New substances
substances *nouvelles*

Consultations on the CEPA New Substances Notification Regulations and New Substances Program

Environment Canada/Health Canada Response to the Consultation Recommendations

Pursuant to
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Disclaimer

This document was prepared by Environment Canada and Health Canada, and has been reviewed by stakeholders. This document is based on the final recommendations resulting from the multistakeholder consultations on the CEPA *New Substances Notification Regulations* and New Substances Program. The publication of this document does not necessarily signify that all of the recommendations described herein will be implemented.

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FOREWORD

This Environment Canada/Health Canada response document addresses the 76 consensus recommendations from the multistakeholder consultations on the New Substances Notification (NSN) Regulations and the New Substances (NS) Program. Environment Canada and Health Canada would like to acknowledge that several additional issues were discussed during the consultations for which consensus was not achieved. These issues include the adequacy of current risk assessment methodologies (section 3.1.2 of the report entitled *Consultations on the CEPA New Substances Notification Regulations and New Substances Program: Final Report of the Multistakeholder Consultations,* hereafter referred to as "the Final Report"), the public advocacy groups' alternative proposal to the current risk assessment process (the Sunrise Protocol) (sections 3.2.1 and A.8 of the Final Report) and international issues such as testing requirements for export-only substances (section 3.2.3 of the Final Report).

While the departments' initial focus is to pursue the implementation of the consensus recommendations as outlined in this document, Environment Canada and Health Canada are committed to addressing these important non-consensus matters with all stakeholders in the longer term to determine whether concrete recommendations should be developed and factored into our agenda for change of the program and regulations.

1. INTRODUCTION

The New Substances Notification (NSN) Regulations for Chemicals and Polymers have been in effect under the *Canadian Environmental Protection Act* (CEPA) since July 1, 1994. Prior to their promulgation, a commitment was made by Environment Canada and Health Canada to review them following three years of implementation. To fulfil this commitment, the departments established a multistakeholder consultative process in 1999, as depicted in Appendix 2.

As part of this process, an NSN Multistakeholder Table (hereafter referred to as "the Table") was established to identify and organize issues, examine these issues in more detail, make recommendations, document its deliberations and deliver the results to the Ministers of the Environment and of Health. The Table featured balanced representation from industry, public advocacy groups (PAGs) and government. Participants included representatives from Environment Canada, Health Canada, Industry Canada, a broad range of industries subject to the NSN Regulations and PAGs whose perspectives included the environment, consumers, public health and labour. The Table and associated consultation process were consistent with Environment Canada's policy to consult on all of its proposed initiatives in an open and transparent manner.

The Table, whose work concluded in August 2001 with 76 consensus recommendations, documented its deliberations in a report entitled *Consultations on the CEPA New Substances Notification Regulations and New Substances Program: Final Report of the Multistakeholder Consultations* (hereafter referred to as "the Final Report"). This document can be found on the CEPA Registry web site at www.ec.gc.ca/Ceparegistry/documents/regulations/nsnr_nsp.cfm.

At the Table's final meeting in August 2001, Environment Canada and Health Canada made a commitment to respond to each recommendation of the consultation and to make both the results of the consultations and the Environment Canada/Health Canada responses to the recommendations public. This document fulfils this commitment by describing key considerations and directions that the government intends to pursue in the implementation of the recommendations. The report is organized along the same five-theme structure that was used during the Table's deliberations. The five themes are:

- Improving the Environmental and Health Assessments for New Substances;
- The Regulatory Framework;
- Transparency of the NSN Regulatory Process;
- Improving Responsiveness of the NSN Regulations and NS Program in the Global Context; and
- Service Delivery.

Section 2 of this document provides a background on the original objectives of the consultations and the resulting recommendations and explains the steps taken by Environment Canada and Health Canada to develop the response. The Environment Canada/Health Canada response to each recommendation is captured in Section 3.

This document, along with the Final Report, will be used to develop a detailed Action Plan and Accountability Framework. As well, this document, along with the Final Report, will help form the basis for preparing legal drafting instructions for amending the NSN Regulations. The amended NSN Regulations are anticipated to be in effect by the end of 2004–05. While every effort will be made to have regulations in place as soon as possible, the timeline identified for the revised regulations to be in place takes into consideration the level of priority that may be assigned to these regulations by the Department of Justice, in comparison with other departmental regulatory initiatives.

Environment Canada and Health Canada will put in place mechanisms for publicly reporting on the progress of the implementation of multistakeholder consensus recommendations, as outlined in this Environment Canada/Health Canada response.

Appendix 2 presents an overview of the consultative process from initiation to implementation of the recommendations.

Appendix 3 presents a table of the 76 consultation recommendations and the Environment Canada/Health Canada response to each recommendation.

Environment Canada and Health Canada NS Program staff would like to express their appreciation to the Table members for their informed and energetic participation in the NSN Multistakeholder Consultations.

2. BACKGROUND

2.1 Objectives of the Consultations on Amending the NSN Regulations and NS Program

The NS (Notification, Assessment and Management) Program ensures that no new substance is imported into, or manufactured in, Canada without a formal review of its potential risks to human health and to the environment. The NSN Regulations, which came into effect on July 1, 1994, apply to chemicals and polymers. While a subsequent amendment to the NSN Regulations included animate products of biotechnology, the consultations did not address or make recommendations related to these other substances. However, it is inevitable that many recommendations of a program nature will lead to concurrent actions relating to the products of biotechnology component of the program (e.g., increasing transparency, service delivery).

The consultation recommendations do not address the specific requirements of Schedule XIV (Information required in respect of biotechnology products not derived from whole animals or whole plants); however, biochemicals and biopolymers will be affected by changes made to the new Regulations, since they are subject to the same regulatory structure.

There are no immediate plans to examine, via a multistakeholder process, the regulations pertaining to animate products of biotechnology (in effect since September 1, 1997), although some changes may be made to certain sections (e.g., research and development, or R&D).

The objectives laid out for the NSN Multistakeholder Consultations were "to identify, discuss and develop consensus recommendations on ways to improve the NSN Regulations and the Program." More specifically, the consultations were to:

- ascertain whether changes to the NSN Regulations are warranted based on five years of experience and on developments in similar programs in other countries, and make specific recommendations within the statutory framework of CEPA;
- ensure that the environment and human health continue to be protected from new toxic substances and substances that are capable of becoming toxic;
- make the NSN Regulations, policies and processes more efficient and more effective; and
- update the NSN Regulations with respect to CEPA 1999, recent government-wide policies and strategies, and future issues.

At the outset, stakeholders agreed that there were certain fundamental principles that the NSN Regulations and NS Program must incorporate and that the consultation must take into consideration. They were as follows:

- to promote high standards in the protection of human health and the environment;
- to incorporate methodology and process improvements that allow better use of industry and government resources to achieve health and environmental objectives;
- to enable government departments to provide a timely, predictable and transparent NS Program; and
- to support the ability of Canadian industry to compete in a global marketplace.

2.2 Final Recommendations of the NSN Multistakeholder Consultations

The final recommendations resulting from the NSN Multistakeholder Consultations, presented in Appendix 3, involve amendments to the Regulations and revisions to the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* (hereafter referred to as "the Guidelines"), changes in program procedures, increased transparency, further collaboration with industry on various issues and intensifying international collaboration. Many of the recommendations touch on program policy, regulatory approach and resource allocations.

Some of the key changes resulting from the implementation of the recommendations include:

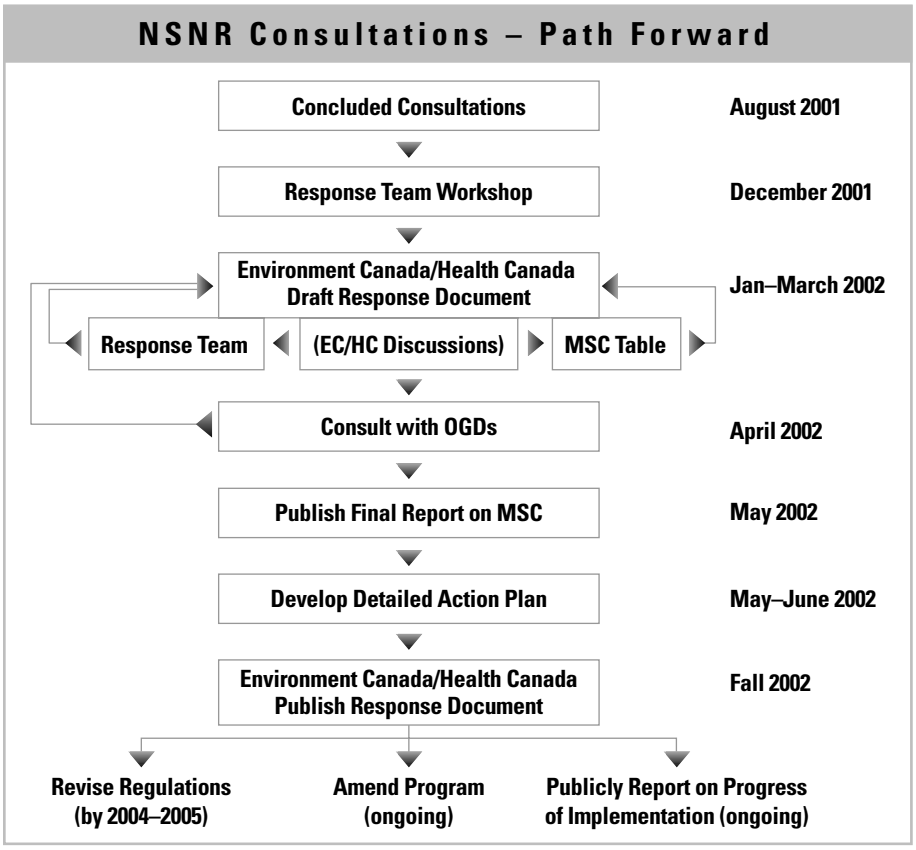
- a reduction in the number of notification schedules and, in some cases, an increase in the volume that triggers the need for a notification;
- a removal of cumulative volume tracking and "in-possession" tracking;

