Consultations on the CEPA
***New Substances Notification Regulations* and**
New Substances Program
(Chemicals and Polymers Portion)

Final Report on Progress: Implementing the Consultation Recommendations for the Period October 2003 to June 2005

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Disclaimer

This document was prepared by Environment Canada and Health Canada, and 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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LIST OF ACRONYMS

4CA	Four Corners Arrangement
CEOH	Committee on Environmental and Occupational Health
CEPA 1999	*Canadian Environmental Protection Act*, 1999
DSL	Domestic Substances List
EDS	endocrine disrupting substance
ENGO	environmental non-governmental organization
EPA	Environmental Protection Agency (USA)
GLP	Good Laboratory Practice
NDSL	Non-domestic Substances List
NS	New Substances
NSN	New Substances Notification
NSNR	*New Substances Notification Regulations*
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PLC	polymers of low concern
PNC	pre-notification consultation
SNAc	Significant New Activity
TSCA	Toxic Substances Control Act (USA)
WIA	Work Item A

1.0 INTRODUCTION

This is the second, and final, formal report on the progress being made in implementing the recommendations resulting from the multistakeholder consultations that took place (1999–2001) on amending the *New Substances Notification Regulations* (NSNR) and the New Substances (NS) Program. Although this is the final formal progress report on the implementation of these recommendations, Environment Canada and Health Canada will continue to work on those recommendations for which implementation has not yet been completed.

The *Final Report of the Multistakeholder Consultations* and the *Environment Canada / Health Canada Response to the Consultation Recommendations* will continue to serve as guidance to Environment Canada and Health Canada during the implementation of the consultation recommendations. These two documents are available on the NS Program web site at **www.ec.gc.ca/substances/**.

The purpose of this progress report is to keep stakeholders and other interested parties informed of the status of both the changes that have been made, based on the recommendations, to the NSNR and the NS Program over the past year and the changes that will be made in the future. Similar to the first progress report, this document is organized along the same five-theme structure that was used during the consultation deliberations and in the Environment Canada / Health Canada response document:

- Theme 1: Improving the Environmental and Health Assessments for New Substances;
- Theme 2: The Regulatory Framework;
- Theme 3: Transparency of the New Substances Notification (NSN) Regulatory Process;
- Theme 4: Improving Responsiveness of the NSNR and NS Program in the Global Context; and
- Theme 5: Service Delivery.

The first part of this report provides a general overview of progress to date in implementing the consultation recommendations. More detailed information is found in Appendix 2, where progress is presented in tabular format, on a recommendation-by-recommendation basis. Information on recommendations that were implemented prior to October 2003 can be found in the first progress report, available on the NS Program web site.

2.0 HIGHLIGHTS

Many of the recommendations resulting from the multistakeholder consultations have already been implemented, in particular those recommendations directly related to the amended NSNR. Please refer to the first progress report for information on recommendations that were implemented prior to October 2003.

Some of the highlights of progress made between October 2003 and June 2005 include the following:

- The proposed amended NSNR were pre-published in the *Canada Gazette*, Part I, on October 30, 2004, for a 60-day comment period. These regulations will replace the current NSNR upon final adoption, which is expected to occur in fall 2005.
- A revised Guidelines document has been drafted to reflect the new regulations and to improve their usefulness and readability. The Guidelines will soon be finalized and are expected to be released in fall 2005 along with the new NSNR.
- A *New Substances Program Operational Policies Manual* containing operational policy documents that describe how the NS Program operates was posted on the NS Program web site in June 2004.
- A Service Delivery Improvement Strategy was developed to guide improvements as well as to develop tools to measure stakeholder satisfaction. A notifier survey was completed in March 2004. The Final Report of the New Substances Notifier Survey was posted on the NS Program web site in June 2004.

The next two sections report on the progress made in implementing recommendations from the multistakeholder consultations and identify a path forward for recommendations that have not been fully addressed to date.

3.0 OVERVIEW OF PROGRESS: REVISING THE *NEW SUBSTANCES NOTIFICATION REGULATIONS* AND GUIDELINES

3.1 Amending the *New Substances Notification Regulations*

Most of the multistakeholder consultation recommendations addressing amendments to the NSNR relate to the regulatory framework (Theme 2), although some of the changes relate to improving assessments for new substances (Theme 1) and transparency (Theme 3).

Status and Next Steps

The proposed amended NSNR were pre-published in the *Canada Gazette*, Part I, on October 30, 2004, for a 60-day comment period.

Next steps: Implementation of the amended NSNR is targeted for fall 2005, after which time the Non-domestic Substances List (NDSL) will be updated annually based on the U.S. Toxic Substances Control Act (TSCA) Inventory from the previous year (as opposed to being annually based on the TSCA of five years previous). Ten information sessions were held in spring 2005 to inform notifiers about the new regulations.

3.2 Revising the Guidelines for the *New Substances Notification Regulations* (Chemicals and Polymers)

Environment Canada and Health Canada intend to release a revised version of the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* as per the recommendations, most notably those recommendations relating to improving assessments for new substances (Theme 1), the regulatory framework (Theme 2), and transparency (Theme 3).

