Health Canada Santé Canada

Consultation on the Development of Environmental Assessment Regulations Report

Health Canada

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The information contained in this document reflects the views of stakeholders that attended the consultation on the Development of Environmental Assessment Regulations on March 29 & 30, 2006 and in no way represents the views of Health Canada and/or Environment Canada.

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1.0 Executive Summary

Health Canada and Environment Canada invited stakeholders to Ottawa to attend the Consultation on the Development of Environmental Assessment Regulations for substances contained in products regulated under the *Food and Drugs Act* (F&DA) on March 29th and 30th, 2006. The two day consultation had four main objectives:

- To provide an analysis of the stakeholder feedback on the Options Analysis Paper;
- To present the Health Canada and Environment Canada recommended legal framework for the Environmental Assessment Regulations;
- To discuss and seek feedback on the key elements of the regulatory framework; and
- To present the path forward in developing the Environmental Assessment Regulations.

These objectives were addressed throughout the consultation in an open and transparent manner. All stakeholders took part in discussions regarding key issues raised during the consultation. Many constructive comments were made throughout the consultation including, but not limited to the following:

- Stakeholder engagement throughout the development of the regulations is important;
- There are many complex issues that need to be addressed throughout the development of the Environmental Assessment Regulations: this initiative is complex;
- There was agreement to proceed with developing the Environmental Assessment Regulations under the *Canadian Environmental Protection Act, 1999* (CEPA 1999);
- There are differences between types of substances in each commodity group and the approaches and requirements should reflect such differences;
- Health Canada and Environment Canada should consider international models/regulations that currently exist;
- Further progress on the revision, prioritization and management of substances on the In Commerce List is needed; and
- Best practices should be developed for the management of substances contained in products regulated under the Food & Drugs Act (F&DA)

The key messages and recommendations that were heard from stakeholders during the consultation have been recorded and are set out in this report in the order in which the issues were presented. Health Canada and Environment Canada will take into consideration all comments made by stakeholders during the development of appropriate Environmental Assessment Regulations and addressing issues related to the In Commerce List.

As presented at the consultation, Health Canada and Environment Canada will continue developing the regulatory framework for the Environmental Assessment Regulations and subsequently the notification data requirements. Consultation with stakeholders will be essential as Health Canada and Environment Canada move forward on this initiative.

2.0 Background and Opening Remarks

On March 29th and 30th, 2006, invited stakeholders gathered in Ottawa for the Consultation on the Development of Environmental Assessment Regulations for substances contained in products regulated under the *Food and Drugs Act* (F&DA). Neil Yeates, Assistant Deputy Minister of the Health Products and Food Branch at Health Canada, opened the consultation by welcoming and thanking the invitees for their keen interest in the development of the regulations.

Mr. Yeates outlined that Health Canada's consultation objective "was to define and strengthen relationships between various stakeholders, to maintain transparency, and to seek input from all of these parties as we move forward." He noted that a major challenge in developing these regulations is the sheer number of stakeholders contributing varying points of view on this issue and, while it is a daunting task, much progress has already been made.

Mr. Yeates also noted that Health Canada and Environment Canada recognize that health and environmental issues related to new substances entering the environment are of great interest to many Canadians and that collaboration is necessary to develop appropriate Environmental Assessment Regulations for new substances contained in products regulated under the F&DA.

2.1 Purpose of the Consultation

The workshop had 4 principle objectives:

- To provide an analysis of the stakeholder feedback on the Options Analysis Paper;
- To present the Health Canada and Environment Canada recommended legal framework for the Environmental Assessment Regulations;
- To discuss and seek feedback on the key elements of the regulatory framework; and
- To present the path forward in developing the Environmental Assessment Regulations

3.0 Presentations

Industry, non-government organizations, provincial and federal government stakeholders attended the Consultation on the Development of Environmental Assessment Regulations. Throughout the consultation stakeholders were invited to ask questions and provide comments on the presentations given by Health Canada and Environment Canada representatives and related issues. After each presentation, stakeholders were given time to discuss the presentation and any questions or issues the presentation may have raised with other stakeholders at their table. Each table had an Environment Canada and/or Health Canada representative to provide additional information to participants. Stakeholders were then invited to bring questions and comments forward to the large group of attendees. All questions were answered by Health Canada and Environment Canada by the end of the consultation.

