FINAL REPORT RECOMMENDING A CONSULTATION PLAN FOR REVIEWING THE NEW SUBSTANCES NOTIFICATION REGULATIONS PERTAINING TO LIVING ORGANISMS

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20 December 2004

Note: A draft of this report was sent for comment to all individuals who were contacted to discuss a process for reviewing the New Substances Notification Regulations for Living Organisms (hereafter referred to as the NSNR (Organisms)). A Focus Group discussion held on 19 November 2004, also provided very positive feedback on the draft. Following the comment period and Focus Group discussions, the consultants prepared this final report recommending a Consultation Plan for reviewing the NSNR (Organisms). Following receipt of this report, senior managers in Environment Canada and Health Canada are expected to determine whether, and when to proceed to Phase Two of the Review process. Phase Two would entail the implementation of the Consultation Plan itself. The consultants recommend that within a reasonable time following receipt of this final report, Environment Canada and Health Canada should update participants on their course of action.

FORWARD

Environment Canada and Health Canada are beginning a process to review the NSNR (Organisms), under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999). Phase One of this exercise involves preparing this report which proposes a Multistakeholder Consultation Plan to most effectively review the NSNR (Organisms). This report has benefited from extensive bilateral discussions and a focus group session with key stakeholders (the list of contacts is attached to this report in Appendix 1). The consultants are of the view that the consultation plan detailed herein has strong support from a broad and representative cross-section of parties (individuals and organizations) with a vested interest in the topic. This report proposes that the Consultation Plan for reviewing the NSNR (Organisms) begins with a fast-tracked multistakeholder workshop that focuses primarily on the review of the Research and Development exemption provisions for organisms other than micro-organisms (ss.29.16) in the NSNR (Organisms). The workshop on ss.29.16 would be completed in late Spring, 2005. The proposed Consultation Plan for reviewing the remaining provisions of the NSNR (Organisms) is a multistakeholder consensus building exercise that would begin following the ss.29.16 workshop, and would take approximately 18 months to complete. Phase Three, which would complete the review exercise, would include the Government's response in a full and transparent manner to the recommendations from Phase Two. Recommendations relating to the Government response to the consultations are detailed in Section 7 of this report.

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1. Background/Context: A Brief History of the NSN Regulations

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires that all "new" substances (chemicals, polymers and living organisms) be assessed before they are imported or manufactured in Canada in order to determine whether or not they may harm or have the potential to harm the environment or human health. CEPA 1999 strengthened the New Substances Program which was created under the 1988 CEPA. The NSNR provide the New Substances Program with the legal authority and the tools to make this assessment. The NSNR, when first published in 1994, were restricted to prescribing the process for notification and assessment of new chemical and polymer substances. In 1997, the Regulations were amended to include Part II.1, which prescribes the process for notification and assessment of new substances that are living organisms (i.e., animate products of biotechnology). *[Note that Environment Canada and Health Canada are in the process of amending the chemicals and polymers portion of the NSNR. One consequence of this amendment process is that the current NSNR are being separated into two Regulations - NSNR (Chemicals and Polymers) and NSNR (Organisms). These Regulations will replace the current NSNR while continuing to ensure the same level of protection for the environment and human health. The modifications made to the NSNR (Organisms) are very minor (for instance, the schedules' numbering has changed), and will not create any changes to the provisions governing organisms.]*

CEPA 1999 allows for new substances to be exempt from CEPA and its NSNR notification and assessment requirements when their use is regulated under other federal Acts and Regulations that have been determined to meet the CEPA 1999 environmental and health protection benchmarks. There are currently five Acts and their related regulations (the *Fertilizers Act*, the *Seeds Act*, the *Health of Animals Act* and the *Feeds Act,* all administered by the Canadian Food Inspection Agency, and the *Pest Control Products Act* administered by the Pest Management Regulatory Agency) listed under Schedule 4 of CEPA 1999 that the Governor in Council has declared meet the CEPA 1999 environmental and health protection benchmarks with respect to new substances that are living organisms. All other new substances, including those that are regulated for uses under other Acts that are not listed in Schedule 4 of CEPA 1999, are subject to CEPA 1999 and must be notified in accordance with the NSNR. *[Note that this review is focused only on the NSNR (Organisms) and will not address any aspects of CEPA 1999, nor any other Acts or regulations.]*

The NSNR require importers and manufacturers to notify substances new to Canada. New substances are defined as substances that do not already appear on the Domestic Substances List under CEPA 1999. Notifiers must submit to Environment Canada a notification package containing prescribed information so that Environment Canada and Health Canada can conduct the regulatory risk assessments to determine whether the new substance is suspected of being

"toxic" or capable of becoming "toxic" in accordance with the criteria set out in s.64 of CEPA 1999. The prescribed information is detailed in the various "schedules" of the NSNR. The notification package typically includes identification information on the new substance, experimental data on toxicity/pathogenicity and associated test protocols and exposure information, such as information on intended use(s), quantities manufactured/imported, disposal, and site of introduction. The assessments of potential risks to human health associated with new substances are carried out by Health Canada, and potential risks to the environment and biodiversity are assessed by Environment Canada. Environment Canada and Health Canada co-administer the New Substances Program.

