New Substances Notification Regulations (Organisms) - Workshop on the provisions dealing with the research and development exemption criteria (ss. 2(4)) and with the notification requirements (s. 4) for organisms other than micro-organisms

Environment Canada and Health Canada

Workshop Proceedings
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**Abstract**

Environment Canada and Health Canada are conducting multi-stakeholder consultations to review and update the New Substances Notification Regulations (Organisms), under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). This first phase in the consultations included a workshop to address only that part of the NSNR (Organisms) dealing with the research and development exemption criteria (ss. 2(4)) and with the notification requirements (s. 4) for organisms other than micro-organisms. The workshop was held on June 15–16, 2006, in Gatineau, Quebec. These proceedings detail the discussion and the outputs from that workshop. Companion documents include background and discussion documents.

This report represents the output of the workshop. Sections 1 and Section 2 include a brief introduction, background information on the issues, and the objectives and structure of the workshop. Section 3 provides an overview of the presentations and related discussions that occurred on Day One, including the panel presentations. Section 4 provides an overview of the presentations and related discussions that occurred on Day Two, including next steps in the consultation process and a summary of key points expressed in the final roundtable. Section 5 summarizes comments received following the workshop. Appendix A lists the workshop participants. Appendix B duplicates the workshop agenda. Most presenters used PowerPoint slide show presentations. These presentations are duplicated as Appendix C of these proceedings, and are attached/available as a separate file.
### Table of Contents

1.0 Background .................................................................................. 5
2.0 Objectives and Structure of the Workshop ................................. 6
3.0 Workshop Proceedings: Day One .............................................. 7
   3.1 Introductory Remarks ............................................................. 7
   3.2 Background: The Need for Review ...................................... 8
   3.3 Overview of Issues .............................................................. 11
   3.4 Panel Presentations on the Issues:
       Preliminary Perspectives ..................................................... 12
   3.5 Table Discussion and Plenary I: Addressing the Issues ....... 19
   3.6 Options Detailed in the Discussion Document ....................... 22
   3.7 Wrap-Up: Day One ............................................................ 25
4.0 Workshop Proceedings: Day Two .............................................. 25
   4.1 Introductory Remarks .......................................................... 25
   4.2 Table Discussion and Plenary II -- Options Detailed in the
       Discussion Document .......................................................... 26
   4.3 Table Discussion and Plenary III -- Containment and
       Confinement Guidelines .......................................................... 29
   4.4 Next Steps ....................................................................... 33
   4.5 Wrap-Up: Day Two ............................................................ 33
5.0 Questions Raised By Stakeholders During Comment Period .. 34
Appendix A – List of Participants ..................................................... 36
Appendix B – Agenda ................................................................. 38
1.0 Background

The New Substances Notification Regulations (Organisms) [NSNR (Organisms)] of the Canadian Environmental Protection Act, 1999 (CEPA 1999) outline notification and information requirements for any person importing into or manufacturing in Canada new substances that are living organisms. Environment Canada (EC) and Health Canada (HC) are presently conducting two phased multi-stakeholder consultations on the NSNR (Organisms). The first phase included a workshop to address the framework for that part of the NSNR (Organisms) dealing with the research and development exemptions (ss. 2(4)) and with the notification requirements (s. 4) for organisms other than micro-organisms (i.e., "higher" organisms). The workshop was held on June 15–16, 2006, in Gatineau, Quebec. These proceedings detail the discussion and the outputs from that workshop. Phase Two of the NSNR (Organisms) consultations, pertaining to specific information requirements within this framework, will be initiated after the results/recommendations from the June 2006 workshop are addressed. At a later date, the New Substances Notification regulatory framework and information requirements for micro-organisms will be revisited.

Two documents were prepared by EC and HC in support of this consultation and have been posted on the New Substances Website (www.ec.gc.ca/substances/nsb/): a Backgrounder document, pertinent to both organisms other than micro-organisms and to micro-organisms, that provides general information on the NSNR (Organisms) and the New Substances Program of EC and HC, and the reasons that EC and HC believe the NSNR (Organisms) need to be reviewed; and, a Discussion Document, focused specifically on the June 2006 workshop, that outlines why EC and HC believe the NSNR provisions dealing with organisms other than micro-organisms must be reviewed first, some of the issues pertaining to the review, and some possible options for proposed revisions to the NSNR (Organisms) pertaining to the research and development exemptions (ss. 2(4)) and with the notification requirements (s. 4) for organisms other than micro-organisms.

The workshop was viewed as a necessary step in a process aimed at identifying changes in the regulatory scheme for organisms other than micro-organisms under the NSNR (Organisms) that will:

- maintain or improve the protection of the environment and human health;
- enhance EC's and HC's awareness and allow the appropriate assessment of all living organisms covered within the scope of the NSNR (Organisms), including those manufactured or imported for R&D purposes;
- strive to make the process and regulatory requirements clear so that they are understood by all parties; and,
- improve the notification and assessment process by ensuring that it remains
  - cost-effective;
  - flexible;
  - science-informed; and
  - fair.
2.0 Objectives and Structure of the Workshop

The stated objectives of the workshop were designed to contribute to the review of ss. 2(4) and 4 of the NSNR (Organisms) by

- providing background information to assist interested parties in developing and sharing their views on the issues and options that need to be addressed to improve ss. 2(4) and 4 of the NSNR (Organisms);
- soliciting feedback from interested parties on the options for ss. 2(4) and 4 of the NSNR (Organisms) detailed in the Discussion Document; and,
- establishing a path forward that will consider the feedback and recommendations developed for revisions to the regulations.

Workshop participation was by invitation only and was focused on bringing together a broad cross-section of stakeholders with an interest in the research and development exemption criteria (ss. 2(4)) and with the notification requirements (s. 4) for organisms other than micro-organisms. Over 40 individuals were in attendance, representing academia, industry, environmental and public health advocacy groups, and interested federal and provincial government departments and agencies from across Canada. Extensive and persistent efforts were made to ensure that a broad cross-section of individuals and organizations with a direct interest in the topic were invited to attend. Participants were asked to read the background information and to come fully prepared to engage in informed and constructive dialogue to address workable improvements to ss. 2(4) and 4 of the NSNR (Organisms).

The workshop included presentations, plenary, and small group discussions on:

- the need for the review of the NSNR (Organisms), including the need to prioritize the review of ss. 2(4) and 4, focused on organisms other than micro-organisms (the workshop theme);
- the issues detailed in the workshop Discussion Document;
- panel perspectives (public advocacy, academia, industry);
- options for amending ss. 2(4) and 4 of the NSNR (Organisms);
- the merits of containment and confinement guidelines; and
- next steps in the process for reviewing the NSNR (Organisms).

The intent of the panel presentations on Day One were to share some preliminary perspectives on the issues detailed in the Discussion Document in order to provide participants with some ideas, particularly for the small group discussions. While the substantive content and the structure of the workshop remained the responsibility of EC and HC, the workshop was planned and organized through the Workshop Organizing Team (WOT).

WOT members included:

- Manon Bombardier, Environment Canada
- George Brook, Ottawa Life Sciences Council
- David Carter, Ministère du développement durable de l'environnement et des parcs, Gouvernement du Québec
- Denise Dewar, CropLife Canada
3.0 Workshop Proceedings: Day One

3.1 Introductory Remarks

Bernard Madé, Director, New Substances Division, Environment Canada, welcomed participants on behalf of EC and HC, and shaped the expectations for the following two days. The consultation was framed by noting that the current consultation was to address organisms other than micro-organisms only and revolved around changes identified by EC and HC needed in ss. 2(4) and 4 of the NSNR (Organisms). For reasons detailed in the backgrounder and the workshop Discussion Document, EC and HC felt very strongly that the status quo with respect to those two sections was no longer acceptable.

Subsection 2(4) states that the Regulations do not apply in respect of an organism, other than a micro-organism, that is a research and development organism and is imported to or manufactured in a facility from which there is no release into the environment of (a) the organism; (b) the genetic material of the organism; or (c) material from the organism involved in toxicity.

Section 4 states that a person who manufactures or imports an organism other than a micro-organism must provide the information specified in Schedule 5.

