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

Report on Progress: Implementing the Consultation Recommendations For Period Ending October 2003

Pursuant to the
New Substances Notification Regulations
of the
Canadian Environmental Protection Act, 1999

November 2003 – EPS M-514

Canada

Government of Canada Gouvernement du Canada

National Library of Canada cataloguing in publication data

Main entry under title:

Consultations on the CEPA *New Substances Notification Regulations* and New Substances Program (chemicals and polymers portion) : Report on progress : implementing the Consultation recommendations for period ending October 2003

(Information report; EPS M-514)
Text in English and French on inverted pages.
Title on added t.p.: Consultations au sujet du *Règlement sur les renseignements concernant les substances nouvelles* de la LCPE et du Programme des substances nouvelles (produits chimiques et polymères).
Co-published by Health Canada.
ISBN 0-662-67920-2
Cat. no. En49-17/514

1. Chemicals – Law and legislation – Canada.
2. Toxicity testing – Canada.
3. Hazardous substances – Risk assessment – Canada.
4. Pollutants – Government policy – Canada.
5. Polymers – Toxicology.
6. Pollution – Environmental aspects.
I. Canada. Environment Canada.
II. Canada. Health Canada.
III. Series: Information report (Canada. Environment Canada); EPS M-514.

TD196.C45C65 2004 344.71'04633 C2004-980020-5E

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.

TABLE OF CONTENTS

FOREWORD

This report is the first attempt made by the New Substances Program at conveying to all stakeholders the progress made in implementing the recommendations resulting from the multistakeholder consultations on amending the *New Substances Notification Regulations* and the New Substances Program. It is hoped that this report is informative and helpful to its readers. Comments and questions are welcome and can be sent 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)
Fax: (819) 953-7155
E-mail: nsn-infoline@ec.gc.ca

1.0 INTRODUCTION

This is the first report on the progress being made in implementing the 76 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.

The *Final Report of the Multistakeholder Consultations* and the *Environment Canada/Health Canada Response to the Consultation Recommendations* 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 New Substances Website at **www.ec.gc.ca/substances/**

The purpose of the progress report is to keep stakeholders and other interested parties informed of the status of the changes that are being made, based on the recommendations, to the NSNR and the NS Program over the next several years. The report 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 NSN Regulatory Process;
- Theme 4: Improving Responsiveness of the NSN Regulations 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 1, where progress is presented in tabular format, on a recommendation-by-recommendation basis.

2.0 HIGHLIGHTS

Implementation of recommendations resulting from the multistakeholder consultations is well underway. Some of the highlights on progress made to date on the implementation of various recommendations include:

- A second draft of the amended *New Substances Notification Regulations* is being prepared and will be distributed to stakeholders by the end of 2003 for a three week comment period. It is expected that the amended *New Substances Notification Regulations* will be pre-published in the *Canada Gazette*, Part I, no later than June 2004. The accompanying Guidelines are being revised to improve their usefulness and readability, in response to the recommendations and in accordance with the changes being made to the *New Substances Notification Regulations*.
- A *New Substances Program Operational Policies Manual* containing policy and procedures documents that describe how the New Substances Program operates was developed and will be published after input from stakeholders has been sought in Fall 2003. This document will be continually updated as additional policies are documented and formally approved.
- A Service Delivery Improvement Strategy is being developed, which will be based on a client expectations/satisfaction survey that will be sent out in February 2004.

3.0 OVERVIEW OF PROGRESS-REVISING THE NSNR AND GUIDELINES

Work to amend the NSNR and to revise the Guidelines has been initiated and will continue until all recommendations under the five themes have been adequately addressed.

Recommendations which are not yet underway will be initiated in accordance with the Environment Canada/Health Canada Response document.

3.1 Amending the NSNR

Environment Canada and Health Canada committed to promulgating the amended NSNR by March 31, 2005. 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

Work on the amendments to the NSNR is on track overall. Drafting instructions were completed January 2003 and were provided to Department of Justice lawyers. Meetings with drafters began in February 2003. The first proposed draft of the amended NSNR was sent to stakeholders on June 12, 2003 for a four week comment period. Many comments were received and all were evaluated. Meetings with drafters occurred in October 2003 to incorporate suggestions in the draft regulations. A second draft of the amended NSNR will be distributed to stakeholders for a three week comment period by end of 2003. For several months, discussions have been taking place with the Privy Council Office about the relevance of our process for amending the NSNR to the Smart Regulations Initiative. We are pursuing every opportunity to expedite approval and publication of consensus based changes.