2. The NSNR (Organisms) (including the Scope of this Review)

Under s.3 of CEPA 1999, biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms". Items covered under the biotechnology term include all organisms, their parts and products. A "substance" is defined in s.3 of the Act as "any distinguishable kind of organic or inorganic matter, whether animate or inanimate". Certain sections of Part 5 and all of Part 6 of CEPA 1999 and the NSNR (Organisms) apply to substances that are living organisms, i.e., that are animate products of biotechnology.

More specifically, the scope of the NSNR (Organisms), and therefore, **the scope of this review,** focuses on:

New substances that are **living organisms** that are:

- micro-organisms used in, for example, bioremediation, industrial enzyme production, food and drug production, waste water treatment, non-livestock feed (e.g., pet food); "micro-organism" as defined in the NSNR means a microscopic living organism that is

  (*a*) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which includes yeasts;

  (*b*) a virus, virus-like particle or sub-viral particle;

  (*c*) a cultured cell of an organism not referred to in paragraph (*a*) or (*b*), other than a cell used to propagate such an organism; or

  (*d*) any culture other than a pure culture

- new substances found in pharmaceuticals, veterinary drugs, human biologics, cosmetics and personal care products, medical devices, novel foods, food additives, and other products regulated under the Food & Drugs Act (F&DA), and for which an environmental risk assessment is currently being done in accordance with the NSNR. (Note: because the F&DA and Regulations are not listed in Schedule 4 of CEPA 1999, it is proposed that these products should be included in the scope of this

regulatory review). For more information regarding the environmental assessment of new substances found in Food and Drugs Act products, please refer to: www.hc-sc.gc.ca/ear-ree/

- new animals (e.g., livestock, fish, pets, reptiles, insects) that are animate products of biotechnology intended for food or for other uses not covered under other Acts and regulations listed in Schedule 4 of CEPA 1999;
- new plants and seeds that are animate products of biotechnology and that are intended for uses not covered under other Acts and Regulations listed in Schedule 4 of CEPA 1999.

Living organisms that are regulated for a use under other federal Acts and/or regulations that are currently listed under Schedule 4 of the CEPA 1999 will **not** be addressed in this review process. These include:

- livestock feed covered under the *Feeds Act* and *Regulations*;
- plants covered under the *Seeds Act* and *Regulations*, including plants with novel traits intended for molecular farming in confined field trials or unconfined environmental releases;
- fertilizers and supplements covered under the *Fertilizers Act* and *Regulations*;
- pest control products regulated under the *Pest Control Products Act* and *Regulations;* and,
- veterinary biologics regulated under the *Health of Animals Act* and *Regulations*.

The **risk assessment process** undertaken by Environment Canada and Health Canada involves reviewing the prescribed information provided in the notification package submitted under Part II.1 of the Regulations, collecting information from other sources and consulting with experts. The purpose of the assessment is to ensure that human health, the environment and biological diversity are protected.

The main regulatory features of the program are: criteria for identifying “new substances”; a mechanism for assessing new substances; the establishment of classes or groups of substances with specific sets of information requirements for assessment; identification of administrative and information requirements; requirement to notify Environment Canada before import or manufacture or prior to the commencement of a new activity that is outside the scope of a significant new activity notice; requirements for the departments to assess a new substance notification within a set time depending on the schedule; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data.

To meet the need for evaluating different categories of living organisms, information requirements are arranged into schedules for different notification

groups of living organisms. Living organisms are classified either as micro-organisms or organisms other than micro-organisms. The information requirements for micro-organisms are prescribed in ss. 29.11 and 29.14 of the Regulations and the corresponding Schedules XV to XVIII. The information requirements for organisms other than micro-organisms are prescribed in ss. 29.16 and 29.19 of the Regulations and the corresponding Schedule XIX. This system of notification groups allows the government to match information requirements with anticipated concerns about the characteristics of specific notification groups of living organisms and to ensure appropriate assessment of potential environmental and human health risks.

3. Why Review the NSNR (Organisms)

Prior to the promulgation of the Chemicals and Polymers portion of the NSNR in 1994, Environment Canada and Health Canada committed to review the regulations after 3 years of implementation. To fulfil this commitment, the Departments established a multistakeholder consensus building consultative process in 1999. The consultations resulted in recommendations for improving the chemicals and polymers portion of the NSNR and the New Substances Program. Many of the recommendations dealing with the administration of the program did not require regulatory amendment and have been implemented or are now in the process of being implemented. Environment Canada and Health Canada are targeting Spring 2005 for implementation of the recommendations that did require regulatory amendments (note that the federal regulatory amendment process routinely takes 18-24 months from the time draft regulations are proposed to the time they are enacted as law). At the beginning of the Chemicals and Polymers NSNR review process all participants agreed not to review the Living Organisms portion of the NSNR as they had just become law in 1997 and not enough experience had been gained with them to propose amendments.

As of September 2004, the NSNR for Living Organisms will have been in force for seven years. Experiences gained by all parties over that time have persuaded Environment Canada and Health Canada that a review on this portion of the Regulations is now timely. The need for the review is particularly apparent given:

- the breathtaking pace of developments in the field of biotechnology, the growth of that sector in Canada and abroad, and consequent concerns voiced by a number of public interest groups and others to ensure the protection of human health and the environment;
- the new developments and approaches in the rapidly evolving science that underpin the environmental and human health risk assessment and management of new substances that are products of biotechnology;
- recent incidents involving transgenic animals in Research and Development facilities;

- the current NSN Regulations for living organisms are complex - the notification Guidelines document is 130 pages long;
- that only 109 notifications have been received since 1997;
- the need to ensure coherence with newer government policies and initiatives such as the Smart Regulations initiative; and
- the successful experience with the 1999 consultation on the chemicals and polymers portion of the NSNR.