It was noted that the structure and focus of how the review of the NSNR (Organisms) would move forward was developed through an extensive multi-stakeholder consultation process initiated in 2004. The report of that process, entitled Final Report Recommending a Consultation Plan for Reviewing the New Substances Notification Regulations Pertaining to Living Organisms, is available on the NSN Website: (www.ec.gc.ca/substances/nsb/pdf/cplan1204_e.pdf). In this connection, the design of this two-day consultation workshop was focused on maximizing discussion and soliciting feedback and comments from stakeholders. Mr. Madé outlined that the workshop would provide some background and context, review the issues involved in updating the R&D exemption criteria and notification sections of the Regulations, and present options to do so. It was stressed that the options presented were designed to elicit discussion and help focus the conversation and were not intended to limit ideas and possibilities; other options/proposals or modifications to those in the Discussion Document were welcomed and encouraged. Mr. Madé concluded his opening remarks by thanking the WOT members for their excellent help in organizing the workshop.
3.2 Background: The Need for Review

Presentation by Jim Louter, Environment Canada

Dr. Jim Louter, Acting Manager, Biotechnology Section, New Substances Division, Environment Canada, presented a review of the history of the NSNR (Organisms) and related events leading up to this June 2006 workshop. This PowerPoint presentation (see Appendix 2) provided a historical overview of biotechnology regulation in Canada, federal legislative efforts to manage biotechnology, and the regulation of new substances that are products of biotechnology under CEPA 1999. The initial NSNR, proclaimed under the 1988 CEPA in 1993, focused exclusively on chemicals and polymers. Consultations to include animate products of biotechnology (living organisms) in the NSNR began in 1993, with related regulations coming into force in 1997.

The guiding principles for federal regulation of biotechnology came from a 1993 policy statement signed by seven federal ministers (The Federal Regulatory Framework for Biotechnology, 1993). This statement set out a number of principles upon which the regulation of biotechnology would proceed, to ensure that the practical benefits of biotechnology products and processes are balanced along with the need to protect human health, worker safety, and the environment. He stressed three of the principles: the development of biotechnology regulation in an open and consultative manner; regulations aim to protect the health of workers, the general public and the environment; and the use of existing legislative and regulatory institutions wherever possible to clarify responsibilities and avoid duplication. Dr. Louter explained how the NSNR and the New Substances Program work within the CEPA 1999 framework (including risk assessment and management principles and practices) and detailed the regulatory provisions describing micro-organisms, organisms other than micro-organisms, and the research and development exemption criteria and notification requirements for organisms other than micro-organisms.

Moving forward to 2005, Dr. Louter detailed the extensive consultation efforts leading up to the workshop, including the holding of information sessions as recommended in the Final Report Recommending a Consultation Plan for Reviewing the New Substances Notification Regulations Pertaining to Living Organisms for interested stakeholders. The information sessions that were held in November/December 2005 in Montréal, Toronto, Vancouver, and Gatineau included extensive and detailed presentations by EC and HC personnel on all aspects of the current NSNR (Organisms) and the New Substances Program. Each information session was followed by a question and answer period that provided ample opportunity for participants to inquire about the NSNR (Organisms) and the New Substances Program as a whole. The primary purpose of the information sessions was to help interested individuals and organizations with an interest in the NSNR (Organisms), including those parties who would be actively participating in the review, to better understand how the Regulations currently work. The Gatineau (EC offices) session was also channeled to a live webcast, allowing the participation of stakeholders who could not travel to the four centres. The information sessions were attended by 123 people in total and were considered very effective in delivering program and regulatory information to stakeholders.
Dr. Louter reinforced the rationale of EC and HC for the review of the research and development exemption criteria (ss. 2(4)) and the notification requirements (s. 4) for organisms other than micro-organisms, including:

- the need for the regulations to keep pace with new developments and the rapid evolution of science leading to new products;
- the need to address significant public concerns with the rapid development of biotechnology in certain areas, particularly in the use of animals for production of pharmaceuticals;
- the need to address accidental releases of transgenic animal carcasses from R&D facilities;
- the concern with the current approach to notification, given that experience has shown that one notification category for organisms other than micro-organisms (i.e., Schedule 5) may not accommodate all organism types sufficiently; and,
- the need for coherence and alignment with other government policies and initiatives (e.g., the SMART regulation initiative).

Dr. Louter reiterated that the objectives of this review/consultation include the need to

- tailor the regulation to the issues in a manner that is cost-effective, fair, pragmatic, and informed by science;
- clarify the notification process and regulatory provisions; and,
- increase EC and HC knowledge of all organisms within the scope of the NSNR (Organisms).

Dr. Louter ended his presentation by cautioning that regulatory development and amendment is a lengthy process and will likely involve at least another iteration of public consultation, and by reassuring participants that this workshop would not be their only opportunity to comment on our initiative and provide feedback.

**Background: The need for review -- questions and answers**

A couple of participants expressed concern that the information sessions were not properly advertised and posed a number of questions with respect to how they were advertised, what information was covered, and the numbers and affiliations of attendees. EC/HC responded that they e-mailed out notifications to more than 6000 individuals, university and college research departments, public advocacy groups, governments, private sector industry and business companies and organizations. The mailing list was based on a detailed study of the stakeholders. Three face-to-face information sessions were held in Montréal, Toronto, and Vancouver, followed by a webcast for persons unable to attend one of the face-to-face meetings. The information sessions were attended by 20 to 50 people and included a mix of NGOs, academics, and industry representatives. The information provided covered the current NSNR (Organisms) and the New Substances Program broadly and was largely a refresher of the current regulations in order to better prepare stakeholders for the June workshop.
Other questions, comments and points of discussion

• The current CEPA 1999 parliamentary review is independent of this review but is a parallel process. It is possible that amendments to CEPA 1999 following the parliamentary review could implicate the current NSNR (Organisms), but this would not be expected to occur, if at all, for a few years. On the other hand, the amendment of regulations is a departmental responsibility and can be addressed now. Given that EC and HC believe that the status quo for ss. 2(4) and 4 of the NSNR (Organisms) is no longer acceptable, the review of the NSNR (Organisms) is proceeding now.

• A key objective of this review of ss. 2(4) and 4 is to amend the current Regulations to allow EC and HC to act in a timely and appropriate manner in consultation with other government departments and agencies.

• Regarding regulation of a "substance" vs a "product," as a generalization, CEPA 1999 does not focus on regulating a product – it regulates substances, in the case of the NSNR (Organisms), substances that are new living organisms, some of which go into a product.

• Regarding timelines, two years is generally the length of time it takes to develop or amend federal regulations.

• CEPA 1999 allows import or manufacture of a new substance when the prescribed information has been provided and the assessment period has expired, unless EC and HC have determined that risk management (control measures) is necessary. This default response of "go ahead unless you hear differently" is a reflection of the government's commitment to providing timely answers in response to complete notifications.

• A couple of public advocacy participants stated that import or manufacture of a new substance should not proceed until government has fully assessed the substance, as opposed to the current CEPA 1999 provisions. Dr. Louter reported to participants that the New Substances Program provides this function; no problems have been encountered with the current system to date.

• Currently there is no CEPA definition of "manufacture."

• Currently the NSNR does not require post-market monitoring of substances. This is regulated in other parts of CEPA, including the provisions for the National Pollutant Release Inventory. If new information comes forward, the current file information can be corrected.

• A substance whose use is regulated under other Acts/Regulations listed in Schedules 2 or 4 of CEPA 1999 is not subject to the notification requirements of CEPA 1999.

• Several participants expressed concern that the cost of regulation could adversely impact the competitiveness of Canadian R&D communities and that efforts to regulate R&D activities should be in accord with those of other jurisdictions that compete with Canada. Some other participants noted that products produced in countries with effective regulation that protects health, safety and the environment have a competitive advantage over similar products that are produced in countries with less than effective protection.

• International frameworks were examined and individuals from several international biotechnology regulatory jurisdictions were contacted to identify approaches to regulating new substances that are living organisms. [Note: In response to this question, a report prepared by EC and HC that provides a brief description/snapshot of some of the jurisdictions that were examined was distributed on Day Two of the workshop.]
3.3 Overview of Issues

Presentation by Manon Bombardier, Environment Canada

Manon Bombardier, Unit Head, Biotechnology Section, Environment Canada, presented a brief overview of the three key issues that EC and HC believe must be addressed at this workshop. The PowerPoint presentation is included in Appendix B to this report. Ms. Bombardier stated the aim is to ensure that the Regulations continue to be cost-effective, flexible, fair, enforceable, and informed by science. EC and HC have a mandate to ensure that human health and the environment is protected; however, innovation should not be deterred or slowed down by bureaucracy.