Next steps: Recommendations related to regulatory changes will continue to be addressed. The departments will consult with stakeholders when appropriate. A review of the draft of the amended NSNR will take place, followed by publication in the Canada Gazette, *Part I for public comment. Once the new NSNR have been promulgated, the NDSL will be updated annually based on the TSCA Inventory from the previous year (as opposed to annually based on the TSCA five years earlier).*

3.2 Revising the Guidelines for the NSNR (Chemicals and Polymers)

Environment Canada and Health Canada intend to revise 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

Work on revising the Guidelines is on track overall. Revisions to the Guidelines have been initiated, although some of the revisions will require further consultation, particularly on the more technical aspects of the Guidelines.

Next steps: Revisions to the Guidelines will be drafted, until all topics have been adequately addressed. Stakeholder input to the Guidelines will be sought, and final publication will occur after promulgation of the amended NSNR. The departments will, in the meantime, continue to communicate guidance to notifiers through the Hotline, 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 (EDSs) considerations, data requirements, the occupational work environment, waiver requests, Good Laboratory Practice, 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)

An in-house EDS Analogs Database has been completed. The database is used to identify whether new substances have structural similarities to substances with known EDS potential. In addition, new commercially available modeling software is being evaluated as tools for estimating a substance's potential for binding to estrogen receptors, and hence signaling a possible relationship to endocrine disruption.

Occupational Exposure Information Sharing Agreement (Intergovernmental)

Preliminary discussions with provincial government representatives regarding occupational exposure were initiated in 2003 by Health Canada.

Next steps: Will depend on the outcome of the discussions.

Process to Inform Notifiers of Potential Hazards

A process to communicate with notifiers about potential hazards about which they are unaware, is being developed by Health Canada.

Next steps: The communication process will be finalized.

Toxic Substances Management Policy

Though it was drafted and finalized following several stakeholder comment periods, the Implementation Strategy for New Substances is being re-examined in light of obligations incorporated in the Stockholm Protocol.

Next steps: Once the internal evaluation is completed and any potential amendments are identified, stakeholders will be asked again to comment if necessary.

Exposure Template

The exposure template was developed with input from industry. It is being used by some notifiers and is included with their notifications. It is also being used by Environment Canada to request additional exposure information when necessary.

Next steps: The exposure template is undergoing further development and review by industry. Although there are no immediate plans to make its use mandatory, the exposure template will be made available on the New Substances website.

Peer Review of Assessment Data

A contract through Health Canada is underway to determine a process for external peer review of program risk assessments. The resulting report, expected in Fall 2003, will make recommendations on a process of external review, and will include recommendations on frequency, process, products, information submitted, conflict of interest considerations, etc.

Next steps: Following a review of the recommendations in the external peer review report, steps will be taken to implement a periodic external review, expected to begin in 2004.

Class Waivers

A document outlining "class waivers" for acid dyes meeting certain criteria has been drafted. Amendments that incorporate this class waiver are already being factored into the regulatory amendments.

Next steps: The draft document for "class waivers" for acid dyes will be circulated by end of 2003 to external stakeholders (e.g. other regulatory agencies, Industry) for review and comment.

Suspicion of Toxicity

A draft document describing how Health Canada has interpreted the suspicion of toxicity provisions of CEPA has been prepared.

Next steps: An internal review will occur by end of 2003, followed by external comment before being published.

Feasibility Study for Verification of Test Data

Terms of Reference for a contract to carry out a feasibility study for a government-funded process to verify test data submitted to the program are being developed.

Next Steps: A contractor will be hired in early 2004 to undertake this study to examine other government-funded processes to verify submitted test data that exist elsewhere and to recommend whether any such processes would be appropriate for the NS Program.

Requiring Additional Information

Clarification is currently being sought on the use of section 84 of CEPA 1999 to require additional information when the prescribed information suggests a suspicion of toxicity, but is considered insufficient to adequately characterize the risk.

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 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

Entry-level Volume Trigger and Cumulative and In-Possession Triggers

The recommendations pertaining to the entry-level volume trigger and the elimination of cumulative and in-possession triggers have been incorporated in the draft amended NSNR.

NSNR Framework, Special Categories, and Assessment Periods

Changes to the framework for the NSNR, to R&D substances and product development substances, to site-limited intermediate substances and export-only substances, and to assessment periods, have been incorporated into the draft amended NSNR as per the consultation recommendations.

SNAc Provisions

An internal consultation was held to develop guidelines for the use of SNAc provisions.

Next steps: A preliminary guidance document for the use of SNAc provisions is being finalized and distributed to program personnel for their use. This guidance document will form the basis of a public document expected to be completed and included in the New Substances Program Operational Policies Manual *in late Fall 2003.*

Flagging Polymers of Low Concern

A mechanism for listing polymers of low concern on the DSL has been developed, as well as a specific definition, based on the existing regulatory criteria, for polymers of low concern which will be published in the *Canada Gazette*, Part II. The first DSL amendment was published on October 22nd using this mechanism.

Next steps: An Advisory Note regarding the DSL polymers of low concern flagging mechanism will be drafted and published.