Therefore, the proposed overall **purpose of the review** of the NSNR (Organisms) is to give interested parties an opportunity to suggest changes, wherever possible by consensus, to the Regulations and the Program to:

- improve the effectiveness of the New Substances Program in terms of the protection of human health and the environment;
- improve the efficiency of the Program, without compromising the protection of human health and the environment. Recommended improvements in efficiency will seek to minimize, wherever possible, the impact of environmental legislation on the biotechnology sector, as well as minimize government costs in the implementation of the Program; and
- achieve a coherent regulatory regime that is aligned wherever appropriate with other federal departments & agencies and other countries.

4. Why "Fast-Track" the Research and Development (R&D) Exemption (ss.29.16)

Subsection 29.16 currently exempts from notification and assessment, research and development organisms, other than micro-organisms, provided that "there is no release, into the environment, of the organism; the genetic material of the organism; or material from the organism involved in toxicity". (Organisms other than micro-organisms include, but are not limited to livestock, fish, invertebrates, and plants.) Thus, an organism other than a micro-organism that is an R&D substance and that meets the specified conditions for containment (i.e., no release as described above) is exempt from notification and assessment. Micro-organisms that are R&D substances and that are intended for use in a contained facility must be notified to Environment Canada if they are manufactured or imported in quantities that exceed the levels prescribed in ss.29.1 of the Regulations.

This Consultation Plan for reviewing the NSNR (Organisms) proposes that Step One of the review fast tracks consultations on ss.29.16 of the NSNR (Organisms). The proposed consultation mechanism is a workshop that is detailed below. Environment Canada and Health Canada have determined that

the review of ss.29.16 must be fast-tracked to provide more appropriate protection to human health and the environment for the following reasons:

- The potential for biotechnology developments involving organisms other than micro-organisms (such as plants and animals, including fish, insects and livestock) is vast and rapidly emerging. Scientific advances are expected to accelerate significantly over the next few years, leading to development and commercialization of a greater number and diversity of animals and plants that are products of biotechnology. Animals and plants are being developed for enhanced nutritional values, production of pharmaceuticals, waste reduction, and so forth.
- In a period of such rapid change, Environment Canada and Health Canada need to be informed of what is happening within R&D before the organisms covered under the NSNR (Organisms) move into the eventual manufacture or release stage. Environment Canada and Health Canada also need to have better knowledge of potential risks associated with those R&D organisms.
- The federal government must also maintain appropriate regulatory oversight, adjusting its requirements based on scientific developments and past experience. Prior to the recent incidents involving the release of transgenic animals from R&D facilities, Environment Canada and Health Canada's position was that R&D organisms other than micro-organisms used in contained facilities from which there is no "release" into the environment, posed no unacceptable risks to the environment or human health. On this basis, R&D organisms other than micro-organisms are exempt from notification and assessment, provided that the criteria set out in ss.29.16 of the NSNR are met. Given the recent accidental releases of R&D transgenic animals from R&D facilities, Environment Canada and Health Canada believe that the regulatory oversight under the NSNR (Organisms) on activities involving R&D organisms other than micro-organisms needs to be strengthened to ensure more appropriate protection of the environment and human health. As the number and diversity of activities involving R&D plants and animals that are products of biotechnology increase, the likelihood of accidental releases may also increase. Environment Canada and Health Canada believe that the NSNR should provide additional safeguards for preventing such accidental releases from happening in the future.

5. Proposing a Discussion Document, and a "One Day" Information Session on How the NSN Regulations and the Program Currently Work

During preliminary bilateral discussions it became increasing clear that, while some interviewees are familiar with the history and implementation of the NSNR (Organisms) and Program, this was not the case for many other interviewees. Indeed subsequent rounds of bilateral discussions between the consultants and

interested parties across all sectors confirmed that many individuals were not familiar with the Regulations and the Program, or with potential issues of concern. Therefore, this report is recommending that Environment Canada and Health Canada prepare a Discussion Document to provide detailed background information to parties participating in, or interested in the consultation process. This report also recommends that Environment Canada and Health Canada sponsor a detailed multistakeholder "face-to-face Information Session" prior to the commencement of the Review. The purposes of the Discussion Document and the Information Session would be to facilitate fair, fully informed participation in the proposed review process.

The **purposes of the Discussion Document** would be to:

- provide a reasonable amount of detailed background information, including references for further information, so that all participants will have an adequate understanding of the NSNR and their administration;
- identify issues of potential concern (from an Environment Canada and Health Canada perspective, with input from other government departments/agencies) and options relating to the effectiveness of the Regulations and the Program in ongoing protection of human health and the environment; and
- identify issues of potential concern and options relating to the administrative efficiency of the Program to ensure that costs to the notifiers and to the government are reasonable. (Note that significant administrative improvements to the Program have already been made as a result of recommendations from the 1999-2000 review of the Chemicals and Polymers portion of the NSNR.)