The issues outlined in the Discussion Document were identified by an inter-departmental federal working group that was initiated in May 2004. Issues presented focused on the need for:

- more information on regulated activities, including R&D;
- clarity in the provisions; and
- a graduated approach towards notification that takes into account the potential level of environmental and human exposure.

The issues pertain to ss. 2(4) and 4 from the perspective of EC and HC. Expanding on those issues, Ms. Bombardier submitted that the New Substances Program to date has received very little information on activities in the R&D sector, which makes it difficult to regulate the sector and to protect the environment and human health. Current Regulations limit the government's ability to collect information, identify which companies or institutions are part of the regulated community and, if so, whether they are in compliance with the law. The government needs more information to better manage risks, including accidental releases, and for emergency preparedness. Advance information will allow determination of appropriateness of containment measures and compliance with the Act and the Regulations.

Ms. Bombardier outlined the need for a graduated approach as a response to the need for more information, such that the level of detail required for the notification/evaluation process would be commensurate with the level of environmental and human health risk. In effect, the more contained a substance, the less potential for exposure, and therefore the less potential for negative impacts. Therefore less information on that substance would be required. Conversely, the less contained a substance, the greater the potential for exposure and risk of harm to human health and/or the environment. Therefore more information would be required to assess that potential risk.

Ms. Bombardier reiterated that this consultation was aimed at soliciting participants' feedback on the issues identified in the Discussion Document but these may not be the only issues. Participants were invited to bring forth any issues which may have been missed.
Overview of issues -- Questions and answers

It was clarified that the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), the Department of Fisheries and Oceans (DFO), the Pest Management Regulatory Agency (PMRA), and Natural Resources Canada (NRCan) all participated in the interdepartmental federal working group. However, as the working group was designed to outline and further refine the issues, the Department of Foreign Affairs and International Trade (DFAIT) was not felt to have a key role at this point but was informed of the working group work, and will be kept informed of progress and developments as this consultation evolves. EC and HC remain responsible for the content of the Backgrounder and the Discussion Document.

A participant from AAFC commented that often the repercussions of an accident or problem can be serious. Agriculture products are very market-dependent, and thus there is a need to make sure that things are done properly in advance (in terms of ensuring appropriate notification and information to better manage risk) so that the industry is not faced with implications that could close markets and/or borders. AAFC is concerned about both sides of any potential regulation – the requirements must be reasonably streamlined, logical, and not overly burdensome on industry, but need to be balanced against potential trade repercussions that are potentially very significant.

Ms. Bombardier added that currently, the public is highly sensitive to biotech issues. The public view supports the perspective that the government does need to know what is going on in all regulated sectors, including R&D.

In terms of protecting confidentiality and trade secrets, it was clarified that provisions in CEPA 1999 (primarily ss. 313 to 318), and not the NSNR, determine confidentiality and disclosure of information rules. Therefore any amendments to the NSNR (Organisms) would not implicate those rules.

3.4 Panel Presentations on the Issues: Preliminary Perspectives

Dr. Cecil Forsberg, Department of Molecular and Cellular Biology, University of Guelph

Cecil Forsberg provided participants with an academic researcher's perspective on the state of research and development activities that involve new substances that are organisms other than micro-organisms. Dr. Forsberg stressed that he does not speak on behalf of academic researchers, but is rather providing his own perspectives. He began his presentation by giving an overview of activities in the university research field, and potential future impacts of the budding technology. He predicted that biotechnology is the next field to revolutionize our economy and society.

The core of his presentation revolved around the large quantity and quality of information currently being collected and tracked by universities (primarily ethics and research review boards) in any research proposal (i.e., before conducting the research). Currently, typical research proposals include extensive information to be
provided to funding bodies (e.g., NSERC) and for institutional oversight. The information supplied covers topics such as:

- type of organism;
- research intent;
- protocols;
- environmental impact;
- facility appropriateness;
- animal care;
- hazardous substances;
- transgenic animals; and
- containment.

Dr. Forsberg stressed throughout his presentation that much of the information that the government is seeking for notification probably currently resides within university and academic research systems. If a conduit could be made between these research offices and government, with assured appropriate protection of confidentiality, this would put large amounts of basic information at the government's disposal and would significantly reduce duplication and paper burdens on researchers and turnaround times for approval of R&D activities.

**Dr. Cecil Forsberg -- Questions and Answers**

It was clarified that all research activities with laboratory mice are contained in Canadian academia research facilities. These animals are easily contained and all material is completely incinerated (organism but not all waste). The emphasis is on bio-exclusion to avoid any pathogens being spread and compromising other aspects of research programs. However in terms of scale, some institutions house upwards of 100,000 mice; bulk and scale are a significant issue when addressing the realities of full containment, which includes rigorous containment and treatment of waste, including somatic cells. It was also noted that for the waste stream, incineration can become problematic -- composting and landfilling must be assessed as viable options. Scale needs to be addressed in the feasibility of any approach.

Incineration is a proven and effective method for destroying all protein, including all transgenic material, and for ensuring that only mineral matter remains. A comprehensive study performed by EC was referenced that concluded that incineration was one of the most effective methods, but with the caveat that monitoring is required to ensure that all materials, including resistant viruses, are destroyed. One participant noted that, if proper procedures are followed, incineration works.

A further comment with respect to the information collection was that the institutions may have much of the information that EC and HC need to assess risk but the information is likely sorted differently. If the data were to be drawn on to meet new information requirements, key pieces would need to be identified, and the approach would need to be harmonized among government, institutions, and researchers.

Several participants expressed optimism that collaboration between EC and HC and the appropriate university/college research oversight bodies could address many of the notification requirements for R&D substances as well as the public's right to know information, while protecting confidential information.
Jessica Ginsburg, speaking from prepared notes, cautioned that her views should not be taken as being shared by all public advocacy groups. This community’s perspective is to ensure that the information required from notifiers, and the assessment methodology and processes, are adequate to protect human health and the environment. Some of the concerns and questions are listed below.

- **Adequacy of risk assessment methodology for the protection of human health and the environment.**
  - Risk assessment incorporates exposure, but should not be focused exclusively on exposure. Must still be able to determine inherent toxicity (hazard) characteristics of an organism, and make determinations appropriately.
  - Need to determine information that is required from notifiers to more fully assess both hazard and exposure.
- **In case of substantial equivalence (when a genetically modified organism appears to be similar enough to its traditional counterpart), organisms may be treated in the same regulatory manner without the need for further assessment.**
  - How will government assessors be able to determine whether basic containment, confined release, or experimental field trials are appropriate for an organism?
  - There is no indication that the new proposed schedule(s) will require enough information to directly assess risk, i.e., none of the core information requirements address toxicity or genetic stability or the adverse outcomes that may occur if human or environmental exposures take place.
  - So how will assessors determine if there is a sufficient level of safety? One possibility is that they will compare new organisms to a related or parent organism on which there is more information available. This is a common risk assessment technique that is comparable to substantial equivalence.
  - How detailed an examination is required to establish equivalence, or to justify the comparison? These are new organisms, so it is hard to claim that they are the same as ones already in existence.
- **When does the organism become eligible for the DSL? Not clear from the flowcharts. Can an organism move directly from one of the new schedules onto the DSL, or would it need to be re-notified under Schedule 5 to be DSL-eligible?**
  - Government may consider allowing the organism to move from one of the new schedules directly onto the DSL with a SNAc notice, but SNAcs require significant changes in use. Would a minor change in containment/confined be sufficient to trigger re-notification? Does government have the capacity to monitor and ensure compliance with SNAc notices once on DSL?
- **Project-based notifications option needs clarification. Is this option only available for organisms currently under the R&D exemption?**
  - Are they intending to assess all intermediate organisms (created through sequential genetic modifications), or only the first organism, or only the final product?
o How will approach be integrated with risk management responses, which often target the distinct risks presented by individual organisms?
o How does one predict the government's assessment timelines, since there may be multiple organisms notified under a single project?

- Transparency
  o This process is a good start. Gathering more information on R&D organisms will help inform government, but how will the public be kept informed?
  o Transparency is important to counter concerns that government is in a conflict of interest since acting as both regulator and sponsor/promoter.
  o In what way will new process provide
    - public access to information;
    - opportunities to comment;
    - independent peer review;
    - rationales for decisions;
    - predictability of process and outcomes;
    - appropriateness of CBI claims;
    - sharing of science;
    - free flow of information between government agencies in cases when the same organism is notified to different agencies?

