thank you for coming in, all the witnesses. It sounds as if we have two different positions at the other end of the table.

It sounds to me as if PMRA actually has to approve a product. When that product is approved by PMRA, then the IMA, the interim marketing approval, is given while the Food and Drugs Act regulations have to be met. Is that in essence what happens?

Mr. Chris Warfield (Director, Regulatory Affairs for Bayer CropScience, CropLife Canada): When the PMRA evaluates its products, they go through a full consultative process. We have to recognize that the types of applications the PMRA deals with are very numerous. In the most complicated case in which we have a brand-new chemical, a brand-new chemical would go out for consultation, and under those circumstances there would not be a prior listing in the Food and Drugs Act. In that particular case, because there was no prior listing, an IMA would not be available to them.

In a second case in which you were expanding a use pattern, say, from a cereal into a fruit, and the cereal had already gone through consultation, and maximum residue limits were already established in the food and drug regulations, under those circumstances the interim marketing authority would be available.

Mr. Rob Merrifield: So that's the process we're under right now, since 1997, I understand. Okay. Then really we have that under regulation. We're not changing anything, as I see it, except that under Bill C-28 we're giving ministerial authority and moving it from a reg into the act. Why not leave it just where it's at? It seems to have been working since 1997.

● (1140)

Mr. Peter MacLeod: One of the issues we had, and we presented it, is the time delay. The PMRA finishes their evaluation; a pesticide is available to be bought on the market; the health and safety have been completed; and there's an administrative time delay between that stage, when a farmer is able to use the product, yet might not be able to sell the crop that this product has been used on, because it has not gone through the process—

Mr. Rob Merrifield: So you ask for the IMA.

Mr. Peter MacLeod: But you're able to do that since 1997 right now.

Mr. Chris Warfield: I'm not a legal expert by any means, but I did deal with this in a past life, as part of PMRA and Health Canada. The issue is that the authority to set maximum residue limits is a regulatory authority and done under the Governor in Council. The authority to exempt, if you will, things from the regulations in an administrative fashion is what the issue is.

The question is whether a director or the Governor in Council can provide his responsibility to a government official to make exemptions. That's caused a huge legal opinion battle within the government, and that's what has led us to this point. What we're really doing is moving this responsibility, before the responsibility is conferred to the Governor in Council, and thereby providing a mechanism of relief, if you will, making it legally responsible, not in question.

Mr. Rob Merrifield: So we understand that, and I think the committee has a grasp of that as well. We're really not changing anything except the red tape. That's really what it amounts to.

I will get back to the other question. This is to Elisabeth—do you have examples of products that have gone on the market since 1997 that you're concerned about, that haven't met the regulatory qualifications?

Ms. Elisabeth Sterken: It's very difficult for us to know. We have to go through the access to information process to know whether this process has been used or not, because we're not informed that this actually happens, but I can give you examples of when we have lodged complaints about specific ingredients added to foods.

We did lodge a warning with Health Canada in December 2001 of a plan to put two fatty acids into the ingredients of an infant formula. What we were concerned about was that the efficacy of these ingredients had not been tested in that format, and there was no full scientific evidence it could actually provide what the company claimed it could provide. Then Health Canada did give the approval, sometime early in 2002.

We lodged complaints about the product because the company was making claims that were unsubstantiated scientifically, and it took until February 2004 to get Health Canada and the Canadian Food Inspection Agency to actually issue a requirement to that particular industry to stop making those claims because they could not be substantiated.

However, where we again see problems is there's no monitoring, at all, of any of these things, and there's no enforcement, even though this company's been told—

Mr. Rob Merrifield: You're saying PMRA is not doing the job? Is that what you're accusing it of?

Ms. Elisabeth Sterken: We're saying it's just not working—

Mr. Rob Merrifield: Or Health Canada, through CFIA?

Ms. Elisabeth Sterken: Even the current status of the Food and Drugs Act is not working, because appropriate monitoring is not in place. Then enforcement, if there are violations of the act, is not in place either.

Mr. Rob Merrifield: That's maybe a different problem from what we've got here.

● (1145)

Ms. Elisabeth Sterken: It is a different problem, but it's certainly the latest.

Mr. Rob Merrifield: See, that's what I'm trying to get at—if you're looking at it as the monitoring is not appropriate, and that's why you oppose this bill, or is it the mechanics of the bill, and the red tape that the bill actually addresses? That's where I'm trying to get to.

Also, you're an advocate as far as products you're not sure of. Are you equally concerned about products that perhaps are on our market? Are you seeing trends that are dangerous? You mentioned trans fats. There are other new products, products we know are much safer from the testing done to this point. Are you advocating that we move those along and accelerate them equally? Do you have a balanced approach to this, or are you just saying to stop everything?

I come from an agricultural background. I'm no fan of pesticides. I don't think any farmer is, but we use them all the time, and we know the newer ones are quite a bit safer and quite a bit better, in terms of efficiency and safety for society. I'm wondering if you look at if from that perspective as well.

Ms. Elisabeth Sterken: We see the trends—the trends in increased cancers, the trends in increased autoimmune disease, the trends in allergies. We see growing trends of disease responses to particular chemicals in our environment.

Mr. Rob Merrifield: I'm aware of the trends and concerns with cancers and diabetes, and we can go on and on, on that side of it. Are those different from what other countries are facing with the same demographic, as far as population? Do you have any stats on that?

Ms. Elisabeth Sterken: Yes, many of these are global trends.

Mr. Rob Merrifield: They're global trends.

Ms. Elisabeth Sterken: Yes, and one of the problems of course in developing countries is that they're seeing a double burden now of malnutrition and these types of diseases as well.

I have also been very active in the whole area of Codex Alimentarius. What we see there is a growing number of food additives and contaminants being permitted—MRLs for these are being permitted. So what we're really seeing is an increased level of chemical burden permitted into the food system. Some of them might be better, some of them might be worse, but generally speaking there is an increase, and Canada at the Codex Alimentarius also supports this.

Mr. Rob Merrifield: You're actually coming to the committee saying, “Don't pass this”. You want it completely turfed.

Ms. Elisabeth Sterken: Yes.

Mr. Rob Merrifield: If we reject Bill C-28, it's not going to help anything, because, if I'm catching what you're actually saying to the committee, the problem is that PMRA is not doing the job in making sure these products are safe before they allow them on, nor is the Food and Drugs Act doing its job to be able to validate the testings they have done. So that's a different problem from what we have in this bill. I want to get that straight and understand where you're coming from on it. Maybe that's a different study that we have to look at, as a committee. I think we actually have looked at some of those issues before.