This report proposes that the Discussion Document is prepared in two parts (to complement the proposed consultation process itself). Part One would provide information on the NSNR (Organisms) and Program, but focus on background information and potential issues needed to understand and address the ss.29.16 Research and Development exemption criteria. The document would be prepared and distributed in advance of the ss.29.16 workshop. Part Two would build on Part One, including the outputs and lessons learned from the workshop experience, and would focus on those potential issues related to the remaining parts of the NSNR (Organisms).

The contents of the Discussion Document (Part One) might include:

- background/context information, including a clear statement of the objectives of the review of the NSNR, including ss.29.16; how the 29.16 review fits into the review of the rest of the NSNR (Organisms); and, the purpose of the Discussion Document;
- overview of Biotechnology Regulations in Canada and Internationally, with a focus on if/how R&D organisms are regulated in other jurisdictions;

- overview of the current applications of ss.29.16 (experience to date);
- key issues relating especially to ss.29.16 (from the perspective of Environment Canada and Health Canada, with input from other government departments/agencies and possible options for addressing those issues). Issues might include:
    - who should notify, when, what/how to notify; when should regulators be "notified" for activities involving R&D organisms other than micro-organisms;
    - definition of R&D organisms other than micro-organisms;
    - what is considered a "Release" as defined in *CEPA 1999*, as applicable to living organisms;
    - should a definition for "Containment" (note the distinctions between plants, animals, fish) be provided and used in the Regulations, and should guidelines be provided;
    - notification requirements (including mechanisms such as Postcard) including criteria to ensure more appropriate protection of the environment and human health and to promote administrative efficiency: triggers may be different for animals, insects, fish, plants, etc;
    - potential ethical issues; and
    - implications on the capacity (human and financial resources, time) of the regulated community, and of the regulators.

The proposed **Information Session** would include presentations by Environment Canada and Health Canada personnel on all aspects of the current NSNR (Organisms) and the Program (including, but not limited to ss.29.16) and would provide ample opportunity for question and answer periods following each presentation. Such a session would assist in ensuring that parties who will be actively participating in the proposed review are more or less on equal footing in terms of their understanding of how the Regulations currently work. This session would probably be most useful if it took place following the release of the proposed Discussion Document (or at least Part One) and also, a few weeks prior to the proposed workshop on ss.29.16. A clear and comprehensive appreciation of how the Regulations work will assist individuals in formulating ideas and suggestions on how to make it better.

6. Proposed Consultation Plan to Review the NSNR (Organisms)

6.1 Step One: The Proposed Workshop for the ss.29.16 R & D Exemption

During the bilateral discussions there was strong agreement that, as the first step in the review of the NSNR (Organisms), a "fast-tracked" workshop would be the most efficient way to consult on the issues of concerns related to ss.29.16 and possible options for addressing them. Several participants stressed the need to

clarify that, by definition, a workshop was not designed to get consensus on all the identified issues. Rather, the expectation from this workshop is that:

- interested parties have an opportunity to help shape the agenda (issues and proposed options for discussion);
- at the workshop, Environment Canada and Health Canada will provide their preliminary perspectives on those issues and options;
- there is full and fair opportunity for participants to discuss and explain their perspectives;
- there is an obligation on all participants to try to understand the views of others;
- common ground among participants on specific issues and options will be recorded in the Proceedings of the workshop; and
- differing perspectives on issues and options will be accurately and concisely recorded in the Proceedings.

6.1.1 Establish the ss.29.16 *Workshop Organizing Team*

There was general agreement among interviewees that a Workshop Organizing Team (hereafter, the Team), managed by an independent facilitator, would be a fair and effective way to develop the substantive, procedural and structural design for the workshop, using the template proposed in this report as a starting point. The Team could also assist in the organization of the Information Session. As detailed in earlier draft documents sent to interviewees, the Team would be comprised of 8 to 10 individuals selected from government (most obviously Environment Canada and Health Canada), Aboriginal organizations, the private sector (including private companies and industry associations that are involved in various aspects of biotechnology), academia, and civil society (including environmental, labour, and public health groups). Some concern was expressed about who actually picks the Team members. This report proposes that members of the Team would be proposed by the key sectors with a vested interest in the workshop in consultation with an independent facilitator. Environment Canada and Health Canada would participate fully in the Team and would provide secretarial support. This report also recommends that Environment Canada considers the development of contracts with not-for-profit organizations to engage representative participants on the Team. It is anticipated that Team members would require 4 to 6 days of time (including preparation for, and participation in 5 to 7 conference calls (2 hours each) prior to the workshop.