- Precautionary principle
  o PP explicitly mentioned in CEPA 1999 four times. How will data gaps be dealt with in a precautionary manner?
  o When will the government require additional information, beyond that which is listed on the existing and proposed schedules?

- Compliance
  o How will EC and HC ensure compliance?

**Jessica Ginsburg -- Questions and Answers**

A participant was concerned about the emphasis of Ms. Ginsburg's speech on the need for transparency and asked how the view of transparency would be reconciled with Intellectual Property protection, particularly with R&D filing, when some information will need to be disclosed. Ms. Ginsberg responded that it would be dealt with through the application of the Confidential Business Information (CBI) provisions in CEPA 1999. These provisions have guidance documents, but they could be improved. The CBI provisions were derived through CEPA guidelines on confidentiality, but the CBI guidelines themselves are not being applied consistently in government and this is a huge problem. Ms. Ginsberg further added that she felt this is not currently being addressed and for any consultation to say it would not be addressed is not appropriate. She would like to see consistency of approach, application, and consistency across all federal departments on this issue.

**Philip Schwab, Vice-President, Policy and Sector Affairs, BIOTECana**

Philip Schwab stated his goal was not to comment specifically on the Discussion Document but to give an overview of the biotech industry and how the ideas discussed today may influence the biotech industry.
There are over 500 biotechnology companies in Canada with combined sales revenues of $3.8 billion and expenditures of $1.5 billion for R&D. A typical Canadian biotech company is private, focused on R&D, and has less than 50 employees.

Mr. Schwab then detailed the overarching principles that the biotech industry would look for in regulatory enhancement:

- clarity and predictability
- integration with existing requirements
  - import regulations
  - statutes and their regulations listed in Schedule 4 (Note: CEPA 1999 exempts new substances from the notification and assessment requirements of the NSNR (Organisms) if their use is regulated under another federal Act that meets the CEPA 1999 environmental and health-protection benchmarks. The *Fertilizers Act, Seeds Act, Health of Animals Act, Feeds Act, Pest Control Products Act*, and their respective regulations have all been declared to meet these benchmarks, and are listed accordingly in Schedule 4.)
- minimal burden
- harmonized with international standards
- time for review
  - notification vs. active review
  - speed of review is critical
- risk-based reporting requirements
- covered Organisms
  - coverage under R&D versus release
- transitional provisions

**Key issues**

- **Timing**
  - before experiment begins
  - after organism is created
- **Definitions**
  - research and development -- when is it R&D?
  - confinement
- **Contract research organizations**
  - liability for reporting

Mr. Schwab also spoke to questions regarding the use of collected data. There are questions around how the data will be stored, how it would be used, and what would be the guarantees of protection with respect to confidentiality, and intellectual property. Intellectual property is what generates venture capital and makes R&D possible; investment in research companies requires strong confidence in the confidentiality of the data. Additionally, excessive regulation may reduce the flow of dollars to universities from industrial investors if the IP system becomes too burdensome or risky. Finally, security is an additional concern -- radical groups have in the past caused extensive damage to experimental facilities; we must protect employees, the public, animals, and equipment.

**Phil Schwab -- Questions and Answers**
One participant questioned the minimal burden principle and suggested the precautionary principle rather than focus emphasis on minimal burden. This participant was also concerned that by conforming to international standards, Canada would deregulate down to the "lowest common denominator" and not adequately protect human health and the environment. Mr. Schwab responded to the minimal burden issue by noting that the industry is moving from an environment of no reporting to a reporting environment and that BIOTECanada would recommend the government consider the most effective way of doing this reporting so that it does not cause undue burden on the industry. In terms of international standards, the desire is not only to be harmonized with our trading partners but also to protect human health and the environment.

It was also clarified that the approximately 200,000 jobs provided by biotech includes those tied directly to the industry as well as indirect jobs via investment in biotech, university scientists and technicians, legal professionals, business development, and all those professionals that support the sector.

Open Panel -- Questions and Answers

A participant asked if BIOTECanada thought that the level of regulatory oversight in Canada should be the same or higher than that of our major trading partners. Mr. Schwab reiterated the company’s position that Canada should harmonize with our major trading partners on all facets of biotech but that protection of human health and the environment is essential.

The panel was asked if its members saw an opportunity for education around best practices. The panel responded that this review process represents an opportunity to educate at multiple levels. A parallel process could be envisioned to fill in the gaps that are now lacking in the university system to meet the needs of the government.

A great deal of the discussion following the panel presentations focused on the confidentiality of information, particularly at the R&D stage. EC and HC noted they are very accustomed to handling confidential information, and additionally there is a project underway to produce risk assessment reporting to meet the need to be transparent without compromising confidentiality. EC and HC are also looking to other departments and agencies for further guidance and ideas to balance out to everyone's benefit the need to protect CBI and the public right to know. One innovative example involves the partnership between CFIA and CropLife in putting their applications on the CFIA website. Mr. Schwab responded that his intent was not to say EC/HC were not handling the information carefully, but to note additional sensitivities that must be considered in moving forward. One difference in the CFIA/CropLife example is that many of those products are just about market-ready, have patent status, and have been fully disclosed. The products discussed in this workshop are highly experimental, have no patent protection, and the cost, time and market advantage implications of premature disclosure or leaks are very significant and damaging to private sector companies.

In response to an inquiry of what is happening in the industry in terms of an ecological paradigm and the spread of genetic material, it was clarified that once you move beyond rodents in containment, most of the genetic material is fairly benign. Thus far, very few situations have demonstrated a transfer of inactivated genetic material from one organism to another, with the exception of some forced model
systems. In this connection, there was concern expressed by a participant with respect to genetically modified (GM) canola and problems that farmers are having with this situation. Another participant noted that whether the material, in this case, canola, is transgenic is not germane to the question. Another participant noted that GM rodents are critical as human disease models in medical research and represent genetic modifications that routinely occur spontaneously in humans.

A comment was made with respect to regulatory sustainability becoming a real challenge for universities. Reporting requirements are high and resources will be strained to supply this information. It was felt that increased regulatory requirements will impede the capacity of researchers to conduct their research.

**Clarifications to issues raised in the panel**

Before moving into the first table discussion, an EC representative made some clarifying comments on some issues raised in the morning panel session:

- Addition of organisms to the DSL
  DSL is a list of substances in commerce -- not substances in research. There may be submission of multiple schedules for an organism en route to commercialization.
- Discussion Document: Appendix 4 -- Core Information Requirements for Proposed Schedules
  The information detailed in this Appendix is the minimum data requirements that would apply to all schedules. There would be more data required, dependent upon activity and schedules.
- Confidential business information can be shared among departments with a role in the risk assessment.

**3.5 Table Discussion and Plenary I: Addressing the Issues**

The facilitator began this section of the agenda by explaining the "small group" process. Groups would have approximately one hour to discuss among themselves the "questions for discussion" (see below). Following this, each group would report to plenary the results of their deliberations.

Questions for discussion:

1. How are the issues detailed in the Discussion Document relevant to you?
   1. need for more information
   2. need for a graduated approach
   3. need for clarity
2. Are there other issues? Please describe.

**Need for more information**

Participants were in general agreement that there is a need for more information with respect to ongoing R&D activities to be collected by the government. From a public perspective, it was felt this information could be quite general -- nature and scope of R&D. Public agencies would need enough information; however, to fulfill
their mandate(s) of protecting human health and the environment. In this regard, a monitoring and verification mechanism was suggested for incoming information.

Concerns with additional collection of information fell into two broad categories: use of information and administration burden. Some participants questioned how the additional information would help the government, wanting more specific details of what the information would be used for. In this same vein, many participants expressed concerns over protection of Intellectual Property and would want assurances of confidentiality. There was a prevailing current of concern surrounding undue burden with respect to information requirements. Clearly, though, participants were supportive of the government's need to know more about ongoing R&D activities and were largely in favour of supporting additional information requirements to meet this need, but cautioned against making requirements too onerous. Increased unnecessary or duplicative administration requirements for R&D were thought to discourage researchers and drive research investment into markets with fewer barriers. In this connection, many participants saw the following as important considerations for streamlined processes of any new regulation or guideline:

- volume of production or import of organisms;
- frequency of production or import of organisms;
- level of containment/confinement; and,
- hazard -- stability, dispersion, inherent hazard.