The following presentations were given at the consultation. A brief overview of each presentation is followed by the key messages that were raised by stakeholders. These key messages were raised by stakeholders in attendance at the consultation and are not those of Health Canada and Environment Canada.

- The Background on the Development of Environmental Assessment Regulations, the Options Analysis Paper Feedback Analysis Report and the Exemptions / Waivers / Special Category Substances
  Kiran Hanspal, Director, Environmental Impact Initiative, Health Canada

- The Regulatory Framework for Health and Food Products in Canada
  Brigitte Zirger, Director, Therapeutic Products Directorate, Health Canada

- New Substances The Canadian Environmental Protection Act 1999 and the New Substances Notification Regulations An Overview
  Bernard Madé, Director, New Substances Division, Environment Canada

- Legislative Authority
  Debra Young, Director General, Office of Regulatory and International Affairs, Health Canada

- In Commerce List
  Neil Tolson, Section Head, In Commerce Substances Unit, Health Canada

- Notification
  Andrew Beck, Section Head, Environmental Assessment Unit at Health Canada

- Path Forward
  Abby Lawrence, Policy Analyst, Environmental Impact Initiative, Health Canada

Complete versions of the presentations can be found at www.healthcanada.gc.ca/eii

Health Canada and Environment Canada will take into consideration all comments given by stakeholders during the development of appropriate Environmental Assessment Regulations and addressing issues related to the In Commerce List (ICL).

3.1 Background on the Development of Environmental Assessment Regulations

Presentation Summary

The need for appropriate Environmental Assessment Regulations is growing as scientific evidence shows that certain substances in products regulated under the *Food and Drugs Act* (F&DA) are being found in the Canadian environment. Furthermore, the *Canadian Environmental Protection Act 1999* (CEPA 1999) requires that all substances new to Canada be evaluated for their potential risks to the Canadian environment and to human health prior to manufacture in or import into Canada. All new substances imported or manufactured in Canada are subject to the *New Substances Notification Regulations* (NSNR) of CEPA 1999. However, the NSNR (chemicals/polymers) were developed for industrial chemicals and polymers and thus, may not be appropriate for all substances contained in products regulated under the F&DA.

On September 1, 2001, the Minister of Health announced Health Canada's intent to develop Environmental Assessment Regulations for new substances contained in products regulated under the F&DA. Health Canada and Environment Canada have been working together to develop appropriate regulations.

The following commitments will guide Health Canada and Environment Canada in developing the Environmental Assessment Regulations for new substances contained in the wide range of products regulated under the F&DA:

- To safeguard human health and the environment;
- To ensure Canadians have continued access to products they need;
- To participate in an open and transparent process with all stakeholders throughout the development of appropriate regulations;
- To meet the legal and policy requirements of CEPA 1999.

Key comments from stakeholders

Considerations for regulatory development

- Health Canada and Environment Canada should look at the scientific research surrounding the need for these regulations. Specifically, the environmental impacts of substances contained in products regulated under the F&DA and any affects these substances are having on human health by being in the environment.
- A tiered approach should be considered as a way to respond to the risk of new substances.
- A variety of stakeholder types, including Non-Government Organizations, should be consulted with as the development of the regulations moves forward.
- Smart regulations and economic considerations should be included as guiding principles for the development of the regulations.
- Stakeholders should be informed as to why the current NSNR are not considered appropriate.
- Stakeholders should be informed as to what will happen to those substances that have been assessed under the current NSNR.
- Trigger quantities should be appropriate for each commodity group.
- All types of media need to be examined including air, soil and water. The impacts on the air and land should be considered in the regulations, not just waste water.
- The regulations should not be based on the perception of risk.

Education considerations

- Educating the consumers of the risk of these substances to the environment could be a way to address some of the issues.
- Health Canada and Environment Canada should educate stakeholders that substances as well as mixtures will be assessed.
- Health Canada and Environment Canada need to educate stakeholders as to why both government departments are working on the regulations.