Early Termination of Assessments

An operational policy document has been drafted and will be incorporated into the *New Substances Program Operational Policies Manual.*

Smart Tool

The Smart Tool is intended to simplify the notification and assessment of low concern polymers. Funding and resources for this project are currently being explored. The subject has been raised with the U.S. and other OECD countries to solicit interest and possible support.

Record-keeping Requirements

The Departments will clarify notifier/Canadian agent obligations with respect to record-keeping requirements and incorporate the changes in the amended NSNR and Guidelines.

4.3 Theme 3: Transparency of the NSN Regulatory Process

Theme 3, Transparency of the NSN Regulatory Process, recommendations 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 New Substances Program operates has been prepared. The manual includes policies addressing general program operations, processing of New Substance Notifications, risk assessment, and risk management. The manual will be continually updated and will be useful to New Substances Program staff, stakeholders, and the general public.

Next steps: The New Substances Program Operational Policies Manual *will be published after input from stakeholders has been sought in Fall 2003. The Manual will be updated as new operational policies are developed.*

Standardized Formats for Assessment Report

Under the OECD New Chemicals Task Force, various governments are working toward establishing a standard format for risk assessment reports, by using an Australian assessment template as a starting point. Discussions have centered on organizational structure and essential template elements. The Working Group has developed an organizational structure of headings and subheadings for risk assessment reports. The proposed structure was put forward to the Task Force for review and discussion in October 2003.

A pilot project was initiated for Health Canada's revised assessment report format for new chemicals' use.

Next steps: A review of the results of the pilot project will occur in December 2003.

Progress Reports

Progress reports for the implementation of the consultation recommendations, such as this current document, will continue to be issued regularly.

Third Party Information and Confidential Business Information

A draft document for the handling of third party information has been prepared. Assessment templates are being developed to provide the notifier/public with assessment summaries that do not contain Confidential Business Information.

4.4 Theme 4: Improving Responsiveness of the NSN Regulations and NS Program in the Global Context

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

Status and Next Steps

International Cooperation

A strategic plan relating to international regulatory and scientific cooperation is being developed, and will be finalized by early 2004, after stakeholders have been consulted. In following the 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.

Next steps: The Departments intend to seek stakeholder perspectives on a draft strategic plan, to amend the plan as appropriate and to make it public. The departments will review progress on implementation of the plan and will release a report by the end of 2005.

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 (for example, an electronic filing system, the Four Corners Agreement, personnel exchanges,

compliance promotion activities, and assessment methods for complex hazard and risk assessment challenges).

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

Status and Next Steps

Service Delivery Improvement Strategy

A Service Delivery Improvement Strategy is being developed to guide improvements, as well as develop tools to measure stakeholder satisfaction.

Next steps: The Strategy will be communicated to senior management in both Environment Canada and Health Canada as well as stakeholders in Spring 2004. Work on recommendations relating to Information Technology will continue, including feasibility of the Smart Tool and development of electronic filing tracking. The departments intend to issue public progress reports such as this one on a regular basis to keep stakeholders and other interested parties informed.

OECD New Chemicals Task Force

The New Substances Program is leading the OECD new chemicals task force. With respect to information sharing activities, following an initial comparison study of assessments conducted by a number of jurisdictions, a second comparison round is underway. Currently, assessment reports on chemicals of higher hazard are being exchanged. The objective is to build on the knowledge gained from the initial comparisons and to understand the risk assessment decision-making process of other jurisdictions. This work may facilitate future sharing between jurisdictions of data, decisions and work.

Next steps: A consensus document on the comparative study for information sharing activities will be developed and discussed at an OECD workshop in Spring 2004.

Science Capacity

With respect to hazard assessments, opportunities for harmonizing approaches to reporting effects data are being explored with other governments.

Next steps: Future work for hazard assessments will include evaluating chemical hazard report summaries from various countries and will involve identifying essential elements of a hazard report. Depending on the outcome, this work may lead to sharing hazard reports between various OECD jurisdictions.

Compliance Promotion

The National Compliance Promotion group continues to make progress with respect to projects they identified and for which resources have been secured.

Service / Performance Indicators

A client expectations/satisfaction survey is being developed.

Next steps: The survey will be distributed in February 2004.

5.0 FOR MORE INFORMATION

Environment Canada and Health Canada have a continued commitment to pursuing the implementation of all recommendations as per the Environment Canada / Health Canada Response document.