- simplified notification requirements for substances for R&D and "site-limited" substances, as well as no volume limit;
- a reduction of the time lag for addition to the Non-Domestic Substances List (NDSL) of substances added to the U.S. *Toxic Substances Control Act* (TSCA) inventory to one year from five years;
- the inventory status of monomers will no longer affect regulatory requirements for polymers of low concern (PLCs);
- increased testing for high-exposure NDSL substances;
- exemptions from mammalian toxicity testing requirements for certain classes of polymers to be specified in the new schedules;
- further opportunities for class waivers or exemptions for groups of substances;
- a requirement for full Good Laboratory Practice (GLP) documentation for toxicity and ecotoxicity studies; and
- improved guidelines to provide more extensive assistance to notifiers.

2.3 Development of the Environment Canada/Health Canada Response[1]

The Environment Canada/Health Canada response describes the manner in which Environment Canada and Health Canada will pursue the implementation of the recommendations and provides a general timeframe for implementation. The iterative process that was used for

Figure 1: Process/Path Forward for Developing the Environment Canada/Health Canada Response



(NSNR = NSN Regulations; EC = Environment Canada; HC = Health Canada; MSC = Multistakeholder Consultations; OGD = Other Government Departments)

1 This Environment Canada/Health Canada response document was developed by Environment Canada and Health Canada. The following federal government departments were briefed via the ADM Committee on Toxics Management on the process related to implementing the consultation recommendations and were subsequently given an opportunity to provide input to the draft Environment Canada/Health Canada response: Industry Canada, Department of Fisheries and Oceans, the Pest Management Regulatory Agency, Natural Resources Canada, Agriculture and Agri-Food Canada, Privy Council Office, the Canadian Food Inspection Agency and the Department of National Defence.

the development of the Environment Canada/Health Canada response is outlined in Figure 1.

A two-day response team workshop for approximately 20 government participants was held on December 12 and 13, 2001, to obtain an objective perspective from staff outside of the NS Program on consultation recommendations and considerations for their implementation. Participants included representatives from Environment Canada and Health Canada programs, regions and common support services who did not participate directly in the consultations. Participants provided their views, based on their experience and involvement in other departmental programs, on specific recommendations and their role in addressing the themes; technical, practical and policy considerations for their implementation; and relative priority and time required for implementation.

The departments then engaged in dialogue with the NSN Multistakeholder Table and other federal government departments, based on a first draft of the response document. Constructive comments were received and addressed appropriately in the finalization of this document.

The departments' overall approach for pursuing the implementation of the recommendations is based on relative priority, timing and ease of implementation.

Amendments to the NSN Regulations and revisions to the Guidelines will be made in parallel and initiated in 2002.

3. ENVIRONMENT CANADA/HEALTH CANADA RESPONSE TO CONSULTATION RECOMMENDATIONS, BY THEMES AND ISSUES

The Environment Canada/Health Canada response to the final recommendations of the NSN Multistakeholder Consultations for improving the NSN Regulations and the NS Program is captured in this section. A brief description of each theme and associated issues is provided, as well as details of the Environment Canada/Health Canada response with respect to each recommendation. See Appendix 3 for a listing of all recommendations as included in the Final Report and the details of our reaction and planned course of action.

The reader will notice that throughout the recommendations there is continual reference to the Guidelines and the revisions that were considered necessary to address many of the issues discussed. It is the intention of the departments to revise the Guidelines as recommended throughout the consultation. Drafting of revisions to the Guidelines will be initiated in 2002 and will continue until all topics have been adequately addressed. Some revisions will involve further consultation. The departments believe that final publication of the Guidelines will not be possible prior to promulgation of the amended NSN Regulations; however, they will continue to communicate guidance to notifiers through Advisory Notes and e-mail web site notification updates. The Guidelines have always been, and will remain, a "living" document that is reviewed and revised from time to time to incorporate new technical guidance.

3.1 Theme 1 – Improving the Environmental and Health Assessments for New Substances

Issues associated with Theme 1 involve regulatory and program matters associated with various aspects of the assessment of environmental and human health risks. Recommendations concern finalization of the Toxic Substances Management Policy (TSMP) Implementation Strategy for New Substances, development of a mechanism for requiring additional information for the risk assessment, incorporation of endocrine disrupting substances (EDSs) considerations, data requirements, the occupational work environment, waiver requests, GLP, toxicity testing using animals, improved characterization of exposure, and the evaluation and validation of data and data quality.

3.1.1 Principles and Policies Affecting the Assessment and Management of New Substances (Recommendation 1)

The departments recognize the need for clarity with respect to implementation of the federal TSMP. During the course of the consultation, stakeholders were consulted on a draft document entitled TSMP – *Environment Canada Implementation Strategy for New Substances* (Draft, April 2001). The final draft of the document and a summary of comments received during the consultations are in the final stages of preparation and will be posted on Environment Canada's Green Lane and the NS Program web site in 2002.

3.1.2 Adequacy of the Risk Assessment Methodology

No specific recommendations were made in this section.

3.1.3 Mechanism for Requiring Additional Information for the Risk Assessment (Recommendations 2, 3, 15, 18, 19, 20 and 37)

The departments are in favour of having clear authority to request additional information beyond that prescribed within the NSN Regulations when it is critical to determining whether a substance is toxic. Since the consultation recognized section 84 of CEPA as a possible authority, the departments will seek legal advice to confirm that it can be used as suggested by the Table. At the same time, the Department of Justice will be asked whether there are any other existing or new mechanisms within CEPA that can be used for this purpose.

Environment Canada and Health Canada will develop criteria by spring 2003 for using authorities, such as section 84, for requesting additional information. The criteria will cover the type of information that could be requested, and under what circumstances. These criteria will be used to prepare guidance, in the form of an Operational Policy for evaluators, by summer 2003.

3.1.4 Endocrine Disrupting Substances (EDSs) (Recommendations 4 to 6)

Environment Canada and Health Canada recognize the potential significance of endocrine disruption on the environment and human health and the urgency to address this issue. At the same time, they face the challenge of awaiting international validation and acceptance of screening and other test methods and of developing the means for interpreting the results in the context of new substance assessments. The departments view the work being done under the 5NR Working Group[2] as well as the efforts taking place within the Test Guideline Program of the Organisation for Economic Co-operation and Development (OECD) as critical to acquiring test methods that could be incorporated within the NSN Regulations. As such, they will continue to support these initiatives and press for timely results. Once suitable test protocols are available, the departments will initiate amendments to appropriately incorporate them within the NS Program by the most appropriate mechanism.

As the test methods associated with endocrine disruption evolve, the Guidelines will reflect new developments, indicating internationally accepted test protocols and how the information will be used in the assessment. Guidance material for notifiers, such as an Advisory Note, will be developed during 2003 and incorporated in the Guidelines. As recommended, information will be included concerning the departments' approach to assessing endocrine disrupting effects and how this would be integrated into a determination of suspicion of toxic. As well, a database of EDS analogues will continue to be developed with other government agencies and research institutes, and peer review from other national governments will be sought. At an appropriate time, this database will be made available to notifiers and the public to assist in understanding this aspect of chemical substances.

3.1.5 Occupational Exposure (Recommendations 7 to 13)

Health Canada and Environment Canada acknowledge the importance of these recommendations to establish an effective means to evaluate the potential risks to people exposed in the workplace and to widely communicate this and related information. At the same time, the departments believe that other jurisdictions, federally and provincially, have a dominant role to play in achieving the intent of these recommendations.

The departments see information sharing as a key intent of these recommendations; as such, the departments will initiate discussions by the end of 2002 to define the information-sharing arrangements that should be put into place at the federal level and with provinces. This will be done through the federal/provincial Committee on Environmental and Occupational Health (CEOH) and through direct discussion with the provinces. These arrangements will address the type of information to be shared, with whom and under what timeframes. These discussions will also investigate whether more formal sharing agreements of the type that are authorized under section 316 of CEPA are appropriate. Health Canada is working towards the development of an effective and efficient process for informing relevant agencies and notifiers of hazards identified during the course of an NSN assessment.

The recommendation to undertake a multistakeholder consultation in relation to the occupational environment remains a priority for the departments. Health Canada intends to undertake a consultative process by the beginning of 2003 after seeking the involvement of the CEOH.