International considerations

- International collaboration should be a main focus for Health Canada and Environment Canada as they move forward in the development of the regulations.
- The science research being done by Health Canada and Environment Canada should be compared to the research that is being done in Europe.
- As Health Canada and Environment Canada develop the Environmental Assessment Regulations, they should ensure that the regulations do not conflict with any other regulations in another jurisdiction.
- International harmonization should be sought for during the development of the regulations.

Other considerations

- Health Canada and Environment Canada should consider that the regulations may not be the answer to all of the problems. Further work on best practices and the scientific agenda should be looked at as well.

3.2 The *Food and Drugs Act*

Presentation Summary

The responsibility for food and health products is shared between the federal and provincial/territorial governments. The federal regulatory responsibilities are divided into seven groups within Health Canada along with the Canadian Food Inspection Agency (CFIA).

The purpose of the *Food and Drugs Act* (F&DA) is to regulate health fraud and consumer deception and consumer and purchaser safety. The *Food and Drug Regulations* are divided into 10 parts.

There are specific requirements for new drugs, generics, and other drug submissions. Once the submission has been received by Health Canada it is reviewed and then Health Canada responds with a regulatory decision. Submissions are also subject to post-market and risk management authorities.

Key comments from stakeholders

- Stakeholders need to be informed on what exactly is covered under the F&DA in regards to importing.
- It needs to be stated as to which department is responsible for adverse reactions.
- The difference between advertising and health claims need to be clearly stated.
- The timelines for product approval need to be defined.

- The goals and objectives of the F&DA review should be defined. The F&DA should be considered to address the gaps in the *Canadian Environmental Protection Act 1999* (CEPA 1999).
- What is covered under the natural health products drug submissions should be defined.
- Educate stakeholders on the policy of the exchange of information between Health Canada and CFIA.

3.3 The *Canadian Environmental Protection Act 1999* and the *New Substances Notification Regulations*

Presentation Summary

Currently under review, the *Canadian Environmental Protection Act 1999* (CEPA 1999) gives the Canadian government the authority to address pollution issues. CEPA 1999 provides the authority to regulate a substance throughout its' lifecycle. Substances subject to Acts or regulations listed in Schedules 2 and 4 of CEPA (covered under another federal law in a manner that provides sufficient protection to the environment and human health) are not subject to CEPA 1999.

CEPA 1999 gives the Minister of Environment authority to maintain a Domestic Substances List (DSL). DSL eligible substances must meet the following criteria:

- Prescribed info has been provided;
- Assessment timeframe has expired;
- Justification for confidentiality requests has been provided;
- A Notice of Manufacture or Import provided; and
- A Notice of Excess Quantity provided.

The *New Substances Notification Regulations* (NSNR) are a shared responsibility between Environment Canada and Health Canada – "New Substances Program". The NSNR ensure that no new substance is introduced into the Canadian marketplace before an assessment of its impacts on human health and the environment is made. The NSNR cover new chemicals, polymers and animate products of biotechnology.

The NSNR prescribe information requirements, assessment period lengths and conditions for adding a substance to the DSL. Information is required before manufacturing/importing a new substance in certain amounts.

Key comments from stakeholders

- Under CEPA, can Health Canada and Environment Canada ask for further information that is not explicitly asked for in the regulations?
- Environment Canada needs to clarify who is responsible for following through with a Significant New Activity (SNAc) Notice and who they will contact if the notification has not been followed through.
- It needs to be explained as to how substances will be assessed in the range of 5-120 days.
- Stakeholders need to be aware of the type of tests done to assess the toxicity of a substance.

- Health Canada and Environment Canada need to inform stakeholders on what their roles are and how both departments work together in the assessments of substances.
- It needs to be clearly stated whether Health Canada will issue a notice of compliance for environmental assessments of new substances as Environment Canada does for patents.
- It needs to be clearly stated as to which department will ensure compliance for environmental assessment measures.
- Consultation should be done with other offices and Ministers with CEPA equivalent Acts to discuss possible regulatory overlap.

3.4 Options Analysis Paper Feedback Analysis Report

Presentation Summary

The Options Analysis Paper – An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act* (OAP) was released to stakeholders in June 2005 for comment ending September 2005.

The OAP presented 3 options:

- Option A: Using the current *New Substances Notification Regulations* (NSNR) (status quo);
- Option B: A new regime under the *Canadian Environmental Protection Act 1999* (CEPA 1999); and
- Option C: A new regime under the *Food and Drugs Act* (F&DA).