Some participants suggested a "single-window" approach for notifications to simplify the interface between notifiers and government. Government would then distribute information appropriately. Participants also noted that the current requirements of many universities and institutions go beyond what is suggested in the Discussion Document. Thus it is physically and scientifically possible to gather necessary information. Participants encouraged EC and HC to look to research bodies (NSERC, Canadian Council for Animal Care, etc.) to review information currently being collected and identify where linkages are possible, thus reducing duplication.

International harmonization of information requirements and transparency was encouraged by some participants. However, it was cautioned that Canada should review best practices and analyze if those options are appropriate in Canada. Canada has differing priorities and should not subsume those priorities in favour of blind harmonization. Public advocacy participants also stressed the paramount importance of transparency, the precautionary principle, and the public's right to know.

**Graduated approach**

There was strong support for a graduated approach to information requirements that changed in parallel with changing level of risk (exposure/hazard). It was felt the approach should include minimum information requirements set for fully contained R&D. It was also suggested that such an approach allow for a phased-in transition to introduce the amended Regulations. One participant did note that it may be possible to maintain exemptions under certain circumstances.

**Need for clarity**
Participants strongly resonated with the need for clarity and "understandability" and the need to know with certainty what information is required for which activities. Additionally, there was a call for protocols to ensure uniformity across R&D facilities for confinement and containment. Connected to this was the suggestion of linkages between government information requirements and those required by NSERC, CIHR and other R&D funding and approval bodies; further suggestions included a single reporting form developed by a roundtable of experts adequate to meet the needs of both bodies. The underlying need continues to be the minimizing of regulatory burden, and clear, predictable requirements.

Other Considerations

Overall approach

- Need well-thought-out tactical/strategic approach to manage risks and advance government objective of knowledge-based economy.
- Timing of process is critical: new technologies are already ahead of current regulations, and evolving rapidly -- need to balance due diligence with timely regulation and need to ensure that regulatory process is flexible enough, without compromising health and environmental protection, to keep pace with evolving technologies.
- Review of "transparency" models in other countries.
- Strive for equivalency with international standards -- but do not copy blindly ("lowest common denominator" is not acceptable).

Communications

- Public advocacy again expressed concern that current system allows a "default" approval to manufacture or import, following a specified time. They feel that notification should not automatically mean approval after a set period of time.
- Hold public education sessions at universities to increase knowledge and awareness of regulations.
- Need to identify what needs to be transparent to the public.
- Details of the requirements are very important.
- Transparency/risk communication approach is needed.

Containment/confinement

- Define containment standards, including disposal requirements explicitly.
- Waste disposal options need to be reviewed in conjunction with containment and confinement activities.
- Some felt two categories (basic, full) for containment is confusing.
- Some saw no reason for full containment if
  o research exists to prove horizontal gene transfer does not occur for a particular case
  o basic containment can include "hazardous" organisms so long as there are conditions to control waste disposal

Accountability
• Accountability of the institution to maintain standards.
• Process ability to verify notified information submitted to EC/HC.
• Third party certification and/or inspection of facilities should also be considered.

3.6 Options Detailed in the Discussion Document

Presentation by Dr. Della Johnston, Environment Canada/Health Canada

Della Johnston from HC (currently on secondment to EC) presented a brief overview of the proposed options and approach as detailed in the Discussion Document. Dr. Johnston outlined the proposed approach including the replacement of the current R&D exemption criteria, producing an exposure-based notification scheme, and development of EC/HC containment and confinement guidelines. It was reinforced that the intent of replacing the current R&D exemption criteria was to put into place some regulation to support a better response in event of release, provide more flexibility to notifiers, enable compliance promotion activities, and improve and safeguard human health and the environment.

Three exposure-based options with increasing notification schedules were proposed. It should be noted that these are proposed options and that this schedule numbering is only for the purposes of this presentation.

**Option 1: Two notification schedules**

- Containment (Schedule 6)
- Full release (Schedule 5)

Option 1 provides a new, single notification category for organisms kept in containment (for R&D or other purposes). The current schedule 5 would remain. This would allow for a single yes/no decision between two schedules.

**Advantages:**

- No legislative changes required -- authority to create additional schedules exists. Minimal regulatory amendment.
- Will enable risk assessments and, if needed, risk management actions prior to manufacture or import.
- Will help sustain and build public confidence in the federal biotech regulatory system.

**Disadvantages:**

- Cost implications for R&D sector.
- Requires additional resources in EC and HC.
- May create confusion for some notifiers.

**Option 2: Five notification schedules**

- 2 levels of containment
• Schedule 9: Full containment, simplified schedule, no release
• Schedule 8: Basic containment, more comprehensive notification information requirements; some release possible
• 2 levels of confinement
• Schedule 7: Experimental field trial release
• Schedule 6: Confined release -- other purposes
• Full release (similar to current Schedule 5)

Option 2 offers separate notification categories and schedules for containment and confinement with full release continuing to fall under Schedule 5.

**Advantages:**

• Include those listed under Option 1; better "tiering" of information requirements to proposed activity.
• Compared to Schedule 5, reduction in notification information requirements, costs, and assessment periods for organisms kept outside of full containment but not in full release.

**Disadvantages:**

• Include those listed under Option 1.

**Option 3: Six notification schedules**

• 3 levels of containment
• **Schedule 10: Full containment; project-based notification**
• Schedule 9: Full containment, simplified schedule
• Schedule 8: Basic containment, more comprehensive notification information requirements
• 2 levels of confinement
• Schedule 7: Experimental field trial release
• Schedule 6: Confined release -- other purposes
• Full release (Schedule 5)

Option 3 only adds Schedule 10 if compared with Option 2: project-based notification to cover groups of organisms fully contained for R&D purposes. Criteria for this schedule are yet to be developed but will likely include organisms of the same species that are being used as part of a single R&D project. The intent is to better align the notification process with the way in which research is conducted.

**Advantages:**

• Include those listed under Option 1; most efficient for "low risk" R&D activities.
• Less onerous in time and cost to the affected R&D sector compared to Option 1.
• Less costly to EC and HC to process and assess notifications for R&D organisms intended for full containment compared to Option 2.
Disadvantages:

- Include those listed under Option 1.
- Regulators would be required to conduct a risk assessment on a group or line of organisms within the same timeframe normally afforded to a single organism.

Options – Questions and Answers

- In the context of transgenic research, each new construct, or each transformation event would constitute a new organism (i.e., a new notification).
- Currently, if over the course of transgenic research, "non-takes" are produced, and the R&D exemption criteria are not met, then the transgenic organism is notifiable (i.e., each new construct, or each transformation event if using the same construct), and the non-takes would be considered waste generated from the process and disposed of accordingly. If non-takes are to be released, they would be considered notifiable. In project-based reporting there could possibly be no need to notify all the non-takes (criteria for a "project" have yet to be developed).
- The need to consider practical implications was raised, such as how thousands of new organisms (e.g., mice) that have been developed in some cases by a single researcher by incorporating point mutations using mutagenesis techniques would be dealt with. One researcher cited one facility in which 40000 rat cages with 5 rats per cage were housed, in which tonnes of waste are generated.
- More details are needed in the Discussion Document around schedules and definitions.
- Right now, notifications for conducting field trials currently require full Schedule 5 notification information.
- Full containment is defined as no release of any material, waste, or products. "Full containment" would have minimal information requirements because the risk of release and therefore exposure is minimal.
- Basic containment would allow for disposal methods other than complete destruction, e.g., by incineration. Allowing for alternative waste disposal may be easier for some researchers to comply with but a risk assessment would be required based on information being supplied.
- Maximum requirements are described in Schedule 5. Anything less than a Schedule 5 full release would have fewer information requirements. As potential for release/escape increases, so do the information requirements. Core requirements across all proposed schedules for all options are outlined in Appendix 4 of the Discussion Document.
- This workshop is meant to cover the concepts -- further consultation will review the details.
- Need definitions of containment and explicit information on application of options. Also, a clarification between assessment and notification is needed; some participants did not agree that assessments are needed for contained organisms.
- Make information requirements step-wise based on a minimum baseline requirement.
- Need for monitoring and enforcement of containment and waste disposal.
- Desire for consistency of definitions across all federal Acts and regulations.
• Assessment of risk is not the decision of a university oversight body; rather, it is the job of EC and HC to protect the public interest. There needs to be a consistent approach with government oversight, based on a better understanding of the risks so that reasonable measures can be implemented.
• When a researcher/institution indicates in writing that it is in compliance with containment guidelines, that statement will be enforceable.

3.7 Wrap-Up: Day One

The facilitator briefly reviewed the events of the day, thanked participants for their thoughtful comments and closed the session.