Ms. Elisabeth Sterken: Yes, I totally agree with you that we need to look at this. My concern is, does this benefit the Canadian public? Does this benefit our safety and our health and our concerns about food? I don't think it does. It turns it upside down.

Mr. Rob Merrifield: Sure it does, if there are safer products out there that we are not using.

Ms. Elisabeth Sterken: It does not reduce our overall body burden of chemicals. In fact, it risks increasing our total body burden of chemicals. Therefore, it will increase the risk of disease, particularly in vulnerable groups. I think that's unconscionable and I don't think that's right for the Canadian government.

Mr. Rob Merrifield: Thank you, Madam Chair.

The Chair: Thank you, Mr. Merrifield.

Mr. Ménard.

[*Translation*]

Mr. Réal Ménard: This is our second meeting hearing witnesses on this bill. I'm trying to understand why we must vote on this bill as parliamentarians. Unless we've decided to adopt an American practice, it seems there's no advantage in voting on this bill, either for consumers or for our fellow citizens. And there's no advantage to it as far as the health of our population is concerned.

I'd like you to explain to me, as seen by the industry, how the consumer would be well-served with a bill like this one. Would we even dream of recommending that the Canadian government set up a provisional marketing mechanism for drugs for human consumption whose registration process isn't completely finished? I know there's a speedier procedure for people in the terminal phase of an illness, but that's a whole other matter. I'd like to hear arguments in favour of the bill.

In view of the information we've been receiving since we've started hearing witnesses, I don't see the advantage to the consumer. We really get the impression that this is a bill being moved forward for economic and commercial reasons aligned on the USA's FDA. As far as the consumer is concerned, I must admit that I'm not quite reassured.

My mind isn't totally made up. We're still listening. That's what this committee's work is meant for. So far, I'm concerned. I'd like someone to explain how the consumer will be well-served by this bill. I'm putting my question to the representatives of the industry because Elizabeth Sterken's point of view is clear enough. We could start with the industry representatives.

● (1150)

[*English*]

Mr. Matt Taylor: I'll take a crack at it first, and if my colleague would like to follow, that's fine.

Essentially, we use these products to provide safer end product to consumers at better value. The more we can minimize disease in a live animal, the better value we can provide to the consumer, in terms of cost of product, and the safer product we can provide. What we understand this bill enables us to do is to ensure that, from the time that drug is given a marketing authorization, it can also be used in accordance with an MRL level, in the absence of which the product cannot be sold with any trace element of such a drug in it.

Dr. Dittberner, if you'd like to add to that....

[*Translation*]

Mr. Réal Ménard: This product you're talking about, is it the drug itself? You say that it will not be possible to give the drug to the animal without this concession and that we'll still be able to sell meat, poultry and so on. Of course, you're in favour of the bill because, in a way, it would allow the use of drugs that have not received Health Canada's final approval.

Am I correct?

[*English*]

Dr. Gordon Dittberner: No, that's not quite correct. Perhaps I'll just start back a little bit.

As far as the IMA is concerned, we have not had any occasion where it's been applied in veterinary drugs. In the case of veterinary drugs or medications, we use a system called administrative MRLs, and Bill C-28, as far as I understand, doesn't seem to be doing anything different or will help or change anything. We'll have to ask the Health Canada experts to explain that difference, but for us it doesn't make any difference. It is similar to what we use for AMRLs.

So in the case of administrative uses of MRLs, it doesn't do anything different to the safety. The safety assessment has been completed and it has already been determined what the maximum residue level should be for those tissues.

We use an administrative level simply to be able to say that this is the level that has been approved for this product because the product is allowed to be sold on the market and it can be used. But it is an amount of residue that we'll put into place, and while we are waiting for the MRLs to be published in the *Canada Gazette* and it becomes part of the regulations, we will use something called the administrative MRL.

So it's not changing the safety. It's not fast-tracking. It's not doing anything. All it is doing is using a means to provide a statement saying that this is the maximum residue level until it is put into regulations. That's the only difference.

[*Translation*]

Mr. Réal Ménard: Besides marketing considerations... I'm not saying it's not important, because it is legitimate. One of you four mentioned one job out of three, earlier on. Absent the marketing reason, there's no reason to support the bill in its present form.

Do you agree with that statement?

[*English*]

Dr. Gordon Dittberner: I think the only thing is really to simply have a system in place that streamlines the regulatory process. That's all we're looking at. It really doesn't change the safety aspects of the drug. It doesn't change the safety of the food.

All it is saying is that by providing authority or providing administrative levels, if you could avoid the levels, you would have that promulgated into regulations right away. If it could be done at the same time as drugs are approved or when drugs were approved, or the regulations could be promulgated without this delay, we'd be equally happy.

● (1155)

The Chair: Thank you, Mr. Ménard.

Mr. Savage.

Mr. Michael Savage (Dartmouth—Cole Harbour, Lib.): Thank you very much, Madam Chair, and thank you all for coming today to give us your points of view on this.

One of the things that occurred to me when I was looking at this bill and in our discussions was that it didn't seem terribly complicated in light of the fact that it really came from the Standing Committee on the Scrutiny of Regulations, a committee that I think is chaired by the opposition. I think there was generally unanimous support that this is something that needed to be thrown back to Health to have a look at.

But it seems to me that one of the big changes is we're actually increasing the ministerial accountability now by having it be the responsibility of the minister to issue the IMAs.

I wonder if I could ask Ms. Sterken.... I certainly enjoyed your presentation and I can see you're very concerned about the foods we eat, particularly the products that might affect infants and unborn children.

Does that give you any sense of comfort at all that this might actually provide for more ministerial accountability in the issuance of this?

Ms. Elisabeth Sterken: I don't see how it does, because it really takes it out of the Food and Drugs Act, and it circumvents the Food and Drugs Act and actually allows the product to state that it is unadulterated. I don't quite understand how this happens.

Mr. Michael Savage: I mean in terms of the fact that it is now going to be the minister's responsibility to issue these, which is to me the essence of accountability—the Minister of Health has to be responsible for these decisions, as opposed to people in the department.

Ms. Elisabeth Sterken: What we would really like to see is greater accountability in relationship to the public need, rather than to fast-tracking for commercial purposes. We already see, as I mentioned, a huge body burden of chemicals. Do we really need to fast-track the increase of this particular dilemma?