Regular reports on the progress of implementing the consultation recommendations will be issued. The reports will be made available on the New Substances website 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)
Fax: (819) 953-7155
E-mail: nsn-infoline@ec.gc.ca

APPENDIX 1: CONSULTATIONS ON AMENDING THE *NEW SUBSTANCES NOTIFICATION REGULATIONS* AND THE NEW SUBSTANCES PROGRAM: ENVIRONMENT CANADA / HEALTH CANADA PROGRESS ON IMPLEMENTING CONSULTATION RECOMMENDATIONS FOR PERIOD ENDING OCTOBER 2003

3.1 THEME 1 - IMPROVING THE ENVIRONMENTAL AND HEALTH ASSESSMENTS FOR NEW SUBSTANCES

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
3.1.1 Principles and Policies Affecting the Assessment and Management of New Substances		
(i) Pollution Prevention		
No specific recommendations were made in this section.		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 implementation strategy for new substances is being re-examined in light of obligations incorporated in the Stockholm Protocol. Stakeholders may be asked again to comment if necessary.
3.1.2 Adequacy of the Risk Assessment Methodology		
No specific recommendations were made in this section.		N/A
3.1.3 Mechanism for Requiring Additional Information for the Risk Assessment		
2. The next review of CEPA should clarify the authority for regulators to require additional information when the prescribed information suggests a suspicion of toxicity, but is considered insufficient to adequately characterize the risk.	The departments will seek legal advice to confirm that section 84 can be used as suggested by the Table. At the same time, the Department of Justice will be asked whether there are any other existing or new mechanisms within CEPA that can be used for this purpose.	No progress to report.
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.	No progress to report.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
3.1.4 Endocrine Disrupting Substances (EDSs)		
4. Environment Canada and Health Canada must continue to work diligently with stakeholders nationally and internationally to develop internationally accepted, validated screening and testing protocols to assess new substances for endocrine disruption potential.	The departments will continue to support the initiatives of the 5NR Working Group and of the OECD Test Guidelines Program and to press for timely results.	Ongoing.
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	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 addressed 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 (SARs) become accessible, they will be used appropriately in the assessment process. Furthermore, where this information leads to a suspicion of toxicity, appropriate control measures will be imposed, or requests for further test data under section 84(1)(c) of CEPA will be made as validated test procedures are determined. Lastly, the section 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 analogs 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.	An in-house EDS Analogs Database has been completed. In addition, an estrogen binding affinity predictive software was put in place in early 2002.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
3.1.5 Occupational Exposure		
7. If Health Canada has information on a hazard pertaining to a notified substance, there is an obligation for Health Canada to share that information with the Canadian agency or agencies that have jurisdictional authority over the workplace. A protocol or process must be identified or developed to share information. The notifier should also be informed. This is consistent with the overriding obligation of due diligence. Health Canada must identify who should receive the information at the time Health Canada identifies the hazard and the specific information.	The departments will initiate discussions by the end of 2002 to define the information-sharing arrangements that should be put into place at the federal level and with provinces. This will be done through the federal/provincial CEOH and through direct discussion with the provinces.	Preliminary discussions with provincial government representatives were initiated in 2003.
8. If Health Canada has information on a hazard pertaining to a notified substance that is not known by the notifier of the substance, there is an obligation for Health Canada to share that information with the notifier.	Health Canada is working towards the development of an effective and efficient process for informing relevant agencies and notifiers of hazards identified during the course of an NSN Regulations assessment.	Health Canada developed first draft of letter to notifiers to inform of hazard. The next version of the letter will be completed by the end of 2003.
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 recommendation 8.
10. The Guidelines should be revised to specify the information "which the notifier has in their possession or might reasonably have access to" that will be required of the notifier (when submitting their notification) with respect to any occupational hazards associated with the notified substance. There is a recognition that for truly new substances, this data set will not normally be available or easily accessed.	The Guidelines will be revised accordingly.	The recommendation will be 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.)	See response to recommendation 7.	Not yet initiated.
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 multistakeholder consultation in relation to new substances in the occupational environment. Among other things, this consultation should identify ways in which: • new substances notified under the NSN Regulations will be assessed for risks associated with the occupational environment; • 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.	Not yet initiated.
3.1.6 Data Requirements		
(i) Suite of Data Requirements for Chemicals and Polymers		
14. Only the information elements that have wide applicability in assessing substances and have internationally accepted test protocols should be included in the Regulations.	The departments are supportive of the data that were identified by the Table for inclusion in the NSN Regulations and, in combination with recommendations under Theme 2, when the data should be notified.	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 pre-notification consultation where these issues could be discussed. If the Program believes these data are necessary for the assessment and the data are not forthcoming from the notifier, they could be required under sections 84(1)(c) and 84(2) of CEPA.	The departments are supportive of the need to elaborate in the Guidelines what additional data may be necessary and under what circumstances they should be generated.	Industry has been approached to review summary documents, which will eventually be incorporated in the Guidelines.
16. The NSN Guidelines should be referenced in the NSN Regulations. The revised Guidelines will be developed by governments and industry representatives. All stakeholders should be given the opportunity to comment on the revised Guidelines.	Implementation of these recommendations will be pursued within the timelines described for renewal of the Guidelines and will be done in cooperation with a multistakeholder Working Group.	Revisions to Guidelines are on track overall, and stakeholders will be given the opportunity to comment before they are finalized. It is not feasible to reference the Guidelines in the NSN Regulations.
17. The NSN Regulations should contain the information in Table 3.1 in the Final Report for chemicals and polymers.	See response to recommendation 14.	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 will be 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 will be 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 document outlining "class waivers" for acid dyes meeting certain criteria has been drafted. The draft will be circulated by end of 2003 to external stakeholders for review and comment. Industry is being encouraged to nominate other classes.
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.	No progress to report.
(iii) Good Laboratory Practice		
22. Toxicological and biodegradation studies required by the Regulations must comply with the compliance monitoring requirements of OECD Principles or the GLP Regulations of the OECD Member country in which the testing was originally performed. These studies include acute and repeated-dose mammalian toxicity studies, genotoxicity studies, skin irritation, skin sensitization, ecotoxicity studies and ready biodegradation.	The departments will amend the NSN Regulations to reflect the shift to mandatory compliance for toxicological and biodegradation studies.	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 NSN Regulations to reflect the shift to mandatory compliance for toxicological and biodegradation studies, while offering greater flexibility for testing and reporting of physical and chemical data, consistent with the recommendation.	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 NSN Regulations. It is proposed that wording to this effect should be added to the revised Guidelines.	The departments are committed to encouraging the use of revised or new protocols, as they are adopted in the OECD for data submitted under the NSN Regulations. Furthermore, through GLP and other practices, the departments will accept data generated for other purposes or in other jurisdictions, thereby eliminating the need for unnecessary duplication of testing. The Guidelines will also identify the availability of alternative, validated test protocols.	Ongoing.
27. When data developed using alternative methods are submitted for the purposes of notification, the onus will be on the notifier to demonstrate the same utility of information. Pre-notification consultations are encouraged in such situations. In addition, the government commits to setting service standards to respond to this type of request.	Notifiers will be encouraged to take advantage of pre-notification consultation services to discuss their use of data resulting from alternative methods.	Ongoing.
(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. It is being used by some notifiers, and by Environment Canada to request additional exposure information when necessary. It is undergoing further development and review by industry, and will eventually be made available on Environment Canada's website.