4.0 Workshop Proceedings: Day Two

4.1 Introductory Remarks

Bernard Madé began the second day by summarizing key messages from Day One and by reminding participants of the context of these consultations. Currently, the options for amending ss. 2(4) and 4 of the NSNR (Organisms), detailed in the Discussion Document, are at the conceptual stage. The workshop is about obtaining inputs and ideas on the proposed concepts/framework. There will be further opportunities for feedback on the proposal(s) when written; the process is lengthy because it is very consultative and iterative. And, since the details have yet to be systematically addressed, they will likely be the subject of proposed technical and focus group sessions in the near future. These opportunities will be addressed at the end of the workshop (Next steps).

Mr. Madé and the facilitator highlighted the following points as a summary of Day One outcomes.

Key messages

• General support for the issues identified by HC/EC, and in particular that regulatory change was necessary and desirable.
• Agreement that there is a need for more information to be collected on R&D activities, but the debate centres on the extent of that added information (how much, when, etc.).
• Agreement that more clarity and certainty in the process is required.
• Support for a graduated notification approach, to be discussed in more detail later in the day.

Other points that were noted as issues to be addressed

• Transparency and communication: Balancing confidential business needs and public right/need to know.
• Regulatory burden should not stifle innovation.
• Harmonization: Balancing facilitating trade with partners and "deregulating" to the lowest common denominator.
• The desire for a single window for notification to minimize duplication and overlap, and if and where possible, to utilize existing reporting systems already in place in research institutes.
- Accountability: To ensure efficiency, monitoring, and compliance goals are met.
- Risk assessment: Considering both hazard and exposure in the assessment process.
- Need for clearer definitions: e.g., manufacture, R&D, confinement, containment.
- Time: New technology is almost always ahead of the regulatory framework.
- Implications: Regulators need to understand the full implications of any amendments for the regulated community -- e.g., waste disposal.
- Need to deal with data gaps in a precautionary way.

4.2 Table Discussion and Plenary II -- Options Detailed in the Discussion Document

As in Day One, the "small groups" were given approximately one hour to discuss among themselves the "questions for discussion" pertaining to the options detailed in the Discussion Document for amending the current NSNR (Organisms) (see below). Participants were again reminded that their deliberations were not restricted to the options detailed in the Discussion Document. Following this, each group reported out to plenary the results of their deliberations.

Questions for discussion:

1. What could a graduated approach look like?
2. Any early advice on the thresholds?
3. Feedback on the project-based approach/concept. How to define a "project"/"group" for notification?

What could a graduated approach look like? Any early advice on the thresholds?

Participants were strongly in favour of a graduated approach. Most felt that the approach needed to be commensurate with the degree of possible risk. Public advocacy participants in particular stressed that where the hazard is known and there is a high possibility of harm to the environment if released, or where there is lack of knowledge of the hazard potential of the substance, the fullest containment is required. In this case, information requirements would need to focus on the efficacy of containment, potential for escape, and possibly a management plan to mitigate risk in the case of accidental release. Where hazards are well characterized and have low possible toxicity, lower levels of confinement are needed, but more information must be provided. For the intermediate stages between confinement and full release, the challenge will be to balance the need for precaution with sufficient detailed information that is not a regulatory burden to either the regulators or regulatees.

The major theme of this discussion centered on the key components of risk assessment: inherent hazard and exposure -- it was felt that both of these factors need to be given substantial weight at all steps throughout the notification/risk assessment process. Indeed, public advocacy participants argued that in appropriate circumstances, hazard information alone could dictate a specific path forward or outcome. Participants generally felt available hazard and exposure data should be provided by the researcher. There were questions raised, particularly by industry and
researchers around how this could be done if the researcher is not sure of what will be created in advance of its existence (while noting that the researcher must describe the proposed research when making research funding requests). In this same vein, some participants suggested the government could inform the researcher of the necessary containment level based on basic information supplied.

Moving through levels of containment/confine ment from initial lab development to commercial release is a logical and step-wise progression -- many participants felt the amended regulation should reflect this (noting that "large animals need to be outdoors" and complete progression through all the stages is not always possible). It was suggested that guidelines be developed at each stage and that they vary depending on the organism; different life forms merit different strategies (e.g., cattle versus insects).

**Other considerations pertaining to a graduated approach included the following**

- Waste disposal options need to be integrated as part of the graduated approach. Some participants felt a "secure landfill" was not feasible and opposed their use as a disposal option without clear proof that such an approach was acceptable for a particular organism. Some participants questioned the necessity and feasibility of incinerating all waste -- hard to get permits, not environmentally friendly.
- The hazard of the host and any vectors utilized should be considered when specifying containment requirements.
- Certification of containment facilities could play a part in regulatory oversight.
- Information requirements could be based on organism type (e.g., fish vs. rodents).
- EC and HC must have the ability (human and financial resources) to sort and screen information in a timely manner.
- Non-compliance would need to be enforceable -- a signed commitment to comply. Would need collaboration and cooperation with municipalities and other jurisdictions.
- Streamline information requirements with what is already supplied/available to other oversight bodies.
- Concern about the dilution of the term "containment" to mean something other than non-release.
- Need to address international transportation of organisms and domestic transfer to other research facilities.
- Take a continuous improvement approach so that performance standards can be developed and updated appropriately.

**Feedback on the project-based approach/concept -- How to define a "project" or "group" for notification?**

Participants were initially concerned with the lack of a clear, understandable definition of "project." Without a clear definition, some participants did not feel comfortable supporting or commenting on this option. Some participants suggested notification based on stock or organism type as an alternative approach. Others supported the over-arching concept of a project-based approach for notification, but stressed again that the "devil was in the details." Participants were reminded that
the definition of a project is yet to be worked out and will be the subject of further consultation.

Comments that did come forth revolved largely around facilities, notification, and the reporting process. There was some concern about the differing and varying work habits and ethics of researchers, and the age and design of facilities. Process controls, audits, and facility accreditation would be desired to ensure standards are uniform and met across the board. Some participants felt that facility accreditation would ensure standards were being met and allow for project reporting based on type of activity.

A clear explanation of what would constitute a new project would be needed. Participants reiterated that researchers would be responsible to come up with anticipated health and environment impacts as part of their protocol. Due consideration should be given to the nature of the conduct of research (e.g., mice that are produced at high throughput levels ... in the range of 10,000 plus). Questions were raised as to what constitutes a "project"/"product" (e.g., would crosses of animals be regulated)? Some participants felt that at the fullest level of containment the species and experimental intent(s) must be included in notification. As long as these remain the same, this should be treated as a project within which a single notification is required. Others added that if transfer of the organism occurred, this would be notifiable or require reassessment to examine if the containment level was changing. Some participants felt that a project could be defined on the basis of the technology utilized or the organism type or even the experimental intent. It was suggested that project notification be reviewed regularly, and a clear statement and definitions relating to conditions, criteria, and types of organisms involved to ensure project acceptability. Some participants proposed four components of a project necessary to adequately inform government as follows:

- definition of project (organism, target outcome, use);
- technology used;
- facility accreditation; and,
- transfers.

Several participants expressed serious concern with the efficiency and process of reporting. The connection between reporting information requirements and the type of information collected by funding bodies was again underscored. Any tool developed would need to be capable of supporting the whole project and take account of other Acts/regulations to ensure, for example, that a project would not be disabled by split decisions between departments. In this connection -- some participants cautioned that individual researchers reporting directly to EC and HC and communications between them may bypass the institutional bodies responsible for containment, waste management, and the movement of organisms within and between institutions. Any reforms would need to facilitate this exchange and not create holes.

**Suggestions include:**

- Creating a grid with mandatory and recommended controls depending on project variables to clearly lay out requirements.
• Web-based reporting tools to facilitate tracking changes, analysis, etc. Would lessen repetition; less burdensome, more transparent, and auditable when EC and HC verify performance and compliance.
• Learning from Bio-safety Guidelines and WHMIS, etc.

4.3 Table Discussion and Plenary III -- Containment and Confinement Guidelines

The "small groups" were given approximately one hour to address among themselves the "questions for discussion" pertaining to the containment and confinement guidelines (see below). Following this, each group reported out to plenary the results of their deliberations.

Questions for discussion:

1. What are the elements of containment and confinement guidelines? What should they look like/address?
2. How should they be developed?