Status and Next Steps

A revised *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* has been drafted to reflect the new NSNR and to improve their usefulness and readability.

Next steps: Final publication of the revised Guidelines will occur after promulgation of the amended NSNR (fall 2005). The departments will, in the meantime, continue to communicate guidance to notifiers through the NSN-Infoline, Advisory Notes, e-mail, and web site updates.

4.0 PROGRESS IN IMPLEMENTING THE RECOMMENDATIONS: BY CONSULTATION THEME

4.1 Theme 1: Improving the Environmental and Health Assessments for New Substances

Recommendations under Theme 1, Improving the Environmental and Health Assessments for New Substances, involve regulatory and program matters associated with various aspects of the assessment of environmental and human health risks. They concern the clarity of guidance for requiring additional information for the risk assessment, incorporation of endocrine disrupting substance (EDS) considerations, data requirements, the occupational work environment, waiver requests, Good Laboratory Practice (GLP), toxicity testing using animals, improved characterization of exposure, and the evaluation and validation of data and data quality.

Status and Next Steps

Endocrine Disrupting Substances (EDSs)

The departments continue to evaluate new commercially available modelling software as tools for estimating a substance's potential for binding to estrogen receptors and hence signalling a possible relationship to endocrine disruption.

Next steps: The departments have purchased an advanced EDS Analogs Database for their use. They will continue to evaluate relevant tools as they become available. More information on the Analogs Database can be obtained by contacting the NSN-Infoline (refer to Section 5.0).

Occupational Exposure Information Sharing Agreement (Intergovernmental)

A contract is under way to research opportunities for the NS Program to share relevant information (taking into

consideration confidential business information aspects) gathered under the NSNR with federal, provincial, and territorial authorities that regulate workplace health and safety.

Next steps: The departments will follow up on opportunities based on recommendations resulting from the contract research.

Process to Inform Notifiers of Potential Hazards

A draft process to inform notifiers about potential hazards about which they are unaware has been developed by Health Canada.

Next steps: The process will undergo internal and external review in early 2005 and is expected to be implemented in fiscal year 2005/06.

Exposure Template

The exposure template is being used by Environment Canada to request additional exposure information when necessary.

Next steps: Although there are no immediate plans to make its use mandatory, the exposure template will be made available on the NS Program web site, and its use will be encouraged.

Periodic Review of Assessment Reports

A consultant's report on determining a process for external periodic review of program risk assessments — *New Substances' Notification Assessments — a Possible Framework for Periodic Review* — was completed in March 2004 and will be released shortly. The report includes recommendations on frequency, process, products, information submitted, conflict of interest considerations, etc.

Next steps: Following a review of the recommendations in the external periodic review report, steps will be taken to implement a periodic external review of assessments, expected to begin in mid-fiscal year 2005/06. An Environment Canada / Health Canada focus group has been formed to carry this forward.

Class Waivers

A document outlining "class waivers" for anionic dyes meeting certain criteria was circulated for external review in June 2004. Wording describing class waivers for certain cationic polymers was incorporated into the revised Guidelines document.

Next steps: Notifiers are encouraged to nominate new classes of substances for consideration of class waivers.

Suspicion of Toxicity

A document describing how Health Canada has used the suspicion of toxicity provisions of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) during the previous decade has been prepared.

Next steps: It is anticipated that the document will be published in 2005.

Toxicity Testing Using Animals

Wording encouraging notifiers to use valid *in vitro* and alternative methods in order to reduce the use of animals in toxicity testing has been incorporated into the revised Guidelines.

Next steps: Notifiers are encouraged to take advantage of pre-notification consultation (PNC) services to discuss their use of data resulting from alternative methods.

Feasibility Study for Verification of Test Data

At this time, the departments feel that a feasibility study for verification of test data is not an efficient use of resources, since other current measures within the program are addressing the issue of data quality. The NS Program relies on many mechanisms to help ensure the quality of data submitted to the departments: evaluator professional judgment; GLP, quality assurance/quality control statement, or documentation submitted by notifier with the tests; searches of published literature and in-house databases for results of similar studies; cross-referencing study results with other data submitted in the notification; comparisons with modelled data; and development of neural networking, which helps identify erroneous data. Further consideration will be given to this recommendation if more resources become available in future years.

Requiring Additional Information

Paragraph 84(1)(c) of CEPA 1999 will be used when the departments have concerns about the hazards of a substance but are unable to quantify the risks. In these instances, the departments will prohibit manufacture pending submission of test data. Information supplied from that action should provide the departments with sufficient information to determine whether there is a suspicion of toxicity.

Next steps: The departments will continue to explore the feasibility of establishing criteria to guide the use of this

provision. Meanwhile, paragraph 84(1)(c) of CEPA 1999 will continue to be used under circumstances similar to those under which it was used in the past, as per its intended use and on a case-by-case basis.

4.2 Theme 2: The Regulatory Framework

Recommendations under Theme 2, The Regulatory Framework, largely involve changes to the NSNR themselves. These include revisions to the notification triggers, the framework for and the specification of data in schedules, special categories such as research and development (R&D), product development, site-limited intermediate and export-only substances, and assessment periods. In addition, amendments relating to record keeping and enforcement were identified.