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.
3.1.7 Evaluation and Validation of Data Quality in the NS Program		
(i) Scrutiny by NS Program Evaluators		
31. Environment Canada should continue its periodic review, and Health Canada should initiate a practice of periodic review of its assessment reports by group(s) outside the NS Program. The methodology and results of these reviews should be made public.	In addition to the internal peer review processes utilized by the departments, Environment Canada commits to periodic, retrospective review of environmental risk assessments, as described to the Table. Health Canada will also initiate, in 2002, a similar practice of periodic review of its assessment reports by group(s) outside the NS Program. By the end of 2004, the departments will make the results of these periodic reviews available to the public.	A contract is underway to determine a process for external peer review. A final report is expected in Fall 2003. Following a review of the recommendations in the report, steps will be taken to implement a periodic external review, expected to begin in 2004.
(ii) Government Verification of Test Results		
32. Environment Canada and Health Canada should undertake a feasibility study that describes the key elements of an efficient and effective government-funded verification testing program, options and costs for implementation and an evaluation of the benefits it would bring to the other measures undertaken by the Program to address data validity. The results of this study should be made public before deciding whether to include this type of testing within the NS Program.	As part of the feasibility study recommended by the Table, the departments will review, during 2003, existing policies, programs and practices in the area of government-funded verification testing in Canada and elsewhere. The results of this review will be made public, as well as the decision whether to proceed with a cost-benefit analysis if such a program were to be implemented for the NSN Regulations.	Terms of Reference for a contract to carry out this work have been drafted. A preliminary review of existing policies, programs and practices was undertaken. A contract will be initiated in early 2004.
3.2 THEME 2 - THE REGULATORY FRAMEWORK		
3.2.1 General Discussions and Recommendations		
(i) Alternative Approach to a Tiered System		
33. An entry-level trigger for non-NDSL chemical notifications should be established at 100 kg/year.	The recommendations pertaining to the entry-level volume trigger and the elimination of cumulative and in-possession triggers will be incorporated in the drafting instructions and, subsequently, in the NSN Regulations.	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 NSN Regulations are necessary to increase information requirements for NDSL substances (Schedule 3), the initial update cannot be published until the amended NSN Regulations are promulgated. In the interim, the departments are willing to meet with industry to discuss how this issue can be temporarily addressed.	Preparations have been put in place to accommodate the annual updates of the NDSL.
3.2.2 Proposed Framework for the New Regulations		
36. The framework as outlined in the proposed framework for NDSL chemicals (Section 3.2.2(ii) of the Final Report) and the proposed framework for NDSL polymers and non-NDSL polymers with all monomers listed on the DSL/NDSL (Section 3.2.2(v) of the Final Report) should replace the current requirements for the relevant categories of substances.	The framework for each of the categories of substances identified by the Table in this theme* will be incorporated into the drafting instructions and into the amended NSN Regulations. The Guidelines will also be revised to reflect the new framework and the information required at each tier.	The recommendation has been incorporated into the draft amended NSNR. It will also be incorporated into 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.	No progress to report.
38. Health Canada and Environment Canada should utilize Significant New Activities (SNAcs) in cases where there is uncertainty that the substance may be used in a consumer application or that the 3 kg/day per site criterion may be exceeded as a result of future activities. These future activities would include multiple users and/or a variety of applications.	The departments are currently developing Guidelines for use of the SNAc provisions (section 85) and will be consulting with stakeholders as per section 69(2).	The recommended application of SNAc will be investigated to determine if it is appropriate in this instance. An internal consultation was held. A preliminary guidance document for the use of SNAc provisions is being finalized and distributed to program personnel for use and comment. This guidance document will form the basis of a public document expected to be completed in Fall 2003.