3.1.6 Data Requirements (Recommendations 14, 16, 17 and 20 to 30)

(i) Suite of Data Requirements for Chemicals and Polymers (Recommendations 14, 16 and 17)

This set of recommendations concerns the identification of data that should be prescribed in the schedules of the NSN Regulations and the recognition that other relevant data are best addressed in the Guidelines. The departments believe that the tiered system of prescribed data and the request of waivers as authorized by CEPA 1999 ought to remain the basis of the notification system. They are supportive of the data that were identified by the Table for inclusion in the NSN Regulations and, in combination with recommendations under Theme 2, when the data should be notified. They are also supportive of the need to elaborate in the Guidelines what

2 The 5NR Working Group consists of the following government departments: Environment Canada, Health Canada, Natural Resources Canada, Department of Fisheries and Oceans and Agriculture and Agri-Food Canada.

additional data may be necessary and under what circumstances they should be generated. Implementation of these recommendations will be pursued within the timelines described for renewal of the Guidelines through a multistakeholder Working Group.

(ii) Class Considerations (Recommendations 20 and 21)

As recommended, the departments will describe the classes of substances and circumstances for which waivers will be accepted for certain tests if requested by the notifier. Furthermore, the departments will describe where additional information will be recommended if a substance meets certain criteria. The Guidelines will describe the benefits of using the waiver provisions. The Guidelines will be used as the principal means to communicate this information, although Advisory Notes will also be used.

(iii) Good Laboratory Practice (Recommendations 22 to 24)

The recommendations pertaining to GLP are aimed at strengthening compliance with GLP principles. This will serve to facilitate review of notified data and the acceptance of these same data by other jurisdictions. The departments will amend the NSN Regulations to reflect the shift to mandatory compliance for toxicological and biodegradation studies, while offering greater flexibility for testing and reporting of physical and chemical data. Also, the obligation of reporting laboratories to state their accreditation will be included in the amendments, as recommended.

(iv) Toxicity Testing Using Animals (Recommendations 25 to 27)

Environment Canada and Health Canada remain committed to minimizing the use of animals in testing, and this includes the NS Program. Modification of test protocols to rely on fewer animals while ensuring valid results is one aspect of the strategy, while pursuit of alternative testing that does not require animals is another. The departments consider the development and validation of new test guidelines by the OECD Test Guidelines Program to be key in implementing this strategy. They are committed to encouraging the use of revised or new protocols as they are adopted in this forum for data submitted under the NSN Regulations. Furthermore, through GLP and other practices, the departments will accept data generated for other purposes or in other jurisdictions, thereby eliminating the need for unnecessary duplication of testing. The Guidelines will also identify the availability of alternative, validated test protocols.

(v) Exposure Template (Recommendations 28 to 30)

During the consultation, limitations relating to notified exposure information and to the assessment of exposure were discussed. An exposure template was identified as a tool to clearly specify the information that should be submitted by notifiers for chemicals and polymers. It will also identify reduced information requirements for exposure data for entry-level polymers and PLCs. The recommendation to evaluate and finalize an exposure template will be addressed in 2002. Notifiers will be encouraged in an Advisory Note to use the template and will be provided with instructions in the Guidelines on how to complete it.

3.1.7 Evaluation and Validation of Data Quality in the NS Program (Recommendations 31 and 32)

(i) Scrutiny by NS Program Evaluators (Recommendation 31)

In addition to the internal peer review processes utilized by the departments, Environment Canada will expand its periodic, retrospective review of environmental risk assessments, as described to the Table. Health Canada will also initiate, in 2002, a similar practice of periodic review of its assessment reports by group(s) outside the NS Program. By the end of 2004, the departments will make the results of these periodic reviews available to the public.

(ii) Government Verification of Test Results (Recommendation 32)

As part of the feasibility study recommended by the Table, the departments will review, during 2003, existing policies, programs and practices in the area of government-funded verification testing in Canada and elsewhere. The results of this review will be made public, as well as the decision whether to proceed with a cost–benefit analysis, if such a program were to be implemented for the NSN Regulations.

3.2 Theme 2 – The Regulatory Framework

Environment Canada and Health Canada view Theme 2 and the issues associated with it as having the greatest impact on the NSN Regulations themselves. This theme addressed revisions to the notification triggers, the framework for and the specification of data in schedules, special categories such as R&D, product development,

site-limited intermediate and export-only substances, and assessment periods. In addition, amendments relating to waivers for substances used for prescribed purposes and to record-keeping and enforcement were identified. Finally, scrutiny was given to updates made to the NDSL. The departments are fully supportive of retaining the tiered approach and of the amendments proposed by the Table.

3.2.1 General Discussions and Recommendations (Recommendations 33 to 35)

The recommendations pertaining to the entry-level volume trigger and the elimination of cumulative and in-possession triggers will be incorporated in the drafting instructions and, subsequently, in the NSN Regulations.

The recommendation to update the NDSL annually based on the TSCA inventory from the previous year pertains to the administrative aspects of the program. During 2003, Environment Canada will initiate preparations for the initial update; however, given that certain amendments to the NSN Regulations are necessary relative to increased information requirements for NDSL substances (Schedule 3), the initial update cannot be published until the amended NSN Regulations are promulgated. Meanwhile, the departments are willing to meet with industry to discuss how this issue might be addressed in the interim.

3.2.2 Proposed Framework for the New Regulations (Recommendations 36 to 41)

The framework for each of the categories of substances identified by the Table in this theme[3] will be incorporated into the drafting instructions and into the amended NSN Regulations. The Guidelines will also be revised to reflect the new framework and the information required at each tier.

The intent of the Significant New Activity (SNAc) provisions is to allow new or existing substances to be added to or remain on the Domestic Substances List (DSL) with an attached list of new "activities" that are not ongoing at the time of the assessment. Activities may relate to the use, process, type of release, disposal, handling, recycling, etc., of the substance. Once the SNAc'd substance is listed on the DSL with a flag, the substance cannot be used outside the bounds of the notice unless additional information about its potential uses or activities is submitted and assessed.

The departments are currently developing Guidelines for use of the SNAc provisions (sections 80, 81 and 85 of CEPA 1999) and will be consulting with stakeholders as per section 69(2). The departments feel that the use of SNAcs is appropriate but are open to investigating a more streamlined method in the next review of CEPA.

Under the current NSN Regulations, PLCs eligible for listing on the DSL could subsequently be manufactured or imported in variations with characteristics outside the low-concern boundaries. The departments will develop administrative procedures in 2002 to identify PLCs on the DSL. These polymers will have to be renotified if they are subsequently imported or manufactured in a form that no longer meets the low-concern criteria. The departments do not intend to make this process retroactive.

The departments will analyze, in 2002, the results of a feasibility study to determine the approach and timing of the implementation of a new "smart tool system" to classify PLCs. The computer software-based "smart system" would assist notifiers in the identification of PLCs. Depending on the outcome of this feasibility study, an appropriate course of action will be developed in consultation with stakeholders.

3.2.3 Special Categories (Recommendations 42 to 48, 50 and 51)

(i) Research and Development and Product Development Substances (Recommendations 42 to 48)

The departments recognize that R&D activities in the chemical sector are important to Canada's innovation agenda. The recommended changes pertaining to R&D substances and to product development substances will reflect the consensus that an amalgamated definition is an important step towards simplification of special categories under the NSN Regulations. Furthermore, revising trigger volumes and schedules associated with these non-commercial activities is considered appropriate.

3 Non-NDSL chemicals, NDSL chemicals, PLCs, non-NDSL polymers excluding PLCs and those with all monomers listed on the Domestic Substances List (DSL)/NDSL, and NDSL polymers.

(ii) Site-limited Intermediate Substances and Export-only Substances (Recommendations 50 and 51)

An important aspect of the recommendations in this section pertains to clarity of definitions. The departments intend to introduce the definitions agreed to by the Table for site-limited intermediate substances, export-only substances and sufficient containment, following thorough legal and enforcement reviews to ensure that the definitions can be operationalized.

3.2.4 Assessment Periods (Recommendations 52 to 54)

Environment Canada and Health Canada will amend the NSN Regulations to incorporate the assessment periods recommended by the Table. Furthermore, in 2002, internal procedures of the NS Program will be reviewed and amended where warranted to increase efficiency, thereby shortening the time needed to reach decisions.

The departments also intend to apply the procedures described above to PLCs. Should the "smart tool system" described in Recommendation 41 prove effective at determining the classification of a polymer (low concern versus not low concern), the efficiency gained may help in completing polymer assessments more quickly, and the "greenlighting" provisions may be applied. In the longer term, the possibility of reducing the regulatory assessment period for PLCs will be examined.

Consistent with the new authorities in CEPA for "greenlighting," the departments will terminate assessment periods on a routine basis where assessments are completed early and will report annually on the extent to which this occurs.

3.2.5 Facilitation of Waivers for Substances Used for a Prescribed Purpose (Recommendations 49 and 55)

The Table also expressed its view that mechanisms that enable the application of the "prescribed purposes" portion of paragraph 81(8)(b) of CEPA to special categories should be explored and the term "purpose" defined or replaced within CEPA. Environment Canada and Health Canada intend to describe and make public by mid-2003 what these mechanisms and changes might be and how to involve stakeholders in discussions on this subject.

The departments will initiate consultations with stakeholders in fall 2003 to identify purposes of use and/or categories of substances that are associated with negligible risk to the point where certain exposure or effect information can be systematically waived. If successful, then the departments will use the authority of paragraph 89(1)(f) to incorporate provisions to this effect in the amended NSN Regulations.