Status and Next Steps

Significant New Activity (SNAc) Provisions

An operational policy on the use of SNAc provisions has been included in the *New Substances Program Operational Policies Manual*, which was posted on the NS Program web site in June 2004.

Flagging Polymers of Low Concern

Since October 2003, polymers of low concern (PLCs) are published on the Domestic Substances List (DSL) with a flag.

Development of the Smart System Software

The Smart System software is intended to simplify the notification and assessment of PLCs. It is, however, very costly software. The subject has been raised with the United States and other Organisation for Economic Co-operation and Development (OECD) countries to solicit interest and possible support.

Next steps: The departments will continue to work with industry and other governments on this project in 2005 in order to find a cost-effective approach.

Record-Keeping Requirements

Notifier / Canadian agent obligations with respect to record-keeping requirements have been clarified and are specified in the amended NSNR and in the revised Guidelines.

4.3 Theme 3: Transparency of the New Substances Notification Regulatory Process

Recommendations under Theme 3, Transparency of the New Substances Notification (NSN) Regulatory Process, relate primarily to transforming the NS Program into a more open and transparent operation. They include the use of plain, understandable language for the NSNR, the Guidelines, and program policy documents. 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.

Status and Next Steps

New Substances Program Operational Policies Manual

A *New Substances Program Operational Policies Manual* containing operational policies documents that describe how the NS Program operates was posted on the NS Program web site in June 2004. The manual includes policies addressing general program operations, processing of new substance notifications, risk assessment, and risk management. The manual is useful to NS Program staff, stakeholders, and the general public.

Next steps: The Manual will be updated as new operational policies are developed.

Standardized Formats for Assessment Report

Environment Canada and Health Canada have developed a draft assessment report template for chemicals, which has been sent to editors for critical review of its format. Once the final template is approved by both departments, the objective is to have it fully implemented by the end of 2005. A similar process has been initiated for polymers. The templates will be developed in a manner to ensure that confidential business information can be easily identified and removed.

Next steps: Environment Canada and Health Canada will review comments from the editors and revise the assessment report template for chemicals accordingly. Similar steps are under way for an assessment report template for polymers.

Third-Party Information and Confidential Business Information in Assessment Summaries

A procedure for handling third-party information was developed and incorporated in the *New Substances Program Operational Policies Manual*. Assessment templates that permit identification of third-party information were developed.

Next steps: The departments plan to publish a limited number of assessment report summaries in 2005/06. Options for identifying third-party confidential business information in the assessment templates have been explored. The pilot will provide information on the level of effort required to resource larger-scale publication of assessment report summaries. Industry and environmental non-governmental organizations (ENGOs) will be approached for input during the development of the draft summaries.

4.4 Theme 4: Improving Responsiveness of the *New Substances Notification Regulations* and New Substances Program in the Global Context

Recommendations under Theme 4, Improving Responsiveness of the NSNR and NS Program in the Global Context, concern a number of initiatives under way within the program relating to international cooperation, such as information and work sharing, bilateral/multilateral arrangements, and management of confidential business information.

Status and Next Steps

International Cooperation

A strategic plan relating to international regulatory and scientific cooperation was released in June 2005. Stakeholders were consulted on the strategy before it was finalized. In this strategy, Canada will work with other countries to find common ways of doing business that will improve decision-making about new chemicals and polymers in Canada and internationally.

As a result of the Canada–Australia bilateral arrangement signed in 2002, a number of teleconferences have been held to strengthen and increase understanding of the two countries' new substances assessment programs. During the period of April 1, 2004, to March 31, 2005, Canada received a total of 18 requests from Australia for assessment reports, and they have been sent to Australia, at the request of notifiers, for use by the Australian authority. The arrangement is being renewed and will be set up as an ongoing arrangement subject to a three-year review.

The NS Program is working with the U.S. Environmental Protection Agency (EPA), under the Four Corners Arrangement (4CA), to advance the Mutual Acceptance of Notifications initiative. From April 1, 2004, to March 31, 2005, Canada received a total of four 4CA submissions.

Next steps: The departments have made public their planned annual activities related to the implementation of the international strategy and will report on progress at the end of each fiscal year beginning with fiscal year 2005/06. The departments will continue to engage stakeholders in discussions on activities to be undertaken and continued in the area of international cooperation.

OECD New Chemicals Task Force

The chemical risk assessment comparison activities across jurisdictions have been completed and compiled in a document that was declassified at the OECD Joint Meeting in November 2004. From this comparison work, areas of cooperation and information sharing were identified. A greater understanding of how assessment comparisons are conducted across jurisdictions was achieved, and it was agreed that the area of hazard assessment presented the most obvious area for future cooperation.

International work sharing, with a focus on sharing of hazard assessments, will be carried out under the auspices of the newly formed Work Item A (WIA) of the New Chemicals Task Force. At the September 2004 New Chemicals Task Force meeting, the WIA work was reorganized as follows: 1) pilot phase and 2) documentation/process/procedures. The WIA Steering Group (chaired by Canada) has been formed and consists of representatives from Canada, Japan, the United States, and the Business and Industry Advisory Committee. A WIA Steering Group Meeting was held in March 2005. The WIA Steering Group presented the meeting outcome, including a proposal for work sharing at the New Chemicals Task Force meeting that was held in April 2005.