We'd really like to see a reversal. Yes, we would like to see the minister very accountable. As well, we would like to see those within Health Canada, the bureaucracy, be far more accountable to the public need and the public interest and public concerns, and we would like to see far more consultation with the public, and information to the public, so we don't have to go through access to information to get details on what's happening behind the scenes.

It's a matter of accountability really being needed throughout the whole system, and we really would like to see a turnaround in priorities in relation to corporate interests versus public health interests.

Mr. Michael Savage: So it's not really this bill you're opposed to; it's the process in place right now?

Ms. Elisabeth Sterken: Yes.

Mr. Michael Savage: I have a question for the folks from CropLife. We heard the other day that since 1997, 82 IMAs have been issued. Would those be to people who are members of your organization?

Mr. Peter MacLeod: Yes, that's correct.

Mr. Michael Savage: I asked this the other day. Do you know how many who applied for that were denied?

Mr. Peter MacLeod: Food additives are not part of our membership. For pesticides in particular, when the PMRA completes their evaluation and goes to public consultation, that is one process. When that process is finished and an IMA is issued, the health and safety evaluation is complete, so it's really an administrative process. That's why we're in support of this bill—to reduce that administrative process. We're not in support of anything that would reduce the health or safety scrutiny of our products.

Mr. Michael Savage: And that's a little bit confusing to me. So these IMAs aren't initiated by companies saying they'd like to have this and would we consider it?

Mr. Peter MacLeod: Yes. When the application is first submitted, before evaluation, the company asks for the use of the product on certain crops, and the use of those certain crops may result in a quantifiable residue that needs a maximum residue limit, or an IMA.

Mr. Michael Savage: Do you have a sense of what the success rate of having these issued from requests would be?

● (1200)

The Chair: That's a question for Health Canada.

Mr. Michael Savage: I did ask Health Canada. That's what I'm asking. I was asking if they knew from the people who were part of their coalition.

Mr. Chris Warfield: Perhaps I could add just a touch to that. It goes to what was brought up earlier with confidential business information. When a company makes an application to the PMRA, they provide data in order to support particular uses. Along the way, the PMRA may agree or may not agree with those requests. Usually, at the end, the IMA covers the things the PMRA has agreed to support, and those requests end up with an IMA, an interim marketing authority, and temporary maximum residue limits, all of which are published in part I of the *Canada Gazette*, so they are made public. They're not secret. At that point, usually, there is.... It's 100%, right, but it may not be 100% relative to what was requested—but that information isn't always available.

Mr. Michael Savage: I will ask Health Canada that question and perhaps expect an answer.

Thank you.

The Chair: Thank you, Mr. Savage.

Next is Ms. Crowder.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): Thank you, Madam Chair. Thank you all for your presentations.

This bill is being promoted as a housekeeping measure and a way to deal with some administrative issues. I think the challenge with it is the resistance we're hearing from a number of community groups that points to the lack of transparency and openness by Health Canada.

In CropLife's statement they talk about pest control products wanting to operate in an open and transparent manner. I go back to May 2004 when the Canadian Association of Journalists awarded Health Canada its fourth annual Code of Silence Award, recognizing it as the most secretive department in Canada. So I think there are some challenges for Canadians to feel any degree of comfort around...and this is an opportunity that people have to express their concerns around things like MRLs.

I want a comment perhaps from industry. I have a presentation to the Pest Management Advisory Council in November 2004 by Diana A. Somers on the use of safety factors in human health risk assessment. She speaks specifically about a number of challenges, including that the elderly population, with declining renal function, is not adequately protected—there's a bunch of variables, and I'm not a scientist; that the issue of children versus adults needs to be considered; that there's almost a complete lack of data for pregnant females and the fetus; that there's emerging data that demonstrate rat and mouse to human differences—interspecies differences—is an issue; that there's controversy around the NAS/NRC recommendations to protect infants and children; and so on.

We have a presentation to PMRA that talks about the fact that there are some safety concerns and some challenges. Yet we're being asked to just look at this as a housekeeping bill and not deal with some of the bigger issues. I wonder if you could comment on that.

Mr. Peter MacLeod: I'll just address the first part regarding transparency. CropLife Canada, as part of its brief, fully support that and we're fully supportive of the Pest Control Products Act 2002, where and when that act is passed, and hopefully that will be before the year-end so that fully all our data is available. If anybody would like to view any piece of data that's submitted, it's available in what's called a "reading room", so any person—

Ms. Jean Crowder: Sorry, that reading room apparently is not yet available. My understanding is the act is passed but the regulations are not. And it's been three years now since the act was initially...2002. Again, we still have that 2,4-D issue that's been brought forward. So people aren't feeling really comfortable around this.

Mr. Peter MacLeod: That's one of the things that will be addressed in the new act, and we support it being brought into force as soon as possible because we believe our data should be available to anybody who would like to see it in a confidential way.

Regarding your second point on some of the health concerns and scientific issues with respect to health and safety, such as safety factors and part of the scientific data, I feel that would be best addressed by the regulatory agency that looks at our data. They're appearing after us, and I think they'd be in the best position to comment on that.

Ms. Jean Crowder: I think CropLife is probably the best to deal with this next question. I was at the agricultural committee on Bill C-27, and one of the farmers' coalitions came forward and talked about the fact that a lot of these initiatives are being touted as trade initiatives. There's this notion that it actually benefits the farmers. They put forward a very graphic representation showing as exports go up, net income to farmers is actually going down. What we're actually doing is undermining the ability of our small and medium-sized farmers to stay in business.

So the argument that we want to support this bill because it supports trade is actually not supporting our small and medium-sized farmers. I wonder if you can comment on that.

● (1205)

Mr. Peter MacLeod: This Bill C-28 will support both trade and domestic use—domestic production of food from our Canadian food growers, both from a domestic standpoint for our food supply in Canada, as well as for export, as well as for import. So it's not just for trade with the United States or some other country; it's for domestic use as well.

Ms. Jean Crowder: What about the issue that a number of European countries ban our imports, I think beef in particular because of some of the residues in it? And there's the issue around bovine growth hormones. We have other countries in the world that don't accept the levels we currently say are acceptable for the Canadian population.

Dr. Gordon Dittberner: Again, in terms of the drug side of things, that's probably something you want to address to BVD. There is considerable debate in the international community that I'm aware of in terms of the safe levels accepted in certain products. I don't think there's a really clear case, or evidence to suggest, that some of the hormones being used or some of the drugs being used in Canada are necessarily harmful. The debate between Europe and North America and South America and Australia is an ongoing thing. I think it requires the input of scientists more informed than I, so I don't think I can really comment on that.