3.2.6 Record-keeping and Enforcement (Recommendations 56 and 57)

To enable effective enforcement of the NSN Regulations, Environment Canada requires notifiers to maintain appropriate records associated with their notifications and to make these records available to enforcement officers when required. Accordingly, the NSN Regulations and associated sections of the Guidelines will be revised to clarify notifier/Canadian agent obligations with respect to record-keeping requirements.

3.3 Theme 3 – Transparency of the NSN Regulatory Process (Recommendations 58 to 65)

Environment Canada and Health Canada regard Theme 3 as critical in transforming the NS Program into a more open and transparent operation. The recommendations in this theme relate to the use of plain, understandable language for the NSN Regulations, the Guidelines and program policy documents. Furthermore, they address the NS Program web site and links, CEPA Environmental Registry search options, confidential business information, access to decisions and the supporting risk assessments, and mechanisms for challenging assessment decisions.

(i) NSN Information – Regulations, Guidelines and Policy Documents (Recommendations 58 to 62)

Environment Canada and Health Canada will alert the Department of Justice to recommendations of the Table pertaining to the requests for plain-language Regulations and to the offer of certain stakeholders to provide feedback on initial drafts. Similarly, the Guidelines will be revised using plain language. This will be done with input from multistakeholder working groups comprising individuals from government and industry, followed by a public review process. As recommended, where appropriate, case studies will be used to illustrate concepts in the Guidelines and will be made available electronically on Environment Canada's web site.

Discussions will occur in 2003 with CEPA Environmental Registry administrators and other impacted programs to address recommendations concerning simplified search facilities and links to other important and related national and international web sites. The departments will engage industry and other stakeholders by 2003 to assist in identifying appropriate sites to be linked to the NS Program web site in a timely manner.

Finally, Environment Canada and Health Canada will, in 2002, inventory and revise as required, the operational policies associated with the NS Program, including the policy documents outlined in the consultation recommendations. Subsequent to this review, the departments will establish an ongoing process for the preparation, review and publication of operational policies and ensure that they are complete and clearly written. As an early example of this exercise, a document entitled *Screening-level Environmental Risk Assessment Guidance Document for New and Existing Substances* will be issued in 2002. As recommended by stakeholders, regularly updated NS Program statistics will become a regular feature of the web site.

(ii) Confidential Business Information and Access to Risk Assessments (Recommendations 63 and 64)

The principal element of these recommendations concerns access to decisions and the supporting risk assessment reports. Environment Canada and Health Canada have been facing challenges, since the NSN Regulations came into force, to balance timely decision-making and addressing program-wide issues with the desire to make information public. The recommendations display the "reasonableness" on the part of the Table in guiding where the departments should attribute priority in this area. As such, the departments are currently embarking on a review of the documents developed, their format, use of third-party information, target audience and other relevant matters as a basis for implementing the Table's recommendations. As an additional priority, the departments will also develop a process to provide notifiers with assessment reports and the public with summaries when substances are subject to section 84 or when they become eligible for addition to the DSL. Every effort will be made to put this process in place by the end of 2002.

(iii) Mechanisms for Challenging Assessment Decisions (Recommendation 65)

Environment Canada and Health Canada acknowledge the desire of stakeholders to amend CEPA to provide appeal mechanisms. Accordingly, by the end of 2003, the departments will initiate a process that will examine the feasibility of incorporating appeal mechanisms into the NS Program and, if appropriate, will develop concrete proposals for amending CEPA.

3.4 Theme 4 – Improving Responsiveness of the NSN Regulations and NS Program in the Global Context (Recommendation 66)

This theme concerned a number of initiatives under way within the program relating to international harmonization, such as information- and work-sharing, bilateral/multilateral arrangements and management of confidential business information. The Table was clear about the eventual economic and social benefits of these initiatives, but equally clear that Canada must withstand any pressure to drop its standards in terms of science-based decision-making.

Equally important, the Table challenged the departments to develop and implement a strategic plan that would guide the program in the international harmonization and cooperation activities it pursues and to continually engage stakeholders in the process. Environment Canada and Health Canada will initiate, by the end of 2002, a process to develop the plan envisaged by the Table. At the same time, the departments will continue their efforts within OECD and through bilateral arrangements with other countries, such as the United States and Australia, and will seek other opportunities relating to this subject. For example, the departments will examine the possibility of introducing a foreign scheme into the NS Program's framework based on the progress made through bilateral arrangements with other countries and through OECD work. By the middle of 2003, the departments intend to seek stakeholder perspectives on the draft plan, to amend the plan as appropriate and to make it public. The departments will review progress on implementation of the plan and release a report by the end of 2005.

3.5 Theme 5 – Service Delivery (Recommendations 67 to 76)

Issues associated with Theme 5, Service Delivery, involve operational program changes and resource considerations. These issues apply to service quality standards and delivery initiatives, performance indicators, education and training, leadership for cultural change and innovation (for example, an electronic filing system, the Four Corners Agreement, personnel exchanges, compliance promotion activities, and assessment methods for complex hazard and risk assessment challenges).

(i) Quality Service (Recommendations 67 to 69, 74 and 75)

The departments will investigate in 2002 what already exists in the departments and elsewhere to document best practices and will adopt a long-term phased approach that will include stakeholders for the implementation of measurable service quality standards and performance indicators. This approach will be in line with the framework developed by the Treasury Board Secretariat and the National Quality Institute. Meanwhile, the departments will develop simple tools to measure stakeholder satisfaction. Internal preliminary discussions have begun to initiate a project to develop an appropriate model associated with performance indicators.

The departments will also endeavour to keep up to date with international service delivery initiatives through participation in international fora such as the OECD New Chemicals Task Force. The departments will periodically review the service and performance indicators and compare them against international service delivery initiatives.

The aim of the departments is to continue to be responsive to client needs by building on current initiatives and considering new ways of enhancing service delivery (i.e., information technology). For compliance promotion activities, the departments have already started to consider the involvement of stakeholders in compliance promotion projects. Discussions with industry will be initiated when the revised Regulations are nearing completion, to identify opportunities for mutually beneficial personnel exchanges.

(ii) Leadership for Cultural Change (Recommendations 70 and 71)

Senior management in both Environment Canada and Health Canada will work in cooperation with managers of other CEPA programs in 2002 to meet expectations for increased transparency and implementation of quality service approaches that are centred on principles of sustainability.

The departments will also continue to explore other avenues for delivering more effective service, including giving consideration to co-location of staff.

(iii) Innovation (Recommendations 72, 73 and 76)

The departments are committed to moving towards a system that allows electronic filing and access to electronic files as resources become available and client demand warrants. The potential for industry financial support in this area will be investigated in 2003. The outcome of the OECD workshop on electronic information systems, held in Ottawa in October 2002, will be considered as part of the path forward for development of electronic filing submission systems.

Canada will continue to exercise its leadership in the area of international cooperation. The departments intend to continue ongoing initiatives, such as the Four Corners Agreement, the impending Canada–Australia arrangement and the OECD new chemicals multilateral exercise.

The departments have expanded their interaction with groups involved in hazard and risk assessment and will continue to allocate resources to the important activity of continuous improvement of science capacity and assessment methodologies.

4. CONCLUSIONS AND NEXT STEPS

It is recognized that both government and stakeholders made a significant investment in the consultation process for amending the NSN Regulations and NS Program, which spanned nearly two years and resulted in 76 consensus recommendations.

The result of this worthwhile exercise is a multiyear agenda of reform for the NS Program. It is an agenda that reflects our fundamental goal to protect human health and the environment while enhancing efficiency, effectiveness and a competitive economic climate for investment and innovation.

Environment Canada and Health Canada will now proceed with initiating the implementation of these recommendations, as outlined in this document, the Environment Canada/Health Canada response to the consultation recommendations.

Appropriate changes will be made to the NSN Regulations and to the operational policies and procedures of the NS Program. These changes will result in high standards for the protection of the environment and human health and a timely, predictable and transparent program, while ensuring effective and efficient use of government and industry resources in a global marketplace.

Comments and questions regarding the consultation process and this Environment Canada/Health Canada response may be addressed to:

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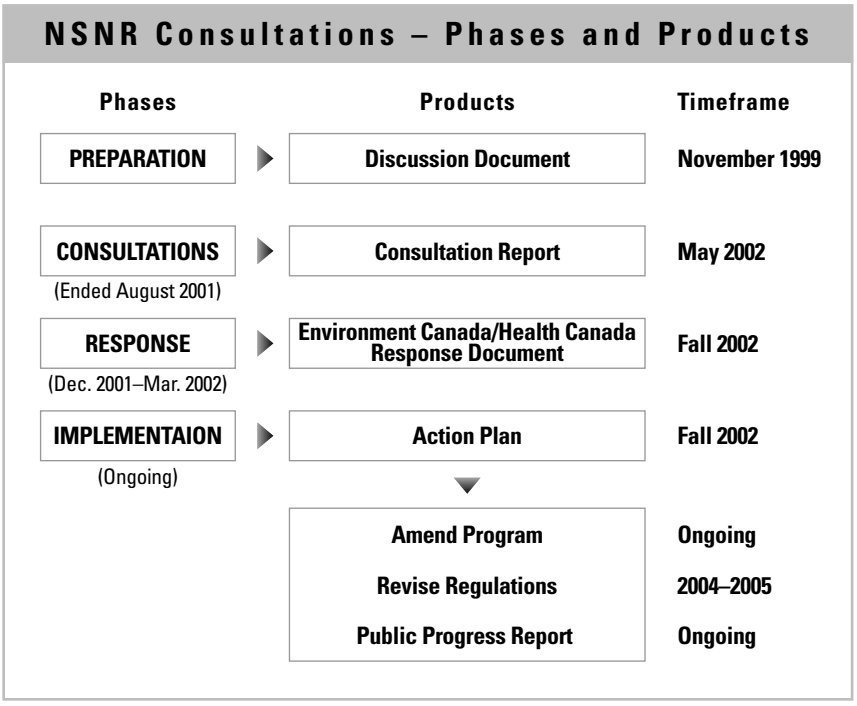
APPENDIX 1: LIST OF ACRONYMS