Next steps: Notifiers will be requested to identify substances for the conduct of international hazard assessments under the pilot phase. Future work under WIA will include standardization of new chemical assessment reports across jurisdictions and standardization of hazard assessments, as well as discussions

on the type of documentation that will be required by companies in order to draft the hazard assessments.

Foreign Schemes

Through international agreements and the OECD New Chemicals Task Force, the NS Program is monitoring work being done in other countries.

Next steps: Environment Canada and Health Canada will consider the addition of foreign scheme provisions to CEPA during the CEPA review process.

4.5 Theme 5: Service Delivery

Recommendations under Theme 5, Service Delivery, address operational program changes and resource considerations. These include service quality standards and delivery initiatives, performance indicators, education and training, leadership for cultural change, and innovation (e.g., an electronic filing system, the 4CA, personnel exchanges, compliance promotion activities, and assessment methods for complex hazard and risk assessment challenges).

Recommendations relating to service delivery are being implemented via operational program changes within available resources. An important initiative in this regard is the Service Delivery Improvement Strategy.

Status and Next Steps

Service Delivery Improvement Strategy

A Service Delivery Improvement Strategy was developed to guide improvements as well as to develop tools to measure stakeholder satisfaction. The strategy was communicated to industry, staff, and senior management in both departments. A notifier survey was completed in March 2004, the results of which were posted on the NS Program web site in June 2004. According to the survey results, the three priority areas for improvement to be targeted for 2005/06 include 1) web site redesign, 2) timeliness of response to notifiers' requests for information, and 3) improving response times for three types of letters (problem statement, final assessment, acknowledgment).

Next steps: The Service Delivery Improvement Initiative document will be published in 2005/06. This document will describe the process used to identify how the areas for improvement of the NS Program were chosen. Performance measurement indicators will be developed to track improvements. Progress reports will be placed on the web site on an annual basis to keep stakeholders and other interested parties informed.

Electronic Service

The NS Program web site is being redesigned and will include improved linkages. A focus group will be targeting areas for improvement of technical aspects and content, including recommendations stemming from the *New Substances Program Notifier Survey.*

Next steps: After undergoing an internal/external review, the redesigned NS Program web site will be implemented using a phased approach. Electronic filing submission will be pursued in step with the longer-term government-wide initiative to establish a secure system ensuring confidentiality of submissions.

Investigation into Co-locating NS Program Staff

A contract to investigate the co-location of NS Program staff as an option for improving program efficiency and service delivery was completed in March 2005 and has resulted in a report with recommendations. The recommendations cover both physical co-location options and virtual co-location options. The results of the investigation reinforce some of the recommendations in the final report of the multistakeholder consultations on amending the NSNR and the NS Program.

Next steps: Recommendations in the final report of the investigation into co-locating NS Program staff will be considered, taking into account priorities and feasibility. The report makes it clear that significant advantages for service delivery and program efficiency may be gained through improvements that do not require both components of the program to be in the same building. These "virtual co-location" recommendations will therefore be given priority.

Personnel Exchanges

Personnel exchange options with the U.S. EPA were investigated without success.

Next steps: The departments will remain open to opportunities for mutually beneficial personnel exchanges and will engage in them when feasible.

Science Capacity

Work is under way to address areas in the risk assessment process that require refinement and to provide an overview of tools that are intended to increase

effectiveness and reduce uncertainty in the overall risk assessment process. The areas in the risk assessment process for which scientific developmental work is currently under way are 1) hazard assessment, 2) fate assessment, 3) exposure/risk assessment, and 4) polymer-specific issues. In addition, joint initiatives with other groups to facilitate and improve the risk assessment process are elaborated. See Appendix 1 for detailed information on various projects.

Compliance Promotion

The National Compliance Promotion Working Group continues to develop compliance promotion tools. Ten information sessions on the amended NSNR were held in spring 2005.

Next steps: Compliance promotion material is being updated to reflect changes to the regulations. Information sessions will take place at the Industry Coordinating Group conference in October 2005. The National Compliance Promotion Working Group will continue to develop innovative ways to inform stakeholders about the requirements of the regulations. In doing so, they intend to involve stakeholders in the development and measurement of performance of compliance promotion activities.

5.0 FOR MORE INFORMATION

This document constitutes the final formal report on the progress of implementing the multistakeholder consultation recommendations. Efforts to address any outstanding or partially completed recommendations will continue, since Environment Canada and Health Canada have a continued commitment to pursue the implementation of all recommendations as per the Environment Canada / Health Canada response document.

This report will be made available on the NS program web site at **www.ec.gc.ca/substances/**.