There was general agreement on the need for containment and confinement guidelines. There was some agreement that a checklist format/model could begin with a list of baseline requirements that apply to all, then list additional requirements that apply in certain circumstances (i.e., organism type, type of modifications, etc.). Notifiers check off which requirements are relevant to their work with confirming/supporting documentation. The checklist would cover such items as the type/nature of the organism, proposed experimental system, and degree of risk, hazard, and potential exposure. Some participants suggested additional information required could include facility engineering/construction standards and biosafety standards where applicable (i.e., viruses).

Elements to be addressed by the guidelines

Organisms

Elements should be specific to different types of organisms (e.g., plants, invertebrates, fish, agricultural animals, rodents) and, as relevant, address:

• Size
• Mobility
• Reproductive capacity
• Fitness or survival ability
• Types of containment: operational, biological controls (stability), chemical control

Release risk/hazard

• Impact on environment and/or human health if organism were released, if high, would dictate whether the proposed level of containment is appropriate
• Identification of risk of introducing those genes into the natural environment
Waste and waste disposal

- Waste-water streams
Organism fate/disposal

- All organic products of that organism (reproductive/non-reproductive)
- Reproductive isolation
- Transportation requirements
- Organism well-being

Personnel

- Risks/exposure of handlers -- occupational health and safety issues
- Indicate biosafety level met with the vector used in research
- Risks/exposure of public through contact with institutional personnel should be addressed
- Standardized training for personnel working with the organisms
- Standard operating procedures required
- Staff education
- Outcome basis vs. prescriptive approach

Operational requirements

- Personnel access (e.g., unauthorized access must be prevented)

Facility

- Cleaning and sterilization of the facilities
- Facility design -- mechanical, electrical, etc.
- Transport facilities, methods, and standards

Reporting/records

- Inventory records (e.g., how many rodents are in the room)
- Movement of organisms (transport within and between facilities)
- Monitoring and reporting of compliance
- Institution accountability -- compliance must be reported internally and externally
- Reporting daily health and well-being of the animals (Canadian Council for Animal Care (CCAC) compliance issue)
- Emergency reporting requirements and contingency plans (i.e., for unplanned escape)
- Performance standards

How should they be developed?

There was strong agreement that the guidelines should draw on existing guidelines wherever possible. Suggestions included reviewing current laboratory procedures followed by researchers and a review of related guidelines such as the Containment Standards for Veterinary Facilities (CFIA), Aquatic Animal and Aquatic Animal Pathogen Containment Guidelines for Live Holding Facilities -- Draft (CFIA), Laboratory Biosafety Guidelines (HC), as well as similar guidelines from US, EU, and other countries, noting that there may be some gaps for some
organisms that would need to be addressed. It was also suggested by one table that for enforcement purposes penalties for non-compliance could be referenced. It was stressed that harmonization among various regulations and guidelines was essential for clarity and consistency. In this regard, a number of participants added that clear, concise definitions relating to containment, confinement, and acceptable disposal methods would be necessary. Additionally, a glossary of such definitions and others should be a part of the guidelines.

Consultative process

It was suggested that government or a third party first conduct supporting research (e.g., research into risks posed by wastes and treatment methodologies, other similar regulations). To draft the guidelines, participants should be split between a collaboration of government and a small, expert working group or having an impartial third party develop the first draft. The next step, supported by most participants, would be preliminary stakeholder (focus group) consultation followed by a larger, multi-stakeholder consultation process. It was suggested that case studies be used to help validate the guidelines and be incorporated for clarification. It was further suggested that during the development of the guidelines, pilot cases be run at selected research facilities. There was also a suggestion that a third party could be used to prepare draft guidelines and some participants suggested that a peer review should be used before conducting multi-stakeholder consultations. Some participants expressed a desire for timelines to be set with respect to this process; specifically, deadlines for final draft guidelines, and for amended regulation to be in place.

The following are suggestions of required stakeholders, supporting documentation, and necessary analyses.

Stakeholders:

- Technical experts group
- Small biotech companies
- Large university research programs
- Lab and facility managers
- Research administrators
- Canadian fund for innovation
- Funding bodies (e.g., NSERC, CIHR)

Potential background documents:

- Research community/industry to supply valid case studies
- Reference documents could include
  - CCME's Guidelines for the Management of Biomedical Waste in Canada
  - CFIA Containment Standards for Veterinary Facilities
  - WHMIS system of classification
  - CropLife Canada document on containment for plants with novel traits

Analysis required:

- Cost–Benefit analysis of proposed path forward
- Economic impact/forecast analysis
• Cost of compliance
• Regulatory Impact Analysis Statement (RIAS)

Other considerations:

• Organisms with no particular/known level of hazard are difficult to categorize.
• There may be other reasons to contain or confine organisms beside biosafety and biosecurity.
• Funding agencies should be consulted as it is easy to see the hazards at funding stage.
• Consider guidelines for plants as well.

4.4 Next Steps

Jacqueline Sitwell, Director, New Substances Assessment and Control Bureau, Health Canada, provided details on the path forward/next steps, as follows:

• EC/HC will consider all comments raised at the workshop by participants. Moreover, any additional thoughts by participants could be submitted to the New Substances Program personnel until July 14, 2006, via the New Substances Notification Information Line (page 7 of the Discussion Document has all relevant contact information).
• Proceedings will also be prepared, which will detail all of the proposals and recommendations that have come forward.
• Draft workshop proceedings will be circulated to participants for feedback and corrections by late summer/early fall, 2006.
• EC and HC will prepare a response to the feedback and ideas received -- fall/winter 2006.
• EC and HC will consider hosting a second workshop consultation in spring 2007.
• Joint EC and HC recommendations and proposals to move forward on amended regulations on R&D and organisms other than micro-organisms will be prepared and distributed to stakeholders, including but not limited to workshop participants for comments.
• Once EC and HC have responded to the comments, recommendations will be sent to regulatory drafters.
• Gazette II notice with publication of the amended regulations.

4.5 Wrap-Up: Day Two

During the final roundtable, participants commended the government on a successful consultation workshop. The collegial open atmosphere was appreciated; issues were able to be addressed in a conscientious and respectful manner. Participants expressed great appreciation for their involvement and urged government for continued involvement of stakeholders throughout the process. The hosts, Environment Canada and Health Canada, were appreciative of the closing comments, and assured participants that further iterations of consultation were forthcoming and stakeholders would be involved. The hosts thanked participants for their participation and feedback and the workshop was adjourned.
5.0 Questions Raised By Stakeholders During Comment Period

This section of the Proceedings summarizes the questions/comments submitted to the New Substances Program personnel following the June 2006 workshop. Comments flagged in this section were mostly raised by stakeholders who did not participate to the workshop but commented on the Discussion Document after the event.

Q. How many carcasses of the genetically modified animals were accidentally released, and how often did the accidental releases happen?

There was one case of research animal material (swine) that entered the animal feed chain through the rendering process in Canada. In USA, two cases (in Illinois and Florida) involved R&D GM pigs that likely entered the food/feed supply.

Q. Will there be a mechanism for data validation once the application is submitted?

Notifiers are responsible to ensure all information provided to the Government is accurate. EC has authority to inspect regulated facilities.

Q. Would blood and tissue samples sent to another facility need special paperwork?

Not if sender can meet ss. 2(4) criteria. Under an amended regulation, this activity could be explicitly recognized, e.g., could be included in containment or confinement standards.

Q. When does a "new" animal not require notification?

When the activity is covered under another Act or regulations listed in CEPA's Schedule 4, or when the organism meets the definition of a research and development organism and the R&D exemption criteria outlined in ss. 2(4) have been met.

Q. If a genetic anomaly occurs in a regular breeding program, does this require notification?

The government recognizes that prior notification of an unexpected mutant is not possible; however, if it is the intention of the researcher to "produce" more of this "anomaly" then it may be subject to notification. In such cases EC should be contacted for clarification.

Q. Is notification needed even when using a well-established strain in use in other labs?

Notification is not required if the organism meets the definition of a research and development organism and the R&D criteria outlined in ss. 2(4) are met. In addition, it might be eligible for listing on the Domestic Substances List (DSL) if it was imported or manufactured and released in Canada between 1984 and 1986. Once on the DSL, it does not need notification. Under an amended regulation, such strains
could be explicitly recognized and handled in a streamlined way. Please note that unless the organism is eligible for listing on the DSL through the grandfathering provisions, only organisms that have been assessed for full-scale commercialization (at the most comprehensive schedule) may be eligible for listing on the DSL.