I think our point is that we really look to have a regulatory system that gives us the level, that says this is a safe product and these are the measures we are to follow in order to ensure the safety of consumers. We want to have a regulatory process that is at least not putting our producers and our practitioners at a competitive disadvantage with others in the world.

The Chair: I'm afraid you're out of time, Ms. Crowder.

Ladies and gentlemen, with your permission, it's past 12 o'clock, and I feel that we should move to our second set of witnesses. I will carry on with the list from where I am now, to ensure that everybody gets a chance.

Do I have your agreement on that?

Some hon. members: Agreed.

● (1210)

The Chair: Thank you very much.

Therefore, on your behalf, I will thank the representatives of the Canadian Animal Health Coalition, CropLife Canada, and the Infant Feeding Action Coalition for their presentations and their answers to your questions.

We'll now welcome the representatives of the Department of Health. Again, we have the executive director of the PMRA, Karen Dodds; the director general of the food directorate in the Health Products and Food Branch, Paul Mayers; the director of food regulatory programs, Ms. Dalpé; the director of alternative strategies and regulatory affairs, Ms. Trish MacQuarrie; and Ms. Diane Kirkpatrick, director general, veterinary drugs directorate.

We wanted to have the Department of Health back, but right now they also wish to make a statement.

Please begin.

Mr. Paul Mayers (Acting Director General, Food Directorate, Health Products and Food Branch, Department of Health): Thank you, Madam Chair. We are happy to be back with you to provide additional information in your review of Bill C-28, and we are particularly appreciative of the opportunity to provide very brief introductory remarks, largely intended to address some of the issues and questions that have arisen in the course of discussions to date.

In that regard, when we last appeared the committee did ask for some additional information related to the actual products for which IMAs had been granted. We have provided a table in that regard. As well, to support the committee's understanding of the process, we have provided a standard operating procedure for how we manage the process of consideration of IMAs. And particularly on an earlier question regarding the consideration of products for which IMAs were not granted, we will note that in addition to the 82 for which IMAs were granted, in the context of the food additives and the addition of nutrients to foods, there were an additional 12 requests for IMAs that, based on their inability to meet the criteria for the granting of an IMA, were not granted.

Madam Chair, as consumer protection legislation, the Food and Drugs Act and regulations provide a range of mechanisms to provide an assurance of food safety. Pre-market review is one of those mechanisms, and that pre-market review requires a comprehensive safety assessment by Health Canada before certain products regulated by Health Canada are permitted for use in Canada.

All of the products we're discussing in the context of the IMA are subject to that rigorous pre-market review. It's our view that the interim marketing authorization mechanism complements this rigorous science-based review. What the mechanism does not do is compromise food safety because it does not relieve the Government of Canada or the Minister of Health of the responsibility to address the safety of the product, subject to pre-market review requirements of the Food and Drugs Act and regulations, such as food additives, vitamins, mineral nutrients, amino acids, veterinary drugs, pest control products, and agricultural chemicals. In each case it is the regulatory requirements that mandate the pre-market review, not the IMA. They provide the requirement for that rigorous scientific assessment that considers risks not only to the general public in a general population sense, but also specific risks to vulnerable groups such as infants, based on the best available science, and often that scientific process of assessment has been developed internationally.

The IMA is not and cannot be considered the relevant means of addressing many food issues, such as chemical contaminants like mercury or lead, or pathogens in foods such as E. coli or salmonella. None of these types of issues are indeed eligible for consideration and coverage in the context of the IMA. What is important is to recognize that the IMA does not provide any means by which products can enter the marketplace without having been the subject of a safety assessment.

In fact, a request for an IMA, because it relates to an extension of use for an already permitted product, results in a new safety assessment in addition to the original safety assessment that was conducted to authorize the initial entry of the product into the marketplace. And that presents a valuable opportunity, not only in the original safety assessment, but also in an updated safety assessment, taking account of any science that may have emerged since the initial assessment. Of course, an IMA would only be issued if Health Canada concludes that the sale of the food products in question would not pose a hazard to the health of consumers.

● (1215)

There was much consideration related to the communication and the consultations related to IMA, so let me just briefly provide you with a little information in that regard.

First and foremost, there is the mechanism itself, as introduced into the food and drug regulations in 1997. Prior to that introduction, Health Canada consulted extensively with stakeholders. In fact, that consultative process began in 1995, of course within the context of the formal consultations associated with the prepublication of the regulatory proposal in part I of the *Gazette*. That too contributed to the consultations on the process itself.

In addition to the process itself, each IMA, as we have previously noted, is made public through government notices in *Canada Gazette*, part I, and on the Health Canada website. Of course, because of the requirement that any issue for which an IMA is granted must also then complete the regulatory amendment process, there is another round of consultation when the proposed regulatory amendment is published in part I of the *Gazette*.

In summary, Madam Chair, before I turn to my colleagues to speak to the veterinary drug and pesticide issues, I will say that Bill C-28, in our view, maintains a mechanism that improves regulatory efficiency. The primary consideration continues to be consumer health protection. The science-based, comprehensive evaluation process addresses the safety of the products. That is not the IMA. That is the regulatory requirement for each of those products. The IMA then represents the mechanism to bridge the period between the completion of that rigorous science review and the formal amendment of the regulations.

Thank you, Madam Chair. With your permission, I will turn to my colleagues.

Ms. Diane Kirkpatrick (Director General, Veterinary Drugs Directorate, Health Products and Food Branch, Department of Health): Thank you very much.

As my colleague has noted, my purpose in being here today is to clarify issues relating to the proposed amendments and veterinary drugs.

Let me begin by confirming that to date there have not been any interim marketing authorizations, or IMAs, for any veterinary drugs. All veterinary drugs, including antibiotics and hormones, that have been approved for sale in Canada have received notices of compliance.

These notices of compliance are not temporary. They are only issued after a thorough scientific assessment is completed and we are satisfied that the proposed use would not jeopardize human or animal health. The scientific assessment is based on a review of data that must demonstrate animal safety and efficacy—that is, that the drug works as it is intended to work—and that any residues remaining in food derived from animals treated with the drug are safe for humans.

In the case of antibiotics, which were specifically referenced in remarks made to this committee earlier this week, the potential for antimicrobial resistance is also assessed.

To ensure that the review process is sound and rigorous, the scientific assessment is conducted by teams of scientists with expertise in different disciplines. Again, debate is very much encouraged in the pursuit of the best possible science to ensure that the health and safety of Canadians is protected.

I'll now turn to my colleague Karen Dodds.