6.1.2 Develop Workshop Objectives

While it was generally agreed that the Team would refine the workshop objectives, most interviewees were fairly comfortable with proposed Objectives as follows:

- *to provide recommendations to Environment Canada and Health Canada to ensure continued protection to the environment and human health from R&D organisms other than micro-organisms*
- *to ensure that information is available to enable the Government to manage the risks associated with accidental releases of organisms other than micro-organisms should they occur.*

6.1.3 Themes and Substantive Issues to be Addressed at Workshop

Subject to refinement by the Team, themes that address the stated Objectives should focus on:

- *the major issues of concern related to ss.29.16 of the NSNR (Organisms);*
- *recommendations on options to address the identified issues of concern related to ss.29.16 of the NSNR (Organisms), such as:*
- *amendments to ss.29.16 that will:*
    - *Be based on sound science and other factors, such as ethical and administrative considerations;*
    - *Be easy to understand;*
    - *Provide a balance between the need for regulatory oversight and the avoidance of unnecessary information/data requirements leading to an expensive and long notification and assessment process;*
    - *Be enforceable.*
- *additional mechanisms (e.g., user friendly guidelines) that should be used to inform individuals involved in activities with R&D organisms other than micro-organisms on what measures need to be taken to ensure protection of the environment and human health.*
- *areas of improvement, including possible inconsistencies in terms of regulatory oversight of R&D organisms in the federal biotechnology regulatory framework.*

Based on comments received during the bilateral discussions, there is an expectation that a well crafted Discussion Document will provide the focal point for identifying specific issues and options for discussion at the workshop. These in turn will be refined by the Team. Some of the specific issues and possible options that would be considered are listed in S.5 above, detailing the content of the Discussion Document.

6.1.4 Procedural Structure of Workshop

The structure of the workshop will depend on the number and complexity of the issues to be addressed, the extent to which participants want to exchange information/ideas or work towards agreement on identified issues, and required outputs for the sponsors (i.e., what Environment Canada and Health Canada need out of the process). Based on the bilateral discussions and subject to refinement by the Team, this report recommends that the workshop be scheduled for 2 full days and include:

- plenary presentations from the different stakeholder perspectives on identified issues;
- breakout groups to come to terms with clusters of specific issues; and
- reporting back sessions in plenary to share findings, recommendations and possible paths forward.

6.1.5 Identify Invitees

Based on bilateral discussions there is a general expectation that workshop participants will be (or will make themselves) knowledgeable about the issues relating to the NSNR (Organisms) in general and the ss.29.16 exemption in particular. In other words, there is an expectation that participants will come to the workshop prepared to fully discuss their views, and to work hard to address issues in a collegial manner to provide advice to Environment Canada and Health Canada on how to address the issues of concern related to ss.29.16. Given this expectation, it is clear that the workshop should not be focused on information exchange. Indeed, the Discussion Document and the proposed Information Session (see S. 5 above) are designed to minimize the need for the basic information exchange at the workshop. This report recommends that, subject to refinement by the Team, the workshop be restricted to 40 – 60 informed individuals representing a broad cross section of individuals and organizations with a vested interest in the review of ss.29.16. The Team would be responsible for finalizing the invitation list.

It is clearly recognized that many individuals and organizations that have a legitimate interest in the workshop and its outputs can not be invited, or will not be able to participate. Therefore, this report recommends that the discussion document and the final proceedings of the workshop be posted on an electronic file (e.g., the Public Consultation link in the CEPA 1999 Public Registry) with opportunity for any one to comment. Section 6.1.8, below, provides further recommendations on pre-and post workshop web-based consultation opportunities.

6.1.6. Decide on Workshop Outputs/Deliverables

Based on comments received, it is recommended that “acceptable” outputs/next steps from the workshop must include draft workshop proceedings prepared by an independent facilitator, summarizing discussions, detailing issues and recommendations that have general agreement, and detailing issues that do not have general agreement, including an accurate, concise description of the differing views and the reasons therefore. The draft would be circulated to participants to determine whether or not the facilitator fairly and accurately captured the views discussed at the workshop. The facilitator would remain responsible for addressing all comments and preparing the final proceedings. The timeline from the workshop to preparation of final proceedings should be six to eight weeks. This report strongly recommends that within a reasonable time following receipt of the final proceeding from the facilitator, Environment Canada and Health Canada report back to workshop participants on their course of action.

6.1.7 Expenses Associated with the Workshop

Environment Canada and Health Canada, as the sponsors would be responsible for all expenses associated with the logistics for the workshop (e.g., venue, independent facilitation services), in accordance with relevant federal policies and guidelines. This report recommends that Environment Canada and Health Canada provide funding for travel and accommodation expenses of individuals invited to participate in the workshop and who meet the criteria defined in the Treasury Board Policy and Guidelines: participants are volunteers or represent a not-for-profit organization; travel and accommodation expenses will not be reimbursed by the organization they represent; and, participants have specific expertise or knowledge to contribute to the process. Some interviewees and most notably some individuals who work for public advocacy and not-for-profit organizations felt strongly that they should be paid to participate in the workshop. These individuals in fact lose income when they participate in such endeavours. This report does not recommend that professional fees or an honorarium be paid to any participant for attendance at the workshop.

6.1.8 Pre- and Post Workshop Web-based Consultations

This report recognizes that a large number of individuals and organizations with a clear vested interest in the review of the NSNR (Organisms) will, for a variety of reasons, not be able to participate in the workshop. To ensure that these parties have full and fair opportunity to express their views concerning the topics addressed at the workshop, this report recommends that a web-based consultation be established. Appropriate background documents, including this report and the discussion document, could be posted prior to the workshop, with

easy links allowing electronic comments. The secretariat for the Workshop Organizing Team, including the independent facilitator, would be responsible for collating all comments received for presentation to the Team. The Team would be responsible for ensuring that all comments are considered in helping to shape the final substantive structure of the workshop. In like manner, the final proceedings of the workshop should be posted for comment. The secretariat would again be responsible for collating all comments received for presentation to the appropriate Environment Canada and Health Canada personnel. The Government Action Plan describing the path forward emanating from the fast tracked ss.29.16 workshop (see the Forward to this report) would include a section that addresses comments received from the web-based consultations.