Comments and questions regarding the implementation of the consultation recommendations and this progress report can be addressed to:

NSN-Infoline
Notification and Client Services Division
New Substances Branch
Environmental Protection Service
Environment Canada
Place Vincent Massey, 14th Floor
Gatineau, QC K1A 0H3
Phone: (800) 567-1999 (toll-free in Canada)
(819) 953-7156 (outside of Canada)
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E-mail: nsn-infoline@ec.gc.ca

APPENDIX 1: SCIENCE CAPACITY

The New Chemicals Evaluation Division of Environment Canada is responsible for conducting environmental risk assessments under CEPA 1999 for new substances introduced in the Canadian marketplace. The assessment of potential health risks to the general population associated with new substances is carried out by the New Substances Assessment and Control Bureau of Health Canada. A Science Strategy was created to address areas in the risk assessment process that require refinement and to provide an overview of tools that are intended to increase effectiveness and reduce uncertainty in the overall risk assessment process. The areas in the risk assessment process for which scientific developmental work is currently under way are 1) hazard assessment, 2) fate assessment, 3) exposure/risk assessment, and 4) polymer-specific issues. In addition, joint initiatives with other groups to facilitate and improve the risk assessment process are elaborated.

Hazard Assessment

In the area of hazard assessment, Environment Canada has developed "Green Sheets" (an ecotoxicity study scoring and ranking tool), which include provisions for assessing the adequacy of experimental ecotoxicity studies that have been collected under the NSNR since 1994. Green Sheets incorporate the raw data of ecotoxicity studies and are envisioned to be used as supporting documentation when sharing hazard assessments with other jurisdictions. The ecotoxicity data obtained from these Green Sheets will be used to build training sets for specific categories of chemicals within an "Artificial Neural Network" system, which will also incorporate physical-chemical parameters.

In order to evaluate the effects of EDSs, OASIS software has been implemented in the risk assessment process, to predict the probability of estrogen receptor binding of new substances. Furthermore, an EDS database has been acquired to assist evaluators with the identification of new substances possessing features similar to those substances with known EDS potential.

The New Substances Assessment and Control Bureau has sponsored laboratory research projects with the Safe Environments Programme of Health Canada in the area of toxicogenomics. One such project, "the application of genomic technologies to problems in risk assessment," involves investigating the use of gene expression data to enhance our ability to extrapolate from the experimental conditions generally used in toxicology assays (e.g., high doses given to rodents or cells in culture) to the dose levels more relevant to potential human exposures.

Fate Assessment

The New Chemicals Evaluation Division is involved with the OECD Multimedia Modelling Expert Group, which is developing guidance on models for use in risk assessments. This guidance will benefit the New Chemicals Evaluation Division by facilitating the interpretation of data from multimedia models used for environmental persistence and long-range transport. In addition, joint efforts have been undertaken with the Canadian Environmental Modelling Network to produce guidance for using these models, for determining degradation half-lives, and for addressing chemical fate for various subclasses of compounds.

The OASIS/CATABOL software system has also been introduced to enable the New Chemicals Evaluation Division to model the biodegradation behaviour of a new substance, as well as to predict the structure and quantity of likely metabolites. A module of the software called OASIS POPs is a system that allows for estimation of bioaccumulation potential, taking into consideration log octanol–water partition coefficient, ionicity, and metabolism.

The New Chemicals Evaluation Division is currently sponsoring a research project called the Halogenated Macro Molecule Research Project to characterize the environmental fate and impact of halogenated substances. This work will focus on the current state of the science and will improve approaches to conducting environmental risk assessments for these substances, including brominated flame retardant polymers.

With respect to food chain assessments, a screening wildlife exposure model has been developed that can be used to assess the potential effects of new substances. The incorporation of food chain assessments and multimedia work in the evaluation process will contribute to improving

the efficiency of assessment methods as well as sound decision-making in the risk assessment process.

Exposure/Risk Assessment

Several emission scenario documents under the OECD Environmental Exposure Assessment Task Force, which Canada is chairing, have been developed. Additional spreadsheets have been developed in-house with the objective of improving upon release estimates from industrial processes, refining predicted environmental concentrations (PECs), and overall risk assessments.

The development of a sludge amended soil fate and exposure model is currently under way with the Canadian Environmental Modelling Network to address the potential for impact to terrestrial environments from sewage sludge applied to agricultural lands. This is of particular importance for very persistent and very bioaccumulative new substances.

ChemSim is another tool under development that allows evaluators to estimate PECs and refine risk assessments. The Existing Substances Branch is currently leading this initiative, along with new chemicals groups from Environment Canada and Health Canada. ChemSim allows the user access to integrated information data banks, identifies Canadian industry and sewage treatment plant locations, and is designed to estimate the dispersion, fate, and environmental concentration of a substance released to a watercourse.

The New Substances Assessment and Control Bureau has ongoing collaboration with the Safe Environments Programme in the development of quantitative structure–activity relationship / quantitative structure–pharmacokinetic relationship methods to predict dermal absorption. This work will improve our ability to quantify potential exposure and risk of new substances for which dermal contact is expected to be a significant route of potential exposure for the general population. The New Substances Assessment and Control Bureau has also developed an in-house spreadsheet tool incorporating permeability constant estimation models available from the open literature for calculating potential human dermal exposure arising from various scenarios.