● (1220)

Ms. Karen L. Dodds (Executive Director, Pest Management Regulatory Agency, Department of Health): Thank you.

Madam Chair and members, I might just start by saying I understand the concerns expressed about food safety and about pesticide safety. The primacy of safety and consumer protection is evident in the Food and Drugs Act; it's explicit in the Pest Control Products Act; and our minister has made it very clear that that's his priority, along with much improvement in transparency. I have worked with hundreds of scientists who are proud that that is the mandate they're working under.

I'd like to clarify that the proposed amendments do not affect the work of the scientists in determining the acceptability of pesticides, in determining the level of the maximum residue limits or the safety of those limits. We have provided the committee with some documents to illustrate the fact.

Before registering a pesticide in Canada and before establishing a maximum residue limit, or an MRL, the scientists at the PMRA must conclude that there is no unacceptable human health risk. Their toxicological review is extensive, and it includes long-term studies, multi-generational studies, and reproductive and developmental studies to determine if there is a potential impact on reproduction, on fertility rates, and on the healthy development of the fetus. It looks at a variety of studies determining whether there is a potential to cause cancer and at other studies.

Looking at the results of all of these studies, the scientists first determine if the pesticide is acceptable and then they look to set the MRL. To set the MRL, what they do first is establish what's called a "no observable adverse effect level". Obviously that is a dose typically several orders of magnitude below any dose that causes any adverse effect. Beyond that, safety factors are then incorporated.

The presentation that Ms. Crowder was discussing was one presented by a former director of human health evaluation. The safety factors are included to address some of the uncertainty. For example, when we know children are going to be high consumers of something where there might be a residue, an additional safety factor is included. These safety factors can vary from a hundredfold lower level residue to even beyond that. The dose we're consuming is in the parts per million range. It is very low. Beyond that, the dietary risk assessment they conduct must show that those residues, if consumed daily for a lifetime, can cause no adverse health effect. As I said, the risk assessment does look at the vulnerabilities of different sectors, including infants, toddlers, and children.

What the proposed amendment to the Food and Drugs Act would do is change what happens administratively to legally establish an MRL only after the scientists have decided if the pesticide is acceptable and they have determined what the MRL should be. There have been 22 IMAs for pesticides. The IMA process has allowed the sale in Canada of a variety of fruits and vegetables, including lettuce, tomatoes, Chinese broccoli, bok choy, cabbage, leeks, spinach, sweet and sour cherries, and strawberries. These are typically crops grown on smaller farms by market gardeners, where there are not the pesticides that are used very largely on the major crops. It has allowed the sale of these pesticides and the use on these crops for an average of 16 months before the regulatory process is finished.

The proposed amendment does go further in the area of pesticides, and it would allow the MRLs to be specified under the new Pest Control Products Act, following the consultations that we do now on pesticides, which are required under the new Pest Control Products Act, and at the same time as we are registering the pesticide, avoiding the timeline that would be required to go through the regulatory process to set the MRL under the Food and Drugs Act. It would also, in those few instances where new science demonstrates unacceptable risk, and in our re-evaluations, allow for faster revocation of an MRL.

Thank you.

● (1225)

The Chair: Thank you very much.

We did ask a question the last time you were here about how many applications you had for an IMA and how many were approved out of the number that were applied for. Do you have that answer for us?

Mr. James Lunney (Nanaimo—Alberni, CPC): I think you gave it to us at the beginning.

I think he said 12 or 13.

The Chair: Twelve out of how many?

Voices: Ninety-four.

The Chair: Okay, thank you. Sorry about that.

The next person on the list is Ms. Dhalla, who will be followed by Mr. Fletcher.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Once again, I just want to take the opportunity to thank all of our witnesses for coming and providing us with information.

The bill itself is going to be providing improvement for regulatory efficiency. We know the government is moving towards smart regulation. Can you comment on how the proposed framework in Bill C-28 is going to be moving forward on smart regulation?

Mr. Paul Mayers: The significant contribution from a smart regulatory perspective is the regulatory efficiency. What the IMA framework recognizes, first of all, is that consumer protection has been maintained by the assurance of the safety assessment prior to any decision-making on the issuance of an IMA. Once that consumer protection assurance is provided and the product in question has been demonstrated in terms of the safety in use, then the IMA framework essentially allows for that product to become available in the marketplace, while the process to formally list that product as an extension of use to the existing listing in the tables to divisions of the food and drug regulations, for example, is accomplished. What that means is those products, after the demonstration of safety, can come into the marketplace while that process is concluded, given that an existing listing already authorizing those products is in place. In fact, those products are in the marketplace, albeit not for use in a particular food for which the extension would apply, for example.

Ms. Ruby Dhalla: The individual from Infant Feeding Action Coalition, Ms. Elisabeth Sterken—I don't know if you were here during her presentation—mentioned some hesitation in regard to receiving, as you call it, consumer protection insurance. From your perspective, do you feel that Health Canada takes into account the subpopulation of toddlers and infants when they're doing evaluation for risk?

Mr. Paul Mayers: As both of my colleagues have noted in their assessments, and certainly in ours, one of the expectations in the review is to consider the exposure. Exposure is an extremely important part of risk assessment. In considering exposure, the population exposed is considered. Where that population exposed is a vulnerable group—not just infants, but the elderly, for example, are also considered a vulnerable group—then that, too, is assessed using the best available science.

We recognize that there will be situations where the body of evidence related to a particular vulnerable group is limited. Those are situations where the application of safety factors, as we heard in the context of the PMRA, become important. That's why, for vulnerable groups where there are extensive intakes, the safety factors are increased in order to address those challenges.

Ms. Karen L. Dodds: I might just add to that. One of the things we do at Health Canada is look at the levels of different contaminants and pesticides in breast milk. It is scientists at Health Canada who are actually the ones doing that work. We have, and have had, volunteers who send us their breast milk. What the levels in the breast milk show us are not just food exposures. They're exposures from food and the environment and in other ways as well. We've monitored different contaminants and levels of pesticides going back a number of decades. That gives us important information on trends. We can say, for example, that levels of things such as PCBs and of certain pesticides in breast milk have declined quite considerably over the last few decades. It's also able to tell us that there's the presence of new contaminants. Then we have to start looking at where we are getting the exposure to some of these new contaminants.

● (1230)

The Chair: Thank you.

Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thank you, Madam Chair.

Many of the arguments we've discussed today are based on the integrity of the science. At the last health committee meeting—where I think you were all in the room—the integrity of the science was challenged. I would like to give you an opportunity to respond to the challenges that we've already heard.