* 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.	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.	A mechanism for listing PLCs on the DSL has been developed, as well as a specific definition, based on existing regulatory criteria, for PLCs which will be published in the *Canada Gazette*, Part II. The first DSL amendment was published on October 22nd, 2003 using this mechanism. An Advisory Note regarding the new mechanism will be drafted and published.
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 subject has been raised with the U.S. and other OECD countries to solicit interest and possible support.
3.2.3 Special Categories		
(i) Research and Development and Product Development Substances		
42. The definitions for R&D and product development substances should be amalgamated to "research and development substance" as follows: "Research and development substance" means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, the primary objective of which is: a) to create or improve a product or process, or b) to determine the technical viability or performance characteristics of a product or process, or c) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials or customer trials other than test marketing, in order to modify the technical specifications in response to the performance requirements of potential customers.	The departments recognize that R&D activities in the chemical sector are important to Canada's innovation agenda. The recommended changes pertaining to R&D substances and to product development substances will reflect the consensus that an amalgamated definition is an important step towards simplification of special categories under the NSN Regulations. Furthermore, revising trigger volumes and schedules associated with these non-commercial activities is considered appropriate.	The recommendation has been incorporated into the draft amended NSNR. It will also be incorporated into 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. It will also be incorporated into 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 • CAS # • MSDS • molecular formula • structural formula • gram molecular weight • egree 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. It will also be incorporated into 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 (section 81(11)).	See response to recommendation 42.	The recommendation has been incorporated into the draft amended NSNR. It will also be incorporated into 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 • CAS # • MSDS • molecular formula • structural formula • composition of the polymer, including monomers/reactants, impurities, additives and solvents • physical state of the polymer • whether the polymer is formulated for dispersal in water • number average molecular weight and % <500 daltons and % <1000 daltons (R&D substances are exempt from this data requirement; instead, the target number average molecular weight must be indicated)* • 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. It will also be incorporated into 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. It will also be incorporated into the draft revised Guidelines.
49. A process should be initiated to explore mechanisms that enable utilization of the "prescribed purposes" portion as defined in section 81(8)(b) of CEPA to special categories.	The Table expressed its view that mechanisms that enable the use of the "prescribed purposes" portion of paragraph 81(8)(b) of CEPA to special categories should be explored and the term "purpose" defined or replaced within CEPA. Environment Canada and Health Canada intend to describe and make public by mid-2003 what these mechanisms and changes might be and how to involve stakeholders in discussions on this subject.	No progress to report.