6.2. Step Two: The Proposed Multistakeholder Consensus Building Process for Reviewing the Rest of the NSNR (Organisms)

During the bilateral discussions there was general agreement that, following the ss.29.16 workshop, a multistakeholder consensus building process would be the most appropriate way to review all of the remaining sections of the NSNR (Organisms). A multistakeholder consensus building process is a voluntary process in which selected individuals representing key interested parties agree to work together to identify, discuss and attempt to reach consensus on a particular set of issues. The selected individuals (in this report, sometimes called “Table” members) will have the right to help shape the issues to be addressed and the procedures to be used to address them. Participants also have the right to share relevant information and to fully explain and discuss their perspectives on the issues. Equally, participants will have the responsibility to commit to the entire exercise, be prepared for each meeting, listen to, and respect the views of others, search for common ground and strive towards consensus on all of the issues under discussion. Where consensus is achieved, Table members and the organizations they represent have an obligation to support that consensus in its entirety. It is not appropriate for members to promote only those parts of the consensus that meet their own particular agendas. The multistakeholder consensus building process is work and time intensive; this report is anticipating that the NSNR (Organisms) review will require 10 to 12 full Table meetings over an 18 to 20 month period, plus “intensive” subcommittee work between scheduled plenary sessions. This report is also recommending that an independent facilitator is contracted to manage the process.

To be successful, a multistakeholder consensus building process must be:

- *representative* of all key interested parties;
- *balanced* to equitably reflect the diversity of interests and to ensure that no one interest dominates the proceedings (for example, about the same numbers of participants representing public advocacy and the biotechnology sectors); and

- manageable, to allow the process to focus on problem solving and consensus building, and to ensure that costs and time commitments are reasonable.

The implications of these principles are reflected in the proposed multistakeholder consensus building process detailed below.

6.2.1 Participation in the NSNR (Organisms) Review

This report proposes that the independent facilitator work in close collaboration with key interested associations, organizations and government bodies to identify 18 to 22 individuals as Table members to participate throughout the review. The individuals should be selected by the affiliations they represent. However, the selection process should be guided by the following considerations: historical involvement in the NSNR (Organisms), level of historical interest/involvement in the subject matter, nature of the organization's interests, willingness to accept responsibilities to work towards common solutions, knowledge of the subject matter by prospective Table members, geographical location, anticipated role and contribution to the process, and level of influence. The Table would be responsible for shaping the substantive and procedural design for the consultation, using the template proposed in this report as a starting point.

6.2.2 Scope and Purpose of the Review

The proposed scope/subject matter of the review is detailed in s. 2, above. The overall purposes of the review are detailed in s.3, above.

6.2.3 Objectives, Themes/Issues for the Review

The proposed Objectives and Themes for the review are similar to those proposed for the workshop. It is however important to stress that the Table members must play a significant role in confirming the review objectives, themes and issues. Most interviewees were fairly comfortable with this proposal, but cautioned that experience gained with the ss.29.16 workshop may further influence the substantive issues to be addressed during the review.

The objective of the review is to *provide recommendations to Environment Canada and Health Canada to improve the NSNR (Organisms) to ensure continued protection to the environment and human health;*

Subject to refinement by the review Table, themes that address the stated Objective should focus on:

- *The major issues of concern related to the NSNR (Organisms);*

- *Recommendations on options to address the identified issues of concern related to the NSNR (Organisms), such as:*
- *Amendments to the Regulations that will:*
  - *Be based on sound science and other factors, such as ethical and administrative considerations;*
  - *Be easy to understand;*
    Provide a balance between the need for regulatory oversight and the avoidance of unnecessary information/data requirements leading to an expensive and long notification and assessment process; and
  - *Be enforceable.*

- *Additional mechanisms (e.g., user friendly guidelines) that should be used to inform individuals involved in notifying new substances that are living organisms on what measures need to be taken to ensure protection of the environment and human health;*
- *Recommendations on areas of improvement, including possible inconsistencies in terms of regulatory oversight of new substances that are living organisms in the federal biotechnology regulatory framework.*

There is a clear expectation that prior to the review, the Discussion Document will provide the focal point for assisting the Table members, and all other interested parties in identifying specific issues and options for discussion. It will be used to assist the Table at its orientation meeting to identify and agree on the review issues. Generally, interviewees agreed that Table members and the review process itself must remain flexible to address unanticipated or evolving circumstances.

6.2.4 Outputs from the Multistakeholder Consensus Building Process

It is anticipated that the Table members will produce a final report to the sponsors detailing all of the consensus recommendations, and if necessary, concisely stating where consensus could not be reached on specific issues and the reasons therefore. Members must appreciate from the outset that consensus recommendations pertaining to amendments of the current NSN Regulations cannot bind the Parliamentary process (Cabinet alone is responsible for, and accountable for making and amending Regulations). Government representatives in particular must undertake to do their best to ensure that consensus recommendations will be reflected in any ensuing changes to the NSNR (Organisms) and NS Program. Where this may not occur, Environment Canada and Health Canada representatives should agree to report back to all Table participants any deviations from the consensus and the reasons therefore. Phase Three of the review exercise is designed to provide full opportunity to all interested parties to monitor the results of the review.