Mr. Paul Mayers: Perhaps I can start, and I'm sure my colleagues will want to add something.

Dr. Dodds mentioned in her opening remarks the views of scientists in Health Canada. I myself am particularly proud to work in that organization. I have colleagues who have been in the organization much longer than I have. When I see scientists who have dedicated an entire career to the department, 35 years plus, that level of commitment speaks, in my view, to a commitment to not just the science but also the department. And I know very few scientists who would continue to work if they believed the scientific integrity of what they were doing was questionable.

I think it is absolutely true that the integrity was challenged. I think it's equally true, and we see it every day in the scientific literature, that science debate occurs around issues. Science debate is to be encouraged, because through that debate we improve our understanding.

So I don't have fault with the challenges to integrity, because they give us the opportunity to speak to the confidence we have in our scientists. I think perhaps the thing that most speaks to this is the reputation that Health Canada scientists have around the world. That reputation is unquestionable. We are routinely asked to assist other countries, not only developing countries but also developed countries, in terms of elaborating our understanding of new challenges.

Mr. Steven Fletcher: Okay. I have a limited amount of time here. I'm sure Health Canada hires scientists of high quality and so on, but we had not one, not two, but three scientists who were hired by Health Canada, who are no longer with Health Canada, and who made some pretty dramatic statements about the Privy Council interfering in the decision-making in Health Canada, particularly around the BSE issue and the enforcement of Health Canada regulations around BSE. We all know the consequences of what can happen with just one BSE incident.

I would like you to address that and provide assurances to this committee one way or the other. We need to know if what the scientists said was true or false.

I expect I know what your answer is going to be, but I'd be remiss if I didn't ask the question.

Ms. Diane Kirkpatrick: I'm actually pleased that you posed the question, because another purpose of coming here today was to affirm and provide the assurances you are seeking.

Above and beyond what Paul has mentioned, in terms of the scientific expertise of our staff, I would also add to that equation that sitting here at this table, we are mothers, we have our own families, we believe in Canada, and we also believe in the importance of what we can contribute to public health. Otherwise, we would not be with this department, I can assure you of that.

One of my primary objectives as a senior manager responsible for the veterinary drug program was to continue, not just to say that it's done. It's an ongoing process. The integrity of the process, the integrity of our reviews, is critical to the decisions we are asked to make in regard to any proposal, in my case, to use veterinary drugs.

We have worked hard to ensure that the decision-making process is not based on any single opinion. It is based on opinions and debate that occur among scientists from varied disciplines. I mentioned that in my opening remarks, but let me give you an example.

A submission comes into the department, into my department. It gets parcelled out to different groups or teams of experts, teams that look after the microbiological safety—which includes residues as well as antimicrobial resistance—teams that look at every aspect of the toxicology of a submission. For example, we even have made sure that we have very specific expertise related to things like endocrinology, which is really at the heart of making judgments related to hormones. Then there are teams of chemists who look at aspects related to residues and the metabolism of drugs. There are teams that look at the clinical aspects of the use of these drugs in animals in terms of safety and efficacy.

Above and beyond all these experts that then come to a conclusion about the product, if there are any outstanding issues in regard to the safety aspects, we also have mechanisms such as calling on experts in our country, in other countries, to join us and provide their expertise in terms of decision-making.

I hope that provides you with some idea of the extent to which we go on an ongoing basis. It's never-ending. Science is always changing. There's always debate about individual substances. Part of our primary objective is the integrity of the process we use to make these decisions to ensure public health and safety.

● (1235)

Mr. Steven Fletcher: But enforcement—

The Chair: Madame Demers.

[*Translation*]

Ms. Nicole Demers (Laval, BQ): Thank you, Madam Chair.

Your presentation does not reassure me. I find that you are laying it on thick. I have read several documents since last week. I suffered from breast cancer five years ago. I am one of the lucky ones who survived. During my research, I found a lot of products approved by Health Canada that are the cause of many cancers, one of which is breast cancer. When you say that the researchers and scientists do not take any risks, I have serious questions about that.

Biochemist Árpád Pousztai, after putting rats on a 10-day diet of genetically modified potatoes, discovered immune system defects, abnormal stimulations of the pancreas, the intestine, the prostate — my colleague will be happy to hear that one — and testicles— and maybe that will worry him even further — not to mention atrophied liver and brain development. It is enough to give you goosebumps.

Other research has shown that in some women, malignant tissues had high concentrations of PCBs, DDT — a pesticide used in North America from 1945 to 1972 — and DDE, higher than what was found in other women in tissues with non-malignant diseases.

I think the Europeans said no to our hormone-raised beef and I think that is still the case: they refuse to buy our beef and I understand why.

Now, the Canadian Animal Health Coalition would like to see C-28 passed to be able to sell hormone-raised beef more quickly. I have a lot of problems accepting that. You have provided us with a list of 82 authorized products: fruits, beans, legumes, vegetables. I do not know what I will be eating anymore because it really worries me. You say that you keep people abreast through the *Canada Gazette* and despite that, Ms. Sterken has told us they had all kinds of problems getting information from Health Canada. Because of all that, I will have huge problems voting in favour of this bill.

Are we not also running the risk of allergies when we manipulate genes? We use mouse genes to get tobacco products that are less...to avoid heavy metals. Butterfly genes are being used to avoid all kinds of potato diseases. I cannot get over it. I was floored by these discoveries. I hope we will pay more attention.

I do not have any questions for you because no matter what the question you are asked, you have a stock answer. I am simply sharing my concerns. I find it is very important. You said before that you were mothers, that you had children, and parents. We have to take the health of Canadians and Quebeckers far more seriously. We are not being serious enough.

Thank you, Madam Chair.

● (1240)

[*English*]

The Chair: Thank you, Madam Demers.

Now it is Mr. Carrie's turn.

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

Actually I have tons of questions for you. I wish you were here a little bit longer.

From what I'm hearing from my constituents on what the concerns are, there seems to be a trend where there are more chemicals being put into our system. The other witness who was here before you mentioned a body burden of chemicals. I think that is a good term that wraps up how a lot of people perceive these issues.

Right now Canadians want the right to know. They see Health Canada as looking after their safety, whereas in the last 20 years there seem to have been more chemicals, more this, and more that, and there's a concern that these chemicals being added to our foods aren't safe for us in the long run.

In particular in this bill there seems to be a concern over fast-tracking and potential for abuse and that this is too industry-friendly. Do you see any areas where, in regard to the bill, there is potential for abuse through fast-tracking?

Mr. Paul Mayers: Again, I can start.