Polymer-Specific Issues

The *NSN Technical Guidance Series* has been developed in an effort to assist notifiers responsible for complying with the upcoming amended NSNR with issues related to data interpretation. Documents in this series are intended to provide detailed guidance on various topics. Under the guidance of the Polymer Working Group, six technical guidance documents will be developed, including 1) Reaction Schemes (draft document has been circulated to the Industry Coordinating Group for comment), 2) Water Availability (under development), 3) Partition Coefficient, 4) Biodegradation, 5) Hydrolysis, and 6) Ecotoxicity.

APPENDIX 2: CONSULTATIONS ON AMENDING THE *NEW SUBSTANCES NOTIFICATION REGULATIONS* PROGRAM AND THE NEW SUBSTANCES PROGRAM: ENVIRONMENT CANADA / HEALTH CANADA PROGRESS ON IMPLEMENTING CONSULTATION RECOMMENDATIONS FOR THE PERIOD OCTOBER 2003 TO JUNE 2005

THEME 1: IMPROVING THE ENVIRONMENTAL AND HEALTH ASSESSMENTS FOR NEW SUBSTANCES		
RECOMMENDATION	**ENVIRONMENT CANADA / HEALTH CANADA RESPONSE**	**COMMENTS**
Principles and Policies Affecting the Assessment and Management of New Substances		
(i) Pollution Prevention		
No specific recommendations were made in this section.		N/A
(ii) The Precautionary Principle		
No specific recommendations were made in this section.		N/A
(iii) Toxic Substances Management Policy (TSMP)		
1. Points of clarification should be summarized and included in the document *TSMP - 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.	The document will be finalized in 2005. A summary will be posted on the NS Program web site.
Adequacy of the Risk Assessment Methodology		
No specific recommendations were made in this section.		N/A
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 1999 that can be used for this purpose.	The departments have sought legal advice. Paragraph 84(1)(c) of CEPA 1999 will continue to be used as per its intended use and on a case-by-case basis, i.e., when the departments have concerns about the hazards of a substance but are unable to quantify the risks.
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 Standard Operating Procedures for evaluators, by summer 2003.	The departments will continue to explore the feasibility of establishing criteria to guide the use of this provision.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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 (five natural resource departments) Working Group and of the OECD Test Guidelines Program and to press for timely results.	Ongoing. National communications regarding EDSs are being maintained.
5. As internationally accepted, validated screening and testing protocols become available that are suitable for a new substance 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 NSNR.	Once suitable test protocols are available, the departments will initiate amendments to incorporate them within the NS Program by the most appropriate mechanism.	A regulatory framework will be developed once tests become available.
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 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 paragraph 84(1)(c) of CEPA 1999 will be made as validated test procedures are determined. Lastly, the section 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.	The departments have purchased an advanced EDS Analogs Database for their use. The departments continue to evaluate new commercially available modelling software as tools for estimating a substance's potential for binding to estrogen receptors. More information on the Analogs Database can be obtained by contacting the NSN-Infoline (see Section 5.0 of the report).