CAS	Chemical Abstracts Service
CEOH	Committee on Environmental and Occupational Health
CEPA	*Canadian Environmental Protection Act*
CEPA 1999	*Canadian Environmental Protection Act, 1999*
DSL	Domestic Substances List
EDS	Endocrine Disrupting Substance
GLP	Good Laboratory Practice
MSDS	Material Safety Data Sheet
NDSL	Non-Domestic Substances List
5NR	Five Natural Resource Departments (Federal Government)
NS	New Substances
NSN	New Substances Notification
NSNR	New Substances Notification Regulations
OECD	Organisation for Economic Co-operation and Development
PAG	Public Advocacy Group
PLC	Polymer of Low Concern
R&D	Research and Development
SAR	Structure–Activity Relationship
SNAc	Significant New Activity
TSCA	*Toxic Substances Control Act* (U.S.)
TSMP	Toxic Substances Management Policy

APPENDIX 2: PHASES & PRODUCTS CHART FOR THE NSN REGULATIONS CONSULTATIONS



APPENDIX 3: TABLE OF MULTISTAKEHOLDER CONSULTATION RECOMMENDATIONS AND ASSOCIATED ENVIRONMENT CANADA/HEALTH CANADA RESPONSES

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.1 Theme 1 – Improving the Environmental and Health Assessments for New Substances	
3.1.1 Principles and Policies Affecting the Assessment and Management of New Substances	
(i) Pollution Prevention	
No specific recommendations were made in this section.	
(ii) The Precautionary Principle	
No specific recommendations were made in this section.	
(iii) Toxic Substances Management Policy (TSMP)	
1. Points of clarification should be summarized and included in the document *Toxic Substances Management Policy – Environment Canada Implementation Strategy for New Substances* (Draft, April 2001). This draft document should then be finalized and made public.	The final draft of the document and a summary of comments received during the consultations are in the final stages of preparation and will be posted on Environment Canada's Green Lane and the NS Program web site in 2002.
3.1.2 Adequacy of the Risk Assessment Methodology	
No specific recommendations were made in this section.	
3.1.3 Mechanism for Requiring Additional Information for the Risk Assessment	
2. The next review of CEPA should clarify the authority for regulators to require additional information when the prescribed information suggests a suspicion of toxicity, but is considered insufficient to adequately characterize the risk.	The departments will seek legal advice to confirm that section 84 can be used as suggested by the Table. At the same time, the Department of Justice will be asked whether there are any other existing or new mechanisms within CEPA that can be used for this purpose.
3. In the meantime, Environment Canada and Health Canada should adopt the proposed interpretation of section 84 and should develop a guidance document that describes how authorities under section 84 (and/or other mechanisms) can be accessed and used to obtain additional information (beyond that prescribed in the notification scheme) required to complete the assessment. This guidance document should provide criteria for use by evaluators in accessing these mechanisms. The intent is that these criteria enable health, ecotoxicity hazards or exposure concerns to be addressed.	Environment Canada and Health Canada will develop criteria by Spring 2003 for using authorities, such as section 84, for requesting additional information. These criteria will be used to prepare guidance, in the form of an Operational Policy for evaluators, by summer 2003.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.1 Theme 1 – Improving the Environmental and Health Assessments for New Substances (CONTINUED)	
3.1.4 Endocrine Disrupting Substances (EDSs)	
4. Environment Canada and Health Canada must continue to work diligently with stakeholders nationally and internationally to develop internationally accepted, validated screening and testing protocols to assess new substances for endocrine disruption potential.	The departments will continue to support the initiatives of the 5NR Working Group and of the OECD Test Guidelines Program and to press for timely results.
5. As internationally accepted, validated screening and testing protocols become available that are suitable for a new substances regulatory system, they should be incorporated into the NS Program by the most appropriate means (Regulations or Guidelines). It is noted that the initial availability of the current projected schedule of validated tests (2002–2005) is consistent with the timing for promulgating amendments to the NSN Regulations.	Once suitable test protocols are available, the departments will initiate amendments to incorporate them within the NS Program by the most appropriate mechanism.
6. The NSN Guidelines Document will be revised, subsequent to these consultations, to include a section dealing with endocrine disruption. In particular, the section will describe Environment Canada and Health Canada's approach to incorporating endocrine disrupting considerations in the course of conducting an assessment and proposed risk management outcomes. This will include development of a database of substances that have shown evidence of endocrine disrupting effects. This database, along with other available information, will be used by evaluators to identify whether substances under review are structurally related to substances shown to have endocrine disrupting activity. Depending upon the severity of the effect and the closeness of the analogue fit, this analogue information may form the basis for a suspicion of toxicity. The guidelines will also indicate that as applicable validated structure-activity relationships (SARs) become accessible, they will be used appropriately in the assessment process. Furthermore, where this information leads to a suspicion of toxicity, appropriate control measures will be imposed, or requests for further test data under section 84(1)(c) of CEPA will be made as validated test procedures are determined. Lastly, the section on endocrine disruption will inform stakeholders of the intent to amend the NS Program (Regulations or Guidelines) to include data requirements for determining endocrine disrupting potential as they become available.	As the issue of endocrine disruption evolves, the Guidelines will reflect new developments, indicating internationally accepted test protocols and how the information will be used in the assessment. Guidance material for notifiers, such as an Advisory Note, will be developed during 2003 and incorporated in the Guidelines. As recommended, information will be included concerning the departments' approach to assessing endocrine disrupting effects and how this would be integrated into a determination of suspicion of toxic. As well, a database of EDS analogues will continue to be developed with other government agencies and research institutes, and peer review from other national governments will be sought. At an appropriate time, this database will be made available to notifiers and the public to assist in understanding this aspect of chemical substances.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.1.5 Occupational Exposure	
7. If Health Canada has information on a hazard pertaining to a notified substance, there is an obligation for Health Canada to share that information with the Canadian agency or agencies that have jurisdictional authority over the workplace. A protocol or process must be identified or developed to share information. The notifier should also be informed. This is consistent with the overriding obligation of due diligence. Health Canada must identify who should receive the information at the time Health Canada identifies the hazard and the specific information.	The departments will initiate discussions by the end of 2002 to define the information-sharing arrangements that should be put into place at the federal level and with provinces. This will be done through the federal/provincial CEOH and through direct discussion with the provinces.
8. If Health Canada has information on a hazard pertaining to a notified substance that is not known by the notifier of the substance, there is an obligation for Health Canada to share that information with the notifier.	Health Canada is working towards the development of an effective and efficient process for informing relevant agencies and notifiers of hazards identified during the course of an NSN Regulations assessment.
9. The sharing of information with the notifier and/or another Canadian agency or agencies that have jurisdictional authority should occur at the time that Health Canada identifies the hazard.	See response to recommendation 8.
10. The Guidelines should be revised to specify the information "which the notifier has in their possession or might reasonably have access to" that will be required of the notifier (when submitting their notification) with respect to any occupational hazards associated with the notified substance. There is a recognition that for truly new substances, this data set will not normally be available or easily accessed.	The Guidelines will be revised accordingly.
11. Health Canada must work closely with appropriate federal authorities (e.g., Human Resources and Development Canada and Labour Canada) that regulate federal workplaces based on hazard information and proposed use patterns provided by the notifier. CEPA seems to allow for this. (Interdepartmental cooperation is required as per section 2 of CEPA.)	See response to recommendation 7.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.1 Theme 1 – Improving the Environmental and Health Assessments for New Substances (CONTINUED)	
***3.1.5 Occupational Exposure* (CONTINUED)**	
12. Health Canada and Environment Canada must work with appropriate federal and provincial/territorial authorities to ensure that the data received by the NS Program are used to conduct occupational risk assessments.	See response to recommendation 7.
13. Health Canada should facilitate a multistakeholder consultation in relation to new substances in the occupational environment. Among other things, this consultation should identify ways in which: • new substances notified under the NSN Regulations will be assessed for risks associated with the occupational environment; and • a process for the identification of preventative and control measures can be implemented by the responsible agencies.	Health Canada intends to undertake a consultative process by the beginning of 2003 after seeking the involvement of the CEOH.
3.1.6 Data Requirements	
(i) Suite of Data Requirements for Chemicals and Polymers	
14. Only the information elements that have wide applicability in assessing substances and have internationally accepted test protocols should be included in the Regulations.	The departments are supportive of the data that were identified by the Table for inclusion in the NSN Regulations and, in combination with recommendations under Theme 2, when the data should be notified.
15. Revised Guidelines should address additional data elements, stating the need for these data and articulating the "profile" of substances where this information may take on significance. It is intended that this would alert notifiers to the potential need for generating these data. Notifiers would be encouraged to contact the Program for a pre-notification consultation where these issues could be discussed. If the Program believes these data are necessary for the assessment and the data are not forthcoming from the notifier, provision of the data could be required under sections 84(1)(c) and 84(2) of CEPA.	The departments are supportive of the need to elaborate in the Guidelines what additional data may be necessary and under what circumstances they should be generated.