Because the responsibility to issue an IMA is entirely criteria-based, it becomes an objective decision-making process as opposed to a subjective one. As a result, there is no particular ability to favour one particular product versus another for earlier entry. It's simply a question, once the safety assessment is concluded, if an IMA is requested, of whether the particular submission meets the criteria that would allow it to have an IMA. If the answer to that is yes, then it can, and if the answer to that is no, it can't. There's no in between.

Mr. Colin Carrie: There's no real abuse with this bill.

I have another question that's very important, which my colleague, Mr. Savage, brought up. He talked about how this bill will give more accountability and responsibility to the minister. I was wondering, from a Canadian standpoint, what does that actually mean? If the minister is more accountable or more responsible, what does that mean for Canadians?

For example, let's say that under his watch something got approved that turned out to be a disaster. What are the consequences and responsibilities that the Minister of Health has for accountability and responsibility?

Mr. Paul Mayers: You've now gone well beyond my personal capacity because you speak to legal liability.

Mr. Colin Carrie: I don't know. I'm just wondering if there is anything in there. He brought forward the point, which is a very good one, that we're going to move it, and now the minister is more accountable. But what does that mean? Can you answer that?

● (1245)

Mr. Paul Mayers: All I can refer to is the advice received from the Standing Joint Committee on the Scrutiny of Regulations, which—

Mr. Colin Carrie: So basically we're saying he's more accountable, but it actually means nothing. Is that what you're saying?

Mr. Paul Mayers: No, that's absolutely not what I'm saying.

Mr. Colin Carrie: Okay, it's not what you're saying, but I'm trying to get to.... There's a purpose here, and I don't blame the manufacturers for wanting to fast-track their product. It's a legal product. It's gone through everything. It's going to be something that makes a lot of sense on a day-to-day basis, but what does it mean for Canadians and the safety of Canadians, and what does that accountability in Health Canada mean to Canadians, that Health Canada is accountable, the minister is accountable? That's what I'd like to find out.

Mr. Paul Mayers: Let me speak to what it means from a safety perspective.

Mr. Colin Carrie: No, that's okay, because I've got some more questions here.

Mr. Paul Mayers: We do have a colleague from Justice who might be able to add some information if you wish.

Mr. Colin Carrie: And he's here?

Mr. Paul Mayers: Yes.

Mr. Colin Carrie: Oh, wonderful, yes. Could he enlighten me on that point?

Mr. Paul Mayers: It's Claude Lesage.

Mr. Colin Carrie: Merci beaucoup.

Mr. Claude Lesage (Senior Counsel, Legal Services, Health, Department of Justice): Good morning.

There are two aspects to ministerial accountability. One, the minister is responsible for the overall administration of the legislation that is incumbent on the department.

The other one is under the theory of crown liability, where if people are injured by a particular product, they may bring a product liability suit against the manufacturer and distributors. At times they also bring in a third party—the department—as a defendant, and the courts will assess whether the department has been negligent in the discharge of its regulatory duties.

So these are the two mechanisms, but overall the department, acting for and on behalf of the minister, is responsible for the enforcement of legislation and regulations.

If there are elements or signals, or if there are adverse events so that things are not having the projected effects or safety profile, there are mechanisms under the existing regulations and also under the current bill that is proposed to withdraw the authorization, cancel it and go back to the status quo, and there are mechanisms under the legislation to put further bans in place or check the registered limits or whatnot.

Mr. Colin Carrie: But basically there's no direct accountability, ministerial or departmental, nothing along those lines for any mistakes that might be made, nothing like that for Canadians wondering who's responsible?

Mr. Claude Lesage: Well, these are the general mechanisms that we have under our—

Mr. Colin Carrie: Could I just cut you off? We only have time for one more quick question.

When you do your testing of the different additives and pesticides and things, do you test them singularly? Do you do the reviews and test the products singularly, or do you do it with combinations of different things that are already on the market? Is that something you do research into?

Ms. Karen L. Dodds: I can speak to that in a few different ways.

The Chair: Succinctly, please; we're running out of time.

Ms. Karen L. Dodds: To the best of our scientific ability, we do. It is difficult now. Again, under the new Pest Control Products Act there is an explicit requirement to look at what is called “aggregate exposure”. What we can do right now is look at the same active ingredient and accumulate all exposures. That would be the same for food additives. It would be the same for veterinary drugs. So we don't look just product by product; we actually look at cumulative exposure from all food sources.

The Chair: Thanks very much.

If I may, I have a couple of things.

When we were dealing with prescription drugs for humans, we were quite dismayed about the lack of post-market surveillance. All the tests for safety had been passed before the drug was approved, but it seemed to us that no one was watching those cumulative effects. In other words, the cumulative effects that you're talking about are mainly in animals, are they not? These are the tests that are done before something is approved. I'm not talking about the IMA or that sort of thing; I'm talking about the basic work of the Food Inspection Agency.

● (1250)

Ms. Karen L. Dodds: All of this assessment is done at Health Canada. There is data submitted that is based on animal studies, but when I'm saying that we're looking at cumulative and aggregate, that is information based on total exposures.

Again, this is Health Canada work—

The Chair: They're all projections, are they not?

Ms. Karen L. Dodds: No, we actually have gone out and done surveys, province by province. As well, we did a national survey of what Canadians are consuming.

So we look at what the levels are of these different additives and/or pesticides. We do what's called a “total diet” study. We have a variety of mechanisms where we're looking at cumulative exposure, and that's assessed.

The Chair: With an examining of human tissue?

Ms. Karen L. Dodds: We do breast milk; I'm not sure whether we do any other tissue. The breast milk study is our best source.

Again, we do a total diet study. It is not food-specific, but it looks at foods consumed as you would consume them. It looks at all contaminants.

The Chair: When we did the pesticide act, I remember we had testimony that certain chemicals don't show up in the blood, for example, because they immediately reside in fatty tissue, and nobody is examining fatty tissue to see these residues building up.

Ms. Karen L. Dodds: Breast milk is examined. One of the reasons we look at breast milk is that, yes, it's mothers, but the milk is high in fat. So you do get a very good indication of what the burden is in any of those fat-soluble contaminants.

The Chair: Okay.

I have two more questions. First, the people who are worried about prescription drugs are suggesting that the elderly are becoming overburdened, simply because they do not get rid of residues as quickly as younger people. So I'm also wondering about the accumulation of these residues in seniors, because it may not have anything to do with the elimination of the residues in younger bodies.

What are you doing about that?