Approximately 600 stakeholders were invited to provide feedback on the OAP. A total of 71 submissions were received by Health Canada. This represents a 12 % response rate. The highest response - 71.8% - came from the industry sector, mainly through their umbrella organizations. Health Canada received responses from several umbrella associations as well as from their member associations. Each response, whether from an individual, an umbrella association, or a member association, was counted as one response.

The feedback on the OAP provided the Government with a good sense of the key issues of concern to stakeholders. This has helped to inform Health Canada and Environment Canada during the selection of the recommended legal framework.

Key comments from stakeholders

- It needs to be further explained as to why modifications cannot be done to the NSNR, as developing new regulations would be very resource intensive.
- The “voting” system for the options needs to be further explained by Health Canada and Environment Canada.
- Stakeholders want to know why only one vote was given to large umbrella associations that could represent 700 companies.
- Responses from industry associations should be weighted.

3.5 Legislative Authority

Presentation Summary

Health Canada and Environment Canada undertook an analysis of the three options that were presented in the Options Analysis Paper (OAP) and the two that were suggested by stakeholders:

- The *New Substances Notification Regulations* (NSNR), with modifications to the data schedules and trigger volumes, under *Canadian Environmental Protection Act 1999* (CEPA 1999); and
- New regulations under a renewed *Food and Drugs Act* (F&DA).

The key issues that were analyzed were whether the option addresses the critical issues/key elements raised in the OAP, whether the option meets the policy and legal requirements outlined in CEPA 1999 and whether it meets specific operational issues including enforcement and timelines for product review.

Health Canada and Environment Canada will proceed with developing appropriate Environmental Assessment Regulations under the New Substances Program under CEPA 1999 at this point in time. This recommendation is based on the following key issues:

- Health Canada is committed to developing Environmental Assessment Regulations that are appropriate for new substances contained in products regulated under the F&DA ;
- The NSNR were developed for industrial chemicals and therefore may not be appropriate for new F&DA substances;
- There is a need to proceed with the development of the regulations with specific information requirements respecting the risks to the environment and human health; and
- The current F&DA does not meet the criteria for listing in either Schedules 2 or 4 of CEPA 1999.

Health Canada and Environment Canada believe that the regulatory framework, notification requirements and risk management measures need to be specific for F&DA substances in order to protect the environment and human health from the potential risks of new substances. These specific details will be developed in consultation with stakeholders.

The Environmental Assessment Regulations will be developed in such a way that they can eventually be transferred under a renewed F&DA that contains the appropriate authorities required by CEPA 1999 for scheduling other Acts. The final placement of the regulations will be dependant on a number of factors, including the CEPA 1999 review and the review of the F&DA. Due to the various uncertainties with respect to timing, the option to place the new Environmental Assessment Regulations under the F&DA will be kept open.

Key comments from stakeholders

- Stakeholders are concerned with one department undertaking both the environmental risk assessments and the human health assessments for new substances.
- Health Canada and Environment Canada need to inform stakeholders if there is sufficient interplay on the chemical issues between the two.
- Health Canada and Environment Canada need to inform stakeholders on how substances with two applications will be regulated.
- Stakeholders want to know how Health Canada and Environment Canada would transfer authority to another Act.

- Health Canada and Environment Canada need to explain if they are committed to transferring the regulations to a renewed F&DA.
- Stakeholders want lawyers to be involved to inform Health Canada and Environment Canada as to whether or not the options are practical.

3.6 In Commerce List

Presentation Summary

The In Commerce List (ICL) is a complex project requiring partnerships between government and stakeholders. The ICL is comprised of approximately 9,000 substances that were in commerce between January 1, 1987 and September 13, 2001. The substances consist of single elements, discrete organic and inorganic substances, organisms, and mixtures.

The ICL is used for the following:

- substances for which notification requirements do not apply at present
- substances that:
    - Are not on Domestic Substances List (DSL);
    - Have not been assessed under the *Canadian Environmental Protection Act 1999* (CEPA 1999) new substance regime; and
    - Will be considered under a future health and ecological assessment scheme.