16. The NSN Guidelines should be referenced in the NSN Regulations. The revised Guidelines will be developed by governments and industry representatives. All stakeholders should be given the opportunity to comment on the revised Guidelines.	Implementation of these recommendations will be pursued within the timelines described for renewal of the Guidelines and will be done in cooperation with a multistakeholder Working Group.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
17. The NSN Regulations should contain the information in Table 3.1 in the Final Report for chemicals and polymers.	See response to recommendation 14.
18. The data elements described in Table 3.2 in the Final Report should be included in the revised Guidelines. Notifiers will be advised that data from these tests are suggested in certain circumstances and may be requested to address evaluators' concerns about "suspicion of toxic."	See response to recommendation 3.
19. The revised Guidelines document should contain text that addresses the need for this information and how it will be used in an assessment. The Guidelines should describe the categories or profiles of substances that may be covered by additional tests in order to assist notifiers in identifying specific issues with a new substance and to allow notifiers to contact Environment Canada in advance of the notification.	See response to recommendation 3.
(ii) Class Considerations	
20. The revised Guidelines should identify classes of substances where test requirements will be waived upon request and also the classes where additional test information is recommended.	As recommended, the departments will describe the classes of substances and circumstances for which waivers will be accepted for certain tests if requested by the notifier. Furthermore, the departments will describe where additional information will be recommended if a substance meets certain criteria.
21. The revised Guidelines document should contain information to be used by notifiers to promote the use of waivers for specific data elements for certain classes of substances. This information should be developed in conjunction with the revised Guidelines.	The Guidelines will be redrafted to describe the benefits of using the waiver provisions. The Guidelines will be used as the principal means to communicate this information, although Advisory Notes may also be used.
(iii) Good Laboratory Practice	
22. Toxicological and biodegradation studies required by the Regulations must comply with the compliance monitoring requirements of OECD Principles or the GLP Regulations of the OECD Member country in which the testing was originally performed. These studies include acute and repeated-dose mammalian toxicity studies, genotoxicity studies, skin irritation, skin sensitization, ecotoxicity studies and ready biodegradation.	The departments will amend the NSN Regulations to reflect the shift to mandatory compliance for toxicological and biodegradation studies.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.1 Theme 1 – Improving the Environmental and Health Assessments for New Substances (CONTINUED)	
***3.1.6 Data Requirements* (CONTINUED)**	
(iii) Good Laboratory Practice (CONTINUED)	
23. Tests for, and reporting of, physical or chemical properties must either comply with the compliance monitoring requirements of OECD GLP for short-term tests of the country in which the testing was performed or provide enough information to evaluate the reliability and adequacy of data (see Appendix A.6 of the Final Report). Full reports for non-GLP tests will be required in order to assess the quality of these studies and their results.	The departments will amend the NSN Regulations to reflect the shift to mandatory compliance for toxicological and biodegradation studies, while offering greater flexibility for testing and reporting of physical and chemical data, consistent with the recommendation.
24. If the laboratory that is generating data submitted to the Program is accredited, the status of that accreditation must be stated and identified.	The obligation of reporting laboratories to state their accreditation will be included in the amendments, as recommended.
(iv) Toxicity Testing Using Animals	
25. Government should encourage the development of alternative testing techniques able to provide the same utility of information as that provided by experiments carried out on animals, but which use fewer or no animals or less painful procedures. These should be developed through international (e.g., OECD) scientific cooperation, and adequate resources should be allocated to support these efforts.	Environment Canada and Health Canada remain committed to minimizing the use of animals in testing, and this includes the NS Program. Modification of test protocols to rely on fewer animals while ensuring valid results is one aspect of the strategy, while pursuit of alternative testing that does not require animals is another. The departments consider the development and validation of new test guidelines by the OECD Test Guidelines Program to be key in implementing this strategy.
26. Alternative methods, once validated, should be available for use for the assessment of new substances under the NSN Regulations. It is proposed that wording to this effect should be added to the revised Guidelines.	The departments are committed to encouraging the use of revised or new protocols, as they are adopted in the OECD for data submitted under the NSN Regulations. Furthermore, through GLP and other practices, the departments will accept data generated for other purposes or in other jurisdictions, thereby eliminating the need for unnecessary duplication of testing. The Guidelines will also identify the availability of alternative, validated test protocols.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
27. When data developed using alternative methods are submitted for the purposes of notification, the onus will be on the notifier to demonstrate the same utility of information. Pre-notification consultations are encouraged in such situations. In addition, the government commits to setting service standards to respond to this type of request.	Notifiers will be encouraged to take advantage of pre-notification consultation services to discuss their use of data resulting from alternative methods.
(v) Exposure Template	
28. The template for providing exposure information should be developed in a separate process from this consultation.	The recommendation to evaluate and finalize an exposure template will be addressed in 2002. Notifiers will be encouraged in an Advisory Note to use the template and will be provided with instructions in the Guidelines on how to complete it.
29. The obligatory exposure information required by the Regulations should be incorporated into a template.	See response to recommendation 28.
30. A reduced list of exposure data and information should be required for PLCs and entry-level chemicals.	See response to recommendation 28.
3.1.7 Evaluation and Validation of Data Quality in the NS Program	
(i) Scrutiny by NS Program Evaluators	
31. Environment Canada should continue its periodic review, and Health Canada should initiate a practice of periodic review of its assessment reports by group(s) outside the NS Program. The methodology and results of these reviews should be made public.	In addition to the internal peer review processes utilized by the departments, Environment Canada commits to periodic, retrospective review of environmental risk assessments, as described to the Table. Health Canada will also initiate, in 2002, a similar practice of periodic review of its assessment reports by group(s) outside the NS Program. By the end of 2004, the departments will make the results of these periodic reviews available to the public.
(ii) Government Verification of Test Results	
32. Environment Canada and Health Canada should undertake a feasibility study that describes the key elements of an efficient and effective government-funded verification testing program, options and costs for implementation and an evaluation of the benefits it would bring to the other measures undertaken by the Program to address data validity. The results of this study should be made public before deciding whether to include this type of testing within the NS Program.	As part of the feasibility study recommended by the Table, the departments will review, during 2003, existing policies, programs and practices in the area of government-funded verification testing in Canada and elsewhere. The results of this review will be made public, as well as the decision whether to proceed with a cost–benefit analysis if such a program were to be implemented for the NSN Regulations.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.2 Theme 2 – The Regulatory Framework	
3.2.1 General Discussions and Recommendations	
(i) Alternative Approach to a Tiered System	
33. An entry-level trigger for non-NDSL chemical notifications should be established at 100 kg/year.	The recommendations pertaining to the entry-level volume trigger and the elimination of cumulative and in-possession triggers will be incorporated in the drafting instructions and, subsequently, in the NSN Regulations.
(ii) Simplifying and Improving the Effectiveness of the Tiered Approach	
34. Cumulative and "in-possession" triggers should be eliminated. The elimination of these triggers will not affect the ability of the regulators to assess persistence, bioaccumulation and toxicity.	See response to recommendation 33.
(iii) Administration of the NDSL	
35. The NDSL should be updated annually, based on the U.S. TSCA Inventory of the previous year.	The recommendation to update the NDSL annually based on the TSCA Inventory from the previous year pertains to the administrative aspects of the program. During 2003, Environment Canada will initiate preparations for the initial update; however, given that certain amendments to the NSN Regulations are necessary to increase information requirements for NDSL substances (Schedule 3), the initial update cannot be published until the amended NSN Regulations are promulgated. In the interim, the departments are willing to meet with industry to discuss how this issue can be temporarily addressed.
3.2.2 Proposed Framework for the New Regulations	
36. The framework as outlined in the proposed framework for NDSL chemicals (Section 3.2.2(ii) of the Final Report) and the proposed framework for NDSL polymers and non-NDSL polymers with all monomers listed on the DSL/NDSL (Section 3.2.2(v) of the Final Report) should replace the current requirements for the relevant categories of substances.	The framework for each of the categories of substances identified by the Table in this theme[4] will be incorporated into the drafting instructions and into the amended NSN Regulations. The Guidelines will also be revised to reflect the new framework and the information required at each tier.
37. The NS Program should revise its internal procedures to ensure that, wherever warranted, additional data are requested at earlier stages in the assessment process. For example, such requests could be made in the assessment of NDSL polymers or those polymers with all monomers on the DSL/NDSL.	See response to recommendation 3.