6.2.5 Identify and Develop Consultation Mechanisms for Organizations and Individuals who are not Represented at the Table

This report recognizes that a number of organizations and individuals with an interest in the NSNR (Organisms) will not be represented at the Table. Therefore, alternative consultation mechanisms, including web-based consultations as detailed in S. 6.1 8 above, are proposed to ensure that these interested parties have a fair opportunity to express their views and comment on various review documents. The Discussion Document should be posted on the Environment Canada web site for comment. Once the review proceedings have been finalized by the facilitator they should also be posted for comment. The review table may also decide to prepare an interim report for more general comment.

6.2.6 Expenses Associated with the Review

Environment Canada and Health Canada, as the sponsors should be responsible for all expenses associated with the logistics for the review (e.g., meeting costs, independent facilitation services). This report recommends that Environment Canada and Health Canada provide funding for travel and accommodation expenses of individuals invited to participate in the workshop and who meet the criteria defined in the Treasury Board Policy and Guidelines (referred to in s. 6.1.7, above). Some interviewees, and most notably some individuals who work for public advocacy and not-for-profit organizations felt strongly that they should be paid to participate at Table and subcommittee meetings. These individuals in fact lose income when they participate in such endeavours. This report recommends that professional fees be paid to any Table member who can demonstrate need (most obviously when the member would otherwise lose income opportunity) for participation in the review. The proposed payments include one day of preparation time for each day of Table and subcommittee meeting time. The actual per diem would be worked out with the facilitator, the members requesting the fee and the sponsors. The fee would be the same for all members. If Environment Canada and Health Canada accept this recommendation, the structure for payment of expenses and fees would be governed by applicable federal polices and guidelines.

7. Government Response to the Consultations (Phase Three)

Environment Canada and Health Canada, as the review sponsors must appreciate that interested parties who are asked to contribute valuable time and energy (and in many cases, financial expense) in a consultative process have a reasonable expectation that their inputs will be given serious consideration.

Equally, review participants must appreciate from the outset that consensus recommendations pertaining to modifications to the NS Program or amendments to the NSNR (Organisms) cannot always be implemented, and in particular can not bind the Parliamentary process (Cabinet alone is responsible for, and accountable for, making and amending Regulations). Government representatives must undertake to do their best to ensure that the views of all participants and in particular consensus recommendations will be reflected in any ensuing changes to the NSNR (Organisms) and NS Program. This report recommends that Environment Canada and Health Canada representatives should agree, at the start of the review process, to report back to all participants their responses and action items emanating from the workshop and the multistakeholder consensus building process. The process for reporting back should be timely, be fully transparent and state the reasons for decisions. The approach by Environment Canada and Health Canada representatives taken in responding to the recommendations from the NSNR (Chemicals and Polymers) consultations provides an excellent precedent that was very well received by participants in that exercise. The response should include the publication of a Government Action Plan describing the path forward emanating from the fast tracked ss.29.16 workshop, and the publication of a separate Government Action Plan for addressing the path forward, and addressing all recommendations emanating from the multistakeholder consensus building exercise for the remaining provisions in the NSNR (Organisms).

APPENDIX ONE: Contact List from Phase One

[(FGC) is Focus Group Candidate]

Last Name	First Name	Affiliation	City
Andrews	David	Canadian Federation of Biological Societies	Ottawa
Barbolet Pritchard	Herb Heather	Farm Folk, City Folk	Vancouver
Barr Jackson	Kevin Sandy	The Royal Society of Canada	Ottawa
Baskerville	Caroline	Canadian Public Health Association	Ottawa
Bennett	Dave	Canadian Labour Congress (FGC)	Ottawa
Blair	Laura	Alberta Environment	Edmonton
Coombs	Shannon	The Canadian Consumer Specialty Products Association	Ottawa
Crupi	Paula	Health Canada	Ottawa
Depow	Jeremy	BIOTECanada (FGC)	Ottawa
Dewar	Denise	Croplife Canada (FGC)	Etobicoke
Dobson	Conor	Bayer Crop Science, Carleton Technology & Training Centre (FGC)	Ottawa
Endiger	Debra	Sierra Club	Ottawa
Fixter	Kristina	Food and Consumer Products Manufacturers of Canada	Toronto
Fletcher	Dr. Garth	AQUA Bounty Canada Inc. (FGC)	St. John's
Fraser	Dr. David	Faculty of Agricultural Sciences, UBC	Vancouver
Germida	Jim	University of Saskatchewan (FGC)	Saskatoon
Griffin	Dr. (Ms.) Gilly	Canadian Council on Animal Care (FGC)	Ottawa
Grushcow	Jack	Linnaeus Plant Sciences Inc.	Vancouver
House	Karla	Canadian Federation of Agriculture	Ottawa
Huc	Jean-François	TGN Biotech (FGC)	Ste-Foy
Inrig	Eileen	Canadian Biotechnology Advisory Committee	Ottawa
Julian Ignace	Maggie Lawrence	Assembly of First Nations	Ottawa
Keen	Alex	ALTECH	Toronto
Khan	Saeed	Industry Canada	Ottawa
Lachance	Claude-André	Dow Chemical Cda Inc	Gatineau
Larsen	John	Pioneer Hi-Bred Ltd.	Monkland
MacLachlan	Janet	Canadian Public Health Association	Ottawa
Marchand	Genevieve	Association des Microbiologistes du Québec	Montréal
Mathur	Pramod	Canadian Center for Swine Improvement (FGC)	Ottawa
May	Elizabeth	Sierra Club	Ottawa
McGee	Gary	Industry Canada	Ottawa
McLane	Herb	Canadian Beef Breeds Council	Calgary
McRonald	Rick	Canadian Livestock Genetics Association (FGC)	Guelph