Ms. Karen L. Dodds: Again, I can speak to the pesticide situation quite specifically. In those animal studies, they actually do metabolic studies. In the animals, they determine not just what the pesticide is but also what the pesticide is metabolized to. They use different models. When we talk about residues, it may not actually be the active ingredient as was in the product sprayed; it may actually be a metabolite.

So we're looking at those kinds of issues as we're doing our toxicological assessment.

The Chair: Okay.

Now, I thought this was articulated rather well by our earlier witnesses, and by some of our own members. The general feeling in the public is that all the additives put in food, and all the pesticides used in the preparation of the crops and all that sort of thing, is increasing the load of foreign substances in our bodies. I'm wondering how much awareness there is of the worry and anxiety that's out there in the general public, and how much you are taking this into consideration as you approve these things.

In other words—and we had this discussion the last time you were here—I don't think the public would want to ingest any kind of chemical substance if it was unnecessary. For instance, if it was to enhance the firmness of a food product, they might not care. It may be the manufacturer who cares, because it looks more appealing or something when it's firmer.

You see, this is what we're concerned about. We wonder how much commercial interests are driving your decisions. In other words, there's a government-wide thing about smart regulation, and it's obvious to me that this is to ease the way for business. How much pressure is on you to move to smart regulation as opposed to your general concern about the health of Canadians and the emerging concern about the anxiety level out there about food?

Ms. Diane Kirkpatrick: I'd like to actually go back to basics in answering that question. There is an unfortunate misperception in the public, and certainly we can do a lot better I think to try to address that perception. When you look at it in the context that all foods are chemicals, there is nothing that you consume that isn't comprised of a multitude of chemical entities. A cup of coffee in the morning, an egg, whatever—there is a multitude of chemicals. Obviously before anything is added, those are what we call naturally occurring chemicals.

If you look at the chemical burden we're exposed to, good estimates around say that 99% plus of what we're exposed to in terms of chemicals is naturally occurring in our food. In fact, we are regulating probably less than 1% of the total chemical exposure. If you then look at what natural equates to—and I know people have a perception that natural equals to good—unfortunately, a long time ago in the field of toxicology, the father of toxicology said that all substances were poisons. The only thing that distinguishes one substance in terms of its poison or not is the dose. That's really true, whether you're talking about naturally occurring chemicals in our food or synthetic chemicals that we might add as a result of food additives, pesticides, or whatever.

I would also say that some of the most toxic chemicals known to man are naturally occurring. So when we talk about studies that are done on population—epidemiological studies, chemical burdens, or whatever, and we talk about all kinds of toxic effects—I would hypothesize, based on information in the literature, that our total dietary exposure to chemicals is what we should be looking at. The links between our diet, nutrition, and adverse effects—obesity, cancers, you name it—are tremendous.

So I'm not trying to dismiss the importance of looking at these other chemicals. This is good. It should be done. Based on the information we presented, you can see that there's a lot of scrutiny and safety built into our assessment. I think a lot of the concern in the public is misplaced, and I agree, we should be doing a better job to explain to the public what they can do themselves to reduce the consequence of exposure to chemicals and toxic effects.

● (1255)

The Chair: Thank you very much.

I think Ms. Crowder had one small question left.

If you have several questions, perhaps you could just express them and they could return the answers in writing. That's another possibility.

Ms. Jean Crowder: That would be great, thanks.

I want to preface my statement by saying I don't think any of the committee members are impugning the hard work of the scientists at Health Canada. That's not what this is about, from my perspective certainly. There is a bigger issue around whether or not people trust the process that's in place at Health Canada. Whether or not people believe they're drinking chemicals in the morning with their coffee is not the issue. If people don't have confidence in the food security and safety in Canada, we have a problem, whether it's how information is processed or whatever.

I pulled out the regulatory directive from the PMRA re-evaluation program.

As you flip through this document—the chair spoke about trade—this whole document talks about harmonization with the United States. Many people don't see the United States as having satisfactory regulations in place. Whether that's true or not...but when our whole drive is around harmonization with the States, that's a problem for people. When we're relying on information from the States in terms of making the decision, people will quickly point to Vioxx as an example of how decisions made in the States are not good for people, including Canadians. So I think there's a great lack of trust around what information is coming out there.

The second piece I pulled was the Pest Management Advisory Council minutes and the economic management advisory committee minutes. Again, there seems to be an overrepresentation in these groups of people who have a particular commercial interest. Certainly there were people like the Canadian Environmental Law Association, but again, how can we trust that Canadians are adequately represented when it appears that a particular interest group is driving an agenda?

The question I have is about estradiol. It came up at the last health committee meeting. We had a particular question about the DNA damage. I understand there is a study being done on estradiol and how it relates to human health. I wonder if that study is available yet, or when it will be available.

● (1300)

Ms. Diane Kirkpatrick: There are many studies the world over looking at the use of hormones. In particular, when you talk about estradiol, one of the key reasons for those studies worldwide relates to the use of hormone replacement therapy. So I'm not sure what study you're referring to, because there are lots going on.

Ms. Jean Crowder: Is there any Health Canada study currently under way?

Ms. Diane Kirkpatrick: Not specifically related to estradiol.

Ms. Jean Crowder: So there's no estradiol study in Health Canada that we can look forward to. There are some allegations out there that it is directly linked to breast cancer.

Ms. Diane Kirkpatrick: I would once again like to clarify that you want to be very careful about references to studies that link hormones to cancers, because often those studies are done at doses that are used in humans for things like hormone replacement therapy. They are done with substances that are specifically formulated to ensure that they are absorbed in humans, so they're not exactly the same thing as what we're talking about in terms of the use of hormones in animals. So I just caution—

Ms. Jean Crowder: But I just wanted to know if there was a....

Okay, thank you.

The Chair: Ms. Crowder, we're losing our committee. I'm going to have to cut it off because we have a procedural motion that Mr. Ménard is going to put forward.

Thank you very much to our witnesses.

[*Translation*]

Mr. Réal Ménard: Madam Chair, I would like to check up on something.

[*English*]

I'm going to start again for you, Mr. Savage.

[*Translation*]

I would like to see if all colleagues agree to ask the clerk to see to it that on May 5, we will be able to do the clause-by-clause of this bill and to give the committee members until Monday, May 2, 5 p. m., to table their amendments.

[*English*]

The Chair: It sounds fine with everyone? That's a Thursday, so that would be the Monday or so for the amendments. All agreed?

(Motion agreed to)

The Chair: I see that motion passes, so we'll look forward to the clause-by-clause on that date.

This meeting is adjourned.

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