* 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 NSN Regulations.	See response to recommendation 50.	The recommendation has been incorporated into the draft amended NSNR.
3.2.4 Assessment Periods		
52. The assessment periods as described in Table 3.5 in the Final Report should be established.	Environment Canada and Health Canada will amend the NSN Regulations to incorporate the assessment periods recommended by the Table.	The recommendation has been incorporated into the draft amended NSNR. It will also be incorporated into 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 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 has been drafted and will be included in the NS Program Operational Policies Manual that will be made public in Fall 2003.
54. In the event that the development of the "smart system" for the characterization of PLCs proves to be successful, in terms of accurately categorizing PLCs, then a reduction in the assessment period for PLCs should be examined.	The departments also intend to apply the procedures described above to PLCs. Should the "smart tool system" described in Recommendation 41 prove effective at determining the classification of a polymer (low concern versus not low concern), the efficiency gained may help in completing polymer assessments more quickly, the early termination provisions may be applied. In the longer term, the possibility of reducing the regulatory assessment period for PLCs will be examined.	Feasibility of this project is still under investigation.
3.2.5 Facilitation of Waivers for Substances Used for a Prescribed Purpose		
55. Environment Canada and Health Canada should work cooperatively with stakeholders to identify purposes of use that can be described in Regulations to facilitate requests for waivers under section 81(8)(b). Regulations under the authority of section 89(1)(f) should be drafted at the same time as the revised NSN Regulations.	The departments will initiate consultations with stakeholders in fall 2003 to identify purposes of use and/or categories of substances that are associated with negligible risk to the point where certain exposure or effect information can be systematically waived. If successful, then the departments will use the authority of paragraph 89(1)(f) to incorporate provisions to this effect in the amended NSN Regulations.	No progress to report.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
3.2.6 Record-keeping and Enforcement		
56. The revised NSN Regulations should include wording, such as that in Section 3.2.6 of the Final Report, that states the obligation of the notifier/agent to maintain in Canada, for at least five years, appropriate records that are available for inspection.	The NSN Regulations and associated sections of the Guidelines will be revised to clarify notifier/Canadian agent obligations with respect to record-keeping requirements.	Wording is currently being developed for inclusion in the amended NSNR and the revised Guidelines.
57. The revised NSN Guidelines should clarify the type of information the notifier must maintain.	See response to recommendation 56.	Wording is currently being developed for inclusion in the amended NSNR and the revised Guidelines.
3.3 THEME 3: TRANSPARENCY OF THE NSN REGULATORY PROCESS		
(i) NSN Information - Regulations, Guidelines and Policy Documents		
Improving Transparency of NSN Regulations and Guidelines		
58. The NSN Regulations should be written in plain language to ensure that all stakeholders with an interest in new substance provisions, including prospective notifiers, can understand them. Plain-language NSN Regulations will minimize notification errors. This, in turn, will reduce administrative burdens and increase efficiencies in the Program. A simplified, more intuitive structure for the Regulations will improve their clarity. A simpler structure will reduce training time for staff in both government and industry.	The departments will alert the Department of Justice to recommendations of the Table pertaining to the requests for plain-language Regulations and to the offer of certain stakeholders to provide feedback on initial drafts.	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 on-line access to illustrative case studies and risk assessment and risk management decisions for each of the case studies.	The Guidelines will be revised using plain language. This will be done with input from multistakeholder working groups comprising individuals from government and industry, followed by a public review process. As recommended, where appropriate, case studies will be used to illustrate concepts in the Guidelines and will be made available electronically on Environment Canada's web site.	Illustrative case studies for Guidelines will be developed on 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.	No progress to report.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
61. The NSN web site should be linked to other appropriate domestic and international sites such as those of the OECD, the International Labour Organization and industry associations. This initiative may best be achieved though partnerships with stakeholders.	For linkages, the departments will engage industry and other stakeholders by 2003 to assist in identifying appropriate sites to be linked to the NSN web site in a timely manner.	No progress to report.
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 (note: this issue of how Environment Canada and Health Canada will deal with confidential information vis-à-vis the NS Program is discussed in Section 3.3(ii) of the Final Report); • published information relating to NSN enforcement actions. This information could be included in the annual Report to Parliament legally mandated under section 342 of CEPA and on the NS Program web site; • published information and statistics on the NS Program each calendar year, including items such as the number of notifications received with appropriate breakdowns by type, number of conditions and bans, and information on international activities with other jurisdictions (e.g., the Four Corners submissions [United States], exchanges with the National Industrial Chemicals Notification and Assessment Scheme [Australia])	Environment Canada and Health Canada will, in 2002, inventory and 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*, containing a first set of operational policies, has been provided to stakeholders for comment. Start publishing Program statistics in Spring 2004.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
(ii) Confidential Business Information and Access to Risk Assessments		
63. The full assessment report should be made available to the notifier. The Table recognizes that this is resource intensive because the government would have to remove any confidential business information received from another source.	The departments are currently embarking on a review of the documents developed, their format, use of third-party information, target audience and other relevant matters as a basis for pursuing the 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 draft policy for the handling of third party information has been prepared. Assessment templates are being developed to provide the notifier/public with assessment summaries that do not contain Confidential Business Information.
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.	It is intended that summaries for the first two items will begin once efforts are concluded under recommendation 63.