There are several reasons why the ICL needs to be revised. The goal of the revised list is to have a complete list with no information missing and that is easily searchable. The following information is required for the ICL revision:

Essential

- Name of substance
- Corresponding CAS number or American Type Culture Collection (ATCC) for organisms
- Information on potential notifier(s)

Additional information

- Use patterns, types of products
- Estimates of annual use quantities
- Chemical structures

The ICL will be assessed using a variety of criteria using a number of tools and considering a wide range of topics. The list will be prioritized. Stakeholders will be consulted for information and feedback.

Key comments heard from stakeholders

International considerations

- Linkages with associations and international countries/jurisdictions should be improved to leverage information regarding practices, experiences and equivalent initiatives to help minimize the timeframe for ICL revision.
- International tools such as the “cosmetics dictionary” contain a wealth of substance/ingredient information and provide CAS numbers, trade names, etc. – it should be used as a main data source.

- Referring to international literature would not only help revise the list, but also remove substances entirely and/or move substances to the DSL.

Resource considerations

- Tap into industry's information to help lessen Health Canada and Environment Canada's burden of reexamination of the ICL and to help identify the minimum information required to have a substance on a list.
- Additional resources must be allocated in order to clean up the list – specifically List 1. A dedicated team would help to accelerate the revision process, simply by removing duplicates.
- Maintaining an updated list, securing adequate resources/staff and funding as well as contending with industry confidentiality issues are ongoing challenges that also must be addressed.
- Designate commodity group experts to refine the list and to communicate with industry.

Inform Industry

- Industry needs to be well-informed on the ICL requirements, submission process, and timelines as well as the proposed framework. It is important to present an accurate and comprehensive list of substances to stakeholders with clear instructions on the ultimate goal and intent of the ICL.
- Publishing a list on the Web site or distributing a list to industry would in turn help them to identify "orphan" substances.

Considerations for the Revision of the ICL

- Be consistent with the categorization and screening of the DSL, involve key players to check the accuracy and add substances to help ensure a more reliable list.
- ¾ of the substances on the In Commerce List (ICL) may not even be imported or manufactured in Canada. These substances should not be on the ICL.
- Imposing submission, revision and assessment timelines would expedite the process. Health Canada, Environment Canada and industry must adhere to an established set of timelines/deadlines.
- Health Canada and Environment Canada should review the ICL and compare it to DSL to eliminate duplication;
- Use the Chemical Abstract Services to get the name of each substance where they exist;
- Use expert resources to develop alternate nomenclature where necessary; and
- Use CEPA section 71 to get additional info from stakeholders.

Considerations for the Prioritization of the ICL

- Prioritizing the list *after* establishing a finite and reliable ICL was proposed as a more efficient approach and would thereby reduce redundancy.
- Using a tiered approach to publishing by setting aside more difficult mixture substances would also expedite finalization of the list.
- Health Canada and Environment Canada should use the same approach for pharmaceuticals as they do for screening and categorization of the DSL.

Other considerations

- Grand fathering some substances that have been on the market for years (that require minimal info) should be considered.
- Effective timelines for finalizing and prioritizing the list must be in place. Also the door to ongoing negotiations should not be closed.

3.7 Notification

Presentation Summary

Notification is required if the substances proposed for importation or manufacture are subject to the provisions of the "Substances and Activities New to Canada" portion of *Canadian Environmental Protection Act 1999* (CEPA 1999) (Sections 80 to 89). Substances that require notification are: (1) "substances" as defined in the Act; (2) "new" in the context of CEPA 1999; and (3) neither excluded nor exempted from notification as specified in section 3 or subsection 81(6) of CEPA 1999. All substances contained in products regulated under the *Food and Drugs Act* (F&DA) are subject to notification.

As outlined in CEPA 1999, notification of a new substance must take place prior to the manufacture or importation of that substance in Canada. Only one notification will be required under CEPA 1999 (i.e. dual use notifications).

CEPA 1999 requires that a prescribed assessment period to conduct a risk assessment be defined within regulations. The notification requirements are yet to be developed.

The information supplied in the notification will be used to determine if the new substance meets any of the following criteria:

- Have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- Constitute or may constitute a danger to the environment on which life depends; or
- Constitute or may constitute a danger in Canada to human life or health (Section 64 of CEPA 1999).