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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 Committee on Environmental and Occupational Health (CEOH) and through direct discussion with the provinces.	A contract in under way to research opportunities for the NS Program to share relevant information (taking into consideration confidential business information aspects) gathered under the NSNR with federal, provincial, and territorial authorities that regulate workplace health and safety. Progress on implementing this recommendation will depend on the outcome of the discussions with other authorities.
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 NSNR assessment.	A draft process to inform notifiers about potential hazards about which they are unaware has been developed by Health Canada. The process will undergo internal and external review in early 2005 and is expected to be implemented in 2005/06.
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.	See comments for recommendations 7 and 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.	The recommendation has been incorporated into the draft revised Guidelines.
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 1999.)	See response to recommendation 7.	See comments for recommendation 7.
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.	See comments for recommendation 7.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
13. Health Canada should facilitate a multi-stakeholder 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 NSNR will be assessed for risks associated with the occupational environment; • 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.	See comments for recommendation 7.
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 NSNR and, in combination with recommendations under Theme 2, when the data should be notified.	The recommendation has been incorporated into the draft amended NSNR.
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 PNC 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, they could be required under paragraph 84(1)(c) and subsection 84(2) of CEPA 1999.	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.	Text on "Other Technical Information" was developed and inserted in the draft revised Guidelines.
16. The NSN Guidelines should be referenced in the NSNR. 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.	The intent is to release the revised Guidelines at the same time as the promulgation of the amended NSNR. It is not possible to reference the Guidelines in the NSNR. However, information about their availability will be distributed with the regulations.
17. The NSNR should contain the information in Table 3.1 in the Final Report for chemicals and polymers.	See response to recommendation 14.	The recommendation has been incorporated into the draft amended NSNR.
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	The recommendation has been incorporated into the draft revised Guidelines.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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.	The recommendation has been incorporated into the draft revised Guidelines.
(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.	A draft document outlining "class waivers" for anionic dyes meeting certain criteria was circulated to external stakeholders for review and comment in June 2004. Wording describing class waivers for certain cationic polymers was incorporated into the revised Guidelines document. Notifiers are encouraged to nominate new classes of substances for consideration of class waivers.
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.	The recommendation has been incorporated into the draft revised Guidelines. An Advisory Note was released.
(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 NSNR to reflect the shift to mandatory compliance for toxicological and biodegradation studies.	The recommendation has been incorporated into the draft amended NSNR.
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 NSNR 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.	The recommendation has been incorporated into the draft amended NSNR.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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.	The recommendation has been incorporated into the draft amended NSNR.
(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.	Ongoing.
26. Alternative methods, once validated, should be available for use for the assessment of new substances under the NSNR. 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 NSNR. 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.	Ongoing. Wording encouraging notifiers to use valid *in vitro* and alternative methods in order to reduce the use of animals in toxicity testing has been incorporated into the revised Guidelines.
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. PNCs 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 PNC services to discuss their use of data resulting from alternative methods.	Ongoing. Internal time frames for responding to PNCs were established (e.g., within a period equivalent to the appropriate assessment period for a substance).
(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.	The exposure template was developed with input from industry and has been incorporated into the NSN form. It is being used by Environment Canada to request additional exposure information when necessary. It will be made available on Environment Canada's web site.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
29. The obligatory exposure information required by the regulations should be incorporated into a template.	See response to recommendation 28.	See comment for 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.	See comment for recommendation 28.
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.	A contract to determine a process for external periodic review of program risk assessments resulted in a report in March 2004 (New Substances' Notification Assessments — A Possible Framework for Periodic Review) with recommendations on frequency, process, products, information submitted, conflict of interest considerations, etc. The report will be released shortly. Implementation of the external review of program risk assessments is targeted for mid fiscal year 2005/06.
(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 NSNR.	At this time, the departments feel that a feasibility study for verification of test data is not an efficient use of resources, since other current measures within the program are addressing the issue of data quality.
THEME 2: THE REGULATORY FRAMEWORK		
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 NSNR.	The recommendation has been incorporated into the draft amended NSNR.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
(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.	The recommendation has been incorporated into the draft amended NSNR.
(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 NSNR are necessary to increase information requirements for NDSL substances (Schedule 3), the initial update cannot be published until the amended NSNR are promulgated. In the interim, the departments are willing to meet with industry to discuss how this issue can be temporarily addressed.	The Program has taken appropriate steps to accommodate the annual updates (based on the TSCA Inventory of the previous year) of the NDSL, which will begin once the amended NSNR have been implemented.
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 will be incorporated into the drafting instructions and into the amended NSNR. The Guidelines will also be revised to reflect the new framework and the information required at each tier.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.
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.	See comment for recommendation 3.
38. Health Canada and Environment Canada should utilize 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 subsection 69(2).	An operational policy on the use of the SNAc provision has been included in the *New Substances Program Operational Policies Manual,* which was posted on the NS Program web site in June 2004.

[*] 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	COMMENTS
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 1999.	Ongoing.
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.	PLCs have been published on the DSL with flags since October 22, 2003.
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.	The Smart System software is very costly. The departments have approached the United States and other OECD countries to solicit interest and possible support and will continue to work with industry and other governments on this project in 2005 in order to find a cost-effective approach.
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 NSNR. Furthermore, revising trigger volumes and schedules associated with these non-commercial activities is considered appropriate.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines. It has also been promoted within the OECD for use by other jurisdictions.
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.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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.	No action necessary.
45. Prior to exceeding 1000 kg/year, the following data will be required: • chemical name • trade names • Chemical Abstracts Service registry number • Material Safety Data Sheet • 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.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.
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. 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 1999 (subsection 81(11)).	See response to recommendation 42.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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 • Chemical Abstracts Service registry number • Material Safety Data Sheet • 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)* • 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.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.
(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.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.
49. A process should be initiated to explore mechanisms that enable utilization of the "prescribed purposes" portion as defined in paragraph 81(8)(b) of CEPA 1999 to special categories.	The Table expressed its view that mechanisms that enable the application of the "prescribed purposes" portion of paragraph 81(8)(b) of CEPA 1999 to special categories should be explored and the term "purpose" defined or replaced within CEPA 1999. 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.	This question will be considered during the CEPA 1999 review.