(iii) Mechanisms for Challenging Assessment Decisions		
65. Health Canada and Environment Canada, in consultation with other government departments and stakeholders, should examine the feasibility of an appeal mechanism and how it could be incorporated into a revised CEPA.	By the end of 2003, Environment Canada and Health Canada will initiate a process that will examine the feasibility of incorporating appeal mechanisms into the NS Program and, if appropriate, will develop concrete proposals for amending CEPA.	No progress to report.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
3.4 THEME 4: IMPROVING RESPONSIVENESS OF THE NSN REGULATIONS AND NS PROGRAM IN THE GLOBAL CONTEXT		
66. Environment Canada and Health Canada should develop and implement a strategic plan covering the next five years that positions Canada to play a leadership role relating to new substances notification in international initiatives aimed at promoting high standards in the protection of human health and the environment in a way that permits better use of industry and government resources. This plan should be flexible and responsive to current and future initiatives, taking into consideration the following elements: • An initial objective of the strategic plan should be the pursuit of international harmonization of hazard assessments, along with clarification of Canada's interests regarding the potential for broader harmonization over the longer term. • Within the framework of the strategic planning process, Canadian support for, and participation in, international initiatives, such as those under the leadership of the OECD Task Force on New Industrial Chemicals, should be strengthened. • Stakeholders, including other government departments, should be continually engaged in the implementation of initiatives undertaken as part of the strategic plan.	Environment Canada and Health Canada will initiate, by the end of 2002, a process to develop the plan envisaged by the Table. At the same time, the departments will continue their efforts within OECD and through bilateral arrangements with other countries, such as the United States and Australia, and will seek other opportunities relating to this subject. For example, the departments will examine the possibility of introducing a foreign scheme into the NS Program's framework based on the progress made through bilateral arrangements with other countries and through OECD work. By the middle of 2003, the departments intend to seek stakeholder perspectives on the draft plan, to amend the plan as appropriate and to make it public. The departments will review progress on implementation of the plan and release a report by the end of 2005.	A strategic plan is being developed, and will be finalized by early 2004, after stakeholders have been consulted. The plan will be made public. The departments will review progress on implementation of the plan and will release a report by the end of 2005.
3.5 THEME 5: SERVICE DELIVERY		
(i) Quality Service		
67. Environment Canada and Health Canada should implement the recommendations of the Auditor General relating to implementation of measurable service quality standards, service/performance indicators, measuring stakeholder satisfaction, and continuous improvement, such as those outlined in the framework developed by the Treasury Board Secretariat and the National Quality Institute.	The departments will investigate in 2002 what already exists in the departments and elsewhere to document best practices and will adopt a long-term phased approach that will include stakeholders for the implementation of measurable service quality standards and performance indicators. This approach will be in line with the framework developed by the Treasury Board Secretariat and the National Quality Institute.	The departments completed the investigation of what already exists in order to document best practices. A strategy is being developed to improve delivery of service to clients, as well as 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).	A client expectations/satisfaction survey is being developed and will be distributed in February 2004. Service/performance indicators will be developed according to the results of the survey.
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.	Discussions have yet to be initiated.
(ii) Leadership for Cultural Change		
70. Senior management in Environment Canada and Health Canada should seek ways to enhance quality service approaches that are more open and transparent and centred on the principles of sustainability, develop a mission statement that captures these values, communicate it to all stakeholders and report annually on actions and results in achieving sustainability, transparency and service quality goals.	Senior management in both Environment Canada and Health Canada will work in cooperation with managers of other CEPA programs in 2002 to meet expectations for increased transparency and implementation of quality service approaches that are centred on principles of sustainability.	A Service Delivery Improvement Strategy is being developed, which will be communicated to senior management in both departments as well as stakeholders in Spring 2004.
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 conduct a cost-benefit analysis for co-locating staff will be let early 2004.
(iii) Innovation		
72. The feasibility of redesigning the program delivery to permit secure electronic filing with access simplified by a "smart" system should be examined.	The departments are committed to moving towards a system that allows electronic filing and access to electronic files as resources become available and client demand warrants. The potential for industry financial support in this area will be investigated in 2003. The outcome of the OECD workshop on electronic information systems, to be held in Ottawa in October 2002, will be considered as part of the path forward for development of electronic filing submission systems.	Work on recommendations relating to Information Technology will continue, including feasibility of the Smart Tool and development of electronic filing tracking.

RECOMMENDATION	ENVIRONMENT CANADA / HEALTH CANADA RESPONSE	COMMENTS
73. Information sharing should be facilitated and international cooperation continued and possibly expanded.	Canada will continue to exercise its leadership in the area of international cooperation. The departments intend to continue ongoing initiatives, such as the Four Corners Agreement, the impending Canada-Australia arrangement and the OECD new chemicals multilateral exercise.	Canada continues to lead the New Chemicals Task Force and information-sharing is addressed under bilateral arrangements with the U.S. and Australia.
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.	No progress to report.
75. Government should work with stakeholders to examine innovative measures for ensuring compliance with the NSN Regulations.	For compliance promotion activities, the departments have already started to consider the involvement of stakeholders in compliance promotion projects.	Ongoing. The National Compliance Promotion group continues to make progress with respect to projects they identified and for which resources have been secured.
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. Opportunities with other governments for harmonizing approaches to reporting effects data are being explored.