If the assessment for the notified substance determines that there is no suspicion that the substance meets any of the criteria of Section 64 for the notified activities but there is a suspicion that a significant new activity in relation to the substance may meet these criteria, the substance can be subject to a Significant New Activity (SNAc) Notice (Section 85 of the Act). If there is no indication that the substance meets any of the criteria listed in Section 64 of CEPA 1999, the substance may be eligible for addition to the Domestic Substances List (DSL).

Key comments from stakeholders

- Health Canada and Environment Canada need to inform stakeholders on how long it takes to perform an environmental assessment, and whether or not the length of time changes for different substances.
- It needs to be clearly stated to where new food substances under the F&DA are reported, Health Canada or Environment Canada.
- Stakeholders want to know if an assessment conclusion document will be required for new active substances as is required for pharmaceuticals.
- Health Canada and Environment Canada need to consider, based on approval time discrepancies, that a substance could be on the DSL before it receives permission of the F&DA.
- Stakeholders ask to be clearly informed on what will happen in the case of a substance being put on the DSL that is used for other purposes in products regulated by other Acts scheduled under CEPA 1999 and how it will impact the other products.
- Health Canada and Environment Canada need to state if the environmental assessments consider biodegradation.

- How the SNAc process works for supplementary measures needs to be clearly explained.
- Health Canada and Environment Canada need to educate stakeholders on who can and cannot be a notifier.
- Stakeholders want to know whether or not the results of the NSNR review by Health Canada and Environment Canada are considered during the final steps in labeling and approval during a drug review.
- Stakeholders raised the questions if there are risk benefit assessments currently being done and if there is communication between the groups approving the drugs, and those the importing and manufacturing.

3.8 Exemptions/ Waivers/ Special Category Substances

Presentation Summary

Notification is required prior to the importation or manufacture for all substances that are not listed on the Domestic Substances List (DSL). Notification is not required for substances that are exempt from the notification requirements.

If the Environmental Assessment Regulations are placed under the *Canadian Environmental Protection Act 1999* (CEPA 1999) the exemptions would apply to new substances contained in products regulated under the *Food and Drugs Act* (F&DA). The exemption applies to:

- A substance that is manufactured or imported for use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic. For example, all the substances that are regulated under the Seeds Act, Feeds Act, etc. are not subject to CEPA 1999.

CEPA 1999 allows the Ministers to waive any of the requirements for prescribed information if:

- In the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;
- The substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment or human health; or
- It is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.

It will be the responsibility of the notifiers to submit a request that the prescribed information requirements be waived by the Ministers.

The *New Substances Notification Regulations* (NSNR) have Special Category provisions for:

- A research and development substance;
- A contained site-limited intermediate substance; and
- A contained export only substance.

For substances contained in products regulated under the F&DA, Health Canada and Environment Canada will examine the need for Special Category provisions for:

- A substance used in an emergency treatment;
- A substance used in a clinical trial; and
- A substance used in new veterinary drugs for experimental studies.

Key comments heard from stakeholders

Regulatory considerations

- The definition is inclusive enough to cover the small quantities needed for Research and Development (R&D) purposes.
- Within the CEPA 1999 framework, use consistent terminology by referring to ALL substances (i.e. food, drug) simply as substances.
- Improve the linkage between food, drug and environmental assessment. It can be done at the policy level. More communication is needed between these groups.
- Clearly communicate the regulations and desired outcomes to the Canadian public to ensure consumers do not misperceive the good work being done by Health Canada and Environment Canada.
- Health Canada and Environment Canada need to clearly state what exactly the waivers pertain to, the substance or a particular requirement.
- It needs to be clearly stated if naturally occurring microorganisms are included in naturally occurring substances.
- The definition of "naturally occurring substance" should be addressed in the development of the regulations.
- Some of the terminology (i.e. "completely converted" and "containment") should be clarified and used consistently across the federal government. The definition should include substances used in new veterinary drugs for experimental studies and should allow for expeditious review in special circumstances such as pandemics.
- The environmental impact must be further expanded to include air, soil, sediment, etc. The word "destroyed" should include incineration and "absolute release limit" should include soil limits.
- Within the CEPA 1999 framework, use consistent terminology by referring to ALL substances (i.e. food, drug) simply as substances.