4 Non-NDSL chemicals, NDSL chemicals, PLCs, non-NDSL polymers excluding PLCs and those with all monomers listed on the DSL/NDSL, and NDSL polymers.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
38. Health Canada and Environment Canada should utilize Significant New Activities (SNAcs) in cases where there is uncertainty that the substance may be used in a consumer application or that the 3 kg/day per site criterion may be exceeded as a result of future activities. These future activities would include multiple users and/or a variety of applications.	The departments are currently developing Guidelines for use of the SNAc provisions (section 85) and will be consulting with stakeholders as per section 69(2).
39. A more streamlined method should be pursued as an alternative to SNAcs.	The departments feel that the use of SNAcs is appropriate but are open to investigating a more streamlined method in the next review of CEPA.
40. A mechanism should be developed (e.g., a flag) when listing PLCs (excluding certain polyesters that have been assessed according to low concern criteria) on the DSL.	The departments will develop administrative procedures in 2002 to identify PLCs on the DSL. These polymers will have to be renotified if they are subsequently imported or manufactured in a form that no longer meets the low concern criteria. The departments do not intend to make this process retroactive.
41. A "smart system" to simplify the notification of PLCs should be developed and implemented.	The departments will analyze, in 2002, the results of a feasibility study to determine the approach and timing of the implementation of a new "smart tool system" to classify PLCs. Depending on the outcome of this feasibility study, an appropriate course of action will be developed in consultation with stakeholders.
3.2.3 Special Categories	
(i) Research and Development and Product Development Substances	
42. The definitions for R&D and product development substances should be amalgamated to "research and development substance" as follows: "Research and development substance" means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, the primary objective of which is: (a) to create or improve a product or process, or (b) to determine the technical viability or performance characteristics of a product or process, or (c) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials or customer trials other than test marketing, in order to modify the technical specifications in response to the performance requirements of potential customers.	The departments recognize that R&D activities in the chemical sector are important to Canada's innovation agenda. The recommended changes pertaining to R&D substances and to product development substances will reflect the consensus that an amalgamated definition is an important step towards simplification of special categories under the NSN Regulations. Furthermore, revising trigger volumes and schedules associated with these non-commercial activities is considered appropriate.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.2 Theme 2 – The Regulatory Framework (CONTINUED)	
***3.2.3 Special Categories* (CONTINUED)**	
(i) Research and Development and Product Development Substances (CONTINUED)	
43. The current schedules for special categories should be replaced within the framework outlined in Section 3.2.2 of the Final Report with the following:	See response to recommendation 42.
a) R&D Chemicals	
44. For chemicals meeting the definition of an R&D substance, there would be no reporting requirements necessary below 1000 kg/year. This is consistent with the current regulations.	See response to recommendation 42.
45. Prior to exceeding 1000 kg/year, the following data will be required: • chemical name • trade names • CAS # • MSDS • molecular formula • structural formula • gram molecular weight • degree of purity • impurities • additives/stabilizers • a summary of all other information and test data on hazard and exposure • identification of other agencies notified and risk management actions taken • (manufacture, use, disposal and exposure information) These data elements are equivalent to the proposed intermediate schedule (Section 3.2.2(i) of the Final Report), but with no requirement to notify test data.	See response to recommendation 42.
46. The notification of the "final" schedule (as outlined in Section 3.2.2(i) of the Final Report) will be required prior to exceeding 10 000 kg/year. This will inform Environment Canada and Health Canada of the increased volume of the R&D substance and provide an opportunity for the notifier to update information supplied in the first notification. There would be no additional information requirements at that time beyond the "correction of information" provision of CEPA (section 81(11)).	See response to recommendation 42.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
b) R&D Polymers	
47. The recommendation for R&D polymers is similar in structure to that for R&D chemicals; however, the data requirements and trigger volume are based on those for polymers. The following are a list of data required prior to exceeding 10 000 kg/year (trigger volume maintained from current regulations): • polymer name • trade names • CAS # • MSDS • molecular formula • structural formula • composition of the polymer, including monomers/ reactants, impurities, additives and solvents • physical state of the polymer • whether the polymer is formulated for dispersal in water • number average molecular weight and % <500 daltons and % <1000 daltons (R&D substances are exempt from this data requirement; instead, the target number average molecular weight must be indicated)[5] • a summary of all other information and test data on hazard and exposure • identification of other agencies notified and risk management actions taken • manufacture, use, disposal and exposure information These data elements are equivalent to the proposed intermediate/final schedule (Section 3.2.2(iv) of the Final Report), but with no requirement to develop test data.	See response to recommendation 42.
(ii) Site-limited Intermediate Substances and Export-only Substances	
48. The framework for the notification of "Contained Site-limited Intermediate Substances" should be identical to that for R&D substances.	See response to recommendation 42.