* 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	COMMENTS
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.	The recommendation has been incorporated into the draft amended NSNR.
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 NSNR.	See response to recommendation 50.	The recommendation has been incorporated into the draft amended NSNR.
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 NSNR to incorporate the assessment periods recommended by the Table.	The recommendation has been incorporated into the draft amended NSNR and the draft revised Guidelines.
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 1999 for early termination 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.	An operational policy document was included in the *New Substances Program Operational Policies Manual,* which is available on the NS Program web site.
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, and the early termination provisions may be applied. In the longer term, the possibility of reducing the regulatory assessment period for PLCs will be examined.	The Smart System software is very costly. The departments have approached the United States and other OECD countries to solicit interest and possible support and will continue to work with industry and other governments on this project in 2005 in order to find a cost-effective approach.
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 paragraph 81(8)(b). Regulations under the authority of paragraph 89(1)(f) should be drafted at the same time as the revised NSNR.	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 NSNR.	Linked to completion of recommendation 49.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
Record Keeping and Enforcement		
56. The revised NSNR 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 NSNR and associated sections of the Guidelines will be revised to clarify notifier / Canadian agent obligations with respect to record-keeping requirements.	Notifier / Canadian agent obligations with respect to record-keeping requirements have been clarified and are specified in the amended NSNR and in the revised Guidelines.
57. The revised NSN Guidelines should clarify the type of information the notifier must maintain.	See response to recommendation 56.	Notifier / Canadian agent obligations with respect to record-keeping requirements have been clarified and are specified in the amended NSNR and in the revised Guidelines.
THEME 3: TRANSPARENCY OF THE NSN REGULATORY PROCESS		
NSN Information – Regulations, Guidelines and Policy Documents		
(i) Improving Transparency of NSN Regulations and Guidelines		
58. The NSNR 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 NSNR 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.	The draft amended NSNR have been written using plain language principles.
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 online 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.	There have been consultations with stakeholders to ensure that the guidelines are written in a clear language. Illustrative case studies will be developed on an as-needed basis.
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.	The NS Program web site is being redesigned and will include improved linkages.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
61. The NS Program 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 NS Program web site in a timely manner.	The NS Program web site is being redesigned and will include improved linkages.
(ii) 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 to 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 1999 (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 1999 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 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 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.	The *New Substances Program Operational Policies Manual* was posted on the NS Program web site in June 2004. Publishing of Program statistics will be factored in to a larger project regarding annual reporting online.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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 implementation 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.	A procedure for handling third-party information was developed and incorporated in the *New Substances Program Operational Policies Manual.* Assessment templates that permit identification of third-party information were developed. Options have been discussed pertaining to the most effective approach for identifying third-party information. The assessment templates and options have been sent to an editor for comment and will be revised accordingly. Similar steps are under way for an assessment report template for polymers. The templates will be developed in a manner to ensure that confidential business information can be easily identified and removed.
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.	Current plans are to pilot, in 2005/06, the publication of five summaries for substances destined for the DSL. The pilot will provide information on the level of effort required to resource larger-scale publication of assessment summaries. Industry and ENGOs will be approached for input during the development of the draft summaries.
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 1999.	The issue of appeal mechanisms will be considered during CEPA 1999 review.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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 release a report by the end of 2005.	A strategic plan relating to international regulatory and scientific cooperation was released in June 2005. The departments have made public a list of planned annual activities related to the implementation of the international strategy and will report on progress at the end of each fiscal year beginning with fiscal year 2005/06.
THEME 5: SERVICE DELIVERY		
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.	A Service Delivery Improvement Strategy was developed to guide improvements as well as to develop tools to measure stakeholder satisfaction.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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).	The results of a notifier survey (completed in March 2004) were posted on the NS Program web site in June 2004. Performance measurement indicators will be developed according to the results of the survey, to track improvements.
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 revised regulations are nearing completion, to identify opportunities for mutually beneficial personnel exchanges.	Personnel exchange options with the U.S. EPA were investigated without success. The departments will remain open to opportunities for mutually beneficial personnel exchanges and will engage in them when feasible.
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.	A Service Delivery Improvement Strategy was developed and communicated to industry, staff, and senior management in both departments.
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.	A contract to investigate the co-location of NS Program staff was completed in March 2005 and has resulted in a report with recommendations that will be considered, taking into account priorities and feasibility. "Virtual co-location" recommendations will be given priority. An Options Analysis is in process with regard to the regulatory framework for environmental assessment of *Food and Drugs Act* substances. The option chosen will determine the notification procedures over the long term.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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, to be held in Ottawa in October 2002, will be considered as part of the path forward for development of electronic filing submission systems.	Electronic filing submission will be pursued in step with the longer-term government-wide initiative to establish a secure system ensuring confidentiality of submissions.
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 Arrangement, the impending Canada–Australia arrangement, and the OECD new chemicals multilateral exercise.	Canada continues to be actively involved in the OECD New Chemicals Task Force and in initiatives under bilateral arrangements with the United States and Australia. Bilateral arrangements with Australia and the United States, including aspects such as harmonization of assessment templates, methodologies, hazard assessments, and other joint undertakings, are within the scope of Environment Canada's and Health Canada's International Strategy. Furthermore, these initiatives reflect the direction of work under the OECD New Chemicals Task Force, which includes the implementation of the Parallel Process.
74. Opportunities for secondments among government and stakeholders should be explored and pursued where mutually beneficial.	Discussions with industry will be initiated when the revised regulations are nearing completion, to identify opportunities for mutually beneficial personnel exchanges.	The departments will remain open to opportunities for mutually beneficial personnel exchanges and will engage in them when feasible.
75. Government should work with stakeholders to examine innovative measures for ensuring compliance with the NSNR.	For compliance promotion activities, the departments have already started to consider the involvement of stakeholders in compliance promotion projects.	Ongoing. The National Compliance Promotion Working Group continues to develop compliance promotion tools. Ten information sessions on the amended NSNR were held in spring 2005.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
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.	Ongoing. The departments continue to participate in areas in the risk assessment process that require refinement and to provide an overview of tools that are intended to increase effectiveness and reduce uncertainty in the overall risk assessment process. The areas in the risk assessment process for which scientific developmental work is currently under way are 1) hazard assessment, 2) fate assessment, 3) exposure/risk assessment, and 4) polymer-specific issues. In addition, joint initiatives with other groups to facilitate and improve the risk assessment process are elaborated.