Trigger quantity considerations

- Both a trigger quantity and risk-based approach could apply and that there should also be a provision/distinction made for clinical trials. In addition, the potency of substances should be considered for research and development substances.
- The use of 1kg was questioned (too high for some substances and too low for others) and it was suggested that both risk based trigger-level and quantity-level approaches may have to be considered for research and development.
- The 1kg limit may have to be revisited to ensure the limit does not violate other Acts.

Category considerations

- There are additional substances that do not fall under the three above mentioned categories and may require their own distinct special category or may be exempted from notification. These include:
    - Special access and orphans drugs – because of limited drug production;
    - Substances that have already been assessed and cleared in other parts of the world (i.e. recognized international programs) – should be exempt to reduce the regulatory burden for Canada;
    - Emergency drugs, treatments for rare diseases – both human and veterinary drugs; and
    - Importation of pharmaceuticals for personal use, as well as medical, academic and governmental low-level risk contained activities – it was noted that changes

to CEPA may be necessary in order to accommodate these additional recommendations.

- Export-Only Substances may have to be considered as a special category as this category does not take into account the entire lifecycle of the substance.

Other considerations

- There is a risk that clinical trials may end in Canada if too many requirements are imposed.
- Improve the linkage between food, drug and environmental assessment. It can be done at the policy level. More communication is needed between these groups.
- Recognize the existing NSNR. Two separate submissions would result in an ineffective administrative burden.
- Engage the provinces and territories to obtain their input, to build greater awareness of the issues and to increase enforcement support. There is a need for more environmental and health association consultation/input.
- Ensure Environment Canada and Health Canada have equal access to all information. A joint approval process would improve consistency and expedite matters.
- A gap analysis should be undertaken to compare what is not being addressed and what should be.
- Ensure that regulators and stakeholders recognize that the F&DA is more than just drugs (separate pharmaceutical and non-pharmaceutical products)
- Animal vaccines should also be included in the framework.
- Health Canada and Environment Canada should reduce timelines of assessments under CEPA 1999 and NSNR for catastrophic, emergency situations.
- Health Canada and Environment Canada should consider that there is a big difference between reduced regulations and exemptions. In order to maintain and enhance research and development and clinical trails in Canada it is important that additional regulations not be placed on these substances.
- Health Canada and Environment Canada should be aware of the differences in processing of a substance. The treatment of these substances should be considered in the development of the regulations.

3.9 Path Forward

Presentation Summary

Health Canada and Environment Canada will explore a number of options as they move forward in the development of Environmental Assessment Regulations. These could include: the need to develop an advisory committee, separate commodity specific consultative groups to consult on the data requirements, another e-questionnaire, consultation documents, etc..

Health Canada and Environment Canada will proceed with developing a regulatory framework for the Environmental Assessment Regulations. What is meant by “regulatory framework” is the actual structure of how the regulations will work.

In addition, Health Canada and Environment Canada need to develop the specific notification requirements for new substances. This information will depend on what the regulatory framework will look like. Health Canada and Environment Canada would also like to establish advisory group(s) to aid/provide feedback on the particular notification requirements.

Key comments from stakeholders

- Stakeholders are ready to address the specific issues/time requirements for regulations.
- As Health Canada and Environment Canada move forward, stakeholders would like them to avoid the perception that all pharmaceutical products pose a risk. Health Canada and Environment Canada should seek further information on determining the actual risk posed by these substances.
- Health Canada and Environment Canada should keep in mind that the European Union is not regulating all of the commodities which Canada is proposing to regulate.

4.0 Closing

Debra Young, Director General of the Office of Regulatory and International Affairs (ORIA) closed the consultation by thanking the speakers from Health Canada and Environment Canada as well as the participants in attendance. She noted that the consultation had proved to be a valuable two-day session providing a richness of information and an opportunity for networking. Ms Young felt that the objectives of the meeting had been met and restated Health Canada's and Environment Canada's commitment to move forward with regulations under the *Canadian Environmental Protection Act 1999* (CEPA 1999) and assured participants that there will be continued meaningful engagement with all interested stakeholders as the development the new regulatory framework unfolds.