5 The revised Guidelines will indicate the type of information (e.g., reaction scheme) that will aid in the characterization of R&D polymers.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.2 Theme 2 – The Regulatory Framework (CONTINUED)	
3.2.3 Special Categories (CONTINUED)	
(ii) Site-limited Intermediate Substances and Export-only Substances (CONTINUED)	
49. A process should be initiated to explore mechanisms that enable utilization of the "prescribed purposes" portion as defined in section 81(8)(b) of CEPA to special categories.	The Table expressed its view that mechanisms that enable the use of the "prescribed purposes" portion of paragraph 81(8)(b) of CEPA to special categories should be explored and the term "purpose" defined or replaced within CEPA. Environment Canada and Health Canada intend to describe and make public by mid-2003 what these mechanisms and changes might be and how to involve stakeholders in discussions on this subject.
50. For the purpose of defining site-limited intermediate and export-only substances, "sufficient containment" means an absolute release limit of 1 kg/day per site to the aquatic environment after wastewater treatment.	The departments intend to introduce the definitions agreed to by the Table for site-limited intermediate substances, export-only substances and sufficient containment, following thorough legal and enforcement reviews to ensure that the definitions can be operationalized.
51. The definitions for "site-limited intermediate" and "export-only" substances that the Table has agreed to (see Section 3.2.3(ii) of the Final Report) should be accepted and used in the revised NSN Regulations.	See response to recommendation 50.
3.2.4 Assessment Periods	
52. The assessment periods as described in Table 3.5 in the Final Report should be established.	Environment Canada and Health Canada will amend the NSN Regulations to incorporate the assessment periods recommended by the Table.
53. Environment Canada and Health Canada should review their procedures so that when assessments are completed before the end of the assessment period, notifiers are informed immediately, and assessment periods are terminated.	In 2002, internal procedures of the NS Program will be reviewed and amended where warranted to increase efficiency, thereby shortening the time needed to reach decisions. Consistent with the new authorities in CEPA for "greenlighting," the departments will terminate assessment periods on a routine basis where assessments are completed early and will report annually on the extent to which this occurs.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
54. In the event that the development of the "smart system" for the characterization of PLCs proves to be successful, in terms of accurately categorizing PLCs, then a reduction in the assessment period for PLCs should be examined.	The departments also intend to apply the procedures described above to PLCs. Should the "smart tool system" described in Recommendation 41 prove effective at determining the classification of a polymer (low concern versus not low concern), the efficiency gained may help in completing polymer assessments more quickly, the "greenlighting" provisions may be applied. In the longer term, the possibility of reducing the regulatory assessment period for PLCs will be examined.
3.2.5 Facilitation of Waivers for Substances Used for a Prescribed Purpose	
55. Environment Canada and Health Canada should work cooperatively with stakeholders to identify purposes of use that can be described in Regulations to facilitate requests for waivers under section 81(8)(b). Regulations under the authority of section 89(1)(f) should be drafted at the same time as the revised NSN Regulations.	The departments will initiate consultations with stakeholders in fall 2003 to identify purposes of use and/or categories of substances that are associated with negligible risk to the point where certain exposure or effect information can be systematically waived. If successful, then the departments will use the authority of paragraph 89(1)(f) to incorporate provisions to this effect in the amended NSN Regulations.
3.2.6 Record-keeping and Enforcement	
56. The revised NSN Regulations should include wording, such as that in Section 3.2.6 of the Final Report, that states the obligation of the notifier/agent to maintain in Canada, for at least five years, appropriate records that are available for inspection.	The NSN Regulations and associated sections of the Guidelines will be revised to clarify notifier/Canadian agent obligations with respect to record-keeping requirements.
57. The revised NSN Guidelines should clarify the type of information the notifier must maintain.	See response to recommendation 56.
3.3 Theme 3 – Transparency of the NSN Regulatory Process	
(i) NSN Information – Regulations, Guidelines and Policy Documents	
Improving Transparency of NSN Regulations and Guidelines	
58. The NSN Regulations should be written in plain language to ensure that all stakeholders with an interest in new substance provisions, including prospective notifiers, can understand them. Plain-language NSN Regulations will minimize notification errors. This, in turn, will reduce administrative burdens and increase efficiencies in the Program. A simplified, more intuitive structure for the Regulations will improve their clarity. A simpler structure will reduce training time for staff in both government and industry.	The departments will alert the Department of Justice to recommendations of the Table pertaining to the requests for plain-language Regulations and to the offer of certain stakeholders to provide feedback on initial drafts.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.3 Theme 3 – Transparency of the NSN Regulatory Process (CONTINUED)	
(i) NSN Information – Regulations, Guidelines and Policy Documents (CONTINUED)	
Improving Transparency of NSN Regulations and Guidelines (CONTINUED)	
59. The NSN Guidelines should be written in plain language by a team made up of "regulators" and the "regulated community." Interested stakeholders should be invited to participate in a peer review before the Guidelines are published. The redrafted Guidelines should include on-line access to illustrative case studies and risk assessment and risk management decisions for each of the case studies.	The Guidelines will be revised using plain language. This will be done with input from multistakeholder working groups comprising individuals from government and industry, followed by a public review process. As recommended, where appropriate, case studies will be used to illustrate concepts in the Guidelines and will be made available electronically on Environment Canada's web site.
60. The CEPA Environmental Registry should allow users to identify all environmental/health regulations/control programs (e.g., National Pollutant Release Inventory, Schedule 1 of CEPA, Priority Substances Lists) that apply to a particular substance in one easy search operation.	Discussions will occur in 2003 with CEPA Environmental Registry administrators and other impacted programs to address recommendations concerning simplified search facilities and links to other important and related national and international web sites.
61. The NSN web site should be linked to other appropriate domestic and international sites such as those of the OECD, the International Labour Organization and industry associations. This initiative may best be achieved though partnerships with stakeholders.	For linkages, the departments will engage industry and other stakeholders by 2003 to assist in identifying appropriate sites to be linked to the NSN web site in a timely manner.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
Improving Transparency of NSN Policy Documents	
62. Several policy documents/statements should be developed in order to comprehensively describe and explain how the NS Program operates. These include: • a comprehensive, understandable policy statement describing the environmental and health risk assessment methodologies used by Environment Canada and Health Canada for the NSN assessment phase; • examples of exposure scenarios used for assessing potential human exposure and potential exposure in the environment; • how the NS Program operationalizes the precautionary principle and pollution prevention principles; • how the NS Program interprets "toxicity" and "suspicion of toxic" in making its risk assessments; • the policy employed by Environment Canada and Health Canada in treating confidential information, including confidential business information, in accordance with Part 11 of CEPA (note: this issue of how Environment Canada and Health Canada will deal with confidential information vis-à-vis the NS Program is discussed in Section 3.3(ii) of the Final Report); • published information relating to NSN enforcement actions. This information could be included in the annual Report to Parliament legally mandated under section 342 of CEPA and on the NS Program web site; • published information and statistics on the NS Program each calendar year, including items such as the number of notifications received with appropriate breakdowns by type, number of conditions and bans, and information on international activities with other jurisdictions (e.g., the Four Corners submissions [United States], exchanges with the National Industrial Chemicals Notification and Assessment Scheme [Australia]).	Environment Canada and Health Canada will, in 2002, inventory and review as required, the operational policies associated with the NS Program, including the policy documents outlined in the consultation recommendations. Subsequent to this review, the departments will establish an ongoing process for the preparation, review and publication of operational policies and will ensure that they are complete and clearly written. As an early example of this exercise, a document entitled *Screening-level Environmental Risk Assessment Guidance Document for New and Existing Substances* will be issued in 2002. As recommended by stakeholders, regularly updated NS Program statistics will become a regular feature of the web site.
(ii) Confidential Business Information and Access to Risk Assessments	
63. The full assessment report should be made available to the notifier. The Table recognizes that this is resource intensive because the government would have to remove any confidential business information received from another source.	The departments are currently embarking on a review of the documents developed, their format, use of third-party information, target audience and other relevant matters as a basis for pursuing the implemention of the Table's recommendations. As an additional priority, the departments will also develop a process to provide notifiers with assessment reports and the public with summaries when substances are subject to section 84 or when they become eligible for addition to the DSL. Every effort will be made to put this process in place by the end of 2002.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.3 Theme 3 – Transparency of the NSN Regulatory Process (CONTINUED)	
(ii) Confidential Business Information and Access to Risk Assessments (CONTINUED)	
64. Summaries of the following assessment reports should be published in descending order of priority: • substances for which controls have been imposed; • substances for which final notification has been received; • all assessments for all substances except PLCs; and • PLCs.	See response to recommendation 63.
(iii) Mechanisms for Challenging Assessment Decisions	
65. Health Canada and Environment Canada, in consultation with other government departments and stakeholders, should examine the feasibility of an appeal mechanism and how it could be incorporated into a revised CEPA.	By the end of 2003, Environment Canada and Health Canada will initiate a process that will examine the feasibility of incorporating appeal mechanisms into the NS Program and, if appropriate, will develop concrete proposals for amending CEPA.
3.4 Theme 4 – Improving Responsiveness of the NSN Regulations and NS Program in the Global Context	
66. Environment Canada and Health Canada should develop and implement a strategic plan covering the next five years that positions Canada to play a leadership role relating to new substances notification in international initiatives aimed at promoting high standards in the protection of human health and the environment in a way that permits better use of industry and government resources. This plan should be flexible and responsive to current and future initiatives, taking into consideration the following elements: • An initial objective of the strategic plan should be the pursuit of international harmonization of hazard assessments, along with clarification of Canada's interests regarding the potential for broader harmonization over the longer term. • Within the framework of the strategic planning process, Canadian support for, and participation in, international initiatives, such as those under the leadership of the OECD Task Force on New Industrial Chemicals, should be strengthened. • Stakeholders, including other government departments, should be continually engaged in the implementation of initiatives undertaken as part of the strategic plan.	Environment Canada and Health Canada will initiate, by the end of 2002, a process to develop the plan envisaged by the Table. At the same time, the departments will continue their efforts within OECD and through bilateral arrangements with other countries, such as the United States and Australia, and will seek other opportunities relating to this subject. For example, the departments will examine the possibility of introducing a foreign scheme into the NS Program's framework based on the progress made through bilateral arrangements with other countries and through OECD work. By the middle of 2003, the departments intend to seek stakeholder perspectives on the draft plan, to amend the plan as appropriate and to make it public. The departments will review progress on implementation of the plan and will release a report by the end of 2005.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.5 Theme 5 – Service Delivery	
(i) Quality Service	
67. Environment Canada and Health Canada should implement the recommendations of the Auditor General relating to implementation of measurable service quality standards, service/performance indicators, measuring stakeholder satisfaction, and continuous improvement, such as those outlined in the framework developed by the Treasury Board Secretariat and the National Quality Institute.	The departments will investigate in 2002 what already exists in the departments and elsewhere to document best practices and will adopt a long-term phased approach that will include stakeholders for the implementation of measurable service quality standards and performance indicators. This approach will be in line with the framework developed by the Treasury Board Secretariat and the National Quality Institute.
68. Service/performance indicators should be developed and reviewed periodically against international service delivery initiatives (e.g., within OECD).	Meanwhile, the departments will develop simple tools to measure stakeholder satisfaction. Internal preliminary discussions have begun to initiate a project to develop an appropriate model associated with performance indicators. The departments will also endeavour to keep up to date with those international service delivery initiatives through participation in international fora, such as the OECD New Chemicals Task Force. The departments will periodically review the service and performance indicators against international service delivery initiatives. The aim of the departments is to continue to be responsive to client needs by building on current initiatives and considering new ways of enhancing our service delivery (i.e., information technology).
69. Education, training and information provision for all stakeholders should be treated as a priority and assigned sufficient dedicated resources to be effective. Partnerships should be utilized, including personnel exchanges.	Discussions with industry will be initiated when the amended Regulations are nearing completion, to identify opportunities for mutually beneficial personnel exchanges.
(ii) Leadership for Cultural Change	
70. Senior management in Environment Canada and Health Canada should seek ways to enhance quality service approaches that are more open and transparent and centred on the principles of sustainability, develop a mission statement that captures these values, communicate it to all stakeholders and report annually on actions and results in achieving sustainability, transparency and service quality goals.	Senior management in both Environment Canada and Health Canada will work in cooperation with managers of other CEPA programs in 2002 to meet expectations for increased transparency and implementation of quality service approaches that are centred on principles of sustainability.

RECOMMENDATION	ENVIRONMENT CANADA/HEALTH CANADA RESPONSE
3.5 Theme 5 – Service Delivery (continued)	
(ii) Leadership for Cultural Change (CONTINUED)	
71. Senior management of both departments should review the organizational options to deliver a more effective, timely, single-window service. The advantages and disadvantages of physically locating all of the NS Program staff together should be considered as an option to improving service delivery.	The departments will also continue to explore other avenues for delivering more effective service, including giving consideration to co-location of staff.
(iii) Innovation	
72. The feasibility of redesigning the program delivery to permit secure electronic filing with access simplified by a "smart" system should be examined.	The departments are committed to moving towards a system that allows electronic filing and access to electronic files as resources become available and client demand warrants. The potential for industry financial support in this area will be investigated in 2003. The outcome of the OECD workshop on electronic information systems, held in Ottawa in October 2002, will be considered as part of the path forward for development of electronic filing submission systems.
73. Information sharing should be facilitated and international cooperation continued and possibly expanded.	Canada will continue to exercise its leadership in the area of international cooperation. The departments intend to continue ongoing initiatives, such as the Four Corners Agreement, the impending Canada–Australia arrangement and the OECD new chemicals multilateral exercise.
74. Opportunities for secondments among government and stakeholders should be explored and pursued where mutually beneficial.	Discussions with industry will be initiated when the amended Regulations are nearing completion, to identify opportunities for mutually beneficial personnel exchanges.
75. Government should work with stakeholders to examine innovative measures for ensuring compliance with the NSN Regulations.	For compliance promotion activities, the departments have already started to consider the involvement of stakeholders in compliance promotion projects.
76. Adequate science resources should be dedicated to addressing the increasingly complex hazard and risk assessment challenges, including innovative improvements to assessment methods that provide greater protection more efficiently.	The departments have expanded their interaction with groups involved in hazard and risk assessment and will continue to allocate resources to the important activity of continuous improvement of science capacity and assessment methodologies.