Q. Would we have to notify before attempting to produce a new transgenic animal?

Currently, yes. However, notification is not required if the organism meets the definition of a research and development organism and the R&D exemption criteria listed in ss. 2(4) are met. Under an amended regulation, this activity may be streamlined.

Q. "Modified" is not defined -- does it apply to genetic mutations in addition to transgenic species?

Yes. The regulatory trigger is not "process" dependent.

Q. Would "modified" also refer to chemical and surgical modification?

A surgical modification would not normally be considered modified unless modified organs or tissues were being used. Organisms where mutations are induced using a chemical mutagen would be notifiable. By "modified," we mean those modifications taking place at the genetic level.

Q. Do the current regulations apply to genetic and transgenic studies on Drosophila?

Yes. However, notification is not required if the organism meets the definition of a research and development organism and the R&D exemption criteria in ss. 2(4) are met. Under an amended regulation, this activity may be streamlined.

Q. In the past, a researcher in our department routinely imported "big blue" mice on a monthly basis -- would such an activity require monthly notification?

Not at all. Under the current regulations, once assessed, all future identical activity with the same organism does not need notification.

Q. Insect and nematode mutations are random and one cannot predict what genetic changes one might induce -- are these new animals also covered in the current regulations?

If mutation is the intention of the research, then they are, as organisms where mutations are induced are notifiables. Under an amended regulation, this activity may be streamlined.

Q. In the case of transiently infected plant (one in which the additional genetic material was not integrated into the plant's genome), what is the new substance -- the plant or the bacterial/viral vector?

The new substance would likely be the vector responsible for the infection and, depending on the use of the micro-organism vector, it could be evaluated by EC and HC in consultation with CFIA (the Plant Protection Act could also be implicated). If
the micro-organism meets the definition of a fertilizer, it would be notifiable under the Fertilizer Act.

Q. Would GM animals purchased from commercial suppliers also be subject to the current regulations?

Under the current regulations, importers and producers have to notify, not end users. However, notification is not required if the organism meets the definition of a research and development organism and the R&D exemption criteria in ss. 2(4) are met.

Q. Does this revision apply also to academic research?

Yes. The current NSNR (Organisms) apply to academic research and the proposed amended regulations would too.

Q. Is it the intention to require all bedding to be incinerated or otherwise destroyed? It would be a simple matter of preventing releases of carcasses in the future by requiring the incineration of carcasses by all institutions.

The government is not concerned about the bedding per se but about the animal waste containing genetic or infectious material that is mixed with the bedding. Incineration would appear to be an effective disposal method for both the bedding and the carcasses.

Q. Could containment be handled at the facility level rather than on a primary investigator by primary investigator basis?

Yes.

Q. Does EC have capacity to monitor and police this regulation? How would you educate the companies? Who will be going to visit the hundreds of facilities?

EC delivers compliance promotion to the regulated community when needed. EC also has the necessary authority to inspect regulated facilities or entities. The need for enforcement resources is considered in the development of regulations. EC establishes priorities for inspections on a yearly basis and uses different approaches to verify compliance.

**Appendix A – List of Participants**

Ali, Kassim (Health Canada)
Beardall, Jan (DFO)
Blondin, Patrick (L'Alliance Boviteq)
Bombardier, Manon (Environment Canada)
Boswell, Sandra (The Allergy and Environmental Illness Group)
Brannen, Kelly (Industry Canada -- CBSec)
Broten, Dolores (Reach for Unbleached Foundation)
Byford, Goef (University of Guelph)
Carter, David (Ministère du Développement durable, de l'Environnement et des Parcs)
Castro, Maria (Beyond Factory Farming Coalition)
Chen, Hong (CFIA)
Danielson, Heather (CFIA)
Darch, Heather (Environment Canada)
Daughton, David (Eastern Co-operative Health Organization)
Delgaty, Kiera (Environment Canada)
Ekker, Dr. Marc (University of Ottawa)
Fleming, Randy (Inter Church Uranium Committee Educational Cooperative)
Forsberg, Cecil (University of Guelph)
Ginsburg, Jessica (Canadian Environmental Law Association)
Griffin, Gilly (Canadian Council for Animal Care)
Johnston, Della (Health Canada)
Keaney, Marilyn (University of Ottawa)
Kelly, John (MaRS Landing)
Lorenz, Patricia (University of Guelph)
Louter, Jim (Environment Canada)
Madé, Bernard (Environment Canada)
Madray, Sandra (Chemical Sensitivities Manitoba)
McBrien, Heather (Health Canada -- PMRA)
Milton, Roddie (Aqua Bounty Technologies Inc.)
Ovemurai, Dr. Sunday (Novartis Animal Health)
Poovadan, Anoop (Health Canada)
Radic, Gina (Environment Canada)
Renlund, Richard (University of Toronto)
Richardson, Mary (Crooked Creek Conservancy Society of Athabasca)
Rodrique, Danielle (Environment Canada)
Schwab, Philip, (Biotech Canada, brought assistant -- Bart P.)
Scott, Harvey (Alberta Environmental Network Society)
Sitwell, Jacqueline (Health Canada)
Stotish, Ronald (Aqua Bounty Technologies Inc.)
Thorleifson, Erika (DFO)
Cosgrove, Sarah (DFO)
Tilman, Anna (STORM Coalition)
Trus, David (AAFC)
Tyshenko, Michael (University of Ottawa)
*Warren, Wilson (Intersol Group)
*Versteeg, Hajo (Intersol Group)
Mader, Charlene (Intersol Group)
*Parent, Anne-Marie (Intersol Group)
Appendix B – Agenda

NEWSUBSTANCES NOTIFICATIONREGULATIONS(ORGANISMS)
WORKSHOP ON THE PROVISIONS DEALING WITH
ORGANISMS OTHER THAN MICRO-ORGANISMS (SS. 2(4) and 4)

Agenda

JUNE 15–16, 2006

Objectives

To contribute to the review of the NSNR (Organisms) (ss. 2(4) and 4) by:

• providing background information to assist interested parties in developing and sharing their views on the issues and options that need to be addressed to improve ss. 2(4) and 4 of the NSNR (Organisms);
• soliciting feedback from interested parties on the options for ss. 2(4) and 4 of the NSNR (Organisms) detailed in the Discussion Document; and
• establishing a path forward that will consider the feedback and recommendations developed for revisions to the regulations.

Anticipated workshop outputs:

• Report of workshop proceedings capturing the information presented, substantive discussion, comments/issues, and recommendations. The Proceedings will be prepared in draft and sent to all attendees to ensure that they accurately and fairly reflect the outputs from the workshop. The facilitation team will address any comments received from attendees on the draft and will prepare final Proceedings.
• Environment Canada and Health Canada will outline, in a public document, how they intend to consider recommendations made at the workshop. Any proposed amendments to ss. 2(4) and 4 of the NSNR (Organisms) will be shared with interested parties for comment.

DAY 1 -- JUNE 15, 2006

8:00
• Coffee, registration

A. Getting Started

8:30
• Call to order/IntroductionsFacilitator
• Welcome/Purpose Bernard Madé
• Process ReviewFacilitator

9:00
• Background: The need for the review Jim Louter
• Q&A

B. Discussing The Issues

10:15

• Health Break

10:30

• Overview presentation on the issues detailed in the Discussion Document Manon Bombardier

10:45

• Questions of clarification

11:15

• Panel presentations from individuals representing the academic, public advocacy, and biotech industry groups Cecil Forsberg, Jessica Ginsburg, Phil Schwab

12:05

• Open Forum -- Q&A

12:30

• Lunch

13:30

• Discussions on the issues -- Table followed by plenary

15:00

• Health break

C. Discussing the Options

15:15

• Presentation on the options detailed in the Discussion Document Della Johnston

16:00
• Open forum -- Q&A

16:45

• Wrap-up Day One Facilitator

17:00

• Adjourn for Day One

Day 2 -- June 16, 2006

8:00

• Coffee

8:30

• Getting started Facilitator
  o Feedback and agenda review
  o Recap of the options

C. Clarifying The Options Proposed By EC/HC

8:45

• Discussion on the options -- Table followed by plenary

10:00

• Health break

10:15

• Discussion on options continued

D. Focus on the Containment and Confinement Guidelines/Standards

11:00

• Discussion on the need for containment and confinement guidelines/standards -- Table followed by plenary

12:00

• Lunch

13:00
• Discussion on the need for guidelines/standards continued

E. The Path Forward

14:00

• Next steps *Jacqueline Sitwell*

14:30

• Closure