Last Name	First Name	Affiliation	City
Meikle	Lorne	Toronto Biotechnology Initiative	Toronto
Messier	Jacques	Semex Alliance Canada (FGC)	Guelph
Middelkoop	Mary Jane	Stratos Inc.	Ottawa
Mitchell	Ann	Canadian Institute for Environmental Law and Policy (FGC)	Toronto
Mohn	Dr. William	UBC, Department of Microbiology	Vancouver
Mohr	Heather	Consumers' Association of Canada	Ottawa
Moony	Mr. Pat	ETC Group	Ottawa
Mowling	Ray	Ray Mowling & Associates	Toronto
Muldoon	Paul	Canadian Environmental Law Association	Toronto
Nickels	Scott	Inuit Tapiriit Kanatami	Ottawa
Niro	Perry	BioQuebec	Montréal
Olivastri	Beatrice	Friends of the Earth Canada (FGC)	Ottawa
Provencher	Michel	Ministère de l'Environnement	Québec
Rancourt	Derrick	Genetics Society of Canada (FGC)	Calgary
Roy	Gaétan	Association des biologistes du Québec (FGC)	Montréal
Rutherford	Sally	Ottawa Life Sciences Council (FGC)	Ottawa
Schaefer	Barbara	Canadian Environmental Network	Ottawa
Secretariat		Nexia Biotechnologies	Vaudreuil
Sharatt	Lucy	Polaris Institute (FGC)	Ottawa
Sobolewski	Dr. Andre	Microbial Technologies, Inc.	Roberts Creek
Sparling (Dr.)	Richard	Canadian Society of Microbiologists (FGC)	Winnipeg
Stiles	Jeremy	BioVectra (FGC)	Charlottetown
Stinson	Paul	BC Biotech (also CEO of NeuroMed Technologies Inc.)	Vancouver
Toth	R.	Alta Genetics	Balzak
Tranberg	Janice	Ag-West Bio Inc. (FGC)	Saskatoon
Van Doormaal	Brian	Canadian Dairy Network	Guelph
van Tongerloo	Bob	Canadian Federation of Humane Societies	Ottawa
Versteeg	Hajo	Facilitation	Manotick
Vizina	Yvone	Metis National Council	Ottawa
Winfield	Mark	Pembina Institute	Toronto

APPENDIX TWO: Preliminary Annotated Bibliography: New Substances Notification Regulations (Organisms). *It is anticipated that this bibliography will be expanded as the review process unfolds.*

Environment Canada's NS Program website is essential reading on various aspects of the NS Program, the NSN Regs relating to Living Organisms, and the detailed Guidelines Document for NS (Living Organisms) Notifiers. These topics are the focal points for the Multistakeholder Consultation exercise to review the NSN Regs (LO). The site also includes valuable information on the 1999-2000 Review of the NS Program and the NSN Regs relating to chemicals and polymers (through the Multistakeholder Consultations link): http://www.ec.gc.ca/substances/nsb/eng/index_e.htm

The Canadian Biotechnology Advisory Committee (CBAC) provides expert advice to the federal government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. Their website provides very useful information on various aspects of biotechnology regulation and policy: http://cbac-cccb.ca

Detailed, excellent overview of the Canadian Biotechnology Strategy and the roles/responsibilities of major players in biotechnology associated with the federal government: http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwapj/11865_CAN_BIO_REP_Ev9.pdf/$FILE/11865_CAN_BIO_REP_Ev9.pdf

Action plan of the federal government on the regulation of food biotechnology:
http://www.hc-sc.gc.ca/english/protection/royalsociety/intro.htm

Some previous and current consultations on biotech regulations by federal departments:

CFIA - Animal biotech
http://www.inspection.gc.ca/english/sci/biotech/tech/aniconsulte.shtml

CFIA, HC - Novel foods, Health Canada guidelines:
http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_consultation_main.html

HC - Environmental Assessment Regs: http://www.hc-sc.gc.ca/ear-ree/ear_infosheet_e.html

Current (March 2003) and comprehensive summary of Canadian public opinion survey/research on biotech issues:
http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwGeneratedInterE/by00148e.html#5

Other Jurisdictions:

http://www.ermanz.govt.nz/no/no-application.asp

http://www.ogtr.gov.au/about/index.htm#ogtr

http://www.hse.gov.uk/infection/gmo/law.htm

Appendix 3: New Substance Notification Regulations – Living Organisms

View the Proposed text for the Regulations to be published in the Canada Gazette, Part II at :

http://www.ec.gc.ca/substances/nsb/eng/reg_e.htm